
Wednesday
August 28, 1996

Registered Federal

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- FOR:** Any person who uses the Federal Register and Code of Federal Regulations.
- WHO:** Sponsored by the Office of the Federal Register.
- WHAT:** Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
 2. The relationship between the Federal Register and Code of Federal Regulations.
 3. The important elements of typical Federal Register documents.
 4. An introduction to the finding aids of the FR/CFR system.
- WHY:** To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

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- WHEN:** September 17, 1996 at 9:00 am.
- WHERE:** National Archives—Northwest Region
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(Federal Information Center)

WASHINGTON, DC

- WHEN:** September 24, 1996 at 9:00 am.
- WHERE:** Office of the Federal Register
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- RESERVATIONS:** 202-523-4538



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Electronic Bulletin Board

Free **Electronic Bulletin Board** service for Public Law numbers, **Federal Register** finding aids, and a list of documents on public inspection is available on 202–275–1538 or 275–0920.

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Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

Common Crop Insurance Regulations; Arizona-California Citrus Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) finalizes specific crop provisions for the insurance of Arizona-California citrus. The provisions will be used in conjunction with the Common Crop Insurance Policy Basic Provisions, which contain standard terms and conditions common to most crops. The intended effect of this action is to provide policy changes to better meet the needs of the insured and combine the current Arizona-California Citrus Crop Insurance Regulations with the Common Crop Insurance Policy for ease of use and consistency of terms.

EFFECTIVE DATE: August 28, 1996.

FOR FURTHER INFORMATION CONTACT: John Meyer, Program Analyst, Research and Development Division, Product Development Branch, Federal Crop Insurance Corporation, United States Department of Agriculture, 9435 Holmes Road, Kansas City, MO 64131, telephone (816) 926-7730.

SUPPLEMENTARY INFORMATION:

Executive Order No. 12866 and Departmental Regulation 1512-1

This action has been reviewed under United States Department of Agriculture (USDA) procedures established by Executive Order No. 12866 and Departmental Regulation 1512-1. This action constitutes a review as to the need, currency, clarity, and effectiveness of these regulations under

those procedures. The sunset review date established for these regulations is June 30, 2001.

This rule has been determined to be not significant for the purposes of Executive Order No. 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Paperwork Reduction Act of 1995

Following publication of the proposed rule, the public was afforded 60 days to submit comments, data, and opinions on information collection requirements previously approved by OMB under OMB control number 0563-0003 through September 30, 1998. No public comments were received.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandate Reform Act of 1995 (UMRA), Pub. L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, FCIC generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures of State, local, or tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any 1 year. When such a statement is needed for a rule, section 205 of the UMRA generally requires FCIC to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) of State, local, and tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order No. 12612

It has been determined under section 6(a) of Executive Order No. 12612, Federalism, that this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. The provisions contained in this rule will not have a substantial direct effect on States or their political subdivisions, or on the distribution of

power and responsibilities among the various levels of government.

Regulatory Flexibility Act

This regulation will not have a significant impact on a substantial number of small entities. Under the current regulations, a producer is required to complete an application and acreage report. If the crop is damaged or destroyed, the insured is required to give notice of loss and provide the necessary information to complete a claim for indemnity. An insured must also annually certify to the previous years production or receive a transitional yield. The producer must maintain the production records to support the certified information for at least 3 years. This regulation does not alter those requirements. The amount of work required of the insurance companies delivering and servicing these policies will not increase significantly from the amount of work currently required. This rule does not have any greater or lesser impact on the producer. Therefore, this action is determined to be exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605), and no Regulatory Flexibility Analysis was prepared.

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order No. 12372

This program is not subject to the provisions of Executive Order No. 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order No. 12778

The Office of the General Counsel has determined that these regulations meet the applicable standards provided in sections 2(a) and 2(b)(2) of Executive Order No. 12778. The provisions of this rule will not have a retroactive effect prior to the effective date. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. The administrative appeal provisions published at 7 CFR parts 11 and 780 must be exhausted before any action for judicial review may be brought.

Environmental Evaluation

This action is not expected to have a significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

National Performance Review

This regulatory action is being taken as part of the National Performance Review Initiative to eliminate unnecessary or duplicative regulations and improve those that remain in force.

Background

On Thursday, June 20, 1996, FCIC published a proposed rule in the Federal Register at 61 FR 31464–31468 to add to the Common Crop Insurance Regulations (7 CFR part 457), a new section, 7 CFR 457.121, Arizona-California Citrus Crop Insurance Provisions. The new provisions will be effective for the 1998 and succeeding crop years. These provisions will replace the current provisions for insuring Arizona-California citrus found at 7 CFR part 409 (Arizona-California Citrus Crop Insurance Regulations), thereby limiting the effect of the current provisions to the 1997 and prior crop years. After this final rule becomes effective, the current provisions for insuring Arizona-California citrus will be removed from 7 CFR part 409 and that part will be reserved.

Following publication of that proposed rule, the public was afforded 30 days to submit written comments, data, and opinions. A total of 14 comments were received from the crop insurance industry. The comments received, and FCIC's response are as follows:

Comment: The crop insurance industry commented that the proposed rule did not contain any reference to acreage reporting and suggested that such reference be added.

Response: Section 6 (Report of Acreage) of the Basic Provisions provides information on the reporting of acreage and specifies that the acreage reporting date will be included in the Special Provisions. No changes have been made to these provisions.

Comment: The crop insurance industry questioned the need to define "FSA" in the provisions and recommended deletion.

Response: FCIC agrees and has deleted the definition for "FSA".

Comment: The crop insurance industry stated that the provisions refer to a pro rata refund when optional units are combined into basic units when the insured reported optional units but does

not qualify. They questioned on what basis a pro rata refund would be determined.

Response: The reference to a pro rata refund has been deleted and the sentence changed to read, "If failure to comply with these provisions is determined to be inadvertent, and the optional units are combined into a basic unit, that portion of the premium paid for the purpose of electing optional units will be refunded to you for the units combined."

Comment: The crop insurance industry stated they did not understand why all optional units must be identified on the acreage report for each crop year. They said that listing every possible combination for every crop on a policy could test the limits on the number of policy lines allowed.

Response: Optional units are only allowed by non-contiguous land. Only those optional units determined for the crop year for which the acreage report is completed must be listed. Optional unit designation from past years or that could have been established for the current year, should not be listed on the current crop years' acreage report. The phrase "established for a crop year" has been added to the provisions for clarification.

Comment: The crop insurance industry suggested that the provision, "You must have records, which can be independently verified, of acreage and production for each optional unit for at least the last crop year used to determine your production guarantee", would cause confusion between the APH or policy year.

Response: The APH is based on the actual production of the producer for each crop year in which a crop is produced to a maximum of 10 crop years. There is no requirement that the producer have insured the crop before its production be included in the APH data base. FCIC believes the provision is clearly stated and has not made changes.

Comment: The crop insurance industry questioned why optional units were allowed only by non-contiguous land without the alternative of optional units by section/legal description whereas in other citrus policies optional units are offered by both criteria.

Response: Offering optional units by legal description would increase the administrative burden on the program without offering any benefit to producers, because most producers in Arizona and California tend to farm within a section. No change has been made to these provisions.

Comment: The crop insurance industry suggested that section 3(a)

begin with the phrase, "You may select only one price percentage * * *" It would not then be necessary to include complex provisions regarding different varieties with different maximum prices.

Response: Methods used to select price elections vary between insurance providers. While some require selection of a percentage, others require selection of a specific dollar amount. The suggested change will not work in all circumstances. No change has been made to the provisions.

Comment: The crop insurance industry suggested that statements listed in section 6(b)(1) "That is not irrigated" and 6(b)(2) "That has not reached the sixth growing season after being set out * * *" be changed to positive statements and listed under 6(a).

Response: FCIC agrees and has rewritten and rearranged the provisions in this section.

Comment: The crop insurance industry questioned why a 10 day delay was incorporated into section 8(a)(1) of the policy that states, "* * * for the first crop year, if the application is accepted by us after November 20, insurance will attach on the 10th day after the application, if approved, is received in our local agent's office * * *" and if the 10 day period would allow enough time to complete inspections.

Response: The language in section 8(a)(1) has been changed as follows, "Coverage begins on November 21 of each crop year, except that for the year of application, if your application is received after November 11 but prior to November 21, insurance will attach on the 10th day after your properly completed application is received in our local office unless we inspect the acreage during the 10 day period and determine that it does not meet insurability requirements. You must provide any information that we require for the crop or to determine the condition of the grove." These provisions were modified to be consistent with other perennial crop provisions, to prevent adverse selection, and for the producer to avoid unnecessary exposure to uninsured losses during the waiting period. The insurance provider must expedite its review of the application and any supporting documentation filed by the producer, determine if a visual inspection is necessary, and perform any necessary inspections within the 10 day period. The period of 10 days is believed appropriate to meet the needs of both the producer and the insurance provider.

Comment: The crop insurance industry stated that some flexibility may be needed for obtaining signatures and for mail time if a transfer takes place shortly before the acreage reporting date, but the transfer form does not reach the company office until after the acreage reporting date.

Response: Section 8(b)(2)(ii) (Insurance Period) states, "We are notified by you or the transferee in writing of such transfer on or before the acreage reporting date;" If the transferor or the transferee signs the properly completed transfer form and gives the form to the crop insurance agent on or before the acreage reporting date, this requirement will be met. No change has been made to the provisions.

Comment: The crop insurance industry believes that the policy should not allow the producer to defer settlement and wait for a later, generally lower, appraisal on insured acreage the producer intends to abandon or no longer care for.

Response: The later appraisal will only be necessary if the insurance provider agrees that such appraisal would result in a more accurate determination, and if the producer continues to care for the crop. If the producer does not care for the crop, the original appraisal is used. If the insurance provider believes the original appraisal is accurate, resolution of the dispute may be sought through arbitration or appeal procedures, whichever is applicable. No change will be made to these provisions.

Comment: The crop insurance industry suggested combining the provisions contained in section 12(e) with the provisions in section 12(a).

Response: The provisions are clearly stated and have not been combined.

Comment: The crop insurance industry stated that they believe the written agreement should be continuous if no substantive changes occur from one year to the next.

Response: The written agreement can only be valid for 1 year because it must contain all the variable terms of the contract including, but not limited to, crop type or variety, the guarantee, premium rate, and price election. One or more of these variables often changes from year to year. No change has been made to these provisions. In addition, written agreements are, by design, temporary and should be replaced by applicable policy provisions.

In addition to the changes described above, FCIC has made the following changes to the Arizona-California Citrus Crop Provisions.

1. Section 1—Revised the definition of "non-contiguous land" so that a

producer who share rents acreage is not prohibited from having optional units on non-contiguous land and to conform to other perennial policies.

2. Section 1—Revised the definition of "carton" and "production guarantee (per acre)" for clarification.

3. Section 1—Added definitions for "crop" and "variety" for clarification.

4. Section 1—Removed the definition of "type" because the word "type" has been changed to "crop" throughout the provisions where appropriate since the citrus type designations used in the past will be replaced with individual crop codes beginning with the 1998 crop year.

5. Section 6—Added a provision to allow citrus sold by direct marketing to be insurable, if specifically allowed by the Special Provisions or by written agreement, to conform to other perennial policies.

6. Section 8(b)—Revised the provisions for when an insured relinquishes an insurable share on any insurable acreage of citrus on or before the acreage reporting date for the crop year.

7. Section 10—Removed the provision requiring the producer to notify the insurance provider within three days of the date harvest should have started if the crop will not be harvested. Citrus is harvested over a long period of time and this provision would be difficult to administer.

Good cause is shown to make this rule effective upon publication in the Federal Register. This rule improves the Arizona-California citrus crop insurance coverage and brings it under the Common Crop Insurance Policy Basic Provisions for consistency among policies. The contract change date required for new policies is August 31, 1996. It is therefore imperative that these provisions be made final before that date so that the reinsured companies and insureds may have sufficient time to implement the new provisions. Therefore, public interest requires the agency to act immediately to make these provisions available for the 1998 crop year.

List of Subjects in 7 CFR Part 457

Crop insurance, Arizona-California citrus.

Final Rule

Pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation hereby amends the Common Crop Insurance Regulations (7 CFR part 457), effective for the 1998 and succeeding crop years, to read as follows:

PART 457—[AMENDED]

1. The authority citation for 7 CFR part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l), and 1506(p).

2. 7 CFR part 457 is amended by adding a new § 457.121 to read as follows:

§ 457.121 Arizona-California Citrus Crop Insurance Provisions

The Arizona-California Citrus Crop Insurance Provisions for the 1998 and succeeding crop years are as follows:

United States Department of Agriculture
Federal Crop Insurance Corporation

Arizona-California Citrus Crop Provisions

If a conflict exists among the Basic Provisions (§ 457.8), these crop provisions, and the Special Provisions; the Special Provisions will control these crop provisions and the Basic Provisions; and these crop provisions will control the Basic Provisions.

1. Definitions

Carton—The standard container for marketing the fresh packed citrus fruit crop as shown below. In the absence of marketing records on a carton basis, production will be converted to cartons on the basis of the following average net pounds of packed fruit in a standard packed carton.

Container size	Fruit crop	Pounds
Container #58 ...	Navel oranges, Valencia oranges & Sweet oranges.	38
Container #58 ...	Lemons	40
Container #59 ...	Grapefruit	32
Container #63 ...	Tangerines (including Tangelos) & Mandarin oranges.	25

Crop—Citrus fruit as listed in the Special Provisions.

Crop year—The period beginning with the date insurance attaches to the citrus crop and extending through normal harvest time. It is designated by the calendar year following the year in which the bloom is normally set.

Days—Calendar days.

Dehorning—Cutting of any scaffold limb to a length that is not greater than one-fourth (1/4) the height of the tree before cutting.

Direct marketing—Sale of the insured crop directly to consumers without the intervention of an intermediary such as a wholesaler, retailer, packer, processor, shipper or buyer. Examples of direct marketing include selling through an on-farm or roadside stand, farmer's market, and permitting the general public to enter the field for the purpose of picking all or a portion of the crop.

Good farming practices—The cultural practices generally in use in the county for the crop to make normal progress toward maturity and produce at least the yield used to determine the production guarantee, and

generally recognized by the Cooperative Extension Service as compatible with agronomic and weather conditions in the county.

Harvest—The severance of mature citrus from the tree by pulling, picking, or any other means, or by collecting marketable fruit from the ground.

Interplanted—Acreage on which two or more crops are planted in any form of alternating or mixed pattern.

Irrigated practice—A method of producing a crop by which water is artificially applied during the growing season by appropriate systems and at the proper times, with the intention of providing the quantity of water needed to produce at least the yield used to establish the irrigated production guarantee on the irrigated acreage planted to the insured crop.

Non-contiguous land—Any two or more tracts of land whose boundaries do not touch at any point, except that land separated only by a public or private right-of-way, waterway or an irrigation canal will be considered as contiguous.

Production guarantee (per acre)—The number of citrus (cartons) determined by multiplying the approved APH yield per acre by the coverage level percentage you elect.

Scaffold limb—A major limb attached directly to the trunk.

Set out—Transplanting a tree into the grove.

Variety—Subclass of crop as listed in the Special Provisions.

Written agreement—A written document that alters designated terms of a policy in accordance with section 12.

2. Unit Division

(a) A unit as defined in section 1 (Definitions) of the Basic Provisions (§ 457.8), will be divided into basic units by each citrus crop designated in the Special Provisions.

(b) Unless limited by the Special Provisions, these basic units may be divided into optional units if, for each optional unit you meet all the conditions of this section or if a written agreement to such division exists.

(c) Basic units may not be divided into optional units on any basis including, but not limited to, production practice, type, and variety, other than as described in this section.

(d) If you do not comply fully with these provisions, we will combine all optional units that are not in compliance with these provisions into the basic unit from which they were formed. We will combine the optional units at any time we discover that you have failed to comply with these provisions. If failure to comply with these provisions is determined to be inadvertent, and the optional units are combined into a basic unit, that portion of the premium paid for the purpose of electing optional units will be refunded to you for the units combined.

(e) All optional units established for a crop year must be identified on the acreage report for that crop year.

(f) The following requirements must be met for each optional unit:

(1) You must have records, which can be independently verified, of acreage and production for each optional unit for at least

the last crop year used to determine your production guarantee; and

(2) You must have records of marketed production or stored production from each optional unit maintained in such a manner that permits us to verify the production from each optional unit, or the production from each unit must be kept separate until loss adjustment is completed by us; and

(3) Each optional unit must be located on non-contiguous land.

3. Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities

(a) In addition to the requirements of section 3 (Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities) of the Basic Provisions (§ 457.8), you may select only one price election and coverage level for each citrus fruit crop designated in the Special Provisions that you elect to insure. The price election you choose for each crop need not bear the same percentage relationship to the maximum price offered by us for each crop. For example, if you choose one hundred percent (100%) of the maximum price election for sweet oranges, you may choose seventy-five percent (75%) of the maximum price election for grapefruit. However, if separate price elections are available by variety within each crop, the price elections you choose for each variety must have the same percentage relationship to the maximum price offered by us for each variety within the crop.

(b) In lieu of reporting your citrus production of marketable fresh fruit for the previous crop year, as required by section 3 of the Basic Provisions (§ 457.8), there is a lag period of one year. Each crop year, you must report your production from two crop years ago, e.g., on the 1998 crop year production report, you will provide your 1996 crop year production.

(c) In addition, you must report, by the production reporting date designated in section 3 (Insurance Guarantees, Coverage Levels, and Prices for Determining Indemnities) of the Basic Provisions (§ 457.8), by type, if applicable:

(1) The number of trees damaged, dehorned or removed; any change in practices or any other circumstance that may reduce the expected yield below the yield upon which the insurance guarantee is based; and the number of affected acres;

(2) The number of bearing trees on insurable and uninsurable acreage;

(3) The age of the trees and the planting pattern; and

(4) For the first year of insurance for acreage interplanted with another perennial crop, and anytime the planting pattern of such acreage is changed:

(i) The age of the interplanted crop, and type, if applicable;

(ii) The planting pattern; and

(iii) Any other information that we request in order to establish your approved yield.

We will reduce the yield used to establish your production guarantee as necessary, based on our estimate of the effect of the following: interplanted perennial crop; damage; dehorning; removal of trees; change in practices and any other circumstance on the yield potential of the insured crop. If you fail to notify us of any circumstance that may

reduce your yields from previous levels, we will reduce your production guarantee as necessary at any time we become aware of the circumstance.

4. Contract Changes

In accordance with section 4 (Contract Changes) of the Basic Provisions (§ 457.8), the contract change date is August 31 preceding the cancellation date.

5. Cancellation and Termination Dates

In accordance with section 2 (Life of Policy, Cancellation, and Termination) of the Basic Provisions (§ 457.8), the cancellation and termination dates are November 20.

6. Insured Crop

In accordance with section 8 (Insured Crop) of the Basic Provisions (§ 457.8), the crop insured will be all the acreage in the county of each citrus crop designated in the Special Provisions that you elect to insure and for which a premium rate is provided by the actuarial table:

- (a) In which you have a share;
- (b) That is adapted to the area;
- (c) That is irrigated;
- (d) That is grown in a grove that, if inspected, is considered acceptable by us;
- (e) That is not sold by direct marketing, unless allowed by the Special Provisions or by written agreement; and
- (f) That has reached at least the sixth growing season after being set out. However, we may agree to insure acreage that has not reached this age if we inspect and approve a written agreement to insure such acreage.

7. Insurable Acreage

In lieu of the provisions in section 9 (Insurable Acreage) of the Basic Provisions (§ 457.8), that prohibit insurance attaching to a crop planted with another crop, citrus interplanted with another perennial crop is insurable unless we inspect the acreage and determine it does not meet the requirements contained in your policy.

8. Insurance Period

(a) In accordance with the provisions of section 11 (Insurance Period) of the Basic Provisions (§ 457.8):

(1) Coverage begins on November 21 of each crop year, except that for the year of application, if your application is received after November 11 but prior to November 21, insurance will attach on the 10th day after your properly completed application is received in our local office unless we inspect the acreage during the 10 day period and determine that it does not meet insurability requirements. You must provide any information that we require for the crop or to determine the condition of the grove.

(2) The calendar date for the end of the insurance period for each crop year is:

- (i) August 31 for Navel oranges and Southern California lemons;
- (ii) November 20 for Valencia oranges; and
- (iii) July 31 for all other citrus crops.

(b) In addition to the provisions of section 11 (Insurance Period) of the Basic Provisions (§ 457.8):

(1) If you acquire an insurable share in any insurable acreage after coverage begins, but on or before the acreage reporting date for the crop year, and after an inspection we

consider the acreage acceptable, insurance will be considered to have attached to such acreage on the calendar date for the beginning of the insurance period.

(2) If you relinquish your insurable share on any insurable acreage of citrus on or before the acreage reporting date for the crop year, insurance will not be considered to have attached to and no premium will be due, and no indemnity paid, for such acreage for that crop year unless:

(i) A transfer of coverage and right to an indemnity, or a similar form approved by us, is completed by all affected parties;

(ii) We are notified by you or the transferee in writing of such transfer on or before the acreage reporting date; and

(iii) The transferee is eligible for crop insurance.

9. Causes of Loss

(a) In accordance with the provisions of section 12 (Causes of Loss) of the Basic Provisions (§ 457.8), insurance is provided only against the following causes of loss that occur during the insurance period:

(1) Adverse weather conditions;

(2) Fire, unless weeds and other forms of undergrowth have not been controlled or pruning debris has not been removed from the grove;

(3) Wildlife;

(4) Earthquake;

(5) Volcanic eruption; or

(6) Failure of irrigation water supply, if caused by an insured peril that occurs during the insurance period.

(b) In addition to the causes of loss excluded in section 12 (Causes of Loss) of the Basic Provisions (§ 457.8), we will not insure against damage or loss of production due to:

(1) Disease or insect infestation, unless adverse weather conditions:

(i) Prevents the proper application of control measures or causes properly applied control measures to be ineffective; or

(ii) Causes disease or insect infestation for which no effective control mechanism is available;

(2) Inability to market the citrus for any reason other than actual physical damage from an insurable cause specified in this section. For example, we will not pay you an indemnity if you are unable to market due to quarantine, boycott, or refusal of any person to accept production.

10. Duties in the Event of Damage or Loss

In addition to the requirements of section 14 (Duties in the Event of Damage or Loss) of the Basic Provisions (§ 457.8), the following will apply:

(a) If the Special Provisions permit or a written agreement authorizing direct marketing exists, you must notify us at least 15 days before any production from any unit will be sold by direct marketing. We will conduct an appraisal that will be used to determine your production to count for production that is sold by direct marketing. If damage occurs after this appraisal, we will conduct an additional appraisal. These appraisals, and any acceptable records provided by you, will be used to determine your production to count. Failure to give

timely notice that production will be sold by direct marketing will result in an appraised amount of production to count of not less than the production guarantee per acre if such failure results in our inability to make the required appraisal.

(b) If you intend to claim an indemnity on any unit, you must notify us before beginning to harvest any damaged production so that we may have an opportunity to inspect it. You must not sell or dispose of the damaged crop until after we have given you written consent to do so. If you fail to meet the requirements of this section, all such production will be considered undamaged and included as production to count.

11. Settlement of Claim

(a) We will determine your loss on a unit basis. In the event you are unable to provide acceptable production records:

(1) For any optional unit, we will combine all optional units for which such production records were not provided; or

(2) For any basic unit, we will allocate any commingled production to such units in proportion to our liability on the harvested acreage for each unit.

(b) In the event of loss or damage covered by this policy, we will settle your claim by:

(1) Multiplying the insured acreage for each crop, or variety if applicable, by its respective production guarantee;

(2) Multiplying the results of section 11(b)(1) by the respective price election for each crop, or variety, if applicable;

(3) Totaling the results of section 11(b)(2);

(4) Multiplying the total production to be counted of each variety, if applicable (see section 11(c)), by the respective price election;

(5) Totaling the results of section 11(b)(4);

(6) Subtracting this result of section 11(b)(5) from the result of section 11(b)(3); and

(7) Multiplying the result of section 11(b)(6) by your share;

(c) The total production to count (in cartons) from all insurable acreage on the unit will include:

(1) All appraised production as follows:

(i) Not less than the production guarantee per acre for acreage:

(A) That is abandoned;

(B) For which you fail to provide acceptable production records;

(C) That is damaged solely by uninsured causes; or

(D) From which production is sold by direct marketing, if direct marketing is specifically permitted by the Special Provisions or a written agreement, and you fail to meet the requirements contained in section 10;

(ii) Production lost due to uninsured causes;

(iii) Unharvested production determined to be marketable as fresh packed fruit; and

(iv) Potential production on insured acreage that you intend to abandon or no longer care for, if you and we agree on the appraised amount of production. Upon such agreement, the insurance period for that acreage will end. If you do not agree with our appraisal, we may defer the claim only if you

agree to continue to care for the crop. We will then make another appraisal when you notify us of further damage or that harvest is general in the area unless you harvested the crop, in which case we will use the harvested production. If you do not continue to care for the crop, our appraisal made prior to deferring the claim will be used to determine the production to count;

(2) All harvested production marketed as fresh packed fruit from the insurable acreage; and

(3) All citrus that was disposed of or sold without an inspection or written consent.

(d) Any production will be considered marketed or marketable as fresh packed fruit unless, due solely to insured causes, such production was not marketed or marketable as fresh packed fruit.

(e) Citrus that cannot be marketed as fresh packed fruit due to insurable causes will not be considered production to count.

(f) If we determine that frost protection equipment was not properly utilized or not properly reported, the indemnity for the unit will be reduced by the percentage of premium reduction allowed for frost protection equipment. You must, at our request, provide us records showing the start-stop times by date for each period the frost protection equipment was used.

12. Written Agreement

Designated terms of this policy may be altered by written agreement in accordance with the following:

(a) You must apply in writing for each written agreement no later than the sales closing date, except as provided in section 12(e);

(b) The application for written agreement must contain all terms of the contract between you and us that will be in effect if the written agreement is not approved;

(c) If approved, the written agreement will include all variable terms of the contract, including, but not limited to, crop type or variety, the guarantee, premium rate, and price election;

(d) Each written agreement will only be valid for one year (If the written agreement is not specifically renewed the following year, insurance coverage for subsequent crop years will be in accordance with the printed policy); and

(e) An application for written agreement submitted after the sales closing date may be approved if, after a physical inspection of the acreage, it is determined that no loss has occurred and the crop is insurable in accordance with the policy and written agreement provisions.

Signed in Washington, D.C., on August 22, 1996.

Kenneth D. Ackerman,
Manager, Federal Crop Insurance Corporation.

[FR Doc. 96-21893 Filed 8-27-96; 8:45 am]

BILLING CODE 3410-FA-P

Agricultural Marketing Service**7 CFR Part 956****[FV96-956-1 FR]****Sweet Onions Grown in the Walla Walla Valley of Southeast Washington and Northeast Oregon; Establishment of Handler Reporting Requirements and Interest Charges on Overdue Assessment Payments****AGENCY:** Agricultural Marketing Service, USDA.**ACTION:** Final rule.

SUMMARY: This final rule establishes handler reporting requirements and establishes interest charges on overdue assessments. This rule will contribute to the efficient operation of the program by helping to ensure that assessments are available in a timely manner to cover budgeted expenses incurred under the marketing order. The Walla Walla Sweet Onion Committee (Committee) believes that these actions are the only alternatives available to ensure timely payments of assessments. These actions are expected to reduce the need for compliance efforts and thereby reduce the costs to administer the order.

EFFECTIVE DATE: August 29, 1996.**FOR FURTHER INFORMATION CONTACT:**

Robert J. Curry, Marketing Specialist, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, 1220 SW Third Avenue, room 369, Portland, Oregon 97204-2807; telephone: (503) 326-2724; or Robert F. Matthews, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, PO Box 96456, room 2523-S, Washington, DC 20090-6456; telephone: (202) 690-0464. Small businesses may request information on compliance with this regulation by contacting: Jay Guerber, Marketing Order Administration Branch, PO Box 96456, room 2523-S, Washington, DC 29909-6456; telephone (202) 720-2491, FAX (202) 720-5698.

SUPPLEMENTARY INFORMATION: This rule is effective under Marketing Agreement and Order No. 956 (7 CFR part 956), regulating the handling of sweet onions grown in the Walla Walla Valley of southeast Washington and northeast Oregon, hereinafter referred to as the "order." The order is authorized by the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act." This final rule was recommended by the Committee, the agency responsible for the local administration of the

marketing order for sweet onions grown in the Walla Walla Valley.

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. If adopted, the rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with the proposal.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the AMS has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 30 handlers of Walla Walla Sweet Onions subject to regulation under the marketing order and approximately 50 producers in the regulated production area. Small agricultural service firms have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than \$5,000,000, and small agricultural producers are defined as those whose annual receipts are less than \$500,000. The majority of Walla Walla Sweet Onion handlers and producers may be classified as small entities.

This final rule establishes interest charges on overdue assessments and establishes handler reporting requirements.

This final rule will contribute to the efficient operation of the program by helping to ensure that assessments are available in a timely manner to cover budgeted expenses incurred under the marketing order. Those persons large and small who pay in a timely manner will not be subject to an interest charge. The changes establishing interest charges are expected to reduce the need for compliance efforts and thereby reduce the costs to administer the order which will benefit all persons who are subject to assessments.

The preparation of one form one time each year with shipment information should not constitute a significant burden on a business unit, small or large. The estimated reporting burden per response is 0.323 hours. In addition, gift box and roadside stand sales are exempt from reporting the region to which shipments are made, which should be particularly favorable to small entities.

Therefore, the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

The Committee meets prior to each season to consider recommendations for modification, suspension, or termination of the regulatory requirements for Walla Walla Sweet Onions. Committee meetings are open to the public and interested persons may express their views at these meetings. The Department reviews Committee recommendations and information submitted by the Committee and other available information, and determines whether modification, suspension, or termination of the regulatory requirements tends to effectuate the declared policy of the Act.

At its February 15, 1996, meeting the Committee unanimously recommended the addition of administrative rules and regulations that provide a late payment charge for delinquent assessments and a reporting requirement for handlers.

The Act provides that each handler shall pay to the Committee such handler's pro rata share of Committee expenses that the Secretary finds are reasonable and likely to be incurred for the maintenance and functioning of the Committee. Section 956.42 authorizes the Committee to levy assessments on handlers of Walla Walla Sweet Onions to cover each handler's share of Committee expenses.

Section 956.42(f) provides the authority for the Committee to impose, with the approval of the Secretary, a late

payment or an interest charge on handlers who fail to pay any assessment in a timely manner. This final rule establishes an interest charge of 1½ percent per month to be applied to any assessment balance remaining unpaid on October 1 of each year.

The Committee depends upon handler assessments for operating funds. Last year, the first season of operation of the order, some handlers were late with their assessment payments, with fewer than half submitting their assessment payments when due. When assessments are not paid in a timely manner, the handlers paying assessments on time are placed in an unfair situation compared to the delinquent handlers.

As part of its collection efforts, the Committee requested delinquent handlers to promptly submit assessment payments. However, such requests did not substantially hasten the payment of such delinquent assessments, a few of which were over 120 days delinquent. To facilitate the collection of assessments needed for the maintenance and functioning of the Committee, the Committee recommended the establishment of an interest charge of 1½ percent per month to be applied to assessment balances unpaid after 30 days. Annual assessments are due from handlers on September 1. The 1½ percent interest charge will be applied monthly, after September 30, to the unpaid balance, including any accumulated interest.

This change is intended to encourage handlers to pay their assessments when due, thereby eliminating potential inequities towards handlers who pay their assessments on time. It contributes to the efficient operation of the program by ensuring that adequate funds are available to cover expenses incurred under the marketing order.

Section 956.80 provides authority for the Committee, with the approval of the Secretary, to require that each handler furnish to the Committee, in such manner and at such time as it may prescribe, such reports and other information as may be necessary for the Committee to perform its duties under the marketing order.

Pursuant to this authority, this final rule also establishes a requirement that each handler submit an annual report, on a form provided by the Committee, showing their weekly and total yearly shipments of Walla Walla Sweet Onions by geographical region. The annual handler reporting requirement will provide the Committee with statistical information regarding total industry shipments which will be useful to the Committee in developing a budget and

in making marketing and promotion plans for the upcoming season. The form includes the total number of 50 pound equivalents of Walla Walla Sweet Onions shipped during each week of the shipping season and an end of season total. The form will also require handlers to indicate the geographical regions to which onions are shipped. Information on the geographical region to which shipments are made will be useful to the Committee in planning marketing and promotional activities. The Committee has drawn up boundaries of 11 geographical regions to help it in developing its marketing and promotional plans. To effectively promote and market Walla Walla Sweet Onions, knowledge of market conditions and access to accurate statistical information is invaluable. The Committee recommended that handlers be exempt from having to indicate the geographical region to where the onions were shipped when making roadside stand and gift box sales. The Committee feels that having to report the geographical region shipped for every bag of onions sold in these outlets will be burdensome to handlers making such shipments.

The form also requires handlers to provide their name and address to properly identify the firm, as a basis for verifying compliance with the assessment provisions of the order.

In addition to marketing and promotion planning, the information on the form will help compliance efforts by keeping the Committee informed of handlers' operations. It will enable the Committee manager to become aware of potential problems and discuss them with the handlers involved before violations occur, thus reducing the need for, and the expense of, compliance action by the Committee and the Department.

To implement these changes, a new Subpart—Rules and Regulations is added to part 956. Sections 956.142 *Interest charges.*, and 956.180 *Reports.* are included in that subpart.

The proposed rule concerning these actions was published in the July 15, 1996, Federal Register (61 FR 36827), with a 15-day comment period ending July 30, 1996. No comments were received.

The proposed rule also announced that AMS intended to request a revision to the currently approved information collection for Walla Walla Sweet Onions under the Paperwork Reduction Act of 1955 (44 U.S.C. Chapter 35). The revision of the approved information collection is necessary to cover the new annual shipment report to be submitted by handlers to the Committee.

Comments concerning this revision must be received not later than September 13, 1996.

Because there is insufficient time for normal clearance procedures, AMS has received temporary approval from the Office of Management and Budget (OMB) for the use of this form for the 1996 shipping season. The form has been added to the other 5 forms currently approved for use under OMB Number 0581–0172. The information collection revision will be sent to OMB for final approval after September 13, 1996. All comments received on the revision will be summarized and included in the request for final OMB approval.

After consideration of all relative material presented, including the committee's recommendation, and other available information, it is hereby found that this final rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this action until 30 days after publication in the Federal Register because: (1) This rule should be effective promptly so the Committee can gather information on shipments prior to the September 1 assessment billing date; (2) this rule was unanimously recommended at a public meeting and all interested persons had an opportunity to express their views and provide input; and (3) Walla Walla Sweet Onion handlers are aware of this rule and need no additional time to comply with the requirements.

List of Subjects in 7 CFR Part 956

Marketing agreements, Onions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 956 is amended as follows:

PART 956—SWEET ONIONS GROWN IN THE WALLA WALLA VALLEY OF SOUTHEAST WASHINGTON AND NORTHEAST OREGON

1. The authority citation for 7 CFR part 956 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. A new Subpart—Rules and Regulations consisting of sections 956.142 and 956.180 are added to read as follows:

Subpart—Rules and Regulations

§ 956.142 Interest charges.

The Committee shall impose an interest charge on any handler who fails to pay his or her annual assessments

within thirty (30) days of the due date of September 1. The interest charge shall, after 30 days, be 1½ percent of the unpaid assessment balance. In the event the handler fails to pay the delinquent assessment amount within 60 days following the due date, the 1½ percent interest charge shall be applied monthly thereafter to the unpaid balance, including any accumulated interest. Any amount paid by a handler as an assessment, including any charges imposed pursuant to this paragraph, shall be credited when the payment is received in the Committee office.

§ 956.180 Reports.

Each handler shall furnish to the Committee by September 1 of each year an annual report containing the following information, except that gift-box and roadside stand sales shall be exempt from paragraph (b):

(a) The number of 50 lb. equivalents of Walla Walla Sweet Onions shipped by each handler during each week of the shipping season and the total for the season;

(b) The geographical regions as defined by the Committee to which each shipment is made; and

(c) The name, address, and signature of each handler.

Dated: August 22, 1996.

Robert C. Keeney,

Director, Fruit and Vegetable Division.

[FR Doc. 96-21958 Filed 8-27-96; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 13

[Docket No. 27873; Amdt. No. 13-26]

RIN 2120-AF36

Civil Penalties: Streamlined Enforcement Procedures for Certain Security Violations

AGENCY: Federal Aviation Administration (FAA), (DOT).

ACTION: Final rule.

SUMMARY: This final rule establishes streamlined procedures to be used to process civil penalty enforcement actions resulting from certain security violations. The procedures were tested as a result of recommendations made by the Vice President's National Performance Review. This streamlined enforcement process will reduce costs and improve efficiency in factually uncomplicated cases.

EFFECTIVE DATE: This final rule is effective August 26, 1996.

FOR FURTHER INFORMATION CONTACT: Brian R. Reed, Attorney, Enforcement Division (AGC-320), Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591; telephone (202) 267-7158.

SUPPLEMENTARY INFORMATION: The changes in this rule involve matters of agency organization, procedure, and practice only. While notice and public comment are not required, the rule changes are being adopted after publishing notice of a temporary Special Federal Aviation Regulation (SFAR), which was implemented to test the procedures. Public comment was invited. Two comments were received.

The first commenter recommended that all actions taken against airmen under the streamlined procedures be appealable to the National Transportation Safety Board (NTSB). The streamlined procedures contained in this rule do not, however, address the jurisdiction of the NTSB. Therefore, the suggestion is beyond the scope of this rule.

The second commenter suggested that the streamlined procedures be used only in instances where the respondent has admitted the violation because the procedures do not require legal review before an enforcement action is initiated. The commenter expressed concern that those initiating the cases would lack the qualifications to conduct an appropriate review of an enforcement investigative report in order to determine whether the FAA's allegations have been substantiated.

In response, the FAA notes that the streamlined procedures only allow for initiation of factually uncomplicated cases without initial legal review. Any investigation revealing that an alleged violator denies the violation occurred would be too factually complicated for use of the procedures, and the case would be referred to the appropriate Assistant Chief Counsel's office for review. Additionally, the evidence used in the cases affected by the streamlined procedures tends to be uncontroverted evidence contained in police records and airport documentation, as well as screener and respondent statements. FAA security agents have been trained to refer any case that contains contradictory evidence to the legal office for initiation of an enforcement action.

Availability of Regulation

Any person may obtain a copy of this final rule by submitting a request to the Federal Aviation Administration, Office

or Rulemaking, ARM-1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-9677. Requests must include the amendment or docket number.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Federal Register electronic bulletin board service (telephone: 202-512-1661) or the FAA's Aviation Rulemaking Advisory Committee Bulletin Board service, at the toll-free number 1-800-322-2722 (1-800-FAA-ARAC). Internet users may reach the Federal Register's web page at: http://www.access.gpo.gov/su_docs

Persons interested in being placed on a mailing list for future rulemaking actions should request a copy of Advisory Circular 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

Under 49 U.S.C. 46301(d), the FAA has authority to assess civil penalties not to exceed \$50,000 for certain violations of 49 U.S.C. Subtitle VIII, the FAA's regulations (14 CFR parts 1-199), and certain other statutes and orders (see 49 U.S.C. Subtitle III, Chapter 51). In the case of persons other than those acting as a pilot, flight engineer, mechanic, or repairman, the procedures for civil penalty assessment actions are those contained in section 13.16 and part 13, subpart G of the FAA's regulations. The current civil penalty assessment process for these actions is outlined as follows:

During the investigation phase of an enforcement action, FAA investigative personnel ordinarily notify alleged violators of an agency investigation by issuing a letter of investigation. This notification is described in FAA Order 2150.3A, Compliance and Enforcement Program, but is not required by statute, regulation, or that order. Following an investigation, a civil penalty may be assessed against individuals only after notice of the proposed charges and an opportunity for a hearing. This process is begun by issuing a notice of proposed civil penalty to an alleged violator (respondent). Section 13.16(c) delegates the authority to the FAA's Deputy Chief Counsel and certain Assistant Chief Counsel in the regions, centers, and headquarters to issue such notices.

Respondents have several options to respond to the notice of proposed civil penalty. The person charged with a violation is required to do one or more of the following:

(1) Submit the amount of the proposed civil penalty or an agreed-upon amount.

(2) Submit written information demonstrating that the violation did not occur, or that a penalty or the penalty amount is not warranted under the circumstances.

(3) Submit a written request for a reduction of the proposed civil penalty, including the amount of reduction along with supporting reasons and documentation, such as records indicating a financial inability to pay the proposed penalty.

(4) Submit a written request for an informal conference to discuss the matter with an agency attorney and submit relevant information or documents.

(5) Request a hearing before an administrative law judge (ALJ) of the Department of Transportation (DOT) Office of Hearings.

If a respondent does not respond to the notice of proposed civil penalty, or chooses to proceed informally in response to a notice of proposed civil penalty and the matter is not resolved, the FAA attorney then serves a final notice of proposed civil penalty. The respondent must either request a hearing before an ALJ or pay the amount of the proposed civil penalty, or an agreed-upon amount, within 15 days of receipt of the final notice. If the respondent does not respond to the final notice within the 15-day period, the FAA attorney serves an order assessing civil penalty, which contains a finding of violation and assesses a civil penalty. That order is final and not appealable.

On September 7, 1993, the Vice President's National Performance Review published a report entitled "From Red Tape to Results: Creating a Government that Works Better and Costs Less." That report included a recommendation that the FAA streamline its civil penalty enforcement program by eliminating several of the procedural steps it takes to issue civil penalties in certain minor, uncontested cases. The FAA has determined that streamlined procedures would be most appropriately applied to those legal enforcement actions that facially appear to be simple and factually straightforward.

On August 26, 1994, the FAA issued a Special Federal Aviation Regulation (SFAR) that adopted interim changes to the current rules governing procedures and delegation of authority that were designed to enhance the efficiency and effectiveness of the processing of civil penalty assessment actions in these types of cases. After testing the procedures for 1 year, the FAA found

that the streamlined enforcement process reduced costs and improved efficiency; the FAA also believes that safety was enhanced by the swift processing of these enforcement actions within reduced time frames.

In addition to shortening the time for initiating certain cases, the test program encouraged prompt settlement of proposed civil penalties in these cases. The program did not eliminate an individual's opportunity to request a hearing or otherwise contest a proposed civil penalty. This SFAR was made effective for two years, and expires on August 26, 1996 or upon publication of this rule, whichever occurs first.

Discussion of Rule

Scope: These regulatory changes will affect civil penalty assessment actions resulting from factually uncomplicated violations by individuals presenting dangerous or deadly weapons for screening at airports or in checked baggage, for which a civil penalty less than \$5,000 is proposed. While the FAA considers these violations to be serious, the initial evaluation and processing of these cases tends to be uncomplicated. Violations of weapons prohibitions, on the other hand, for which a penalty of \$5,000 or more is sought ordinarily are more factually complex and involve evidence of several aggravating factors. As a result, these cases tend to be more difficult to process, and, therefore, would not be appropriate for handling under these procedures. The FAA does not intend to apply these procedures to complex civil penalty actions, including factually complicated cases under \$5,000.

Procedures and delegations: Current enforcement practice will undergo internal policy change as well as changes resulting from these procedures. For example, the FAA's current practice of ordinarily issuing to the alleged violator a letter of investigation seeking information about the alleged violation will be dispensed with in cases subject to this rule. Experience has indicated that in the majority of factually clear, uncomplicated cases, the respondent often does not provide additional relevant information that is not already known to the FAA. The information received by the FAA from local law enforcement offices regarding weapons violations at airport screening checkpoints tends to be complete and beyond serious dispute. A respondent, however, will continue to have an opportunity to make any statements and submit any evidence regarding the alleged violation following notification of the alleged violation.

Under these procedures, FAA regional Civil Aviation Security Division Managers and Deputy Division Managers, instead of FAA attorneys, will initiate a legal enforcement action by issuing a notice of violation (NOV) to the respondent. The NOV will cite the relevant facts and circumstances pertaining to the alleged infraction and will include a proposed civil penalty amount. The authority to issue NOV's will not be delegated below the division level. By delegating to the Office of Civil Aviation Security the authority to send the initial notification to a respondent of an alleged violation, the FAA believes that it can reduce significantly the time currently expended before a respondent is given this notification. The name and phone number of a security agent involved in the investigation will be included in the NOV in case the respondent has any question about the action being proposed.

The NOV will serve the same purpose that the notice of proposed civil penalty now serves under current procedures. The NOV, however, will include the following specific information:

- (1) A description of the alleged violation;
- (2) The proposed amount of civil penalty;
- (3) An offer of settlement of the case, if appropriate, as described below;
- (4) The name and phone number of an FAA security special agent involved in the investigation of the violation;
- (5) Information regarding informal procedures; and
- (6) Information on how to request a formal hearing before a DOT ALJ.

In the NOV, the agency may extend to the respondent a settlement offer to resolve the case immediately with a reduction of the proposed civil penalty, on the condition either that the penalty is paid within 30 days, or, within 30 days, the respondent agrees to execute a promissory note for the penalty amount. A reduced penalty settlement offer will not be extended in cases that involve intentional conduct, repeated violations, or violations associated with felony conduct (other than possession of the weapon itself).

The FAA evaluated the test program for a 1-year period, from December 1, 1994 through December 1, 1995, and discovered that swifter notification of a violation, coupled, in most cases, with an immediate offer of settlement, encouraged quick resolution of simple cases and, at the same time, had no negative impact on the effectiveness of the enforcement process. As a result, the program was expanded to all airports in each of the FAA's domestic regions in January, 1996. The National

Performance Review studied a similar program offered by the Federal Highway Administration and found that approximately 40% of proposed civil penalties were paid in this manner within 30 days. The test program data evaluated by the FAA indicates that, during the 1-year evaluation period, approximately 87% of proposed civil penalties processed under these procedures were paid within 90 days of the violation date.

The provisions of the Federal Aviation Regulation will not limit a respondent's rights in any way. An individual may choose to proceed under the current informal and formal procedures, including requesting an informal conference with an FAA attorney or formal hearing before a DOT ALJ. If the FAA and respondent are unable to resolve the case informally, or if the respondent fails to respond to the NOV within 30 days after receiving it, a final notice of violation and civil penalty assessment order ("final notice and order") will be issued to the respondent. This document serves two purposes:

(1) It provides a second opportunity for the respondent to request a hearing on the record before a DOT ALJ; and

(2) It becomes an order assessing a civil penalty if the respondent pays the civil penalty proposed in the final notice and order, or the respondent does not request a hearing in accordance with the final notice and order and fails to pay the amount of the proposed civil penalty.

This streamlined process dispenses with the current procedure requiring a separate order assessing civil penalty to be sent to the respondent when the respondent pays the amount of the civil penalty reflected in the final notice of proposed civil penalty, or when the respondent fails to request a hearing in accordance with the final notice of proposed civil penalty and fails to pay the amount of the proposed civil penalty. The final disposition of the assessment action results from the respondent's act or failure to act upon receipt of the final notice. Issuance of a separate document entitled "order assessing civil penalty" under the existing procedures provides no additional rights of notice to the respondent that is not otherwise given in the final notice and order under these procedures. Accordingly, elimination of the issuance of a separate order assessing civil penalty under these circumstances will not alter the procedural protections afforded respondents.

The final notice and order will be issued by an appropriate Assistant Chief

Counsel. The final notice and order will result in either a civil penalty assessment or a formal hearing.

Regulatory Evaluation Summary

Changes to Federal regulations are required to undergo several economic analyses. First, Executive Order 12866 directs each Federal agency to propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic effect of regulatory changes on small entities. Third, the Office of Management and Budget directs agencies to assess the effect of regulatory changes on international trade. With respect to this rule, the FAA has determined that it: (1) is not "a significant regulatory action" as defined in the Executive Order; (2) is not significant as defined in the Department of Transportation's Regulatory Policies and Procedures; (3) will not have a significant impact on a substantial number of small entities; and (4) will not constitute a barrier to international trade. Therefore, a full regulatory analysis, which includes the identification and evaluation of cost-reducing alternatives to this rule, has not been prepared. Instead, the agency has prepared a more concise analysis of this rule which is presented in the following paragraphs.

The rule establishes new procedures to be implemented nation-wide. The procedures cover certain civil penalty cases against individuals submitting dangerous or deadly weapons for screening at airport checkpoints or in checked baggage. The rule will apply only to those cases that facially appear to be simple and are factually straightforward, and that are uncomplicated to process. The rule delegates authority to program office Division and Deputy Division managers to initiate legal enforcement actions and reduces the number of documents issued in these actions. The rule is intended to streamline the agency's civil penalty enforcement process for certain violations by processing these actions within reduced time frames.

Cost

There will be no costs associated with this rule because it consists only of changes to agency rules of procedure or practice in part 13 of the FAA's regulations. The changes do not impose any new economic requirements on the affected parties.

Benefits

The streamlined procedures will reduce the number of documents to be served upon individuals. Additionally, this rule will reduce the time between the violation and the processing of the enforcement action.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily and disproportionately burdened by Federal regulations. The RFA requires a Regulatory Flexibility Analysis if a rule will have "a significant economic impact on a substantial number of small entities." FAA Order 2100.14A outlines FAA's procedures and criteria for implementing the RFA. Small entities are defined as independently owned and operated small businesses and small not-for-profit organizations. Because this rule will directly affect certain individuals (who are not defined as entities), the rules will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

Because the rule only will affect certain individuals, it will not constitute a barrier to international trade, including the export of American goods and services to foreign countries and the import of foreign goods and services to the United States.

Federalism Implications

The rule will not have substantial direct effects on the states, on the relationship between the national government and that of any state, or on the distribution of power and responsibilities among the various levels of government. The respondents affected by the amendments are private citizens, not state governments. Therefore, in accordance with Executive Order 12612, it is determined that this regulation will not have federalism implications to warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

This rule contains no information collection requests requiring approval of the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3507 *et seq.*).

Conclusion

For the reasons discussed in the preamble, and based on the findings in the Regulatory Flexibility Determination and the International Trade Impact Analysis, the FAA has determined that this regulation is not a significant

regulatory action under Executive Order 12866. This rule is not considered significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). In addition, this rule will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 13

Administrative practice and procedure, Air transportation, Investigations, Law enforcement, Penalties.

The Amendments

Accordingly, the Federal Aviation Administration amends part 13 of Title 14, Code of Federal Regulations, by adding section 13.29, as follows:

PART 13—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

1. The authority citation for part 13 continues to read as follows:

Authority: 18 U.S.C. 6002; 49 U.S.C. 106(g), 5121–5124, 40113–40114, 44103–44106, 44702–44703, 44709–44710, 44713, 46101–46110, 46301–46316, 46501–46502, 46504–46507, 47106, 47111, 47122, 47306, 47531–47532.

2. Section 13.29 is added to read as follows:

§ 13.29 Civil penalties: Streamlined enforcement procedures for certain security violations.

This section may be used, at the agency's discretion, in enforcement actions involving individuals presenting dangerous or deadly weapons for screening at airports or in checked baggage where the amount of the proposed civil penalty is less than \$5,000. In these cases, sections 13.16(a), 13.16(c), and 13.16 (f) through (l) of this chapter are used, as well as paragraphs (a) through (d) of this section:

(a) *Delegation of authority.* The authority of the Administrator, under 49 U.S.C. 46301, to initiate the assessment of civil penalties for a violation of 49 U.S.C. Subtitle VII, or a rule, regulation, or order issued thereunder, is delegated to the regional Civil Aviation Security Division Manager and the regional Civil Aviation Security Deputy Division Manager for the purpose of issuing notices of violation in cases involving violations of 49 U.S.C. Subtitle VII and the FAA's regulations by individuals presenting dangerous or deadly weapons for screening at airport checkpoints or in checked baggage. This authority may not be delegated below the level of the regional Civil Aviation Security Deputy Division Manager.

(b) *Notice of violation.* A civil penalty action is initiated by sending a notice of violation to the person charged with the violation. The notice of violation contains a statement of the charges and the amount of the proposed civil penalty. Not later than 30 days after receipt of the notice of violation, the person charged with a violation shall:

(1) Submit the amount of the proposed civil penalty or an agreed-upon amount, in which case either an order assessing a civil penalty or a compromise order shall be issued in that amount; or

(2) Submit to the agency attorney identified in the material accompanying the notice any of the following:

(i) Written information, including documents and witness statements, demonstrating that a violation of the regulations did not occur or that a penalty or the penalty amount is not warranted by the circumstances; or

(ii) A written request to reduce the proposed civil penalty, the amount of reduction, and the reasons and any documents supporting a reduction of the proposed civil penalty, including records indicating a financial inability to pay or records showing that payment of the proposed civil penalty would prevent the person from continuing in business; or

(iii) A written request for an informal conference to discuss the matter with an agency attorney and submit relevant information or documents; or

(3) Request a hearing in which case a complaint shall be filed with the hearing docket clerk.

(c) *Final notice of violation and civil penalty assessment order.* A final notice of violation and civil penalty assessment order ("final notice and order") may be issued after participation in any informal proceedings as provided in paragraph (b)(2) of this section, or after failure of the respondent to respond in a timely manner to a notice of violation. A final notice and order will be sent to the individual charged with a violation. The final notice and order will contain a statement of the charges and the amount of the proposed civil penalty and, as a result of information submitted to the agency attorney during any informal procedures, may reflect a modified allegation or proposed civil penalty.

A final notice and order may be issued—

(1) If the person charged with a violation fails to respond to the notice of violation within 30 days after receipt of that notice; or

(2) If the parties participated in any informal procedures under paragraph (b)(2) of this section and the parties

have not agreed to compromise the action or the agency attorney has not agreed to withdraw the notice of violation.

(d) *Order assessing civil penalty.* An order assessing civil penalty may be issued after notice and opportunity for a hearing. A person charged with a violation may be subject to an order assessing civil penalty in the following circumstances:

(1) An order assessing civil penalty may be issued if a person charged with a violation submits, or agrees to submit, the amount of civil penalty proposed in the notice of violation.

(2) An order assessing civil penalty may be issued if a person charged with a violation submits, or agrees to submit, an agreed-upon amount of civil penalty that is not reflected in either the notice of violation or the final notice and order.

(3) The final notice and order becomes (and contains a statement so indicating) an order assessing a civil penalty when the person charged with a violation submits the amount of the proposed civil penalty that is reflected in the final notice and order.

(4) The final notice and order becomes (and contains a statement so indicating) an order assessing a civil penalty 16 days after receipt of the final notice and order, *unless* not later than 15 days after receipt of the final notice and order, the person charged with a violation does one of the following—

(i) Submits an agreed-upon amount of civil penalty that is not reflected in the final notice and order, in which case an order assessing civil penalty or a compromise order shall be issued in that amount; or

(ii) Requests a hearing in which case a complaint shall be filed with the hearing docket clerk.

(5) Unless an appeal is filed with the FAA decisionmaker in a timely manner, an initial decision or order of an administrative law judge shall be considered an order assessing civil penalty if an administrative law judge finds that an alleged violation occurred and determines that a civil penalty, in an amount found to be appropriate by the administrative law judge, is warranted.

(6) Unless a petition for review is filed with a U.S. Court of Appeals in a timely manner, a final decision and order of the Administrator shall be considered an order assessing civil penalty if the FAA decisionmaker finds that an alleged violation occurred and a civil penalty is warranted.

Issued in Washington, D.C. on August 23, 1996.

David R. Hinson,
Administrator.

[FR Doc. 96-22021 Filed 8-26-96; 8:51 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 95-NM-240-AD; Amendment 39-9725; AD 96-18-01]

RIN 2120-AA64

Airworthiness Directives; Learjet Model 60 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Learjet Model 60 airplanes, that requires modification of the aft core cowl nozzle of the engine nacelles. This amendment is prompted by a report that the sealant material in the aft core cowl nozzle of the engine nacelle was found to extend higher than the nozzle's forward flange, which can allow it to interfere with the proper operation of the emergency fuel shutoff actuating mechanism. The actions specified by this AD are intended to prevent physical interference of the emergency fuel shutoff actuating mechanism and resultant engine shutdown.

DATES: Effective October 2, 1996.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 2, 1996.

ADDRESSES: The service information referenced in this AD may be obtained from Learjet, Inc., One Learjet Way, Wichita, Kansas 67209-2942. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Wichita Aircraft Certification Office, Small Airplane Directorate, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jeffrey Janusz, Aerospace Engineer, Systems and Propulsion Branch, ACE-116W, FAA, Small Airplane Directorate, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas

67209; telephone (316) 946-4148; fax (316) 946-4407.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Learjet Model 60 airplanes was published in the Federal Register on May 30, 1996 (61 FR 27030). That action proposed to require modification of the aft core cowl nozzle of the engine nacelles.

Comments

No comments were submitted in response to the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

There are approximately 39 Learjet Model 60 airplanes of the affected design in the worldwide fleet. The FAA estimates that 26 airplanes of U.S. registry will be affected by this AD, that it will take approximately 44 work hours per airplane to accomplish the required actions, and that the average labor rate is \$60 per work hour. Required parts will be supplied by the manufacturer at no cost to the operators. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be \$68,640, or \$2,640 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has

been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

96-18-01 Learjet: Amendment 39-9725.
Docket 95-NM-240-AD.

Applicability: Model 60 airplanes, as listed in Learjet Service Bulletin SB 60-71-2, dated May 12, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent the sealant material in the aft core cowl nozzle of the engine nacelles from interfering with the lever of the emergency fuel shutoff actuating mechanism, which could result in the failure of the emergency fuel shutoff actuating mechanism and resultant engine shutdown, accomplish the following:

(a) Within 90 days after the effective date of this AD, modify the aft core cowl nozzle of the engine nacelles in accordance with Learjet Service Bulletin SB 60-71-2, dated May 12, 1995.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Wichita Aircraft Certification Office (ACO), FAA, Small Airplane Directorate. Operators shall

submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The modification shall be done in accordance with Learjet Service Bulletin SB 60-71-2, dated May 12, 1995, which includes Nordam Service Bulletin PW300L71-1, dated April 26, 1995. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Learjet, Inc., One Learjet Way, Wichita, Kansas 67209-2942. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Wichita Aircraft Certification Office, Small Airplane Directorate, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on October 2, 1996.

Issued in Renton, Washington, on August 20, 1996.

Darrell M. Pederson,
*Acting Manager, Transport Airplane
Directorate, Aircraft Certification Service.*
[FR Doc. 96-21742 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-13-U

14 CFR Part 39

[Docket No. 96-CE-36-AD; Amendment 39-9726; AD 96-18-02]

RIN 2120-AA64

Airworthiness Directives; American Champion Aircraft Corporation Models 8KCAB, 8GCBC, 7GCBC, 7ECA, 7GCAA, and 7KCAB Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes Airworthiness Directive (AD) 96-03-11, which currently requires the following on American Champion Aircraft Corporation (American Champion) Models 8KCAB, 8GCBC, 7GCBC, and 7ECA airplanes that are equipped with metal spar wings: inspecting (one-time) the wing front strut attach fittings for cracks, scratches, or surface deformities; replacing any wing front strut attach fitting with cracks, scratches, or surface

deformities; and reporting the inspection results to the Federal Aviation Administration (FAA). This action results from reports submitted as a requirement of the existing AD that reference 24 fittings with cracks, scratches, or surface deformities on 7 different airplanes, and the FAA's determination that improved wing front strut attach fittings (developed by American Champion) are not susceptible to cracks, scratches, or surface deformities. This action requires installing removable inspection hole covers for the wing front strut attach fittings, and replacing the wing front strut attach fittings with fittings of improved design. The action also provides the provision of repetitively inspecting the wing front strut attach fittings (provided no cracks, scratches, or surface deformities are found) if parts have been ordered but are not available. The actions specified by this AD are intended to prevent structural failure of a wing caused by cracked wing front strut attach fittings, which, if not detected and corrected, could result in loss of control of the airplane.

DATES: Effective September 20, 1996.

The incorporation by reference of American Champion Service Letter 409, Revision A, dated April 22, 1996; American Champion Service Letter 410, dated May 6, 1996; American Champion Service Letter 411, dated May 6, 1996; American Champion Service Letter 412, dated May 6, 1996; American Champion Service Letter 413, dated May 6, 1996; American Champion Service Letter 414, Revision A, dated June 25, 1996; and American Champion Service Letter 415, Revision A, dated June 25, 1996, is approved by the Director of the Federal Register as of September 20, 1996.

The incorporation by reference of American Champion Service Letter 408, dated January 24, 1996, was previously approved as of February 26, 1991 (61 FR 5501, February 13, 1996) by the Director of the Federal Register.

Comments for inclusion in the Rules Docket must be received on or before October 25, 1996.

ADDRESSES: Submit comments in triplicate to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket 96-CE-36-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Service information that applies to this AD may be obtained from the American Champion Aircraft Corporation, 32032 Washington Avenue, Rochester, Wisconsin 53167. This information may also be examined at the FAA, Central Region, Office of the Assistant Chief Counsel, Attention:

Rules Docket No. 96-CE-36-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Karen Forest, Aerospace Engineer, FAA, Chicago Aircraft Certification Office, 2300 E. Devon Avenue, Des Plaines, Illinois 60018; telephone (847) 294-7697; facsimile (847) 294-7834.

SUPPLEMENTARY INFORMATION:

Events Leading to This Action

On January 31, 1996, the FAA issued AD 96-03-11, Amendment 39-9598 (61 FR 5501, February 13, 1996), to require the following on American Champion Models 8KCAB, 8GCBC, 7GCBC, and 7ECA airplanes that are equipped with metal spar wings:

- Inspecting (one-time) the wing front strut attach fittings for cracks, scratches, or surface deformities;
- Replacing any wing front strut attach fitting with cracks, scratches, or surface deformities; and
- Reporting the inspection results to the FAA.

AD 96-03-11 resulted from an investigation of an American Champion Model 8KCAB airplane accident that revealed fatigue cracking of the wing front strut attach fittings. The design of the wing and fuselage structure of this airplane is such that the outboard ends of the wing fittings for each primary strut are bolted to the web of the wing's front spar. One fitting is on the forward side of the web and one is on the aft side of the web. The fittings then transition to a wider area where the strut is attached with a bolt. On the airplane involved in the accident that resulted in AD 96-03-11, the forward fitting fractured through the transition area (approximately in the center of the fitting length), causing the fitting to separate. This wing front strut attach fitting transition area contains an aft leg that is assembled against the forward face of the wing spar web and a forward leg.

Investigation of the fitting from the accident aircraft revealed that small, sharp scratches in the forward edge of the shorter portion of the aft leg contributed to the fatigue cracking in the wing fitting. Metallurgical examination of the fitting indicated that these fatigue cracks formed in scratches and surface deformities that resulted during the manufacturing process, and existed prior to the accident.

After that accident and prior to issuing AD 96-03-11, the FAA and American Champion inspected another Model 8KCAB airplane and found

fatigue cracks on two of the four wing front strut attach fittings. These fatigue cracks also originated from scratches and surface deformities in the wing front strut attach fitting. In addition, an evaluation of new uninstalled wing front strut attach fittings revealed these scratches and surface deformities. American Champion Models 8GCBC, 7GCBC, and 7ECA airplanes incorporate this same design fitting, and thus were included in the Applicability section of AD 96-03-11.

The results of the inspections required by AD 96-03-11 revealed 24 wing front strut attach fittings with cracks, scratches, or surface deformities. These cracked and scratched fittings were from 7 different affected airplanes that had between 103 to 666 total hours time-in-service.

Improved Design Parts and Service Information

American Champion has designed improved wing front strut attach fittings, part number (P/N) 3-1691 and P/N 3-1692, which, when manufactured according to design specifications, will not contain the surface deformities and scratches found on the existing design fittings. After extensive analysis, these fittings have proven to not have the cracking susceptibility of those currently in service. The following presents service information that American Champion has issued that relates to this issue:

- American Champion Service Letter (SL) 408, dated January 24, 1996, and American Champion SL 409, Revision A, dated April 22, 1996, which specify procedures for accessing and inspecting wing front strut attach fittings, part number (P/N) 3-1632-1 and P/N 3-1632-2; and P/N 3-1646L and 3-1646R, respectively.

- American Champion SL 410, dated May 6, 1996, which includes procedures for installing removable inspection hole covers for the wing front strut attach fittings on Model 8KCAB airplanes that have complied with American Champion SL 408;

- American Champion SL 411, dated May 6, 1996, which includes procedures for installing removable inspection hole covers for the wing front strut attach fittings on Model 8KCAB airplanes that have not complied with American Champion SL 408;

- American Champion SL 412, dated May 6, 1996, which specifies procedures for installing removable inspection hole covers for the wing front strut attach fittings on Models 7ECA, 7GCAA, 7GCBC, and 8GCBC airplanes that have complied with American Champion SL 409;

- American Champion SL 413, dated May 6, 1996, which specifies procedures for installing removable inspection hole covers for wing front strut attach fittings on Models 7ECA, 7GCAA, 7GCBC, and 8GCBC airplanes that have not complied with American Champion SL 409.

- American Champion SL 414, Revision A, dated June 25, 1996, which specifies procedures for replacing the wing front strut attach fittings on Model 8KCAB airplanes with improved wing front strut attach fittings, P/N 3-1691, and also includes procedures for inspecting the wing front strut attach fittings on these airplanes; and

- American Champion SL 415, Revision A, dated June 25, 1996, which specifies procedures for replacing the wing front strut attach fittings on Models 8GCBC, 7ECA, 7GCAA, 7GCBC, and 7KCAB airplanes with improved wing front strut attach fittings, P/N 3-1692, and also includes procedures for inspecting the wing front strut attach fittings on these airplanes.

FAA's Determination

After examining the circumstances and reviewing all available information related to the events described above, the FAA has determined that (1) The wing front strut attach fittings on American Champion Models 8KCAB, 8GCBC, 7ECA, 7GCAA, 7GCBC, and 7KCAB airplanes should incorporate P/N 3-1691 and 3-1692, as applicable; and (2) AD action should be taken in order to prevent structural failure of a wing caused by cracked wing front strut attach fittings, which, if not detected and corrected, could result in loss of control of the airplane.

In addition, based on results of an in-depth analysis of the existing wing front strut attach fittings, the FAA has determined that if the fittings were not replaced with the improved design fittings, repetitive inspections would need to be performed at intervals not to exceed 20 hours TIS. Allowing repetitive inspections of these airplanes over a long period of time goes against FAA policy, which states that if a modification exists for critical structure that could eliminate or reduce the number of short-term inspections, the modification should be incorporated. The FAA makes short-term allowances on this policy to account for parts availability provided analysis shows that an acceptable level of safety can be maintained through a short-term repetitive inspection program.

The Provisions of the Required AD Action

Since an unsafe condition has been identified that is likely to exist or develop in other American Champion Models 8GCBC, 7ECA, 7GCAA, 7GCBC, and 7KCAB airplanes of the same type design, this AD supersedes AD 96-03-11 with a new AD that requires installing removable inspection hole covers for the wing front strut attach fittings, and replacing the wing front strut attach fittings with P/N 3-1691 (Model 8KCAB) or P/N 3-1692 (Models 8GCBC, 7ECA, 7GCAA, 7GCBC, and 7KCAB) wing front strut attach fittings, as applicable. The FAA is including a provision of repetitively inspecting the wing front strut attach fittings (provided no cracks, scratches, or surface deformities are found) if parts have been ordered but are not available. Accomplishment of these actions is in accordance with the service information previously referenced.

Since a situation exists (structural failure of the wing caused by a cracked wing front strut attach fitting) that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting immediate flight safety and, thus, was not preceded by notice and opportunity to comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that

summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 96-CE-36-AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing AD 96-03-11, Amendment

39-9598 (61 FR 5501, February 13, 1996), and by adding a new airworthiness directive (AD) to read as follows:

96-18-02 American Champion Aircraft Corporation: Amendment 39-9726; Docket No. 96-CE-36-AD. Supersedes AD 96-03-11, Amendment 39-9598.

Applicability: The following airplane models and serial numbers, certificated in any category, that are equipped with metal spar wings:

- Model 8KCAB airplanes, serial numbers 643-90 through 768-96;
- Model 8KCAB airplanes, all serial numbers, that are equipped with metal spar wings, wing assembly part number (P/N) 7-1521 (installed in accordance with American Champion Service Kit 403);
- Model 8GCBC airplanes, serial numbers 361-91 through 377-96;
- Model 8GCBC airplanes, all serial numbers, that are equipped with metal spar wings, wing assembly part number 7-1542;
- Model 7GCBC airplanes, serial numbers 1200-94 through 1215-96;
- Model 7GCBC airplanes, all serial numbers, that are equipped with metal spar wings, wing assembly part number 7-1545;
- Model 7ECA airplanes, serial numbers 1355-95 through 1358-96; and
- Models 7ECA, 7GCCA, and 7KCAB airplanes, all serial numbers, that are equipped with metal spar wings, wing assembly part number 7-1567.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within the next 20 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished.

To prevent structural failure of a wing assembly caused by cracked wing front strut attach fittings, which, if not detected and corrected, could result in loss of control of the airplane, accomplish the following:

- (a) Install removable inspection hole openings for the wing front strut attach fittings in accordance with one of the following, as applicable:
 - (1) American Champion Service Letter (SL) 410, dated May 6, 1996, for Model 8KCAB airplanes that have complied with American Champion SL 408, dated January 24, 1996;
 - (2) American Champion SL 411, dated May 6, 1996, for Model 8KCAB airplanes that have not complied with American Champion SL 408, dated January 24, 1996;

(3) American Champion SL 412, dated May 6, 1996, for Models 7ECA, 7GCCA, 7GCBC, and 8GCBC airplanes that have complied with American Champion SL 409, Revision A, dated April 22, 1996; and

(4) American Champion SL 413, dated May 6, 1996, for Models 7ECA, 7GCCA, 7GCBC, and 8GCBC airplanes that have not complied with American Champion SL 409, Revision A, dated April 22, 1996.

Note 2: American Champion SL 408 and American Champion SL 409, when complied with, incorporate permanent inspection holes for access to the wing front strut attach fittings, P/N 3-1632-1 and P/N 3-1632-2; and P/N 3-1646L and 3-1646R, respectively.

(b) Replace the wing front strut attach fittings with P/N 3-1691 (Model 8KCAB) or P/N 3-1692 (Models 8GCBC, 7ECA, 7GCCA, 7GCBC, and 7KCAB) wing front strut attach fittings, as applicable. Accomplishment of these actions is required in accordance with the instructions in American Champion SL 414, Revision A, dated June 25, 1996; or American Champion SL 415, Revision A, dated June 25, 1996, as applicable.

(c) If the improved design wing front strut attach fittings referenced in paragraph (b) have been ordered from the manufacturer, but are not available, repetitively inspect the wing front strut attach fittings for cracks, scratches, or surface deformities at intervals not to exceed 20 hours TIS in accordance with the instructions in American Champion SL 408, dated January 24, 1996, or American Champion SL 409, Revision A, dated April 22, 1996, as applicable. Figure 3 of these service letters depicts the crosshatched areas of the fittings that must be inspected. These service letters also specify both a visual inspection and the choice of either a dye penetrant, Zyglol test, ultrasonic, or x-ray inspection.

(d) The repetitive inspections allowed in paragraph (c) of this AD may be continued until one of the following occurs at which time the replacement required by paragraph (b) of this AD must be accomplished prior to further flight:

- (1) Cracks, scratches, or surface deformities are found on a wing front strut attach fitting;
- (2) Parts become available from the American Champion Aircraft Corporation; or
- (3) Six repetitive inspection intervals are accomplished (120 hours TIS).

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) An alternative method of compliance or adjustment of the initial or repetitive compliance time that provides an equivalent level of safety may be approved by the Manager, Chicago Aircraft Certification Office (ACO), 2300 E. Devon Avenue, Des Plaines, Illinois 60018. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Chicago ACO. Alternative methods of compliance approved in accordance with AD 96-03-11 (superseded by this action), are not considered approved as alternative methods of compliance for this AD.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Chicago ACO.

(g) The incorporation of certain documents referenced in this AD is as follows:

(1) The installations required by this AD shall be done in accordance with American Champion Service Letter 410, dated May 6, 1996; American Champion Service Letter 411, dated May 6, 1996; American Champion Service Letter 412, dated May 6, 1996; or American Champion Service Letter 413, dated May 6, 1996, as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The replacements required by this AD shall be accomplished in accordance with American Champion Service Letter 414, Revision A, dated June 25, 1996; or American Champion Service Letter 415, Revision A, dated June 25, 1996, as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(3) The inspections (if parts are not available) required by this AD shall be accomplished in accordance with American Champion Service Letter 408, dated January 24, 1996, or American Champion Service Letter 409, Revision A, dated April 22, 1996.

(i) The incorporation by reference of American Champion Service Letter 408 reference was previously approved as of February 26, 1996 (61 FR 5501, February 13, 1996) by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(ii) The incorporation by reference of American Champion Service Letter 409 was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(4) Copies may be obtained from the American Champion Aircraft Corporation, 32032 Washington Avenue, Rochester, Wisconsin 53167. Copies may be inspected at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment (39-9726) supersedes AD 96-03-11, Amendment 39-9598.

(i) This amendment (39-9726) becomes effective on September 20, 1996.

Issued in Kansas City, Missouri, on August 20, 1996.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96-21746 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-13-U

Coast Guard

33 CFR Part 100

RIN 2115-AE46

Special Local Regulation; 1996 Blessing of The Fleet for The LA. Shrimp & Petroleum Festival, Morgan City, LA

AGENCY: Coast Guard, DOT.

ACTION: Notice of Implementation.

SUMMARY: This notice implements 33 CFR 100.801, "Annual Marine Events in the Eighth Coast Guard District", Table One, listed as The Blessing of the Fleet and Fireworks Display, Louisiana Shrimp & Petroleum Festival. The event is being held on September 1, 1996, from 9 a.m. until 12:30 p.m. and from 9 p.m. until 11:00 p.m. on Berwick Bay in Morgan City, Louisiana. Implementation of section 33 CFR 100.801 (Table One) is necessary to provide for safety of life on the navigable waters during the event.

EFFECTIVE DATES: Section 33 CFR 100.801 (Table One) is effective from 7 a.m. until 11 p.m. on September 1, 1996.

FOR FURTHER INFORMATION CONTACT: BM1 Perry W. Bowman, Group ATON, Marine Events Division, U.S. Coast Guard Group New Orleans, Louisiana, Tel: (504) 942-3064.

DISCUSSION OF NOTICE: The 1996 Blessing of The Fleet for The Louisiana Shrimp & Petroleum Festival will consist of approximately 60 participating boats, ranging from 32 to 75 feet in length. The event will also include a fireworks display. Non-participating vessels will not be permitted to transit the area during the actual parade. All vessels will proceed at *NO WADE SPEED* unless permission is granted by the patrol commander. Special Local Regulations permit Coast Guard control of vessel traffic in order to ensure the safety of spectators and participants.

Dated: August 8, 1996.

T.W. Josiah,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 96-21933 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 100

[CGD 05-96-064]

Special Local Regulations for Marine Events; Hampton Bay Days Festival; Hampton River, Hampton, VA

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements 33 CFR 100.508 for the Hampton Bay Days Festival, to be held on September 14 and 15, 1996 on the Hampton River, in Hampton, Virginia. These special local regulations are necessary to control vessel traffic in the immediate vicinity of this event. The effect will be to restrict general navigation in the regulated area for the safety of spectators and participants.

EFFECTIVE DATES: 33 CFR 100.508 is effective from 7 a.m., September 14, 1996 until 7 p.m., September 15, 1996.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Junior Grade R. Christensen, marine events coordinator, Commander, Coast Guard Group Hampton Roads, 4000 Coast Guard Blvd., Portsmouth, VA 23703-2199, (804) 483-8521.

SUPPLEMENTARY INFORMATION: Hampton Bay Days, Inc. will sponsor the Hampton Bay Days Festival on September 14 and 15, 1996. The marine portion of the festival will consist of a parade of boats, water ski shows, a fireworks display and assorted boat races. A large number of spectator vessels is anticipated. Therefore, to ensure the safety of participants, spectators and transiting vessels, 33 CFR 100.508 will be in effect for the duration of the event. Under provisions of 33 CFR 100.508, a vessel may not enter the regulated area unless it receives permission from the Coast Guard patrol commander. 33 CFR 100.508 also implements as special anchorage areas the spectator anchorages designated in that section for use by vessels during the event. Vessels less than 20 meters long may anchor in these areas without displaying the anchor lights and shapes required by Inland Navigation Rule 30 (33 U.S.C. 2030(g)). These restrictions will be in effect for a limited period and should not result in significant disruption of maritime traffic. The Coast Guard patrol commander will announce the specific periods during which the restrictions will be enforced.

Dated: August 2, 1996.

Kent H. Williams,

Vice Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

[FR Doc. 96-21934 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 100**[CGD08-96-039]****RIN 2115-AE46****Special Local Regulations; Mississippi Blackhawks Water Ski Show Upper Mississippi River Mile 633.0-634.0, McGregor, IA****AGENCY:** Coast Guard, DOT.**ACTION:** Temporary final rule.

SUMMARY: Special local regulations are being adopted for the Mississippi Blackhawks Water Ski Show. This event will be held on August 31, 1996 at McGregor, Iowa. These regulations are needed to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATE: These regulations are effective from 1:30 p.m. to 4 p.m. local time on August 31, 1996.

FOR FURTHER INFORMATION CONTACT: SCPO J.R. Van Reese, U.S. Coast Guard, Marine Safety Detachment, P.O. Box 65428, St. Paul, MN 55165-0428. Tel: (612) 290-3991.

SUPPLEMENTARY INFORMATION:**Regulatory History**

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking for these regulations has not been published and good cause exists for making them effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impracticable. Specifically, the details of the event were not finalized until August 5, 1996, and there was not sufficient time remaining to publish proposed rules in advance of the event or to provide for a delayed effective date.

Background and Purpose

The marine event requiring this regulation is a water ski show consisting of large acts involving up to twenty performers. The event is sponsored by the McGregor Chamber of Commerce. Spectators are to maintain a safe distance which will be determined by event sponsor and controlled by Coast Guard patrol commander.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040;

February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary because of the event's short duration.

Federalism Assessment

The Coast Guard has analyzed this action in accordance with the principles and criteria of Executive Order 12612 and has determined that this rule does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Small Entities

The Coast Guard finds that because of the event's short duration the impact on small entities, if any, is not significant. Therefore, the Coast Guard under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et. seq.*) certifies that this temporary rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no information collection requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et. seq.*).

Environmental Assessment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2.B.2.C. of Commandant Instruction M16475.1B, (as revised by 61 FR 13563; March 27, 1996) this rule is excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine Safety, Navigation (water), Reporting and Recordkeeping requirements, Waterways.

Temporary Regulations

In consideration of the forgoing, Part 100 of Title 33, Code of Federal Regulations, is amended as follows:

PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46.

2. A temporary section 100.35-T08-039 is added to read as follows:

§ 100.T08-35-039 Upper Mississippi River near McGregor, Iowa.

(a) *Regulated Area.* Upper Mississippi River mile 633.0-634.0.

(b) *Special Local Regulation:* All persons and vessels not registered with the sponsors as participants or official

patrol vessels are considered spectators. "Participants" are those persons and vessels identified by the sponsor as taking part in the event. The "official patrol" consists of any Coast Guard, public, state or local law enforcement and sponsor provided vessels assigned to patrol the event.

(1) No spectators shall anchor, block, loiter in or impede the through transit of participants or official patrol vessels in the regulated area during effective dates and times, unless cleared for such entry by or through an official patrol vessel.

(2) When hailed or signaled, by an official patrol vessel, a spectator shall come to an immediate stop. Vessels shall comply with all directions given; failure to do so may result in a citation.

(3) The Patrol Commander is empowered to forbid and control the movement of all vessels in the regulated area. The Patrol Commander may terminate the event at any time it is deemed necessary for the protection of life or property and can be reached on VHF-FM Channel 16 by using the call sign "PATCOM".

(c) *Effective Date:* This section is effective from 1:30 p.m. to 4 p.m. local time on August 31, 1996.

Dated: August 8, 1996.

T.W. Josiah,

Rear Admiral, U.S. Coast Guard Commander, Eighth Coast Guard District.

[FR Doc. 96-21932 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52****[CA 13-13-6749; FRL-5557-2]****Approval and Promulgation of Implementation Plans, California State Implementation Plan Revision, San Joaquin Valley Unified Air Pollution District**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing limited approval and limited disapproval of a revision to the California State Implementation Plan (SIP) proposed in the Federal Register on March 21, 1994. The revision concerns Rule 465.01 from the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD). This final action will incorporate this rule into the federally approved SIP. The intended effect of finalizing this action is to regulate emissions of

volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). The rule controls VOC emissions from steam-enhanced crude oil production well vents. Thus, EPA is finalizing a simultaneous limited approval and limited disapproval under CAA provisions regarding EPA action on SIP submittals and general rulemaking authority because this revision, while strengthening the SIP, also does not fully meet the CAA provisions regarding plan submissions and requirements for nonattainment areas. As a result of this limited disapproval, sanctions will be automatically imposed in accordance with EPA's Order of Sanctions rule unless the State submits and EPA approves corrections to the identified deficiencies within 18 months of the effective date of this disapproval. Moreover, EPA will be required to promulgate a Federal implementation plan (FIP) unless the deficiencies are corrected within 24 months of the effective date of this disapproval.

EFFECTIVE DATE: This action is effective on September 27, 1996.

ADDRESSES: Copies of the rule and EPA's evaluation report are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule are available for inspection at the following locations:

Rulemaking Section (A-5-3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 "M" Street, S.W., Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 95814

San Joaquin Valley Unified Air Pollution Control District, 1999 Tuolumne Street, Suite #200, Fresno, CA 95814.

FOR FURTHER INFORMATION CONTACT:

Daniel A. Meer, Rulemaking Section, (A-5-3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744-1185.

SUPPLEMENTARY INFORMATION:

Background

On March 21, 1994 in 59 FR 13289, EPA proposed granting limited approval and limited disapproval of SJVUAPCD's Rule 465.1, Steam-enhanced Crude Oil Production Well Vents, into the

California SIP. Rule 465.1 was adopted by SJVUAPCD on September 19, 1991. This rule was submitted by the California Air Resources Board (CARB) to EPA on January 28, 1992. This rule was submitted in response to EPA's 1988 SIP Call and the CAA section 182(a)(2)(A) requirement that nonattainment areas fix their reasonably available control technology (RACT) rules for ozone in accordance with EPA guidance that interpreted the requirements of the pre-amendment Act. A detailed discussion of the background for the above rule and nonattainment area is provided in the notice of proposed rulemaking (NPRM) cited above.

EPA has evaluated the above rule for consistency with the requirements of the CAA and EPA regulations and EPA's interpretation of these requirements as expressed in the various EPA policy guidance documents referenced in the NPRM. EPA is finalizing the limited approval of this rule in order to strengthen the SIP and finalizing the limited disapproval requiring the correction of the remaining deficiencies. The rule contains deficiencies which were required to be corrected pursuant to the section 182(a)(2)(A) requirement of part D of the CAA. Rule 465.1 lacks clarity in specifying rule applicability, lacks sufficient recordkeeping requirements, and includes an unapprovable provision which exempts certain equipment from New Source Review (NSR) requirements. Section III.G. of Rule 465.1 states that if a new incineration device is required solely to comply with the requirements of Rule 465.1 for existing cyclic wells, then the device will not be subject to New and Modified Source Review requirements, provided the device includes best available control technology for all air contaminants and is under a District permit. This provision is unapprovable and in order to correct the deficiency, section III.G. must be amended to be consistent with the memorandum entitled, "Pollution Control Projects and New Source Review Applicability" issued by John Seitz, Office of Air Quality Planning and Standards, on July 1, 1994. In addition, any emissions previously allowed under this NSR exemption must be offset. A detailed discussion of the rule provisions and evaluation have been provided in the NPRM and in the technical support document (TSD) available at EPA's Region IX office.

Response to Public Comments

A 30-day public comment period was provided in NPRM at 59 FR 13289. EPA received one comment letter on the

NPRM from the Independent Oil Producers' Agency (IOPA). The comment letter has been evaluated by EPA and a summary of the comment and EPA's response are set forth below.

Comment: In the TSD for SJVUAPCD Rule 465.1, EPA stated that no data were submitted to justify the exemption in Section III.F. The IOPA asked why EPA is questioning the small producer exemption for exempting 10 wells responding to another operator's steam injection when the emissions from the 100 cyclic wells in III.B exemption were not considered significant.

Response: Data submitted by SJVUAPCD demonstrate that emissions from the cyclic wells (exempted by section III.B) were not significant. However, emissions from non-cyclic wells tend to be much higher than from cyclic wells. SJVUAPCD did not submit sufficient data to show that the emissions from non-cyclic wells (exempted by section III.F) were also insignificant.

Comment: There is no need to require small producers to keep production records because oil producers always keep production records in order to monitor production levels.

Response: The EPA believes that recordkeeping, as outlined in the "Blue Book" is necessary to ensure that the sources are complying with the rule. If the producers are already keeping production records, there should be no difficulties in complying with the recordkeeping requirement.

Comment: According to the commenter, the word "county" was purposely left in the small production definition to delineate between the Kern County and Fresno County oilfields.

Response: EPA recognizes the point raised by the commenter. However, since the SJVUAPCD is comprised of eight counties, the word district is more appropriate to use, particularly for the applicability of promulgating rules and regulations.

EPA Action

EPA is finalizing a limited approval and a limited disapproval of the above-referenced rule. The limited approval of this rule is being finalized under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations necessary to further air quality by strengthening the SIP. The approval is limited in the sense that the rule strengthens the SIP. However, the rule does not meet the section 182(a)(2)(A) CAA requirement because of the rule deficiencies which were discussed in the NPRM. Thus, in order to strengthen the SIP, EPA is granting limited approval of this rule under

sections 110(k)(3) and 301(a) of the CAA. This action approves the rule into the SIP as federally enforceable.

At the same time, EPA is finalizing the limited disapproval of this rule because it contains deficiencies that have not been corrected as required by section 182(a)(2)(A) of the CAA, and, as such, the rule does not fully meet the requirements of Part D of the Act. As stated in the NPRM, upon the effective date of this NFRM, the 18 month clock for sanctions and the 24 month FIP clock will begin. Sections 179(a) and 110(c). If the State does not submit the required corrections and EPA does not determine within 18 months of the effective date of the NFRM that the State has corrected the deficiency, sanctions will be imposed in accordance with EPA's Order of Sanctions rule. See 59 FR 39832 (Aug. 4, 1994), to be codified at 40 CFR 52.31. It should be noted that the rule covered by this NFRM has been adopted by SJVUAPCD and is currently in effect in the SJVUAPCD. EPA's limited disapproval action will not prevent the SJVUAPCD, or the EPA from enforcing this rule.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Regulatory Process

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 28, 1996. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

Unfunded Mandates

Under Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of \$100 million or more to the private sector or to State,

local, or tribal governments in the aggregate.

Through submission of this state implementation plan or plan revision, the State and any affected local or tribal governments have elected to adopt the program provided for under Part D of the Clean Air Act. These rules may bind State, local, and tribal governments to perform certain actions and also require the private sector to perform certain duties. The rule being approved by this action will impose no new requirements because affected sources are already subject to these regulations under State law. Therefore, no additional costs to State, local, or tribal governments or to the private sector result from this action. EPA has also determined that this final action does not include a mandate that may result in estimated costs of \$100 million or more to State, local, or tribal governments in the aggregate or to the private sector.

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a major rule as defined by 5 U.S.C. 804(2).

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214-2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866 review.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Oxides of nitrogen, Ozone, Reporting and recordkeeping requirements, Volatile organic compound.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Dated: August 9, 1996.
Felicia Marcus,
Regional Administrator.

Subpart F of part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7671q.

Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(187)(i)(A)(6) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(187) * * *

(i) * * *

(A) * * *

(6) Rule 465.1, adopted on September 19, 1991.

* * * * *

[FR Doc. 96-21907 Filed 8-27-96; 8:45 am]

BILLING CODE 6560-50-W

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA-7647]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This rule identifies communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The dates listed in the third column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the NFIP at: Post Office Box 6464, Rockville, MD 20849, (800) 638-6620.

FOR FURTHER INFORMATION CONTACT: Robert F. Shea, Jr., Division Director, Program Implementation Division, Mitigation Directorate, 500 C Street, SW., room 417, Washington, DC 20472, (202) 646-3619.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return,

communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map (FHBM) or Flood Insurance Rate Map (FIRM). The date of the flood map, if one has been published, is indicated in the fourth column of the table. In the communities listed where a flood map has been published, Section 102 of the Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4012(a), requires the purchase of flood insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard areas shown on the map.

The Director finds that the delayed effective dates would be contrary to the public interest. The Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Acting Associate Director certifies that this rule will not have a significant economic impact on a substantial number of small entities in accordance with the Regulatory Flexibility Act, 5 U. S. C. 601 et seq., because the rule creates no additional burden, but lists those communities eligible for the sale of flood insurance.

Regulatory Classification

This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*, Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 64.6 [Amended]

2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date of eligibility	Current effective map date
NEW ELIGIBLES—Emergency Program			
Michigan: Ewing, township of, Marquette County	260957	July 2, 1996	
Kansas: Linn County, unincorporated areas	200194	July 3, 1996	
Nebraska: Guide Rock, village of, Webster County	310234	do	July 9, 1976.
Nevada: Fallon, city of, Churchill County	320002	do	Do.
Texas: Coleman County, unincorporated areas	480750	July 4, 1996	
Georgia: Molena, city of, Pike County	130376	July 25, 1996	Apr. 11, 1975.
Indiana: Washington County, unincorporated areas	180446	July 30, 1996	Apr. 21, 1978.
NEW ELIGIBLES—Regular Program			
Georgia: Hapeville, city of, Fulton County	130502	July 2, 1996	Aug. 24, 1993.
Tennessee: Rockford, city of, Blount County ¹	470320	July 26, 1996	June 3, 1991.
Wisconsin: Potter, village of, Calumet County	550609	July 30, 1996	June 15, 1983.
REINSTATEMENTS			
Pennsylvania:			
Fallowfield, township of, Washington County	422148	Oct. 15, 1975, Emerg.; Feb. 17, 1989, Reg.; Sept. 30, 1995, Susp.; July 9, 1996, Rein.	Sept. 30, 1995.
Edgeworth, borough of, Allegheny County	420032	Aug. 5, 1974, Emerg.; May 1, 1980, Reg.; Oct. 4, 1995, Susp.; July 10, 1996, Rein.	Oct. 4, 1995.
Monroeville, borough of, Allegheny County	420054	May 23, 1973, Emerg.; Aug. 1, 1979, Reg.; Oct. 4, 1995, Susp.; July 25, 1996, Rein.	Do.
Texas: Rising Star, city of, Eastland County	480795	Sept. 2, 1976, Emerg.; Oct. 31, 1978, Reg.; Jan. 18, 1989, Susp.; July 31, 1996, Rein..	Oct. 31, 1978.
REGULAR PROGRAM CONVERSIONS			
Region II			
New Jersey: Flemington, borough of, Hunterdon County.	340520	July 16, 1996, Suspension Withdrawn	July 16, 1996.
Region III			
Pennsylvania: Smithfield, township of, Huntingdon County.	420494	do	Do.

State and location	Community No.	Effective date of eligibility	Current effective map date
Virginia: Norfolk, independent city	510104	do	Do.
Region V			
Michigan: Cadillac, city of, Wexford County	260247	do	Mar. 18, 1996.
Region VI			
Arkansas: Pulaski County, unincorporated areas	050179	do	July 16, 1996.
New Mexico:			
Bernalillo, town of, Sandoval County	350056	do	Do.
Corrales, village of, Sandoval County	350094	do	Do.
Jemez Springs, village of, Sandoval County	350096	do	Do.
Rio Rancho, city of, Sandoval County	350146	do	Do.
Sandoval County, unincorporated areas	350055	do	Do.
Truth or Consequences, city of, Sierra County	350073	do	Do.
Sierra County, unincorporated areas	350071	do	Do.
Oklahoma:			
Chandler, city of, Lincoln County	400237	do	Do.
Lincoln County, unincorporated areas.	400457	do	Do.
Region VII			
Iowa:			
Clayton County, unincorporated areas	190858	do	Do.
Elkader, city of, Clayton County	190073	do	Do.
Region VIII			
Utah: Wendover, town of, Tooele County	490222	do	Do.

¹ The City of Rockford has adopted Blount County's FIRM dated June 3, 1991, (panels 0030 and 0040) and Flood Insurance Study for flood-plain management and flood insurance purposes.

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Rein.—Reinstatement; Susp.—Suspension; With.—Withdrawn.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Issued: August 19, 1996.

Richard W. Krimm,
Acting Associate Director, Mitigation
Directorate.

[FR Doc. 96-21961 Filed 8-27-96; 8:45 am]

BILLING CODE 6718-05-P

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: Modified base (1% annual chance) flood elevations are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified base flood elevations are indicated on the following table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect for each listed community prior to this date.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard

Identification Branch, Mitigation Directorate, 500 C Street S.W., Washington, DC 20472, (202) 646-2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below of modified base flood elevations for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Acting Associate Director has resolved any appeals resulting from this notification.

The modified base flood elevations are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection.

The modifications are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 et seq., and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain

qualified for participation in the National Flood Insurance Program.

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities.

These modified elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

The changes in base flood elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Acting Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105,

and are required to maintain community eligibility in the National Flood Insurance Program. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive

Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements. Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Alabama:					
Calhoun (FEMA Docket No. 7174).	Unincorporated areas.	Mar. 6, 1996, Mar. 13, 1996, <i>The Anniston Star</i> .	Mr. Kenneth Joiner, Calhoun County Administrator, 1702 Noble Street, Suite 103, Anniston, Alabama 36201.	Feb. 28, 1996	010013 C
Calhoun and Talladega (FEMA Docket No. 7174).	City of Oxford	Mar. 6, 1996, Mar. 13, 1996, <i>The Anniston Star</i> .	The Honorable Leon Smith Mayor of the City of Oxford, P.O. Box 3383, 100 Choccolocco Street, Oxford, Alabama 36203.	Feb. 28, 1996	010023 C
Connecticut: Fairfield (FEMA Docket No. 7165).	City of Stamford	Oct. 13, 1995, Oct. 2, 1995, <i>The Advocate</i> .	The Honorable Stanley Esposito, Mayor of the City of Stamford, Stamford Government Center, 888 Washington Boulevard, Stamford, Connecticut 06904-2152.	Oct. 2, 1995	090015 C
Florida:					
Broward (FEMA Docket No. 7174).	Town of Hillsboro Beach.	Feb. 1, 1996, Feb. 8, 1996, <i>Observer</i> .	The Honorable Howard Sussman, Mayor of the Town of Hillsboro Beach, 1210 Hillsboro Mile, Hillsboro Beach, Florida 33062.	Jan. 24, 1996	120040 F
Duval (FEMA Docket No. 7174).	City of Jacksonville	Feb. 1, 1996, Feb. 8, 1996, <i>The Florida Times-Union</i> .	The Honorable John Delaney, Mayor of the City of Jacksonville, 220 East Bay Street, 14th Floor, Jacksonville, Florida 32202-3495.	Jan. 25, 1996	120077 E
Lee (FEMA Docket No. 7173).	Unincorporated areas.	Dec. 22, 1995, Dec. 29, 1995, <i>News-Press</i> .	Mr. Donald P. Stilwell Lee County Manager, Administration Department, P.O. Box 398, Fort Myers, Florida 33902-0398.	Dec. 7, 1995	125124 B
Georgia:					
Bryan (FEMA Docket No. 7178).	Unincorporated areas.	Mar. 27, 1996, Apr. 3, 1996, <i>Richmond Hill-Bryan County News</i> .	Mr. Thomas Bacon, Chairman of the Bryan County Board of Commissioners, P.O. Box 430, Pembroke, Georgia 31321.	Mar. 19, 1996	130016 A
Fulton (FEMA Docket No. 7174).	City of Fairburn	Feb. 29, 1996, Mar. 7, 1996, <i>The South Fulton Neighbor</i> .	The Honorable Betty Hannah, Mayor of the City of Fairburn, P.O. Box 145, Fairburn, Georgia 30213.	June 5, 1996	130314 B
Fulton (FEMA Docket No. 7174).	Unincorporated areas.	Feb. 8, 1996, Feb. 15, 1996, <i>Daily Report</i> .	Mr. Mitchell Skandalakis, Chairman of the Fulton County Board of Commissioners, 141 Pryor Street, S.W., Atlanta, Georgia 30303.	May 15, 1996	135160 B
Florida: Pinellas (FEMA Docket No. 7174).	City of St. Petersburg.	Jan. 26, 1996, Feb. 2, 1996, <i>St. Petersburg Times</i> .	The Honorable David J. Fisher, Mayor of the City of St. Petersburg, P.O. Box 2842, St. Petersburg, Florida 33731.	Jan. 19, 1996	125148C
Illinois:					
Lake and Cook (FEMA Docket No. 7130).	Village of Deerfield	Apr. 20, 1995, Apr. 27, 1995, <i>Deerfield Review</i> .	The Honorable Bernard Forrest, 850 Waukegan Road, Deerfield, Illinois 60015.	Apr. 13, 1995	170361C
Marion and Clinton (FEMA Docket No. 7174).	City of Centralia	Feb. 23, 1996, Mar. 1, 1996, <i>Centralia Sentinel</i> .	Ms. Becky Roeckeman, Community Development Director, 222 South Poplar Street, Centralia, Illinois 62801.	Aug. 16, 1996	170453 C
Tazewell (FEMA Docket No. 7174).	Village of Morton ...	Mar. 6, 1996, Mar. 13, 1996, <i>Tazewell News</i> .	Robert D. Hertenstein, M.D., President of the Village of Morton Board of Trustees, P.O. Box 28, 120 North Main Street, Morton, Illinois 61550-0028.	Feb. 28, 1996	170652 D

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Will (FEMA Docket No. 7165).	Village of New Lenox.	Oct. 11, 1995, Oct. 18, 1995, <i>Herald-News</i> .	Mr. John Nowakowski, President of the Village, of New Lenox, 701 West Haven Avenue, New Lenox, Illinois 60451-2137.	Apr. 3, 1996	170706 E
Cook (FEMA Docket No. 7173).	City of Prospect Heights.	Jan. 3, 1996, Jan. 10, 1996, <i>Daily Herald</i> .	The Honorable Edward Rotchford, Mayor of the City of Prospect Heights, No. 1 Elmhurst Road, Prospect Heights, Illinois 60070.	Dec. 20, 1995	170054 B
Indiana: Hamilton (FEMA Docket No. 7174).	Town of Westfield	Feb. 13, 1996, Feb. 20, 1996 <i>Noblesville Daily Ledger</i> .	Mr. Mike McDonald, Westfield Town Council President, 130 Penn Street, Westfield, Indiana 46074.	May 20, 1996	180083 C
Massachusetts: Bristol (FEMA Docket No. 7174).	Town of Mansfield	Jan. 26, 1996, Feb. 2, 1996 <i>Mansfield News</i> .	Mr. William F. Williams, Mansfield Town Manager, 50 West Street, Mansfield, Massachusetts 02048.	May 2, 1996	250057
Middlesex (FEMA Docket No. 7158).	City of Lowell	Oct. 3, 1995, Oct. 10, 1995, <i>The Sun</i> .	Mr. Richard Johnson, Manager of the City of Lowell, 375 Merrimack Street, Lowell, Massachusetts 01852.	Jan. 8, 1996	250201 C
New Jersey: Union (FEMA Docket No. 7183).	Borough of Kenilworth.	Apr. 10, 1996, Apr. 17, 1996, <i>Cranford Chronicle</i> .	The Honorable Michael Tripodi, Mayor of the Borough of Kenilworth, 567 Boulevard, Kenilworth, New Jersey 07033.	Apr. 3, 1996	340466 B
Union (FEMA Docket No. 7178).	Borough of Roselle	Apr. 11, 1996, Apr. 18, 1996, <i>Roselle Spectator</i> .	The Honorable Joseph L. Picaro, Mayor of the Borough of Roselle, 210 Chestnut Street, Roselle, New Jersey 07203.	Apr. 2, 1996	340472 A
New York: Erie (FEMA Docket No. 7174).	Town of Amherst ...	Jan. 31, 1996, Feb. 7, 1996, <i>Amherst Bee</i> .	Mr. Thomas Ahern, Town of Amherst Supervisor, Amherst Municipal Building, 5583 Main Street, Williamsville, New York 14221.	May 8, 1996	360226 D
Erie (FEMA Docket No. 7174).	Village of Williamsville.	Jan. 31, 1996, Feb. 7, 1996, <i>Amherst Bee</i> .	The Honorable Basil Piazza, Mayor of the Village of Williamsville, P.O. Box 1557, Williamsville, New York 14231-1557.	May 8, 1996	360263 B
North Carolina: Haywood (FEMA Docket No. 7174).	Unincorporated areas.	Jan. 31, 1996, Feb. 7, 1996, <i>The Mountaineer</i> .	Mr. Ed Russell, Chairman of the Haywood County Board of Commissioners, 420 North Main Street, Waynesville, North Carolina 28786.	Jan. 24, 1996	370120 B
Henderson (FEMA Docket No. 7169).	City of Hendersonville.	Nov. 3, 1995, Nov. 10, 1995, <i>The Times News</i> .	The Honorable Fred Neihoff, Mayor of the City of Hendersonville, P.O. Box 1670, Hendersonville, North Carolina 28793.	May 6, 1996	370128 B

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Dated: August 15, 1996.

Richard W. Krimm,
Acting Associate Director for Mitigation.
[FR Doc. 96-21963 Filed 8-27-96; 8:45 am]
BILLING CODE 6718-03-P

44 CFR Part 65

[Docket No. FEMA-7191]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the

base (1% annual chance) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Acting Associate Director reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street S.W., Washington, DC 20472, (202) 646-2756.

SUPPLEMENTARY INFORMATION: The modified base flood elevations are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 et seq., and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program.

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact

stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities.

The changes in base flood elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Acting Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the National Flood Insurance Program. No regulatory flexibility analysis has been prepared.

Regulatory Classification

This interim rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Connecticut: Fairfield	City of Bridgeport	June 14, 1996, June 21, 1996, <i>Connecticut Post</i> .	The Honorable Joseph P. Ganim, Mayor of the city of Bridgeport, 45 Lyon Terrace, Bridgeport, Connecticut 06604.	Sept. 19, 1996	090002 C
Fairfield	Town of Stratford	June 14, 1996, June 21, 1996, <i>Connecticut Post</i> .	Mr. Mark S. Barnhart, Stratford Town Manager, 2725 Main Street, Stratford, Connecticut 06497.	Sept. 19, 1996	090016 D
Illinois: Will and DuPage Counties.	City of Naperville	Dec. 13, 1995, Dec. 20, 1995, <i>The Naperville Sun</i> .	The Honorable A. George Pradel, Mayor of the City of Naperville, 400 South Eagle Street, Naperville, Illinois 60540.	Dec. 5, 1996	170213 C
Cook	City of Country Club Hills.	June 13, 1996, June 20, 1996, <i>The Star</i> .	The Honorable Dwight W. Welch, Mayor of the City of Country Club Hills, 4200 West 183rd Street, Country Club Hills, Illinois 60478.	June 6, 1996	170078 C
Kane	Village of Hampshire ...	June 5, 1996, June 12, 1996, <i>Hampshire Register</i> .	Mr. William Schmidt, President of the Village of Hampshire, 234 South State Street, P.O. Box 457, Hampshire, Illinois 60140.	June 5, 1996	170327 C
Indiana:					

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Allen	Town of Grabill	July 16, 1996, July 23, 1996, <i>Journal Gazette</i> .	Ms. Joanne Sauder, Grabill Town Council, P.O. Box 321, Grabill, Indiana 46741.	July 9, 1996	180499 D
Allen	Unincorporated areas	July 16, 1996, July 23, 1996, <i>Journal Gazette</i> .	Mr. Jack McComb, Allen County Commissioner, City/County Building, 1 East Main Street, Room 220, Fort Wayne, Indiana 46802.	Oct. 21, 1996	180302 D
Minnesota: Washington	Unincorporated areas	July 17, 1996, July 24, 1996, <i>Oakdale-Lake Elmo Review</i> .	Mr. Dave Engstrom, Chairman of the Washington County Board of Commissioners, 14900 61st Street North, Stillwater, Minnesota 55082.	Oct. 22, 1996	270499 B
North Carolina: Orange, Durham, and Chatham.	Town of Chapel Hill	July 2, 1996, July 9, 1996, <i>The Chapel Hill Herald</i> .	The Honorable Rosemary Waldorf, Mayor of the Town of Chapel Hill, 306 North Columbia Street, Chapel Hill, North Carolina 27516-2124.	June 25, 1996	370180 E
Puerto Rico	Commonwealth	Aug. 7, 1996, Aug. 14, 1996, <i>El Nuevo Dia</i> .	Ms. Norma N. Burjos-Andujar, Chairperson of the Puerto Rico Planning Board, Centro Gubernamental Minillas, P.O. Box 41119, San Juan, Puerto Rico 00940-9985.	July 18, 1996	720000 E
Tennessee: Shelby	City of Memphis	June 14, 1996, June 21, 1996, <i>The Commercial Appeal</i> .	The Honorable W.W. Harrenton, Mayor of the City of Memphis, 125 North Main Street, Memphis, Tennessee 38103.	Sept. 19, 1996	470177 E

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Dated: August 15, 1996.

Richard W. Krimm,

Acting Associate Director for Mitigation.

[FR Doc. 96-21962 Filed 8-27-96; 8:45 am]

BILLING CODE 6718-03-P

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Base (1% annual chance) flood elevations and modified base flood elevations are made final for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the

National Flood Insurance Program (NFIP).

EFFECTIVE DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646-2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA or Agency) makes final determinations listed below of base flood elevations and modified base

flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the Federal Register.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

The Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and Flood Insurance Rate Map available at the address cited below for each community.

The base flood elevations and modified base flood elevations are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Acting Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the National Flood Insurance Program. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
CONNECTICUT			
Clinton (Town), Middlesex County (FEMA Docket No. 7172)		Approximately 50 feet upstream of the confluence with Sanborn and Sheldens Brooks	*162
<i>Spencer Hill Brook:</i>		Approximately 1 mile upstream of Hillcrest Drive	*221
Approximately 820 feet downstream of River Road	*14	<i>Sheldens Brook:</i>	
Approximately 1,460 feet upstream of Fox Hill Drive	*122	At upstream side of School Street	*169
<i>West Branch Boulder Lake Brook:</i>		Approximately 1.4 miles upstream of School Street	*184
At confluence with Boulder Lake Brook	*22	Maps available for inspection at the Planning and Zoning Office, 9 Center Street, East Granby, Connecticut.	
Approximately 0.5 mile upstream of West Shore Road	*51		
<i>Boulder Lake Brook:</i>		Ellington (Town), Tolland County (FEMA Docket No. 7172)	
Approximately 20 feet downstream of CONRAIL	*22	<i>Pecks Brook:</i>	
Approximately 480 feet upstream of Kenilworth Drive ...	*96	At corporate limits	*192
<i>Old Nod Brook:</i>		Approximately 0.7 mile upstream of upstream Middle Road crossing	*246
Approximately 64 feet downstream of the CONRAIL track	*12	<i>Ketch Brook:</i>	
Approximately 260 feet upstream of Airline Road	*94	Approximately 2,300 feet downstream of Tripp Road	*188
Maps available for inspection at the Clinton Town Hall, Land Use Office, 54 East Main Street, Clinton, Connecticut.		Approximately 900 feet upstream of Tripp Road	*197
		<i>Broad Brook:</i>	
East Granby (Town), Hartford County (FEMA Docket No. 7172)		At corporate limits	*145
<i>South Tributary of Austin Brook:</i>		Approximately 1 mile upstream of Bridge Street	*239
At confluence with Austin Brook	*169	<i>Charters Brook:</i>	
Approximately 1.7 miles upstream of Ridge Road	*189	At corporate limits	*557
<i>Austin Brook:</i>		At downstream side of the upstream crossing of Webster Road	*713
Approximately 800 feet downstream of State Route 187 ...	*162	<i>Abbey Brook:</i>	
At upstream corporate limits	*170	At corporate limits	*222
<i>Muddy Brook:</i>		Approximately 1,600 feet upstream of Strawberry Road	*230
Approximately 0.9 mile upstream of confluence of Marsh Pond Brook	*164	Maps available for inspection at the Ellington Town Hall, 55 Main Street, Ellington, Connecticut.	
Approximately 1.3 miles upstream of confluence with Marsh Pond Brook			
<i>Marsh Pond Brook:</i>		FLORIDA	
Approximately 700 feet upstream of confluence with Muddy Brook	*164	Destin (City), Okaloosa County (FEMA Docket No. 7172)	
Approximately 450 feet upstream of Hatchett Hill Road	*253	<i>Gulf of Mexico:</i>	
<i>West Brook:</i>		Approximately 1,000 feet east northeast of the intersection of Gulf Shore Drive and Moreno Point Road	*4
At downstream corporate limits	*165	Approximately 400 feet south of the intersection of Mathew Boulevard and Ocean View Drive	*12
Approximately 270 feet upstream of Sweetbriar Road	*176	Maps available for inspection at the City Hall, P.O. Box 399, Destin, Florida.	
<i>DeGraves Brook:</i>			
At downstream corporate limits	*136		
Approximately 500 feet upstream of Nicholson Road ...	*169		
<i>Creamery Brook:</i>			

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
MARYLAND					
Cecil County (Unincorporated Areas) (FEMA Docket No. 7172)		Approximately 0.64 mile upstream of the confluence with the Susquehanna River	*825	Approximately 1,500 feet upstream of Bamboo Road	*3127
<i>Christina River:</i>		Maps available for inspection at the Town Hall, 2354 State Route 434, Apalachin, New York.		<i>South Fork New River:</i>	
Approximately 200 feet upstream of Wedgewood Road	*160			Approximately 350 feet downstream of U.S. Routes 421/321	*3089
At the upstream county boundary	*269	Trenton (Town), Oneida County (FEMA Docket No. 7172)		At confluence of Middle Fork and East Fork	*3113
<i>West Branch Christina River:</i>		<i>West Canada Creek:</i>		<i>Mutton Creek:</i>	
Approximately 200 feet upstream of the downstream county boundary	*107	Approximately 500 feet downstream of State Route 28	*715	At confluence with South Fork New River	*3096
Approximately 250 feet upstream of Jackson Hall School Road	*196	Approximately 6,000 feet upstream of State Route 28	*720	Approximately 900 feet downstream of Wilson's Ridge Road	*3114
Maps available for inspection at the Cecil County Office of Planning and Zoning, 129 East Main Street, Room 300, Elkton, Maryland.		Maps available for inspection at the Town Municipal Center, Old Poland Road, Barneveld, New York.		Maps available for inspection at the Department of Planning and Inspections, 1510 Blowing Rock Road, Boone, North Carolina.	
MICHIGAN					
Torch Lake (Township), Antrim County (FEMA Docket No. 7164)		NORTH CAROLINA		Marion (City), McDowell County (FEMA Docket No. 7182)	
<i>Torch Lake:</i>		Blowing Rock (Town), Watauga County (FEMA Docket No. 7172)		<i>Catawba River:</i>	
Entire shoreline within community	*591	<i>Middle Fork:</i>		Approximately 340 feet (or 0.1 mile) downstream of the U.S. Route 221 bridge	*1,222
<i>Grand Traverse Bay:</i>		At downstream corporate limits approximately 250 feet upstream of Shoppes on the Parkway Entrance	*3,480	Approximately 0.4 mile upstream of the U.S. Route 221 Bypass bridge	*1,228
Entire shoreline within community	*585	Approximately 700 feet upstream of U.S. Route 321	*3,517	Maps available for inspection at the Marion City Hall, 200 North Main Street, Marion, North Carolina.	
Maps available for inspection at the Torch Lake Township Hall, 5085 U.S. 31 North, Eastport, Michigan.		Maps available for inspection at the Blowing Rock Town Hall, 1036 Main Street, Blowing Rock, North Carolina.		McDowell County and Incorporated Areas (FEMA Docket No. 7128)	
NEW YORK					
Newport (Town), Herkimer County (FEMA Docket No. 7175)		Boone (Town), Watauga County (FEMA Docket No. 7172)		<i>Catawba River:</i>	
<i>West Canada Creek:</i>		<i>Winkler Creek:</i>		At Yancey Road	*1,202
Approximately 200 feet downstream of Old State Road	*686	At confluence with South Fork New River	*3113	Approximately 2.6 miles upstream of State Route 1273	*1,525
Approximately 1.02 miles upstream of Old State Road	*696	Approximately 300 feet downstream of Blowing Rock Road	*3113	<i>Mill Creek:</i>	
Maps available for inspection at the Newport Town Hall, West Street, Newport, New York.		<i>Hodges Creek:</i>		Approximately 1,350 feet upstream of Norfolk Southern Railway	*1,449
		Approximately 200 feet downstream of State Route 105 ...	*3148	Approximately 0.4 mile upstream of State Route 1401	*1,483
		Approximately 640 feet upstream of State Route 105 and Highland Commons Shopping Center	*3285	Maps available for inspection at the McDowell County Administration Building, 10 East Court, Marion, North Carolina.	
Owego (Town), Tioga County (FEMA Docket No. 7164)		<i>Middle Fork:</i>		Old Fort (Town), McDowell County (FEMA Docket No. 7128)	
<i>Susquehanna River:</i>		At confluence with South Fork New River	*3113	<i>Catawba River:</i>	
Approximately 1.4 miles downstream of confluence of Apalachin Creek	*822	Approximately 0.2 mile upstream of State Route 321/221	*3297	At the confluence of Curtis Creek	*1,375
Approximately 2.2 miles upstream of confluence of Apalachin Creek	*828	<i>Rocky Knob:</i>		Approximately 1,300 feet downstream of Catawba Avenue	*1,412
<i>Apalachin Creek:</i>		At confluence with South Fork New River	*3105	<i>Mill Creek:</i>	
At the confluence with the Susquehanna River	*825	At upstream side of State Route 194/U.S. Route 421/221	*3141	At the confluence with the Catawba River	*1,409
		<i>East Fork:</i>		At the State Route 1119	*1,455
		At confluence with South Fork New River	*3113		

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Maps available for inspection at the Old Fort City Hall, 106 South Catawba, Old Fort, North Carolina.		Approximately 350 feet downstream of U.S. Routes 421/321		Approximately 850 feet upstream of Johnston Avenue	*238
Mecklenburg County (Unincorporated Areas) (FEMA Docket No. 7172)		<i>Watauga River:</i> Approximately 700 feet downstream of Greer Bridge	*3089	<i>Tacony Creek:</i> Approximately 350 feet upstream of Greenwood Avenue	*206
<i>Blankmansion Branch:</i> Approximately 210 feet downstream of county boundary with York County, South Carolina	*617	Approximately 890 feet upstream of State Route 1598 (Grandfather Road)	*3598	Approximately 1,200 feet upstream of Greenwood Avenue	*212
Approximately 190 feet upstream of Smith-Boyd Road	*617	<i>Aho Branch:</i> At confluence with Middle Fork At State Route 1533 (Aho Road)	*3366	<i>Pennypack Creek:</i> A point approximately 1,700 feet downstream of Moredon Road	*100
<i>Steele Creek:</i> At State boundary	*571	<i>Laurel Fork:</i> At confluence with Watauga River	*2740	A point approximately 1,300 feet downstream of Moredon Road	*100
At approximately 1,900 feet upstream of Red Hickory Lane	*622	<i>Dutch Creek:</i> At confluence with Watauga River	*2666	Maps available for inspection at the Township Engineer's Office, 1176 Old York Road, Abington, Pennsylvania.	
<i>Polk Ditch:</i> At confluence with Walker Branch	*571	Approximately 425 feet upstream of State Route 1134	*2741	Bridgeport (Borough), Montgomery County (FEMA Docket No. 7140)	
At approximately 600 feet upstream of Choate Circle	*571	Maps available for inspection at the Department of Planning and Inspections, 331 Queen Street, Boone, North Carolina.		<i>Schuylkill River:</i> Approximately 1.0 mile downstream of Dekalb Street (U.S. Route 202 North)	*72
<i>Walker Branch:</i> At confluence with Steele Creek	*571	Whiteville (City), Columbus County (FEMA Docket No. 7179)		Approximately 50 feet upstream of Norristown Dam ...	*76
At approximately 0.4 mile upstream of confluence of Polk Ditch	*571	<i>Griffith Branch:</i> Approximately 0.5 mile downstream of Nolan Avenue	*55	Maps available for inspection at the Borough Hall, 4th and Mill Street, Bridgeport, Pennsylvania.	
Maps available for inspection at the Mecklenburg County Engineering Building, 700 North Tyron, Charlotte, North Carolina.		Approximately 210 feet upstream of Bentmoor Drive ...	*79	Cheltenham (Township), Montgomery County (FEMA Docket No. 7140)	
Watauga County (Unincorporated Areas) (FEMA Docket No. 7172)		<i>Mollies Branch:</i> At Seaboard Coastline Railroad	*59	<i>Tacony Creek:</i> At East Cheltenham Avenue ...	*79
<i>East Fork:</i> At the upstream side of Bamboo Road	*3123	Approximately 800 feet upstream of U.S. Business Routes 74-76	*70	Maps available for inspection at the Cheltenham Township Administrative Building, 8230 Old York Road, Elkins Park, Pennsylvania.	
At the upstream side of Bamboo Road/State Route 1514	*3204	<i>Soules Swamp:</i> Approximately 0.9 mile downstream of U.S. Route 701 Bypass	*53	Conshohocken (Borough), Montgomery County (FEMA Docket No. 7172)	
<i>Howard Creek:</i> At the confluence with South Fork New River	*3064	Approximately 1,860 feet upstream of U.S. Route 701 Bypass	*58	<i>Plymouth Creek:</i> At confluence with the Schuylkill River	*66
Approximately 480 feet upstream of the dam at Howard Creek Pumping Station	*3213	<i>White Marsh:</i> At Seaboard Coastline Railroad	*54	Approximately 100 feet downstream of West Elm Street ...	*66
<i>Middle Fork:</i> At confluence with South Fork New River	*3113	Approximately 20 feet upstream of U.S. Route 74-76 Bypass	*59	<i>Schuylkill River:</i> Approximately 0.9 mile downstream of Fayette Street	*61
Approximately 250 feet upstream of Shoppes on the Parkway Entrance	*3480	Maps available for inspection at the Whiteville City Hall, 317 South Madison Street, Whiteville, North Carolina.		Approximately 250 feet upstream of Plymouth Dam	*66
<i>Mutton Creek:</i> Approximately 900 feet downstream of Wilson's Ridge Road	*3114	PENNSYLVANIA		Maps available for inspection at the Borough Hall, 8th and Fayette Street, Conshohocken, Pennsylvania.	
Approximately 60 feet upstream of Wilson's Ridge Road	*3138	Abington (Township), Montgomery County (FEMA Docket No. 7140)			
<i>South Fork New River:</i> At the downstream corporate limit	*2920	<i>Sandy Run Tributary No. 1:</i> At confluence with Sandy Run	*236		

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Hatfield (Borough), Montgomery County (FEMA Docket No. 7179)		At confluence with the Schuylkill River	*53	At confluence with Schuylkill River	*94
<i>West Branch Neshaminy Creek:</i> Approximately 300 feet downstream of Lakewood Avenue	*300	Approximately 375 feet upstream of confluence with the Schuylkill River	*55	Approximately 400 feet upstream of the confluence with the Schuylkill River	*96
Approximately 150 feet upstream of Lakewood Avenue	*301	<i>Schuylkill River:</i> At the county boundary (just downstream of U.S. Route 1)	*37	Maps available for inspection at the Lower Providence Township Building, 100 Park Lane Drive, Eagleville, Pennsylvania.	
Maps available for inspection at the Borough Hall, 401 South Main Street, Hatfield, Pennsylvania.		Approximately 3.7 miles upstream of confluence of Mill Creek	*63	Lower Salford (Township), Montgomery County (FEMA Docket No. 7182)	
Hatfield (Township), Montgomery County (FEMA Docket No. 7149)		Maps available for inspection at the Lower Merion Building Department, 75 E. Lancaster Avenue, Ardmore, Pennsylvania.		<i>Skipack Creek:</i> At Quarry Bridge Road	*176
<i>West Branch Neshaminy Creek:</i> Approximately 300 feet downstream of Lakewood Avenue	*300	Lower Moreland (Township), Montgomery County (FEMA Docket No. 7140)		Near Wampole Road approximately 950 feet upstream of State Highway 63	*199
Approximately 150 feet upstream of Lakewood Avenue	*301	<i>Pennypack Creek:</i> Approximately 0.4 mile downstream of confluence of Huntingdon Valley Creek	*117	<i>Skipack Creek Tributary No. 2:</i> Approximately 150 feet downstream of Wampole Road	*211
Maps available for inspection at the Borough Hall, 401 South Main Street, Hatfield, Pennsylvania.		Maps available for inspection at the Lower Moreland Municipal Building, 640 Red Lion Road, Huntingdon Valley, Pennsylvania.		Approximately 525 feet upstream of Wampole Road	*212
Jenkintown (Borough), Montgomery County (FEMA Docket No. 7182)		Lower Pottsgrove (Township), Montgomery County (FEMA Docket No. 7140)		Maps available for inspection at the Township Office, 474 Main Street, Harleysville, Pennsylvania.	
<i>Tacony Creek:</i> Approximately 200 feet upstream of Greenwood Avenue	*206	<i>Sanatoga Creek:</i> At confluence with the Schuylkill River	*127	New Hanover (Township), Montgomery County (FEMA Docket No. 7140)	
At the confluence of Baeder Run	*220	Approximately 150 feet upstream of South Pleasantview Road	*131	<i>Minister Creek:</i> Approximately 0.62 mile upstream of the confluence of Minister Creek Tributary	*270
<i>Baeder Run:</i> At the confluence with Tacony Creek	*220	<i>Sprogels Run:</i> At confluence with the Schuylkill River	*130	Approximately 0.74 mile upstream of the confluence of Minister Creek Tributary	*271
Approximately 586 feet upstream of confluence with Tacony Creek	*220	At upstream side of Sanatoga Station Road	*133	<i>Swamp Creek:</i> Approximately 900 feet upstream of Colonial Road	*235
Maps available for inspection at the Jenkintown Borough Offices, 700 Summit Avenue, Jenkintown, Pennsylvania.		<i>Schuylkill River:</i> Approximately 0.7 mile downstream of Sanatoga Road	*125	Approximately 1,450 feet upstream of Colonial Road	*236
Limerick (Township), Montgomery County (FEMA Docket No. 7140)		Approximately 800 feet upstream of U.S. Route 422	*137	Maps available for inspection at the New Hanover Township Municipal Building, 2943 North Charlotte Street, Gilbertsville, Pennsylvania.	
<i>Schuylkill River:</i> Approximately 2.0 mile downstream of Vincent Dam	*113	Maps available for inspection at the Lower Pottsgrove Municipal Building, 2199 Buchert Road, Pottstown, Pennsylvania.		Norristown (Borough), Montgomery County (FEMA Docket No. 7140)	
Approximately 1.6 mile upstream of Legislative Route 462 (Main Street)	*125	Lower Providence (Township), Montgomery County (FEMA Docket No. 7140)		<i>Stony Creek:</i> At confluence with the Schuylkill River	*77
Maps available for inspection at the Code Enforcement Office, 646 West Ridge Pike, Limerick, Pennsylvania.		<i>Schuylkill River:</i> Approximately 1,100 feet upstream of U.S. Route 422	*83	Approximately 380 feet upstream of Factory Bridge	*80
Lower Merion (Township), Montgomery County (FEMA Docket No. 7140)		At confluence of Perkiomen Creek	*94	<i>Schuylkill River:</i> Approximately 0.7 mile downstream of confluence of Sawmill Run	*72
<i>Mill Creek:</i>		<i>Perkiomen Creek:</i>		Approximately 0.5 mile upstream of Hawes Avenue	*78

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Maps available for inspection at the Borough Hall, 235 East Airy Street, Norristown, Pennsylvania.		Approximately 0.6 mile upstream of State Route 683 ...	*113	Approximately 0.2 mile upstream of Interstate Route 476 (Mid County Expressway)	*68
Pennsburg (Borough), Montgomery County (FEMA Docket No. 7140)		Maps available for inspection at the Royersford Borough Hall, 300 Main Street, Royersford, Pennsylvania.		At confluence of Valley Creek	*88
<i>Macoby Creek:</i>		Salford (Township), Montgomery County (FEMA Docket No. 7140)		<i>Valley Creek:</i>	
Approximately 0.2 mile downstream of Otts Road	*331	<i>East Branch Perkiomen Creek:</i>		Approximately 0.4 mile downstream of the county boundary	*96
Approximately 325 feet downstream of Otts Road	*334	Approximately 100 feet upstream of Moyer Road	*220	At county boundary	*104
Maps available for inspection at the Pennsburg Borough Building, 76 West 6th Street, Pennsburg, Pennsylvania.		Approximately 1,400 feet upstream of Moyer Road	*222	<i>Trout Creek:</i>	
Plymouth (Township), Montgomery County (FEMA Docket No. 7140)		Maps available for inspection at the Zoning Office, 139 Ridge Road, Tylersport, Pennsylvania.		At the confluence with the Schuylkill River	*81
<i>Schuylkill River:</i>		Springfield (Township), Montgomery County (FEMA Docket No. 7140)		Approximately 450 feet upstream of the confluence with the Schuylkill River	*81
Approximately 0.2 mile downstream of Interstate Route 476 (Mid County Expressway)	*67	<i>Oreland Run:</i>		Approximately 300 feet upstream Old State Route 363	*107
Approximately 1,000 feet upstream of I-276 Pennsylvania Turnpike	*72	At confluence with Wissahickon Creek	*149	Approximately 750 feet upstream Old State Route 363	*108
Maps available for inspection at the Office of Public Works, 700 Belvoir Road, Norristown, Pennsylvania.		Approximately 650 feet upstream of confluence with Wissahickon Creek	*150	Maps available for inspection at the Department of Public Works, 175 West Valley Forge Road, King of Prussia, Pennsylvania.	
Pottstown (Borough), Montgomery County (FEMA Docket No. 7140)		Maps available for inspection at the Springfield Township Municipal Building, 1510 Paper Mill Road, Wyndmoor, Pennsylvania.		Upper Providence (Township), Montgomery County (FEMA Docket No. 7140)	
<i>Manatawny Creek:</i>		Upper Dublin (Township), Montgomery County (FEMA Docket No. 7140)		<i>Schuylkill River:</i>	
At confluence with the Schuylkill River	*142	<i>Tannery Run (Backwater Area):</i>		At confluence of Perkiomen Creek	*94
Approximately 400 feet upstream of confluence with the Schuylkill River	*144	Approximately 150 feet east of intersection of Butler of intersection of Butler	*198	Approximately 0.8 mile upstream of confluence of Mingo Creek	*109
<i>Sprogels Run:</i>		Maps available for inspection at the Municipal Building, 801 Loch Alsh Avenue, Fort Washington, Pennsylvania.		<i>Mingo Creek:</i>	
Approximately 0.24 mile upstream of U.S. Route 422	*144	Upper Frederick (Township), Montgomery County (FEMA Docket No. 7140)		Approximately 100 feet downstream of Old Mill Road	*149
Approximately 0.32 mile upstream of East High Street	*144	<i>Swamp Creek:</i>		Approximately 100 feet upstream of Old Mill Road	*150
<i>Schuylkill River:</i>		Approximately 685 feet upstream of Neiffer Road	*200	<i>Perkiomen Creek:</i>	
Approximately 0.4 mile downstream of South Kiem Street	*137	Approximately 1,425 feet upstream of Neiffer Road	*204	At the confluence with the Schuylkill River	*94
Approximately 100 feet upstream of U.S. Route 422	*145	Maps available for inspection at the Township Building, 3205 Big Road, Obelisk, Pennsylvania.		Approximately 400 feet upstream of the confluence with the Schuylkill River	*97
Maps available for inspection at the Code Enforcement Office, Borough Hall, 241 King Street, Pottstown, Pennsylvania.		Upper Merion (Township), Montgomery County (FEMA Docket No. 7140)		Maps available for inspection at the Upper Providence Township Administration Office, 1286 Black Rock Road, Box 406, Oaks, Pennsylvania.	
Royersford (Borough), Montgomery County (FEMA Docket No. 7140)		<i>Schuylkill River:</i>		West Norriton (Township), Montgomery County (FEMA Docket No. 7140)	
<i>Schuylkill River:</i>		Approximately 0.6 mile downstream of State Route 683 (Main Street)	*110	<i>Schuylkill River:</i>	
				Approximately 0.2 mile downstream of U.S. Route 202 (South)	*76
				Approximately 0.2 mile upstream of U.S. Route 422	*83
				Maps available for inspection at the Township Building, 1630 West Marshall Street, Jeffersonville, Pennsylvania.	

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)	Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
West Pottsgrove (Township), Montgomery County (FEMA Docket No. 7140)		Maps available for inspection at the Borough Hall of West Conshohocken, 112 Ford Street, Conshohocken, Pennsylvania.		At confluence with Windhall River	*1,021
<i>Schuylkill River:</i>				At upstream corporate limits	*1,266
Approximately 100 feet upstream of U.S. Route 422	*145	TENNESSEE		<i>Lowell Lake Brook:</i>	
Approximately 1.5 miles upstream of U.S. Route 422 (at the county boundary)				At confluence with West River	*1,021
Maps available for inspection at the Municipal Offices, 980 Grosstown Road, Stowe, Pennsylvania.				At Lowell Lake Dam	*1,344
Whitemarsh (Township), Montgomery County (FEMA Docket No. 7140)		Sevierville (City), Sevier County (FEMA Docket No. 7172)		<i>Utley Brook:</i>	
<i>Schuylkill River:</i>		<i>Dumplin Creek:</i>		At confluence with West River	*1,135
At the county boundary		Approximately 350 feet upstream of State Route 139 ...	*878	At upstream corporate limit	*1,370
Approximately 0.9 mile upstream of confluence of Andorra Creek	*148	Approximately 0.8 mile upstream of South Snyder Road		<i>West River:</i>	
<i>Oreland Run:</i>		Maps available for inspection at the Sevierville City Hall, 120 Church Street, Sevierville, Tennessee.		At downstream corporate limits	*1,021
At confluence with Wissahickon Creek	*54			At upstream corporate limits	*1,171
Approximately 1,700 feet upstream of the confluence with Wissahickon Creek		Shelbyville (City), Bedford County (FEMA Docket No. 7175)		<i>Windhall River:</i>	
Maps available for inspection at the Whitemarsh Township Administrative Building, 4021 Joshua Road, Lafayette Hill, Pennsylvania.		<i>Duck River:</i>		At confluence with West River	*1,021
Whitpain (Township), Montgomery County (FEMA Docket No. 7140)		Approximately 0.6 mile downstream of Sims Road	*719	At upstream corporate limits	*1,070
<i>Wissahickon Creek:</i>		Approximately 0.65 mile upstream of the confluence of Bomar Creek		<i>Lowell Lake:</i>	
At a point approximately 320 feet upstream of Swedesford Road	*149	<i>Bomar Creek:</i>		Entire shoreline	*1,355
At a point approximately 1,200 feet upstream of Swedesford Road	*154	At confluence with Duck River		Maps available for inspection at the Londonderry Town Office Building, Old School Street, South Londonderry, Vermont.	
Maps available for inspection at the Whitpain Township Administration Building, 960 Wentz Road, Blue Bell, Pennsylvania.		Approximately 750 feet upstream of State Route 64 (Wartrace Pike)	*747	Weston (Town), Windsor County (FEMA Docket No. 7136)	
West Conshohocken (Borough), Montgomery County (FEMA Docket No. 7172)		<i>Flat Creek:</i>		<i>Greendale Brook:</i>	
<i>Schuylkill River:</i>		At the confluence with Duck River	*745	At the confluence with West River	*1363
Approximately 0.2 mile downstream of Fayette Street (Matsonford Bridge)		Approximately 1.1 miles upstream of U.S. Route 231 (South Cannon Boulevard)	*750	Approximately 1.7 miles upstream of Greendale Road	*1595
Approximately 900 feet upstream of Interstate Route 476 (Mid County Expressway)		<i>Pettus Branch:</i>		<i>Ludlow Mountain Brook:</i>	
		Approximately 700 feet upstream of River Road	*749	At the confluence with West River	*1466
		At Cemetery Road	*753	Approximately 110 feet upstream of State Route 100 (Ludlow Road)	*1769
		<i>Little Hurricane Creek:</i>		<i>Trout Club Brook:</i>	
		At Peacock Lane	*749	At the confluence with West River	*1294
		Approximately 0.8 mile upstream of State Route 10 and 82 (U.S. Route 231)	*779	Approximately 1,100 feet upstream of Trout Club Road	*1762
		<i>Tributary to Little Hurricane Creek:</i>		<i>Trout Club Brook Backside:</i>	
		At confluence with Little Hurricane Creek	*761	At the confluence with West River	*1300
		At Fairfield Pike	*785	Approximately 650 feet upstream of Parker Lane	*1627
		Maps available for inspection at the Shelbyville City Hall, 109 Lane Parkway, Shelbyville, Tennessee.		<i>West River:</i>	
				Approximately 0.9 mile downstream of most downstream crossing of State Route 100 (Wantastiquet Road)	*1171
				Approximately 0.8 mile upstream of State Route 155 (Wantastiquet Road)	*1748
				Maps available for inspection at the Weston Town Office, Lawrence Hill, Weston, Vermont.	
		VERMONT			
		Londonderry (Town), Windham County (FEMA Docket No. 7172)		Martinsburg (City), Berkeley County (FEMA Docket No. 7172)	
		<i>Cook Brook:</i>		<i>Tuscarora Creek:</i>	
				Approximately 80 feet downstream of CONRAIL	*451

Dated: August 21, 1996.
Joseph J. Angelo,
*Director of Standards, Marine Safety and
Environmental Protection.*
[FR Doc. 96-21935 Filed 8-27-96; 8:45 am]
BILLING CODE 4910-14-M

William F. Caton,
Acting Secretary.
[FR Doc. 96-21580 Filed 8-27-96; 8:45 am]
BILLING CODE 6712-01-U

Coast Guard
46 CFR Part 159
[CGD 93-055]
RIN 2115-AE58

**Approval of Inflatable Personal
Flotation Devices (PFDs) for
Recreational Boaters**

AGENCY: Coast Guard, DOT.

Schedule of Application Fees:
Correction
AGENCY: Federal Communications
Commission.

47 CFR Parts 25 and 101**[CC Docket No. 92-297, FCC 96-311]****Redesignating the 27.5-29.5 GHz Frequency Band, Reallocating the 29.5-30.0 GHz Frequency Band, and Establishing Rules and Policies for Local Multipoint Distribution Service and for Fixed Satellite Services****AGENCY:** Federal Communications Commission.**ACTION:** Final rule.

SUMMARY: By this *First Report and Order*, the Commission designates band segments in the 27.5-30.0 GHz band ("28 GHz band") for several types of wireless systems, clearing the way for licensing Local Multipoint Distribution Service ("LMDS") providers, Fixed Satellite Service ("FSS") systems, and feeder links for certain Mobile Satellite Service ("MSS") systems. The associated downlink bands for satellite services at 17.7-20.2 GHz, are designated as well. Our band segmentation plan seeks to promote competition by permitting all proposed services to develop and offer innovative consumer services such as video program distribution, two-way interactive video, teleconferencing, telemedicine, telecommuting, and high speed data services within our borders and around the globe.

EFFECTIVE DATE: October 28, 1996.**FOR FURTHER INFORMATION CONTACT:**

Robert James, Wireless Telecommunications Bureau, (202) 418-

0798; Jennifer Gilsenan, International Bureau, Satellite Policy Branch, (202) 418-0757; Kathleen Campbell, International Bureau, Satellite Policy Branch, (202) 418-0753.

SUPPLEMENTARY INFORMATION: This is a summary of the First Report and Order portion of the Commission's First Report and Order and Fourth Notice of Proposed Rulemaking in CC Docket No. 92-297; FCC 96-311, adopted July 17, 1996 and released July 22, 1996. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC, and also may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

The *First Report and Order* contains information collections and third party disclosure requirements subject to the Paperwork Reduction Act of 1995, Pub. L. 104-13 (PRA). Notice of this collection appeared at 61 FR 43058, August 20, 1996. It will be submitted to the Office of Management and Budget (OMB) for review under PRA.

As required by section 603 of the Regulatory Flexibility Act, the Commission has prepared a Final Regulatory Flexibility Act (FRFA) of the expected impact on small entities of the *First Report and Order* adopted.

Summary of First Report and Order

1. This is the *First Report and Order* in a proceeding that involves the

development of one of the largest contiguous spectrum segments available to the Commission, the 28 GHz band. The commercialization of this spectrum enables consumers to receive emerging domestic and global technologies via multiple service providers.

2. With this *First Report and Order*, the Commission designates band segments in the 28 GHz band for several types of wireless systems, clearing the way for licensing Local Multipoint Distribution Service ("LMDS") providers, Fixed Satellite Service ("FSS") systems, and feeder links for certain Mobile Satellite Service ("MSS") systems. The associated downlink bands for satellite services are designated as well.¹ We will address issues relating to service rules for both GSO/FSS and NGSO/FSS systems proposing to operate in the 28 GHz band in a forthcoming Report and Order. Service and auction rules relating to LMDS will also be addressed in a separate Report and Order.

3. The band segmentation plan seeks to promote competition by permitting all proposed services to develop and offer innovative consumer services such as video program distribution, two-way interactive video, teleconferencing, telemedicine, telecommuting, and high speed data services within our borders and around the globe.

4. The Commission's band segmentation plan is depicted graphically as follows:

UPLINK BAND 27.5-30.0 GHz

LMDS fss 850 MHz	GSO/FSS ngso/fss 250 MHz	NGSO/FSS gso/fss 500 MHz	MSS feeder links & LMDS (h-s) 150 MHz	MSS feeder links & GSO/FSS 250 MHz	GSO/FSS ngso/fss 500 MHz	GOVT	LMDS (h-to-s) (s-to-h) 300 MHz
27.5	28.35	28.60	29.1	29.25	29.5	30.0	31.0 31.3 GHz

5. The Commission's plan designates co-frequency sharing in band segments where the Commission and the parties have concluded it is technically feasible. This band plan promotes spectrum efficiency and facilitates the deployment of diverse, interactive, competitive services for consumers.

6. The band segmentation plan will be implemented through appropriate changes in part 25 and part 101 of the Commission's rules. The Commission designates discrete spectrum bands for specific types of systems. Services

designated for domestic licensing priority are specified in capital letters in the graphic depiction of the band plan. These services have licensing priority vis-a-vis any other type of service allocated domestically or internationally in the band. Lower-case letters indicate services in a particular band segment which also have licensing priority vis-a-vis any third service allocated domestically or internationally in the band, but have no licensing priority over the service in capital letters in the band segment and must operate on a

non-interference basis and must accept interference vis-a-vis that service. Services designated with two priority users have equal licensing rights based on the sharing principles adopted for that particular band segment.

7. In implementing this band plan, the Commission set out procedures for "grandfathering" the existing LMDS system, CellularVision, in the 28 GHz band. Specifically, the Commission requires CellularVision to vacate the 28.35-28.50 GHz band by 24 months following the release date of the *First*

¹ Satellite downlinks paired with satellite uplinks in the 28 GHz band are in the 17.7-20.2 GHz band.

Report and Order, or by the date of launch of the first GSO/FSS satellite intended to provide service in the United States in this band, whichever occurs later. In order to ensure certainty for both CellularVision's customers and for potential GSO/FSS systems planning to provide service in the United States in the 28.35–28.50 GHz band, the Commission clarified its reference to "launch" as the date which the first GSO/FSS satellite, intended to operate

in the 28.35–28.50 GHz band, leaves the Earth's surface. The satellite licensee is responsible for notifying CellularVision six months prior to the planned launch date, and for giving CellularVision, upon its request, updates on the satellite's status. CellularVision has the responsibility to remain apprised of the satellite's status and to ensure that LMDS operations cease on the 150 MHz allocated for GSO/FSS operations in accordance with the order herein.

8. To ensure the implementation of this band plan, the Commission adopted specific inter-service sharing rules for those services designated in the same band segment.

9. The Commission also designated band segments for the associated satellite downlink band at 17.7–20.2 GHz. The 17.7–20.2 GHz band segmentation plan can be depicted as follows:

DOWNLINK BAND 17.7–20.2 GHz

GSO/FSS fixed ngso/ fss 1100 MHz	NGSO/FSS fixed gso/ fss 500 MHz	MSS F.L. fixed gso/ fss 400 MHz	GSO/FSS ngso/fss 500 MHz
17.7	18.80	19.30	19.70 20.20 GHz

This plan specifically designates downlinks in the 17.7–18.8 GHz band for GSO/FSS uses, the 18.8–19.3 GHz band for NGSO/FSS uses, the 19.3–19.7 GHz band for NGSO/MSS feeder links, and the 19.7–20.2 GHz band for GSO/FSS uses. These designations do not preclude the authorized use of these bands by other satellite applications on a secondary basis to the primary satellite application designated in the band.

10. GSO/FSS, NGSO/MSS feeder links and NGSO/FSS systems are all fixed satellite services. Under current rules, such services share the 17.7–19.7 GHz band with fixed services on a coequal basis.² Current rules require coordination of these services pursuant to the requirements in § 25.130(b) of the rules, and under the procedures outlined in § 101.103 of the rules. These coordination rules will continue to be applied in these bands; however, should the affected parties wish to propose slightly modified procedures to facilitate the deployment of these services, we would consider such a proposal in the future. The record does not indicate that other requirements for coordination between non-government satellite systems are necessary at this time.³

Final Regulatory Flexibility Analysis of First Report and Order

11. As required by section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603 (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Third Notice of Proposed Rulemaking in this proceeding (*Third NPRM*), 60 FR

43470 (August 23, 1995). The Commission sought written public comments on the proposals in the *Third NPRM*, including on the IRFA. The Commission's Final Regulatory Flexibility Analysis (FRFA) in this *First Report and Order* conforms to the RFA, as amended by the Contract With America Advancement Act of 1996, (CWAAA), Pub. L. 104–121, 110 Stat. 847 (1996).⁴

Need for and Purpose of this Action

12. In this decision, the Commission, adopts a band plan designating discrete spectrum segments for the Local Multipoint Distribution Systems ("LMDS"), Fixed Satellite Service (FSS) systems, and feeder links for certain Mobile Satellite Service ("MSS") systems in the 27.5–30.0 GHz band ("28 GHz band"). The Commission also adopts rules and procedures intended to facilitate the efficient use of this large spectrum segment among these three different types of services. The purposes of this action are to help launch two new broadband industries well-suited to compete in the domestic and global marketplace.

Summary of Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis

13. No comments were filed in direct response to the IRFA. In general, comments on the *Third NPRM*, however, the only licensee in the band, CellularVision, an LMDS small entity believed that the plan proposed in the *Third NPRM* accommodated all competing interests for spectrum in the band. Furthermore, the proposal to

grandfather CellularVision's existing system in the New York Primary Metropolitan Statistical Area was supported by CellularVision as a reasonable plan to facilitate its existing operations as it phases into licensing under the new band segmentation scheme.

Description and Estimate of the Small Entities Subject to the Rules

14. The Commission has not developed a definition of small entities applicable to GSO/FSS licensees. Therefore, the applicable definition of small entity is the definition under the Small Business Administration (SBA) rules applicable to Communications Services, Not Elsewhere Classified. This definition provides that a small entity is expressed as one with \$11.0 million in annual receipts.⁵

Estimates for GSO/FSS Satellite System Applicants for the 28 GHz Band

15. At present there are no GSO/FSS satellite licensees in the band and the Commission has not adopted any final service rules for satellite systems proposing to operate in the 28 GHz band. Therefore, there are no small businesses currently providing these types of broadband interactive services in the band. However, there has been a cut-off date for applications to be considered in the first GSO/FSS processing round.⁶ There are a total of thirteen applications currently on file proposing to provide GSO/FSS services in the band. Eight of these systems propose global systems. Five systems

² See 47 CFR 25.202 (a)(1).
³ With respect to government systems, parties should take note of footnote US 334 of the Table of Frequency Allocations. See 47 CFR 2.106.

⁴ Subtitle II of the CWAAA is "The Small Business Regulatory Enforcement Fairness Act of 1996" (SBREFA), codified at 5 U.S.C. 601 *et seq.*

⁵ 13 CFR 121.201, Standard Industrial Classification (SIC) Code 4899.
⁶ See *Ka-Band Satellite Applications Accepted For Filing: Cut-Off Established for Additional Applications*, Public Notice, Report No. SPB–20, Release No. DA 95–1689, July 28, 1995.

propose regional coverage. The Commission acknowledges that a couple of these applications are start-up companies and assumes that new satellite systems may be developed in this frequency band that may qualify as small entities pursuant to the SBA's definition.

Estimates for NGSO/FSS System Applicant in the Band

16. At present there are no NGSO/FSS satellite licensees in the 28 GHz band and final service rules have not been adopted for such satellite systems proposing to operate in the band. Therefore, there are no small businesses currently providing these services in the band. However, there has been a cut-off date for applications to be considered in the first GSO/FSS processing round. Currently, there is only one NGSO/FSS application on file. The Commission assumes that new satellite systems may be developed in this frequency band that may qualify as small entities pursuant to the SBA's definition.

Estimates for NGSO/MSS Systems With Feeder Links in the 28 GHz Band

17. At present there are two licensed NGSO/MSS systems proposing feeder links for their systems in the 28 GHz band. The Commission assumes that new satellite systems may be developed in this frequency band that may qualify as small entities pursuant to the SBA's definition.

Estimates for LMDS

18. The rules adopted in this *First Report and Order* will apply to any company which chooses to apply for a license in the new services. In addition, the new rules impact fixed microwave licensees, some of whom requested that the Commission institute a channeling plan in the 28 GHz band to set standards for point-to-point microwave equipment manufacturers. With regard to both the traditional point-to-point entities and the Local Multipoint Distribution Service (LMDS), the Commission has not developed a definition of small entities applicable to such licensees. The SBA definitions of small entity for LMDS are the definitions applicable to radiotelephone companies and to pay television services. The definition of radiotelephone companies provides that a small entity is a radiotelephone company employing fewer than 1,500 persons.⁷ The definition of a pay television service is one which has annual receipts of less than \$11

million.⁸ Since the Regulatory Flexibility Act amendments were not in effect until the record in this proceeding was closed, the Commission was unable to request information regarding the potential number of small businesses interested in LMDS and is unable at this time to determine the precise number of potential applicants which are small businesses.

19. The size data provided by the SBA does not enable us to make a meaningful estimate of the number of telecommunications providers which are small entities because it combines all radiotelephone companies with 500 or more employees.⁹ The Commission used the 1992 Census of Transportation, Communications, and Utilities, conducted by the Bureau of the Census, which is the most recent information available. This document shows that only 12 radiotelephone firms out of a total of 1,178 such firms which operated during 1992 had 1,000 or more employees.¹⁰ Therefore, a majority of LMDS entities providing radiotelephone services could be small businesses under the SBA's definition. Likewise, the size data provided by the SBA does not enable us to make a meaningful estimate of the number of cable and pay television providers which are small entities because it combines all such providers with revenues of less than \$11 million.¹¹ The Commission used the 1992 Census of Transportation, Communications, and Utilities (Table 2D), conducted by the Bureau of the Census, which is the most recent information available. This document shows that only 36 of 1,788 firms providing cable and pay television service have a revenue of greater than \$10 million. Therefore, the vast majority of LMDS entities providing video distribution could be small businesses under the SBA's definition.

20. However, in the *Third NPRM*,¹² we proposed to define a small business

⁸ *Id.*, SIC Code 4841.

⁹ U.S. Small Business Administration 1992 Economic Census Employment Report, Bureau of the Census, U.S. Department of Commerce, SIC Code 4812 (radiotelephone communications industry data adopted by the SBA Office of Advocacy).

¹⁰ U.S. Bureau of the Census, U.S. Department of Commerce, 1992 Census of Transportation, Communications, and Utilities, UC92-S-1, Subject Series, Establishment and Firm Size, Table 5, Employment Size of Firms: 1992, SIC Code 4812 (issued May 1995).

¹¹ *Id.*, SIC 4841.

¹² *In the Matter of Rulemaking to Amend parts 1, 2, 21, and 25 of the Commission's Rules to Redesignate the 27.5-29.5 GHz Frequency Band, to Reallocate the 29.5-30.0 GHz Frequency Band, to Establish Rules and Policies for Local Multipoint Distribution Service and for Fixed Satellite Services and Suite 12 Group Petition for Pioneer's*

as an entity that, together with affiliates and attributable investors, has average gross revenues for the three preceding years of less than \$40 million. We have not yet received approval by the SBA for this definition because the service rules for LMDS have not been finalized. A definition of small point-to-point entities have not yet received approval by the SBA because such entities have not as yet been subject to competitive bidding procedures.

21. The Commission assumes, for purposes of our evaluations and conclusions in this FRFA, that nearly all of the LMDS licensees will be small entities, as that term is defined by the SBA. Many of the competitors using LMDS to compete with LECs or cable companies could be small businesses.

22. With regard to traditional point-to-point microwave entities, the same analysis for small radiotelephone entities as made above applies to these entities. In the *First Report and Order*, the Commission declines to specify a channeling plan for point-to-point entities. It is the Commission's opinion that retaining maximum system design flexibility for LMDS licensees within their service areas precludes our specifying a point-to-point channeling plan. Entities interested in providing point-to-point service may seek other spectrum or may become LMDS licensees and configure their systems as they choose. In addition, such entities may lease spectrum, or seek partitioning or disaggregation opportunities from LMDS licensees. Moreover, the traditional point-to-point microwave equipment manufacturing industry could seek to establish standards for its members to use in the 28 GHz band. Accordingly, this *First Report and Order* does not provide direct relief requested by, e.g., the Telecommunications Industry Association, which represents fixed microwave entities, the majority of whom may be small businesses.

23. Another category of small entities affected by this *First Report and Order* are those operating in the 17.5-19.5 GHz frequency band. These entities are fixed point-to-point microwave entities of many subcategories. The same analysis for these entities as made for traditional fixed microwave entities made above applies to these entities (a definition of small point-to-point entities has not been submitted for approval by the SBA because such entities have not as yet been subject to competitive bidding procedures). The *First Report and Order* does not change the Commission's treatment of these entities, but it adds

Preference, CC Docket No. 92-297, 11 F.C.C. Rcd. 53 (1995) (*Third NPRM*), para. 188.

⁷ 13 CFR 121.201, Standard Industrial Classification (SIC) Code 4812.

potential additional satellite operators in the band with which the entities will have to coordinate in the future. The Commission has coordination procedures in effect; should they prove inadequate in the future, we will reconsider the issue at that time.

Summary of Projected Reporting, Recordkeeping and Other Compliance Requirements

24. There are some reporting requirements imposed by the *First Report and Order*. In some instances, it is likely that the entities filing the reports will require no professional skills for the preparation of such requests. In other cases, the services of persons with technical or engineering expertise may be required to prepare the reports. First, in one band segment, a satellite licensee is required to notify the one existing licensed LMDS operator, CellularVision, of its launch date six months prior to the satellite's launch date. It is also required to provide, upon CellularVision's request, updates on the satellite's status. Such a request is reasonable of CellularVision. At this time, it is not clear how many potential GSO/FSS licensees this will effect. Second, in another shared band segment, LMDS licensees are required to serve copies of their application on all NGSO/MSS applicants. At this time, it is not clear how many LMDS entities will be participating. Currently there are only two NGSO/MSS licensees who will be using this band for feeder links. Feeder links for a third NGSO/MSS system could possibly also be accommodated in this band. Third, NGSO/MSS feeder link earth stations are required to specify a set of geographic coordinates for the location of these earth stations, 15 days after the release of a public notice announcing the commencement of LMDS auctions. Finally, one NGSO/MSS licensee is required to provide its feeder link earth station locations to the GSO/FSS licensees. At this time, it is not clear how many potential GSO/FSS licensees this will effect.

Steps Taken to Minimize the Economic Impact on Small Entities

25. The Commission adopts a band plan that facilitates the accommodation of all proposed systems in the 28 GHz band. It believes this plan is a reasonable accommodation of all competing interests in this new band segment, including small entities. The band plan along with the *Fourth Notice of Proposed Rulemaking* for the 31 GHz band provides both small entities and larger businesses the same opportunity to develop and operate viable systems

within the band, and initiate competitive services. The band plan also accords, CellularVision, the only licensee in the band, flexibility during the implementation phase of the band plan.

Significant Alternatives Considered and Rejected

26. The Commission considered and rejected several alternatives to the band plan adopted.¹³ The Commission considered various band segmentation plans over the last several months with the goal of accommodating the various divergent proposals made in response to the band plan proposed in the *Third NPRM*.¹⁴ For example, the Commission considered plans which ultimately proved to require difficult inter-service sharing rules and to not completely support interactivity of LMDS systems.¹⁵ The Commission also considered a band plan that designated 1000 MHz each for GSO/FSS and LMDS service. That plan, however, would have divided LMDS among three non-contiguous spectrum segments.¹⁶ This option was not acceptable to the potential LMDS service providers, including small providers, because, they argued, it would have significantly decreased spectrum efficiency for LMDS, resulting in increased cost and delay in offering both subscriber and hub equipment.¹⁷ The Commission also considered two band plans that designated GSO/FSS systems with less than 1000 MHz.¹⁸ These options were unacceptable to the GSO/FSS applicants because, they argued, any of these plans would result in a significant loss of system capacity and revenue.¹⁹ Such loss and capacity could affect potential small entities. Another plan, resulting from a GSO/FSS applicant's proposal, was also considered. It would have designated a total of 1010 MHz to GSO/FSS applicants and 985 MHz to LMDS, but required sharing of 135 MHz between GSO/FSS and LMDS.²⁰ However, the mutually acceptable sharing principles required to implement this plan were not developed by the LMDS and GSO/FSS parties.²¹

¹³ See *First Report and Order* at ¶¶ 38–40.

¹⁴ See *ex parte* submission filed by the International Bureau to William F. Caton, Acting Secretary (Feb. 6, 1996), for diagrams of Commission Band Plan Options 1, 2, 2A, 2B, 3(a), 4 and 5.

¹⁵ See *First Report and Order* note 76.

¹⁶ *Id.* note 77.

¹⁷ *Id.* note 78.

¹⁸ *Id.* note 79.

¹⁹ *Id.* note 80.

²⁰ *Id.* note 81.

²¹ *Id.* note 82.

The Commission staff was also unable to successfully propose sharing criteria.

27. In March 1996, NASA was also asked to undertake an immediate study to assess whether its space services and LMDS could share spectrum below 27.5 GHz.²² NASA concluded three weeks later that no rules acceptable to all parties could be drafted which would guarantee protection of NASA space services from harmful interference.²³ NASA also concluded that coordination with other space service systems in the band from other administrations would make this a difficult option to implement effectively.

28. One alternative of not adopting a band segmentation plan for this spectrum is the preclusion of LMDS service or satellite service in the 28 GHz band. In the *Third NPRM*, the Commission tentatively concluded that denying one or the other of the proposed services for the band was not in the public interest and that both proposed services bring the promise of competition and innovative services to the nation's infrastructure. Moreover, preclusion of either service potentially affects small businesses on both the satellite side and the LMDS side.

Report to Congress

29. The Commission shall send a copy of this Final Regulatory Flexibility Analysis, along with this *First Report and Order*, in a report to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801(a)(1)(A). A copy of this FRFA will also be published in the Federal Register.

Ordering Clause

30. Accordingly, it is ordered that part 25 and part 101 of the Commission's rules are amended as specified below, effective October 28, 1996.

List of Subjects

47 CFR Part 25

Satellites.

47 CFR Part 101

Communications equipment, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

Rule Changes

Parts 25 and 101 of Title 47 of the Code of Federal Regulations are amended as follows:

²² *Id.* note 83.

²³ *Id.* note 84.

PART 25—SATELLITE COMMUNICATIONS

1. The authority citation for part 25 continues to read as follows:

Authority: Secs. 101–404, 76 Stat. 419–427; 47 U.S.C. 701–744, Sec. 4, 48 Stat. 1066, as amended; 47 U.S.C. 154. Interprets or applies sec. 303, 48 Stat. 1082, as amended; 47 U.S.C. 303.

2. Section 25.203 is amended by adding paragraph (h) to read as follows:

§ 25.203 Choice of sites and frequencies.

* * * * *

(h) Sites and frequencies for GSO and NGSO earth stations, operating in a frequency band where both have a co-primary allocation, shall be selected to avoid earth station antenna mainlobe-to-satellite antenna mainlobe coupling, between NGSO systems and between NGSO and GSO systems, in order to minimize the possibility of harmful interference between these services. Prior to filing an earth station application, in bands with co-primary allocations to NGSO and GSO earth stations, the applicant shall coordinate the proposed site and frequency usage with existing earth station licensees and with current earth station authorization applicants.

* * * * *

3. A new § 25.250 is added to subpart C to read as follows:

§ 25.250 Sharing between NGSO MSS Feeder links Earth Stations in the 19.3–19.7 GHz and 29.1–29.5 GHz Bands.

(a) NGSO MSS applicants shall be licensed to operate in the 29.1–29.5 GHz band for Earth-to-space transmissions and 19.3–19.7 GHz for space-to-Earth transmissions from feeder link earth station complexes. A “feeder link earth station complex” may include up to three (3) earth station groups, with each earth station group having up to four (4) antennas, located within a radius of 75 km of a given set of geographic coordinates provided by NGSO–MSS licensees or applicants.

(b) Licensees of NGSO MSS feeder link earth stations separated by 800 km or less are required to coordinate their operations, see § 25.203. The results of the coordination shall be reported to the Commission.

4. A new § 25.257 is added to subpart C to read as follows:

§ 25.257 Special requirements for operations in the band 29.1–29.25 GHz between NGSO MSS and LMDS.

(a) Non-geostationary mobile satellite service (NGSO MSS) operators shall be licensed to use the 29.1–29.25 GHz band for Earth-to-space transmissions from

feeder link earth station complexes. A “feeder link earth station complex” may include up to three (3) earth station groups, with each earth station group having up to four (4) antennas, located within a radius of 75 km of a given set of geographic coordinates provided by a NGSO MSS licensee or applicants pursuant to § 101.147.

(b) A maximum of seven (7) feeder link earth station complexes in the contiguous United States, Alaska and Hawaii may be placed into operation, in the largest 100 MSAs, in the band 29.1–29.25 GHz in accordance with § 25.203 and § 101.147 of this chapter.

(c) One of the NGSO MSS operators licensed to use the 29.1–29.25 GHz band may specify geographic coordinates for a maximum of eight feeder link earth station complexes that transmit in the 29.1–29.25 GHz band. The other NGSO MSS operator licensed to use the 29.1–29.25 GHz band may specify geographic coordinates for a maximum of two feeder link earth station complexes that transmit in the 29.1–29.25 GHz band.

(d) Additional NGSO MSS operators may be licensed in this band if the additional NGSO MSS operator shows that its system can share with the existing NGSO MSS systems.

(e) All NGSO MSS operators shall cooperate fully and make reasonable efforts to identify mutually acceptable locations for feeder link earth station complexes. In this connection, any single NGSO MSS operator shall only identify one feeder link earth station complex protection zone in each category identified in § 101.147(c)(2) of this chapter until the other NGSO MSS operator has been given an opportunity to select a location from the same category.

5. A new § 25.258 is added to subpart C to read as follows:

§ 25.258 Sharing between NGSO MSS Feeder links Stations and GSO FSS services in the 29.25–29.5 GHz Bands.

(a) Operators of NGSO MSS feeder link earth stations and GSO FSS earth stations in the band 29.25 to 29.5 GHz where both services have a co-primary allocation shall cooperate fully in order to coordinate their systems. During the coordination process both service operators shall exchange the necessary technical parameters required for coordination.

(b) Licensed GSO FSS systems shall, to the maximum extent possible, operate with frequency/polarization selections, in the vicinity of operational or planned NGSO MSS feeder link earth station complexes, that will minimize instances of unacceptable interference to the GSO FSS space stations.

(c) NGSO MSS satellites operating in this frequency band shall compensate for nodal regression due to the oblate shape of the Earth, and thus maintain constant successive sub-satellite ground tracks on the surface of the Earth.

(d) NGSO MSS systems applying to use the 29.25–29.5 GHz band, for feeder link earth station uplink, will have to demonstrate that their system can share with the authorized U.S. GSO/FSS systems operating in this band.

PART 101—FIXED MICROWAVE SERVICES

1. The authority citation for part 101 continues to read as follows:

Authority: 47 U.S.C. 154, 202, unless otherwise noted.

2. Section 101.3 is amended by adding the following definitions, in alphabetical order, to read as follows:

§ 101.3 Definitions.

* * * * *

Local Multipoint Distribution Service Backbone Link. A point-to-point radio service link in a Local Multipoint Distribution Service System that is used to interconnect Local Multipoint Distribution Service Hub Stations with each other or with the public switched telephone network.

Local Multipoint Distribution Service Hub Station. A fixed point-to-multipoint radio station in a Local Multipoint Service System that provides one-way or two-way communication with Local Multipoint Distribution Service Subscriber Stations.

Local Multipoint Distribution Service Subscriber Station. Any one of the fixed microwave radio stations located at users' premises, lying within the coverage area of a Local Multipoint Distribution Service Hub Station, capable of receiving one-way communications from or providing two-way communications with the Local Multipoint Distribution Service Hub Station.

Local Multipoint Distribution Service System. A fixed point-to-multipoint radio system consisting of Local Multipoint Distribution Service Hub Stations and their associated Local Multipoint Distribution Service Subscriber Stations.

* * * * *

3. Section 101.109 is amended by removing the entry for 27,500 MHz to 29,500 MHz and adding the entries for 27,500 to 28,350 MHz and 29,100 to 29,250 MHz in the table in paragraph (c) to read as follows:

§ 101.109 Bandwidth.

* * * * *

(c) * * *

Frequency band (MHz)	Maximum authorized bandwidth
* * * *	
27,500 to 28,350 MHz	850 MHz.
29,100 to 29,250 MHz	150 MHz.
* * * *	

4. Section 101.113 is amended by removing the entry for 27,500 to 29,500 MHz and adding new entries 27,500 to 28,350 MHz and 29,100 to 29,250 MHz in the table in paragraph (a) and by adding a new paragraph (c) to read as follows:

§ 101.113 Transmitter power limitations.

(a) * * *

Frequency band (MHz)	Maximum allowable EIRP ¹	
	Fixed (dBW)	Mobile (dBW)
27,500 to 28,350	55	
29,100 to 29,250	(7)	

¹ Per polarization.⁷ See § 101.113(c).

* * * * *

(c) (1) Transmitter power limitations: Point-to-point stations in the 29.1–29.25 GHz band for the LMDS backbone between LMDS hubs shall be limited to a maximum allowable e.i.r.p. density per carrier of 23 dBW/MHz in any one megahertz in clear air, and may exceed this limit by employment of adaptive power control in cases where link propagation attenuation exceeds the clear air value due to precipitation and only to the extent that the link is impaired.

(2) Hub Transmitter EIRP Spectral Area, Density Limit: LMDS applicants shall demonstrate that, under clear air operating conditions, the maximum aggregate of LMDS transmitting hub stations in a Basic Trading Area in the 29.1–29.25 GHz band will not transmit a co-frequency hub-to-subscriber e.i.r.p. spectral area density in any azimuthal direction in excess of X dBW/(MHz–km²) when averaged over any 4.375 MHz band, where X is defined in Table 1. Individual hub stations may exceed their clear air e.i.r.p.s by employment of adaptive power control in cases where link propagation attenuation exceeds the clear air value and only to the extent that the link is impaired.

(i) The e.i.r.p. aggregate spectral area density is calculated as follows:

$$10 \log_{10} 1/A \sum_{i=1}^N p_{gi} \text{ dBW/MHz-km}^2$$

where:

N=number of co-frequency hubs in BTA.

A=Area of BTA in km².

p_i=spectral power density into antenna of i-th hub (in W/MHz).

g_i=gain of i-th hub antenna at zero degree elevation angle.

Each p_i and g_i are in the same 1 MHz within the designated frequency band.

(ii) The climate zones in Table 1 are defined for different geographic locations within the US as shown in Appendix 28 of the ITU Radio Regulations.

TABLE 1¹

Climate zone	e.i.r.p. Spectral Density (Clear Air) (dBW/MHz–km ²) ²
1	–23
2	–25
3,4,5	–26

¹ LMDS system licensees in two or more BTAs may individually or collectively deviate from the spectral area density computed above by averaging the power over any 200 km by 400 km area, provided that the aggregate interference to the satellite receiver is no greater than if the spectral area density were as specified in Table 1. A showing to the Commission comparing both methods of computation is required and copies shall be served on any affected non-GSO 20/30 GHz MSS providers.

² See § 21.1007(c)(i) for the population density of the BTA.

(3) Hub Transmitter e.i.r.p. Spectral Area Density Limit at Elevation Angles Above the Horizon: LMDS applicants shall demonstrate that, under clear air operating conditions, the maximum aggregate of LMDS transmitting hub stations in a Basic Trading Area in the 29.1–29.25 GHz band will not transmit a co-frequency hub-to-subscriber e.i.r.p. spectral area density in any azimuthal direction in excess of X dBW/(MHz–km²) when averaged over any 4.375 MHz band where X is defined in Table 2. Individual hub stations may exceed their clear air e.i.r.p.s by employment of adaptive power control in cases where link propagation attenuation exceeds the clear air value and only to the extent that the link is impaired.

(i) The e.i.r.p. aggregate spectral area density is calculated as follows:

$$10 \log_{10} 1/A \sum_{i=1}^N \text{e.i.r.p.}(a_i) \text{ dBW/MHz-km}^2$$

where:

N=number of co-frequency hubs in BTA.

A=Area of BTA in km².

e.i.r.p. (a_i)=equivalent isotropic radiated spectral power density of the i-th hub (in W/MHz) at elevation angle a where a is the angle in degrees of elevation above horizon. e.i.r.p.(0°) is the hub e.i.r.p. area density at the horizon used in Section 101.113(c)(2). The nominal antenna pattern will be used for elevation angles between 0° and 8°, and average levels will be used for angles beyond 8°, where average levels will be calculated by sampling the antenna patterns in each 1° interval between 8° and 9015, dividing by 83.

TABLE 2

Elevation angle (a)	Relative e.i.r.p. density (dBW/MHz–km ²)
0° ≤ a ≤ 4.0°	e.i.r.p.(a) = e.i.r.p.(0°) + 20 log (sinΠx)/(1/Πx) where x = (a + 1)/7.5°.
4.0° < a ≤ 7.7°	e.i.r.p.(a) = e.i.r.p.(0°) - 3.85a + 7.7.
a > 7.7°	e.i.r.p.(a) = e.i.r.p.(0°) - 22.

(ii) LMDS system licensees in two or more BTAs may individually or collectively deviate from the spectral area density computed above by averaging the power over any 200 km by 400 km area, provided that the aggregate interference to the satellite receiver is no greater than if the spectral area density were as specified in Table 1. A showing to the Commission comparing both methods of computation is required and copies shall be served on any affected non-GSO MSS providers.

(4) Power Reduction Techniques: LMDS hub transmitters shall employ methods to reduce average power levels received by non-geostationary mobile satellite receivers, to the extent necessary to comply with paragraphs (c)(1) and (c)(2) of this section, by employing the methods set forth below:

(i) Alternate Polarizations. LMDS hub transmitters in the LMDS service area may employ both vertical and horizontal linear polarizations such that 50 percent (plus or minus 10 percent) of the hub transmitters shall employ vertical polarization and 50 percent (plus or minus 10 percent) shall employ horizontal polarization.

(ii) Frequency Interleaving. LMDS hub transmitters in the LMDS service area may employ frequency interleaving such that 50 percent (plus or minus 10 percent) of the hub transmitters shall employ channel center frequencies which are different by one-half the channel bandwidth of the other 50

percent (plus or minus 10 percent) of the hub transmitters.

(iii) Alternative Methods. As alternatives to paragraphs (c)(4)(i) and (c)(4)(ii) of this section, LMDS operators may employ such other methods as may be shown to achieve equivalent reductions in average power density received by non-GSO MSS satellite receivers.

5. Section 101.133 is amended by adding new paragraph (d) to read as follows:

§ 101.133 Limitations on use of transmitters.

* * * * *

(d) LMDS Subscriber Transmissions: LMDS licensees shall not operate transmitters from subscriber locations in the 29.1–29.25 GHz band.

6. Section 101.147 is amended by adding new paragraph (y) to read as follows:

§ 101.147 Frequency assignments.

* * * * *

(y) Special requirements for operations in the band 29.1–29.25 GHz:

(1)(i) LMDS receive stations operating on frequencies in the 29.1–29.25 GHz band within a radius of 75 nautical miles of the geographic coordinates provided by a non-GSO MSS licensee pursuant to paragraphs (c)(2) or (c)(3)(i) of this section (the “feeder link earth station complex protection zone”) shall accept any interference caused to them by such earth station complexes and shall not claim protection from such earth station complexes.

(ii) LMDS licensees operating on frequencies in the 29.1–29.25 GHz band outside a feeder link earth station complex protection zone shall cooperate fully and make reasonable efforts to resolve technical problems with the non-GSO MSS licensee to the extent that transmissions from the non-GSO MSS operator’s feeder link earth station complex interfere with an LMDS receive station.

(2) No more than 15 days after the release of a public notice announcing the commencement of LMDS auctions, feeder link earth station complexes to be licensed pursuant to Section 25.257 shall be specified by a set of geographic coordinates in accordance with the following requirements: no feeder link earth station complex may be located in the top eight (8) metropolitan statistical areas (“MSAs”), ranked by population, as defined by the Office of Management and Budget as of June 1993, using estimated populations as of December 1992; two (2) complexes may be located in MSAs 9 through 25, one of which must be Phoenix, AZ (for a complex at

Chandler, AZ); two (2) complexes may be located in MSAs 26 to 50; three (3) complexes may be located in MSAs 51 to 100, one of which must be Honolulu, Hawaii (for a complex at Waimea); and the three (3) remaining complexes must be located at least 75 nautical miles from the borders of the 100 largest MSAs or in any MSA not included in the 100 largest MSAs. Any location allotted for one range of MSAs may be taken from an MSA below that range.

(3) (i) Any non-GSO MSS licensee may at any time specify sets of geographic coordinates for feeder link earth station complexes with each earth station contained therein to be located at least 75 nautical miles from the borders of the 100 largest MSAs.

(ii) For purposes of paragraph (c)(3)(i) of this section, non-GSO MSS feeder link earth station complexes shall be entitled to accommodation only if the affected non-GSO MSS licensee preapplies to the Commission for a feeder link earth station complex or certifies to the Commission within sixty days of receiving a copy of an LMDS application that it intends to file an application for a feeder link earth station complex within six months of the date of receipt of the LMDS application.

(iii) If said non-GSO MSS licensee application is filed later than six months after certification to the Commission, the LMDS and non-GSO MSS entities shall still cooperate fully and make reasonable efforts to resolve technical problems, but the LMDS licensee shall not be obligated to re-engineer its proposal or make changes to its system.

(4) LMDS licensees or applicants proposing to operate hub stations on frequencies in the 29.1–29.25 GHz band at locations outside of the 100 largest MSAs or within a distance of 150 nautical miles from a set of geographic coordinates specified under paragraph (c)(2) or (c)(3)(i) of this section shall serve copies of their applications on all non-GSO MSS applicants, permittees or licensees meeting the criteria specified in § 25.257(a). Non-GSO MSS licensees or applicants shall serve copies of their feeder link earth station applications, after the LMDS auction, on any LMDS applicant or licensee within a distance of 150 nautical miles from the geographic coordinates that it specified under paragraph (c)(2) or (c)(3)(i) of this section. Any necessary coordination shall commence upon notification by the party receiving an application to the party who filed the application. The results of any such coordination shall be reported to the Commission within sixty days. The non-GSO MSS earth station licensee shall also provide all such

LMDS licensees with a copy of its channel plan.

[FR Doc. 96–21795 Filed 8–27–96; 8:45 am]

BILLING CODE 6712–01–P

47 CFR Part 73

[MM Docket No. 96–96; RM–8791]

Radio Broadcasting Services; Castana, IA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Gene Zortman, allots Channel 298A to Castana, Iowa, as the community’s first local aural transmission service. See 61 FR 20789, May 8, 1996. Channel 298A can be allotted to Castana in compliance with the Commission’s minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 298A at Castana are 42–04–24 and 95–54–36. With this action, this proceeding is terminated.

DATES: Effective September 30, 1996. The window period for filing applications will open on September 30, 1996, and close on October 31, 1996.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission’s *Report and Order*, MM Docket No. 96–96, adopted August 9, 1996, and released August 16, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission’s copy contractor, ITS, Inc., (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC. 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Iowa, is amended by adding Castana, Channel 298A.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96-21870 Filed 8-27-96; 8:45 am]

BILLING CODE 6712-01-F

47 CFR Part 73

[MM Docket No. 96-65; RM-8773]

Radio Broadcasting Services; Kiowa, KS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Kiowa Broadcasters, allots Channel 252C1 to Kiowa, Kansas, as the community's first local aural transmission service. See 61 FR 14733, April 3, 1996. Channel 252C1 can be allotted to Kiowa in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 252C1 at Kiowa are 37-01-00 and 98-29-12. With this action, this proceeding is terminated.

DATES: Effective September 30, 1996. The window period for filing applications will open on September 30, 1996, and close on October 31, 1996.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418-2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MM Docket No. 96-65, adopted August 9, 1996, and released August 16, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Kansas, is amended by adding Kiowa, Channel 252C1.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96-21867 Filed 8-27-96; 8:45 am]

BILLING CODE 6712-01-F

47 CFR Part 73

[MM Docket No. 95-87; RM-8644]

Radio Broadcasting Services; Hatfield, AR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots FM Channel 281C2 to Hatfield, Arkansas, as that community's first local aural transmission service, in response to a petition for rule making filed by John Harle. See 60 FR 34213, June 30, 1995. Coordinates used for Channel 281C2 at Hatfield are 34-31-41 and 94-21-32. With this action, the proceeding is terminated.

DATES: Effective September 30, 1996. The window period for filing applications will open on September 30, 1996, and close on October 31, 1996.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418-2180. Questions related to the window application filing process for Channel 281C2 at Hatfield, Arkansas, should be addressed to the Audio Services Division, (202) 418-2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MM Docket No. 95-87, adopted August 9, 1996, and released August 16, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., (202) 857-3800, located at 1919 M Street, NW., Room 246, or 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Arkansas, is amended by adding Hatfield, Channel 281C2.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 96-21868 Filed 8-27-96; 8:45 am]

BILLING CODE 6712-01-F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 950725189-5260-02; I.D. 082096G]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Closure

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS closes the commercial fishery for king mackerel in the exclusive economic zone (EEZ) in the western zone of the Gulf of Mexico. This closure is necessary to protect the overfished Gulf king mackerel resource.

EFFECTIVE DATE: The closure is effective 12:01 a.m., August 26, 1996, through June 30, 1997.

FOR FURTHER INFORMATION CONTACT: Mark Godcharles, 813-570-5306.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and, in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented by regulations at 50 CFR part 622 under the authority of the Magnuson Fishery Conservation and Management Act.

Catch limits recommended by the Councils and implemented by NMFS for

the Gulf of Mexico migratory group of king mackerel set the annual commercial quota at 0.77 million lb (0.35 million kg) for the western zone.

Under 50 CFR 622.43(a), NMFS is required to close any segment of the king mackerel commercial fishery when its quota has been reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the commercial quota of 0.77 million lb (0.35 million kg) for the western zone of the Gulf migratory group of king mackerel was reached on August 25, 1996. Hence, the commercial fishery for Gulf group king mackerel from the western zone is closed effective 12:01 a.m., local time, August 26, 1996, through June 30, 1997, the end of the fishing year. The boundary between the eastern and western zones is 87°31'06" W. long., which is a line directly south from the Alabama/Florida boundary.

Except for a person aboard a charter vessel or headboat, during the closure, a person aboard a vessel for which a commercial permit for king and Spanish mackerel has been issued may not fish for king mackerel in the EEZ in the western zone and may not retain king mackerel in or from the western zone EEZ. A person aboard a charter vessel or headboat may continue to retain king mackerel in or from the western zone EEZ under the bag and possession limits set forth in § 622.39(c)(1) and (2), provided the vessel is operating as a charter vessel or headboat and the vessel has an annual charter vessel/headboat permit, as specified in § 622.4(a)(1). A charter vessel or headboat that also has a commercial permit is considered to be operating as a charter vessel or headboat when it carries a passenger who pays a fee or when there are more than three persons aboard, including operator and crew.

During the closure, king mackerel from the western zone taken in the EEZ, including those harvested under the bag and possession limits, may not be purchased, bartered, traded, or sold. This prohibition does not apply to trade in king mackerel from the western zone that were harvested, landed ashore, and bartered, traded, or sold prior to the effective date of the closure and were held in cold storage by a dealer or processor.

Classification

This action is taken under 50 CFR 622.43(a) and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 23, 1996.

Richard H. Schaefer,
Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 96-22000 Filed 8-23-96; 3:21 pm]

BILLING CODE 3510-22-F

50 CFR Part 660

[Docket No. 951227306-5306-01; I.D. 081296C]

Fisheries Off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Nontrawl Sablefish Regular Season

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: End of nontrawl sablefish regular season.

SUMMARY: NMFS announces that the regular season for the nontrawl sablefish limited entry fishery will end at 12 noon local time (l.t.), September 6, 1996. This action is intended to provide advance notice of the duration of the nontrawl sablefish regular season.

DATES: The closing date of the nontrawl sablefish regular season and the reimposition of the daily trip limits are effective at 12 noon l.t., September 6, 1996, until the effective date of the 1997 annual specifications and management measures for the Pacific Coast Groundfish Fishery, which will be published in the Federal Register. Comments will be accepted until September 11, 1996.

ADDRESSES: Comments on these actions should be sent to Mr. William Stelle, Jr., Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way NE., Seattle, WA 98115-0070; or Ms. Hilda Diaz-Soltero, Director, Southwest Region, National Marine Fisheries Service, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213. Information relevant to these actions has been compiled in aggregate form and is available for public review during business hours at the office of the Director, Northwest Region, NMFS.

FOR FURTHER INFORMATION CONTACT: William L. Robinson 206-526-6140; or Rodney R. McInnis 310-980-4040.

SUPPLEMENTARY INFORMATION: These actions are authorized by the Pacific Coast Groundfish Fishery Management Plan, which governs the harvest of groundfish in the U.S. exclusive economic zone off the coasts of Washington, Oregon, and California.

The "regular season" for the limited entry nontrawl sablefish fishery begins at 1201 hours l.t. on September 1, 1996, and ends when 70 percent (1,928 mt) of the 2,754-mt nontrawl allocation is projected to be taken. (The remainder of the allocation is to be taken in a mop-up fishery about 3 weeks later, if sufficient amounts remain.) The regulations at 50 CFR 660.323(a)(2)(ii) state that the end of the regular season may be announced in the Federal Register either before or during the regular season. NMFS is announcing the closure date in advance of the regular season in 1996, because, as in 1995, effort is expected to be so intense that there will be inadequate time to monitor landings and make a projection during the season. An early announcement enables fishers to plan more carefully and to decide whether to participate.

NMFS consulted with the Pacific Fishery Management Council (Council) and its Groundfish Management Team (Team) at the April 1996 Council meeting. At that meeting, the best available estimates of expected catch and effort indicated that 70 percent of the nontrawl allocation would be taken in about 5 days. The Council recommended a season length of 5 days, unless new information became available before its July 1996 meeting. A review of 1996 and historical landings data at the June Team meeting confirmed the 5-day projection. Because no new information was presented to the Council at its July 1996 meeting, its April 1996 recommendation remained in effect. The Director, Northwest Region concurs with the Council's recommendation, which is based on current and past landings data, and has determined that the regular season, which starts at 1201 hours on September 1, 1996, will end just 5 days later, at 12 noon l.t., September 6, 1996. Commencing at 12 noon l.t., September 6, 1996, the following daily trip limits for nontrawl sablefish will resume: 300 lb (136 kg) per day north of 36° N. lat., and 350 lb (159 kg) per day south of 36° N. lat. (Daily trip limits apply to calendar days. Therefore, on September 6, 1996, a daily trip limit may be landed between 12 noon and 12 midnight l.t. At 0001 hours l.t. on September 7, 1996, daily trip limits will apply to the full 24 hours.) A vessel must begin landing its catch before 12 noon l.t., September 6, 1996, and complete the offloading before returning to sea or continuing a trip at sea, or the daily trip limit will apply to the fish remaining on board after 12 noon l.t. on September 6, 1996. One exception applies: A vessel landing sablefish in Puget Sound, WA, that was

taken under a limited entry permit with nontrawl gear during the regular season is not subject to the daily trip limit for that trip if the landing complies with Washington State regulations governing such sablefish landings (50 CFR 660.323(a)(2)(iv)). However, the regular season trip limit for sablefish smaller than 22 inches (56 cm) still applies.

Further information regarding the nontrawl sablefish fishery and the closure before the start of the regular season are contained in the proposed and final rules for that action at 60 FR 11062 (March 1, 1995) and 60 FR 34472 (July 3, 1995), respectively, which are found in the Federal regulations at 50 CFR 660.323(a)(2).

NMFS Actions

NMFS announces the following changes to the 1996 fishery specifications and management

measures published at 61 FR 279, January 4, 1996, as modified:

Paragraph IV.E.(3)(c) introductory text is revised to read as follows:

IV. * * *

E. * * *

(3) * * *

(c) *Nontrawl trip and size limits.* The daily trip limits in paragraphs (i) and (ii) below, which apply to sablefish of any size, are in effect until 12 noon, August 29, 1996, at which time all fixed gear used to take and retain groundfish must be removed from EEZ waters according to the regulations at 50 CFR 660.323(a)(2). These same daily trip limits will be reimposed at 12 noon, September 6, 1996, the end of the regular season.

Classification

The determination to take this action is based on the most recent data available. The aggregate data upon which the determination is based are

available for public inspection at the office of the Director, Northwest Region, NMFS (see **ADDRESSES**) during business hours. Because of the need for immediate action, and because the public had an opportunity to comment on these actions at the Council meeting, NMFS has determined that good cause exists for this action to be published without affording a prior opportunity for public comment or a 30-day delayed effectiveness period. This action is taken under the authority of 50 CFR 660.323(a)(2)(ii) and (b)(1)(i)(E), and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 22, 1996.

Richard H. Schaefer,
Director, Office of Fisheries Conservation and
Management, National Marine Fisheries
Service.

[FR Doc. 96-21874 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-22-F

Proposed Rules

Federal Register

Vol. 61, No. 168

Wednesday, August 28, 1996

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

GENERAL ACCOUNTING OFFICE

4 CFR Part 2

Prohibited Personnel Practices

AGENCY: General Accounting Office.

ACTION: Proposed rule.

SUMMARY: This rule revises the provision concerning prohibited personnel practices against an applicant or employee with a disability, by eliminating the reference to the Rehabilitation Act and replacing it with the Americans with Disabilities Act (ADA), to clarify that GAO's legal responsibilities to the disabled derive from the ADA rather than the Rehabilitation Act.

DATES: Comments must be submitted on or before September 27, 1996.

ADDRESSES: Comments may be mailed to the U.S. General Accounting Office, Office of General Counsel, Legal Services Division, Room 7861, 441 G Street, NW., Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Barbara J. Simball, Senior Attorney, (202) 512-8404.

SUPPLEMENTARY INFORMATION: A review of GAO's Personnel System regulations has shown that the current version of 4 CFR 2.5(a)(4) should be revised. In prohibiting certain personnel actions against persons with disabilities, 4 CFR 2.5(a)(4) implies that GAO is covered by section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791). As a legislative branch agency, GAO is not covered by the Rehabilitation Act of 1973, but rather by the ADA. The ADA prohibits discrimination against persons with disabilities. 4 CFR 2.5 is being amended to reflect GAO's coverage by the ADA.

List of Subjects in 4 CFR Part 2

Civil rights, Nondiscrimination, Employment, Handicapped.

For the reasons set out in the preamble, part 2 of title 4, chapter I, subchapter A of the Code of Federal Regulations is amended as follows:

PART 2—[AMENDED]

1. The authority citation to part 2 continues to read as follows:

Authority: 31 U.S.C. 732.

2. Section 2.5 is amended by revising paragraph (a)(4) to read as follows:

§ 2.5 Prohibited personnel practices.

* * * * *

(a) * * *

(4) On the basis of disability as prohibited under section 509(c) of the Americans with Disabilities Act of 1990 (42 U.S.C. 12209(c)); or

* * * * *

Robert P. Murphy,

General Counsel.

[FR Doc. 96-21434 Filed 8-27-96; 8:45 am]

BILLING CODE 1610-01-P

4 CFR Part 7

Personnel Relations and Services

AGENCY: General Accounting Office.

ACTION: Proposed rule.

SUMMARY: This rule revises the provision concerning GAO's prohibition of discrimination against employees or applicants with disabilities by eliminating the reference to the Rehabilitation Act and replacing it with the Americans with Disabilities Act (ADA), to clarify that GAO's legal responsibilities to the disabled derive from the Americans with Disabilities Act rather than the Rehabilitation Act.

DATES: Comments must be submitted on or before 30 days from September 27, 1996.

ADDRESSES: Comments may be mailed to the U.S. General Accounting Office, Office of General Counsel, Legal Services Division, Room 7861, 441 G Street, NW., Washington, DC. 20548.

FOR FURTHER INFORMATION CONTACT: Barbara J. Simball, Senior Attorney, (202) 512-8404.

SUPPLEMENTARY INFORMATION: A review of GAO's Personnel Relations regulations has shown that the current version of 4 CFR 7.2(c)(4) should be revised. In setting forth GAO's equal employment opportunity commitments, 4 CFR 7.2(c)(4) implies that GAO is covered by sections 501 and 505 of the Rehabilitation Act of 1973 (29 U.S.C. 791, 794a). As a legislative branch agency, GAO is not covered by the Rehabilitation Act of 1973, but rather by

the ADA, which prohibits discrimination against persons with disabilities. 4 CFR 7.2 is being amended to reflect GAO's coverage by the ADA.

List of Subjects in 4 CFR Part 7

Civil rights, Nondiscrimination, Employment, Handicapped.

For the reasons set out in the preamble, part 7 of title 4, chapter I, subchapter A of the Code of Federal Regulations is amended as follows:

PART 7—[AMENDED]

1. The authority citation to part 7 continues to read as follows:

Authority: 31 U.S.C. 732.

2. Section 7.2 is amended by revising paragraph (c)(4) to read as follows:

§ 7.2 Equal employment opportunity.

* * * * *

(c) ***

(4) By section 509(c) of the Americans with Disabilities Act of 1990 (42 U.S.C. 12209(c)); or

* * * * *

Robert P. Murphy,

General Counsel.

[FR Doc. 96-21435 Filed 8-27-96; 8:45 am]

BILLING CODE 1610-01-P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 905

[Docket No. FV-96-905-2PR]

Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Procedures to Limit the Volume of Small Florida Red Seedless Grapefruit and Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposal invites comments on the addition of a section to the rules and regulations currently prescribed under the marketing order for oranges, grapefruit, tangerines, and tangelos grown in Florida. This action also announces the Agricultural Marketing Service's (AMS) intention to request an extension for and revision to the currently approved information

collection requirements issued under the marketing order. The marketing order is administered locally by the Citrus Administrative Committee (committee). This rule would establish procedures for limiting the volume of small red seedless grapefruit entering the fresh market during the first 11 weeks of each season. The committee believes these procedures could be used, when necessary, to help stabilize the market and improve grower returns.

DATES: Comments must be received by September 27, 1996. Pursuant to the Paperwork Reduction Act, comments on the information collection burden must be received by October 28, 1996.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, room 2525-S, P.O. Box 96456, Washington, D.C. 20090-6456, Fax # (202) 720-5698. All comments should reference the docket number and the date and page number of this issue of the Federal Register and will be made available for public inspection in the Office of the Docket Clerk during regular business hours. Small businesses may request information on compliance with this regulation by contacting: Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523-S, Washington, DC 20090-6456; telephone (202) 720-2491, Fax # (202) 720-5698.

FOR FURTHER INFORMATION CONTACT: William G. Pimental, Southeast Marketing Field Office, AMS, USDA, P.O. Box 2276, Winter Haven, Florida 33883-2276; telephone: (941) 299-4770, Fax # (941) 299-5169; or Caroline Thorpe, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2522-S, Washington, D.C. 20090-6456; telephone: (202) 720-8139, Fax # (202) 720-5698.

SUPPLEMENTARY INFORMATION: This proposal is issued under Marketing Agreement and Marketing Order No. 905 (7 CFR Part 905), as amended, regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, hereinafter referred to as the "order." This order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This proposal has been reviewed under Executive Order 12988, Civil

Justice Reform. This rule is not intended to have retroactive effect. This proposal will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after date of the entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 100 handlers subject to regulation under the order and approximately 11,000 producers of citrus in the regulated area. Small agricultural service firms, which includes handlers, have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than \$5,000,000, and small agricultural producers are defined as those having annual receipts of less than \$500,000. The majority of handlers and producers of citrus grown in Florida may be classified as small entities.

This proposed rule would add procedures to the rules and regulations itself. It would not establish any volume regulation. Any implementation of these procedures concerning regulation would require further committee action and additional public rulemaking by the Department.

However, if the procedures in this proposal were used and volume

regulations established, all growers and handlers would be impacted equitably. Before any implementation would occur, the committee would meet and consider any and all economic data available. The goal of this proposal is to provide an additional tool, if needed, to help stabilize the price of red grapefruit. In the past three seasons, during the period which would be covered by this proposed rule, prices of red seedless grapefruit have fallen from an average f.o.b. of \$7.80 per box to an average f.o.b. of \$5.50 per box. On tree prices for fresh red seedless grapefruit have declined steadily from \$9.60 per box during the 1989-90 season, to \$3.45 per box during the 1994-95 season. In many cases, prices during the past two seasons have provided returns less than production costs. This price reduction is forcing many small producers out of business. A stabilized price that returns a fair market value would be beneficial to both small and large producers and handlers.

Based on this information, the AMS has determined that this action would not have a significant economic impact on a substantial number of small entities. Interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

The order provides for the establishment of grade and size requirements for Florida citrus. These grade and size requirements are designed to provide fresh markets with citrus fruit of acceptable quality and size, thereby maintaining consumer confidence for fresh Florida citrus. This helps create buyer confidence and contributes to stable marketing conditions. This is in the interest of producers, handlers, and consumers, and is designed to increase returns to Florida citrus producers. The current minimum grade standard for red seedless grapefruit is U.S. No. 1, and the minimum size requirement is size 56 (at least 3³/₁₆ inches in diameter).

This proposal invites comments on the addition of a section to the rules and regulations under the order. This rule would establish procedures for limiting the volume of small red seedless grapefruit entering the fresh market during the first 11 weeks of each season. The red seedless grapefruit season runs from mid-September to May. This rule would provide an additional tool under the order to help stabilize the market and improve returns to growers. These changes were recommended by the committee at its meeting on May 24, 1996, by a 10 to 4 vote.

Section 905.52 of the Florida citrus marketing order provides authority to

limit shipments of any grade or size, or both, of any variety of Florida citrus. Such limitations may restrict the shipment of a portion of a specified grade or size of a variety. Under such a limitation, the quantity of such grade or size that may be shipped by a handler during a particular week shall be established as a percentage of the total shipments of such variety by such handler in a prior period, established by the committee and approved by the Secretary, in which the handler shipped such variety. This proposed rule would add § 905.153 to the rules and regulations to establish a specified prior period and other procedures necessary to limit the volume of small red seedless grapefruit, sizes 48 and 56, entering the fresh market during the first 11 weeks of the season.

Currently, there are no limitations on the amount of size 48 and size 56 red seedless grapefruit that can be shipped to market. This rule in itself would not limit shipments, but would outline procedures to do so if needed. Implementation of these procedures to limit shipments would require further rulemaking.

The committee recommended this rule to address problems currently facing the industry. For the past few seasons, returns on red seedless grapefruit have been at all time lows, often not returning the cost of production. Fifty-nine percent of red seedless grapefruit is shipped to fresh market channels. There is a processing outlet for grapefruit not sold into the fresh market. The vast majority of processing is squeezing the grapefruit for juice. Because of the properties of the juice of red seedless grapefruit, including problems with color, the processing outlet is limited, and not currently profitable.

Several areas of new plantings in the southern growing region are just beginning to bear fruit. Young trees normally produce mostly small fruit when they first come into production. Florida producers and handlers realize that these new acres will add to the abundance of small sizes of red seedless grapefruit.

The committee believes that to stabilize the market and improve returns to producers, demand for fresh red seedless grapefruit must be stabilized and increased. One problem contributing to the current state of the market is the excessive number of small sized grapefruit shipped early in the marketing season. While there is a market for early grapefruit, the shipment of large quantities of small red seedless grapefruit in a short period oversupplies the fresh market for these sizes and

negatively impacts the market for all sizes.

The committee believes that the overshipment of smaller sized red seedless grapefruit early in the season has contributed to below production cost returns for producers. Based on statistical information from past seasons, there is an indication that once shipments of sizes 48 and 56 reach levels above 250,000 cartons a week, prices decline on those and most other sizes of red seedless grapefruit. Thus, even though later in the season the crop has sized to naturally limit the amount of smaller sizes available for shipment, the price structure in the market has already been negatively affected.

For the majority of the season, larger sizes return better prices than smaller sizes. If these small grapefruit were allowed to remain on the tree to increase in size and maturity, they could provide greater returns to producers. Delaying the harvest of small sizes may also extend the season, thereby increasing the total volume of fresh shipments and improving producer returns. Without volume regulation, the industry has been unable to limit the shipments of small sizes. The committee believes that if shipments of small sizes could be maintained at around 250,000 cartons a week, prices should stabilize and demand for larger, more profitable sizes should increase.

Similar procedures to those considered in this rule are already in place for Dancy tangerines under § 905.152. While the committee has not utilized these procedures for several years, they were successfully implemented for several seasons.

Under the proposed procedures, the authority to limit the shipment of sizes 48 and 56 red seedless grapefruit would only be available for the 11-week period from the third Monday in September (week #1) through the first Sunday in December (week #11), hereinafter called the regulatory period. The committee recommended these weeks for regulation because the majority of small sizes are shipped during this period. By the end of the regulatory period, fruit has begun to size naturally, and there are fewer small sizes available.

The committee may recommend that only a certain percentage of size 48 ($3\frac{1}{16}$ minimum diameter in inches) and size 56 ($3\frac{5}{16}$ minimum diameter in inches) red seedless grapefruit be made available for shipment into fresh market channels for any week or weeks during the regulatory period. Should the committee decide to recommend the limitation of shipments of sizes 48 and 56 red seedless grapefruit, they would

meet and recommend to the Secretary a percentage on which to base the amount of sizes 48 and 56 that could be shipped during a particular week or weeks during the regulatory period. The committee realizes that markets for these sizes do exist. Therefore, the percentage set could not be less than 25 percent of the calculated shipment base. These procedures are designed not to eliminate shipments of sizes 48 and 56, but to keep them from saturating the entire market.

Section 905.52 provides that whenever any size limitation restricts the shipment of a portion of a specified size, the quantity of such size that may be shipped by a handler during a particular week shall be established as a percentage of the total shipments of such variety by such handler in such prior period as established by the committee and approved by the Secretary.

This proposed rule would establish the prior period as an average week within the immediately preceding five seasons. An average week would be calculated as follows. The total red seedless grapefruit shipments by a handler during the 33-week period beginning the third Monday in September and ending the first Sunday in May during the past five seasons would be added and divided by five to establish an average season. This average season would then be divided by the 33 weeks in a season to derive the average week. This week would be the basis for each shipper for each of the 11 weeks contained in the regulation period.

To illustrate, suppose Handler A shipped a total of 50,000 cartons, 65,000 cartons, 45,000 cartons, 80,000 cartons, and 25,000 cartons of red seedless grapefruit in the last five seasons, respectively. Adding these season totals and dividing by five yields an average season of 53,000 cartons. The average season would then be divided by 33 weeks to yield an average week, in this case, 1,606 cartons. This would be Handler A's base.

The committee chose to use the past five seasons for the average season to provide the most accurate picture of an average season. The use of an average week helps adjust for variations in growing conditions that may affect when fruit matures in different seasons and growing areas. The committee believes that this definition of prior period would provide each handler with an equitable base from which to establish shipments.

The average week for handlers with less than five previous seasons of shipments would be calculated by

averaging the total shipments for the seasons they did ship red seedless grapefruit during the immediately preceding five years and dividing that average by 33. New handlers with no record of shipments would have no prior period on which to base their average week. Therefore, if a volume regulation was established before such handlers have shipped any red seedless grapefruit, the new handlers could ship small sizes as a percentage of their total shipments equal to the percentage applied to other handlers' base. Once new handlers have established shipments, the average week would be calculated as an average of the weeks they have shipped during the current season.

To use these new procedures, the committee would meet and recommend a base percentage of sizes 48 and 56 that could enter the fresh market in any week or weeks from the first Monday in September through the first Sunday in December. If approved by the Secretary, this percentage would be applied to each handler's average week of fresh shipments to determine the amount (allocation) of sizes 48 and 56 red grapefruit each handler could ship. Each regulation period would begin Monday at 12:00 a.m. and end at 11:59 p.m. the following Sunday, since most handlers keep records based on Monday being the beginning of the work week.

When a size limitation is recommended to restrict the shipment during a particular week, the committee would compute each handler's allotment by multiplying the handler's average week by the percentage established by regulation for that week. Such set percentage could vary from week to week, but could not be less than 25 percent. The committee would notify each handler prior to the particular week of the quantity of sizes 48 and 56 red seedless grapefruit such handler could handle during a particular week.

To provide handlers with some flexibility, these procedures would provide allowances for overshipments, loans, and transfers of allotment. These allowances should allow handlers the opportunity each week to supply their markets while limiting the impact of small sizes.

During any regulation week for which the Secretary has fixed the percentage of sizes 48 and 56 red seedless grapefruit, any person who has received an allotment could handle, in addition to their weekly allotment, an amount of size 48 and 56 red seedless grapefruit not to exceed 10 percent of that week's allotment. The quantity of overshipments would be deducted from the handler's allotment for the following

week. Overshipments would not be allowed during week 11 because there would be no allotments the following week from which to deduct the overshipments.

If handlers fail to use their entire allotments in a given week, the amounts undershipped would not be carried forward to the following week. However, a handler to whom an allotment has been issued could lend or transfer all or part of such allotment (excluding the overshipment allowance) to another handler. In the event of a loan of allotment, each party would, prior to the completion of the loan agreement, notify the committee of the proposed loan and date of repayment. If a transfer of allotment is desired, each party would promptly notify the committee so that proper adjustments of the records could be made. In each case, the committee would confirm in writing all such transactions prior to the following week. The committee could also act on behalf of handlers wanting to arrange allotment loans or participate in the transfer of allotment. Repayment of an allotment loan would be at the discretion of the handlers party to the loan.

In considering these procedures, the committee discussed several possible alternatives. One alternative considered was an amendment to the marketing order. The amendment would have changed the language regarding the "prior period" in section 905.52. However, this alternative was rejected because of the time required to amend the order.

The committee also discussed limiting or eliminating only shipments of size 56 grapefruit. However, the committee found that it is important to include both sizes 48 and 56 for this regulation to be effective. Also, the committee did not want to eliminate a size entirely. They realize there is a market for small sizes and wish to allow handlers to take advantage of this market without negatively affecting the market for other sizes.

Other concerns were raised during discussion of these procedures. One committee member questioned whether these procedures would allow him to continue to increase his business. It was explained that this action would only put tools in place to allow the limitation of just a certain percentage of the smaller sized red seedless grapefruit. A handler would not in any way be limited from shipping any amount of larger sizes. Another concern raised was the impact these procedures would have on harvesting. It was explained again that this rule would just establish procedures. However, if implemented, it

would require more selective picking of only the sizes desired, something that many are doing already.

After a lengthy discussion, the committee decided that it needs to have available a tool to regulate shipments of small sized red seedless grapefruit early in each marketing season. The committee voted to recommend the establishment of these procedures to provide them with that tool.

The committee reports that it expects that more red seedless grapefruit will be produced in Florida during the 1996-97 season than last season. The committee also expects that supplies of fresh Florida red seedless grapefruit will be adequate to meet consumer demand during the entire 1996-97 season.

This rule does not affect the order provision that handlers may ship up to 15 standard packed cartons (12 bushels) of fruit per day exempt from grade and size requirements. Fruit shipped in gift packages that are individually addressed and not for resale, and fruit shipped for animal feed are also exempt from grade and size requirements under specific conditions. Also, fruit shipped to commercial processors for conversion into canned or frozen products or into a beverage base are not subject to the handling requirements under the order.

Section 8(e) of the Act requires that whenever grade, size, quality or maturity requirements are in effect for certain commodities under a domestic marketing order, including grapefruit, imports of that commodity must meet the same or comparable requirements. This rule does not change the minimum grade and size requirements under the order. Therefore, no change is necessary in the grapefruit import regulations as a result of this action.

The information collection requirements contained in this section must be approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) and assigned OMB number 0581-0094 for Florida citrus.

This rule would increase the reporting burden on an estimated 10 handlers of red seedless grapefruit who would be taking about 0.083 hour to complete a report regarding allotment loans or transfers an average of 11 times per year. The total annual increase in burden would be about 9 hours.

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments received within the comment period will be considered before a final determination is made on this matter.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the AMS announces its intention to request an extension for and revision to a currently approved information collection for Florida oranges, grapefruit, tangerines, and tangelos.

Title: Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida, Marketing Order No. 905.

OMB Number: 0581-0094.

Expiration Date of Approval: August 31, 1998.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: Marketing order programs provide an opportunity for producers of fresh fruits, vegetables and specialty crops, in a specified production area, to work together to solve marketing problems that cannot be solved individually. Order regulations help ensure adequate supplies of high quality product and adequate returns to producers. Under the Act, industries enter into marketing order programs. The Secretary of Agriculture is authorized to oversee the order operations and issue regulations recommended by a committee of representatives from each commodity industry.

The information collection requirements in this request are essential to carry out the intent of the Act, to provide the respondents the type of service they request, and to administer the Florida citrus marketing order program, which has been operating since 1939.

The Florida citrus marketing order authorizes the issuance of grade, size, container, and pack regulations. It also authorizes the limitation of shipments of certain grades or sizes. Regulatory provisions apply to oranges, grapefruit, tangerines and tangelos shipped outside of the production area, except for those shipments specifically exempt.

The order, and rules and regulations issued thereunder, authorize the committee to require handlers and producers to submit certain information. Much of this information is compiled in aggregate and provided to the industry to assist in marketing decisions.

The committee has developed forms as a means for persons to file required information with the committee relating to citrus supplies, shipments, dispositions, and other information needed to effectively carry out the purpose of the Act and order. As shipments occur throughout the year, these forms are utilized accordingly. A USDA form is used to allow producers

to vote on amendments to the order and whether the order should be continued. In addition, producers and handlers who are nominated by their peers to serve as representatives on the committee must file nomination forms with the Secretary.

This proposed collection includes a new requirement for handlers to report to the committee any allotment loans or transfers during volume regulation of smaller size 48 (at least $3\frac{3}{16}$ inches) or 56 (at least $3\frac{5}{16}$ inches) red seedless grapefruit. Allowing transfers and loans would provide flexibility during such regulation, by allowing handlers to loan or transfer their individual allotments of smaller sized red seedless grapefruit. Requiring such transactions to be reported to the committee would ensure compliance with volume regulations and assist the committee and the Department with oversight and planning of volume regulation of red seedless grapefruit. This new requirement would increase the reporting burden on an estimated 10 handlers of red seedless grapefruit who would be taking about 0.083 hour to complete a report regarding allotment loans or transfers an average of 11 times per year. The total annual increase in burden would be about 9 hours.

These forms require the minimum information necessary to effectively carry out the requirements of the order, and their use is necessary to fulfill the intent of the Act as expressed in the order.

The information collected is used only by authorized representatives of the USDA, including AMS, Fruit and Vegetable Division regional and headquarter's staff, and authorized employees of the committee. Authorized committee employees are the primary users and AMS employees are the secondary users of the information.

Estimate of Burden: Public reporting burden for this proposed collection of information is estimated to average 0.089 hours per response.

Respondents: Florida citrus producers and for-profit businesses handling fresh citrus.

Estimated Number of Respondents: 1,176.

Estimated Number of Responses per Respondent: 1

Estimated Total Annual Burden on Respondents: 204 hours.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Florida citrus marketing order program and the Department's oversight of that program, including whether the information will have practical utility; (b) the accuracy of AMS's burden estimate of the proposed

collection of information including the validity of methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of appropriate information on those who are to respond, including through the use of appropriate, automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments should reference OMB No. 0581-0094 and the Florida citrus Marketing Order No. 905, and be sent to USDA in care of Caroline C. Thorpe, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, PO Box 96456, room 2522-S, Washington, DC 20090-6456; telephone: 202-720-5127 or Fax: 202-720-5698.

All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Because there is insufficient time for a normal clearance procedure, AMS is seeking temporary approval from OMB for the use of a new form for this upcoming season. The form would be added to the forms which are currently approved for use under OMB Number 0581-0094.

List of Subjects in 7 CFR Part 905

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements, Tangelos, Tangerines.

For the reasons set forth in the preamble, 7 CFR part 905 is proposed to be amended as follows:

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

1. The authority citation for 7 CFR Part 905 continues to read as follows:

Authority: 7 U.S.C. 601-674.

2. A new § 905.153 is added to read as follows:

§ 905.153 Procedure for determining handlers' permitted quantities of red seedless grapefruit when a portion of sizes 48 and 56 of such variety is restricted.

(a) For the purposes of this section, the prior period specified in § 905.52 is hereby established as an average week within the immediately preceding five seasons. Each handler's average week shall be computed by adding the total volume of red seedless grapefruit handled in the immediately preceding five seasons and dividing the total by

165. The average week for handler with less than five previous seasons of shipments shall be calculated by adding the total volume of shipments for the seasons they did ship red seedless grapefruit, divided by the number of seasons, divided further by 33. New handlers with no record of shipments could ship size 48 and 56 red seedless grapefruit as a percentage of total shipments equal to the percentage applied to other handlers' average week; once such handlers have recorded shipments, their average week shall be calculated as an average of total shipments for the weeks they have shipped red seedless grapefruit during the current season. When used in the regulation of red seedless grapefruit the term season means the weeks beginning the third Monday in September and ending the first Sunday in the following May. The term regulation period means the 11 weeks beginning the third Monday in September and ending the first Sunday in December of the current season.

(b) When a size limitation restricts the shipment of a portion of sizes 48 and 56 red seedless grapefruit during a particular week as provided in § 905.52, the committee shall compute the quantity of sizes 48 and 56 red seedless grapefruit that may be shipped by each handler by multiplying the handler's calculated average week shipments of such grapefruit by the percentage established by regulation for red seedless grapefruit for that week.

(c) The committee shall notify each handler of the quantity of size 48 and 56 red seedless grapefruit such handler may handle during a particular week.

(d) During any regulation week for which the Secretary has fixed the percentage of sizes 48 and 56 red seedless grapefruit, any person who has received an allotment may handle, in addition to their total allotment available, an amount of size 48 and 56 red seedless grapefruit up to 10 percent greater than their allotment. The quantity of the overshipment shall be deducted from the handler's allotment for the following week. Overshipments will not be allowed during week 11. If the handler fails to use his or her entire allotment, the undershipment is not carried forward to the following week.

(e) Any handler may transfer or loan any or all of their shipping allotment (excluding the overshipment allowance) of size 48 and 56 red seedless grapefruit to any other handler. Each handler party to such transfer or loan shall promptly notify the committee so the proper adjustment of records may be made. In each case, the committee shall confirm in writing all such transactions, prior to

the following week, to the handlers involved. The committee may act on behalf of handlers wanting to arrange allotment loans or participate in the transfer of allotments.

Dated: August 22, 1996.

Robert C. Keeney,

Director, Fruit and Vegetable Division.

[FR Doc. 96-21960 Filed 8-27-96; 8:45 am]

BILLING CODE 3410-02-P

7 CFR Part 998

[Docket No. FV96-998-3 PR]]

Domestically Produced Peanuts Handled by Persons Subject to Peanut Marketing Agreement No. 146; Changes in Terms and Conditions of Indemnification

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposal invites comments on modifying, for 1996 and subsequent crop peanuts, the indemnification program for signatory handlers under Peanut Marketing Agreement No. 146 (Agreement). The proposed rule would reduce indemnification payment coverage to certain costs involved with appeal and product claims. This would reduce the Peanut Administrative Committee's (Committee's) indemnification payments for losses incurred by signatory handlers in not being able to ship unwholesome peanuts for edible purposes from a ceiling of \$7 million for each of the last two years, to about \$2300,000. With the proposed reduction in indemnification claim payments, the Committee will have adequate funds in its indemnification reserve to cover costs. No handler assessments for indemnification would be necessary. This would reduce signatory handlers' costs, enabling them to be more competitive with non-signatory handlers, and importers. The changes were recommended by the Committee, the administrative agency which oversees the quality assurance program under the Agreement.

DATES: Comments must be received by September 12, 1996.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, room 2523-S, P.O. Box 96456, Washington, DC 20090-6456; Fax: (202) 720-5698. All comments should reference the docket number, the date, and page number of this issue of the Federal Register and will be made

available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Jim Wendland, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523-S, Washington, D.C. 20090-6456; telephone: (202) 720-2170, or Fax: (202) 720-5698; or William G. Pimental, Marketing Specialist, Southeast Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, P.O. Box 2276, Winter Haven, Florida 33883-2276; telephone: (941) 229-4770, or Fax: (941) 299-5169. Small businesses may request information on compliance with this proposed regulation by contacting: Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523-S, Washington, D.C. 20090-6456; telephone: (202) 720-2491, or Fax: (202) 720-5698.

SUPPLEMENTARY INFORMATION: This proposal is issued under Peanut Marketing Agreement No. 146 (7 CFR part 998). The program regulates the quality of domestically produced peanuts handled by Agreement signers. The Agreement is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The U.S. Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to apply to 1996 (beginning July 1, 1996) and subsequent crop year peanuts. This proposal will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing agreements and orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

About 32 signatory peanut handlers are subject to regulation under the

Agreement. There are about 47,000 peanut producers in the 16-State production area. Small agricultural service firms, which includes handlers, have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than \$5,000,000, and small agricultural producers have been defined as those having annual receipts of less than \$500,000. Although approximately 25 percent of the signatory handlers may be classified as small entities, they are seed shellers who ship almost no peanuts to human consumption outlets. This proposal would have virtually no effect on them. A majority of the producers may be classified as small entities. Interested persons are invited to submit information on the regulatory impact of this proposed rule on small businesses.

Domestic peanut production in 1995 was 1.76 million tons, with a farm value of \$1 billion.

The objective of the Agreement is to ensure that only high quality and wholesome peanuts enter human consumption markets in the United States. About 70 percent of domestic handlers, handling approximately 95 percent of the crop, have signed the Agreement.

Under the regulations, farmers stock peanuts with visible *Aspergillus flavus* mold (the principal source of aflatoxin) are required to be diverted to non-edible uses. Each lot of milled peanuts must be sampled and tested and those certified "positive" as to aflatoxin must be diverted to non-edible uses. Handlers of such peanuts currently may be eligible to receive indemnification payments for losses incurred in not being able to ship the peanuts for edible uses. Costs to administer the Agreement and make indemnification payments are paid by assessments levied on signatory handlers.

The Committee, which is composed of producers and handlers of peanuts, meets at least annually to review the Agreement's rules and regulations, which are effective on a continuous basis from one year to the next. Committee meetings are open to the public, and interested persons may express their views at these meetings. The Department reviews Committee recommendations and justifications, as well as information from other sources, to determine whether modification of the Agreement regulations would tend to effectuate the declared policy of the Act.

The Committee believes that the domestic peanut industry is undergoing a period of great change. The Committee endorses the findings in a recent study

entitled "United States Peanut Industry Revitalization Project" developed by the National Peanut Council and the Department's Agricultural Research Service. According to the study, since 1991, the U.S. peanut industry has been in a period of dramatic economic decline because of (1) decreasing consumption of peanuts and peanut products, (2) decreasing U.S. peanut production and increasing production costs, and (3) increasing imports of peanuts and peanut products.

The study shows that peanut per capita consumption has steadily declined; between 1991 and 1994, a total of 11 percent. Harvested acres of peanuts in the U.S. have declined 25 percent between 1991 and 1995. Production has fluctuated downward, with 1995 production 30 percent below that of 1991. Farm value of peanut production has dropped 29 percent in the same period. Farmer production costs and revenue are projected to be equal by the year 2000, as are handler costs and revenue, which would leave no profit.

All of these factors combine to show that the domestic peanut industry is in decline and that the outlook is not expected to improve without affirmative actions taken by the industry. The Committee has been meeting for the past two years to develop major improvements and cut costs to its program and to the signatory handlers by streamlining handling procedures and making them consistent with current industry economies and technological developments.

Over the last several years, the Committee has been reducing the indemnification benefits. This reduction has made indemnification of failing peanuts a less viable economic option and has put more responsibility on each handler to decide whether it is economical to recondition a failing lot. Peanut processing machinery has improved through technological advances to the point that virtually any lot of peanuts, regardless of original (incoming) quality, can now be shelled, remilled and/or blanched (processed) to meet outgoing quality requirements established under the Agreement. The Committee concluded that handlers should bear more responsibility for reconditioning their own peanuts and in shipping quality peanuts to their customers, and that Committee and handler indemnification costs should be reduced.

The Committee met on May 23, 1996, and recommended a substantial reduction in indemnification coverage to reduce costs. Signatory handlers have indicated they would rather have the Committee eliminate the

indemnification assessment currently collected from them than continue the current indemnification coverage. The Committee's indemnification payments for handler losses would decline from a record high net loss of \$21.6 million for crop year 1990, and ceilings of \$9 million for crop years 1991-1993 and \$7 million for each of the last two years, to approximately \$300,000. This would reduce signatory handlers' costs, enabling them to be more competitive with non-signatory peanut handlers, and importers.

The Committee currently pays claims based on the initial sampling of any peanut lot failing to meet aflatoxin requirements for human consumption before the peanuts are shipped from the handler's plant to the buyer, product and appeals claims. Payments are made for blanching fees and/or remilling fees, freight charges for moving the peanuts from one production area to another for marketing, and for losses for the rejected peanuts.

Under the modified program, on an "appeal claim" the Committee would pay only for freight costs from the handler's plant to the manufacturer and return from manufacturer to the destination requested by the handler (handler's plant, blancher, or remiller). "Appeal claims" involve lots of peanuts, which had been certified as meeting all quality requirements, prior to shipment, and then rejected by the buyer on the basis of appeal aflatoxin test results. The deadline for filing "appeal" indemnification claims with the Committee would remain November 1 following the end of the crop year. The Committee recommended that "product claims" continue to be handled as they have been in the past. That is, claims may be filed by any handler sustaining a loss as a result of a buyer withholding from human consumption a portion or all of the product made from a lot of peanuts which has been determined to be unwholesome due to aflatoxin. The Committee would indemnify the amount of the raw peanuts in the product at \$0.35 per pound. The product is destroyed under the supervision of USDA's Processed Products Branch inspectors and the Committee pays these charges. The deadline for filing "product claims" remains November 1 of the second year following the year in which the peanuts were produced.

An estimated \$2.0 to \$2.5 million indemnification reserve (after all 1995 crop claims are paid) should be available to cover claims under the proposed program. With annual costs under the proposed program estimated

at \$200,000 to \$300,000, there is enough money in reserves to cover claims for about 10 crop years. Thus, handlers would not be required to pay indemnification assessments during that period. Indemnification assessments during the 1994 and 1995 crop years totalled approximately \$3.4 million and \$1.3 million (to date), respectively.

If the Committee had recommended maintaining the current coverage at the \$7,000,000 ceiling, an indemnification assessment rate of about \$4.00 per ton on the 1996 crop would have been necessary to finance the program. All signatory handlers, both large and small, would benefit from the substantially lower costs associated with the elimination of annual indemnification assessment obligations. This would enable handlers to be more competitive with non-signatory handlers and importers. Handlers who believe they may be adversely impacted by aflatoxin can obtain private insurance coverage against such losses.

Therefore, the AMS has determined that this proposed action would not have a significant economic impact on a substantial number of small entities. Interested persons are invited to submit information on the regulatory and informational impacts of this proposed rule on small businesses.

To implement the reduced indemnification coverage, substantive changes to § 998.300 *Terms and conditions of indemnification* are necessary. As a consequence, § 998.300 has been completely revised and reorganized, and is set forth below in its entirety. Handler application and Committee payment procedures for appeal and product claims remain the same.

The proposed changes to the signer indemnification program should be in effect as close to the beginning of the crop year as possible. The crop year began July 1, 1996. This leaves a very short time period in which to receive industry comments and evaluate the recommendations prior to issuing a final rule. Thus, a 15-day (rather than a 30-day) comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made in this matter.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), any information collection requirements that may be contained in this proposal have been previously approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581-0067. This proposal would likely result in less

reports having to be filed, particularly because there would likely be less indemnification claims filed under the reduced program coverage.

The Committee also recommended numerous relaxations to the Agreement's incoming and outgoing quality regulations for 1996 and subsequent crop peanuts, which are being proposed in a separate rulemaking action.

List of Subjects in 7 CFR Part 998

Marketing agreements, Peanuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 998 is proposed to be amended as follows:

1. The authority citation for 7 CFR part 998 continues to read as follows:

Authority: 7 U.S.C. 601-674.

PART 998—MARKETING AGREEMENT REGULATING THE QUALITY OF DOMESTICALLY PRODUCED PEANUTS

2. Section 998.300 is revised to read as follows:

§ 998.300 Terms and conditions of indemnification for 1996 and subsequent crop peanuts.

(a) For the purpose of paying indemnities on a uniform basis pursuant to § 998.36 of the peanut marketing agreement, each handler shall promptly notify or arrange for the buyer to notify the Manager, Peanut Administrative Committee, of any lot of cleaned inshell or shelled peanuts, milled into one of the categories listed in paragraph (a) of the *Outgoing quality regulation* (7 CFR 998.200) or paragraph (j) of this section, on which the buyer, including the user division of a handler, has withheld usage due to a finding as to aflatoxin content as shown by the results of further chemical assay, after shipment.

(b) To be eligible for indemnification, such a lot of peanuts shall have been inspected and certified as meeting the quality requirements for Indemnifiable Grades as specified in paragraph (a) of the *Outgoing quality regulation* (7 CFR 998.200), shall have met all other applicable regulations issued pursuant thereto, including the pretesting requirements in paragraphs (a) and (c) of the *Outgoing quality regulation* and the lot identification shall have been maintained. If the Committee concludes, based on further assays, that the lot is so high in aflatoxin that it should be handled pursuant to this section and such is concurred in by the Agricultural Marketing Service, the lot shall be accepted for indemnification.

(c) The indemnification payment shall be transportation expenses (excluding demurrage, loading and unloading charges, custom fees, border re-entry fees, etc.) from the handler's plant or storage to the point within the Continental United States or Canada where the rejection occurred and from such point to a delivery point specified by the Committee if the lot is found by the Committee to be unwholesome as to aflatoxin after such lot had been certified negative as to aflatoxin prior to being shipped or otherwise disposed of for human consumption by the handler pursuant to requirements of the *Outgoing quality regulation* (7 CFR 998.200).

(d) Claims for indemnification may be filed by any handler sustaining a loss as a result of a buyer withholding from human consumption a portion or all of the product made from a lot of peanuts which has been determined to be unwholesome due to aflatoxin. The Committee shall pay such claims as it determines to be valid, to the extent of the equivalent indemnification value applicable to the peanuts used in the product so withheld. On products manufactured from edible quality grades of peanuts, such claims may be filed with the committee no later than November 1 of the second year following the year in which the peanuts were produced.

(e) Notice of claims for indemnification on peanuts of the current crop year shall be received by the Committee (by mail or legible facsimile) no later than the close of the business day on November 1, following the end of the crop year. For the purpose of this paragraph, "notice" shall be defined as the covering (executed and signed) Form PAC-5, accompanied by a copy of the applicable valid grade inspection certificate and the lab certificate showing the aflatoxin assay results which caused the request for rejection.

(f) Each handler shall include, directly or by reference, in the handler's sales contract, the following provisions:

(1) Buyer shall give the Peanut Administrative Committee (Committee) office notice of any request made to the Federal or Federal-State Inspection Service for an "appeal" inspection for aflatoxin. Results of the "appeal" inspection will be reported by the Federal or Federal-State Inspection Service or other designated lab to Committee management. If the Committee management determines that the test results of the "appeal" sample show the lot to be high in aflatoxin, Committee management shall inform the buyer and handler of the results. In

this case, the buyer may apply to reject the lot and return it to the handler by filing a rejection letter with Committee management. Upon a determination of the Committee, confirmed by the Agricultural Marketing Service, authorizing rejection, such peanuts, and title thereto, if passed to the buyer, shall be returned to the seller. Buyer must return the rejected lot to the seller within 45 days of the date on which Committee management informs buyer of the "appeal" sample test results, otherwise the buyer agrees that he/she forfeits the right to reject the lot and return it to the seller.

(2) Seller shall, prior to shipment of a lot of shelled peanuts covered by this sales contract, cause appropriate samples to be drawn by the Federal or Federal-State Inspection Service from such lot, shall cause the sample(s) to be sent to a USDA laboratory or if designated by the buyer, a laboratory listed on the most recent Committee list of approved laboratories to conduct such assay, for an aflatoxin assay and cause the laboratory, if other than the buyer's to send one copy of the results of the assay to the buyer. A portion of the costs of aflatoxin sampling and testing, as provided in § 998.200(c)(3), shall be for the account of the buyer and the buyer agrees to pay such costs.

(g) Any handler who fails to include such provisions in his/her sales contract shall be ineligible for indemnification payments with respect to any claim filed with the Committee on current crop year peanuts covered by the sales contract.

(h)(1) Any handler who fails to conform to the requirements of paragraph (g) of the *Incoming quality regulation* (7 CFR 998.200) shall be ineligible for any indemnification payments until such condition or conditions are corrected to the satisfaction of the Committee.

(2) Any handler who fails to comply with the requirements of paragraph (h)(1) or (h)(2) of the *Outgoing quality regulation* (7 CFR 998.200) shall be ineligible for any indemnification payments until such non-compliance is corrected to the satisfaction of the Committee.

(i) Any handler who fails to cause positive lot identification on any lot of peanuts to accurately reflect the crop year in which such peanuts were produced, pursuant to paragraph (d) of the *Outgoing quality regulation* (7 CFR 998.200), shall be ineligible for any indemnification payments until such non-compliance is corrected to the satisfaction of the Committee.

(j) Categories of cleaned inshell peanuts eligible for indemnification are as follows:

- (1) Cleaned inshell peanuts ¹
- (i) U.S. Jumbos
- (ii) U.S. Fancy Handpicks
- (iii) Valencia-Roasting Stock ²
- (k) The indemnification value for peanuts indemnified shall be 35 cents per pound.

Dated: August 22, 1996.
Robert C. Keeney,
Director, Fruit and Vegetable Division.
[FR Doc. 96-21959 Filed 8-27-96; 8:45 am]
BILLING CODE 3410-02-M

Rural Utilities Service

7 CFR Part 1755

RUS Standard for Acceptance Tests and Measurements of Telecommunications Plant

AGENCY: Rural Utilities Service, USDA.
ACTION: Proposed rule.

SUMMARY: The Rural Utilities Service (RUS) proposes to amend its regulations on Telecommunications Standards and Specifications for Materials, Equipment and Construction, by rescinding RUS Bulletin 345-63, RUS Standard for Acceptance Tests and Measurements of Telephone Plant, PC-4, and codifying the revised RUS Standard for Acceptance Tests and Measurements of Telecommunications Plant in the Code of Federal Regulations. The revised standard: Updates the acceptance tests and measurements for copper conductor telecommunications plant; includes a section on acceptance tests and measurements for fiber optic cable plant; includes a section on acceptance tests and measurements for voiceband data transmission; and includes a shield or armor ground resistance test to determine outer jacket cable damage.

DATES: Comments concerning this proposed rule must be received by RUS or postmarked no later than October 28, 1996.

ADDRESSES: Comments should be mailed to Orren E. Cameron III, Director, Telecommunications Standards Division, Rural Utilities Service, room 2835, STOP 1598, South Building, U.S. Department of Agriculture, Washington,

¹ Eligible lots of cleaned inshell peanuts which are found, after shipment, to contain excessive aflatoxin, may be rejected to the handler. Transportation expenses (excluding demurrage, loading and unloading charges, custom fees, border reentry fees, etc.) from the handler's plant or storage to the point within the Continental United States or Canada where the rejection occurred and from such point to a delivery point specified by the Committee shall be the extent of the indemnification payment.

² Inshell peanuts with not more than 25 percent having shells damaged by discoloration, which are cracked or broken, or both.

DC 20250-1598. RUS requests an original and three copies of all comments (7 CFR part 1700). All comments received will be made available for public inspection at room 2835, South Building, U.S. Department of Agriculture, Washington, DC 20250-1598, between 8:00 a.m. and 4:00 p.m. (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Charlie I. Harper, Jr., Chief, Outside Plant Branch, Telecommunications Standards Division, Rural Utilities Service, room 2844, STOP 1598, South Building, U.S. Department of Agriculture, Washington, DC 20250-1598, telephone number (202) 720-0667.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed rule has been determined to be not significant and therefore has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. RUS has determined that this proposed rule meets the applicable standards provided in section 3 of that Executive Order.

Regulatory Flexibility Act Certification

The Administrator of RUS has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This proposed rule involves standards and specifications, which may increase the direct short-term costs to RUS borrowers. However, the long-term direct economic costs are reduced through greater durability and lower maintenance cost over time.

Information Collection and Recordkeeping Requirements

The reporting and recordkeeping requirements contained in the proposed rule were approved by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended) under control number 0572-0059.

Send questions or comments regarding this burden or any aspect of these collections of information, including suggestions for reducing the burden, to F. Lamont Heppe, Jr., Director, Program Support and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, STOP 1522, Washington, DC 20250-1522, FAX: (202) 720-4120.

National Environmental Policy Act Certification

The Administrator of RUS has determined that this proposed rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) Therefore, this action does not require an environmental impact statement or assessment.

Catalog of Federal Domestic Assistance

The program described by this proposed rule is listed in the Catalog of Federal Domestic Assistance programs under No. 10.851, Rural Telephone Loans and Loan Guarantees; and No. 10.852, Rural Telephone Bank Loans. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC 20402.

Executive Order 12372

This proposed rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation, which may require consultation with State and local officials. A Notice of Final rule titled Department Programs and Activities Excluded from Executive Order 12372 (50 FR 47034) exempts RUS and RTB loans and loan guarantees, and RTB bank loans, to governmental and nongovernmental entities from coverage under this Order.

Background

RUS issues publications titled "Bulletin" which serve to guide borrowers regarding already codified policy, procedures, and requirements needed to manage loans, loan guarantee programs, and the security instruments which provide for and secure RUS financing. RUS issues standards and specifications for the construction of telephone facilities financed with RUS Loan Funds. RUS proposes to rescind Bulletin 345-63, "RUS Standard for Acceptance Tests and Measurements of Telephone Plant, PC-4," and to codify this standard at 7 CFR 1755.400 through 7 CFR 1755.407, RUS Standard for Acceptance Tests and Measurements of Telecommunications Plant.

This standard is used to determine the acceptability of installed telecommunications plant. The current standard with regard to copper cable plant acceptance tests and measurements has become outdated as a result of technological advancements made in copper cable plant acceptance test methods during the past fourteen years. Therefore to assure RUS borrowers that their installed copper

cable plant is of the highest quality, the revised standard will update acceptance test and measurement methods for copper cable plant.

There is currently a need to include into the standard a section dealing with standardized test methods and measurements for installed fiber optic cable plant. Presently acceptance test methods and measurements for fiber optic cable plant are developed by each consulting engineer resulting in a variety of test methods and measurements which in turn results in higher construction costs to RUS borrowers. By providing standardized acceptance test methods and measurements for fiber optic cable plant, RUS will be assisting its borrowers by decreasing their construction costs for fiber optic cable installation.

There is currently a need to include into the standard a section dealing with standardized test methods and measurements for voiceband data transmission. Because RUS borrowers are increasing their usage of modems to transmit data over telecommunications transmission facilities, standardized test methods and measurements are needed to ensure that the transmission facilities are acceptable for data transmission.

There is presently a need to include into the current standard a standardized shield or armor ground resistance test method and a minimum requirement to determine when the outer cable jacket is damaged as a result of the installation procedures. This standard test method and minimum requirement will result in cost savings to RUS borrowers because the variety of test methods and minimum requirements presently being used by consulting engineers and contractors will be eliminated.

This action establishes RUS standardized acceptance test methods and measurements to determine acceptability of installed telecommunications plant. These standardized acceptance test methods and measurements will afford RUS telephone borrowers an economical and efficient means of reducing their construction costs.

List of Subjects in 7 CFR Part 1755

Loan programs-communications, Reporting and recordkeeping requirements, Rural areas, Telephone.

For the reasons set out in the preamble, RUS proposes to amend chapter XVII of title 7 of the Code of Federal Regulations as follows:

PART 1755—TELECOMMUNICATIONS STANDARDS AND SPECIFICATIONS FOR MATERIALS, EQUIPMENT AND CONSTRUCTION

1. The authority citation for part 1755 continues to read as follows:
Authority: 7 U.S.C. 901 *et seq.*, 1921 *et seq.*, 6941 *et seq.*

§ 1755.97 [Amended]

2. Section 1755.97 is amended by removing the entry RUS Bulletin 345-63 from the table.

3. Section 1755.98 is amended by adding the entry 1755.400 through 1755.407 to the table in numerical order to read as follows:

§ 1755.98 List of telephone standards and specifications included in other 7 CFR parts.

* * * * *					
Section		Issue date		Title	
1755.400 through 1755.407.		[Effective date of final rule.]		RUS Standard for Acceptance Tests and Measurements of Telecommunications Plant.	
* *		* *		* *	

4. Sections 1755.400 through 1755.407 are added to read as follows:

§ 1755.400 RUS standard for acceptance tests and measurements of telecommunications plant.

Sections 1755.400 through 1755.407 cover the requirements for acceptance tests and measurements on installed copper and fiber optic telecommunications plant and equipment.

§ 1755.401 Scope.

(a) Acceptance tests outlined in §§ 1755.400 through 1755.407 are applicable to plant constructed by contract or force account. This testing standard provides for the following:

- (1) Specific types of tests or measurements for the different types of telecommunications plant and equipment;
- (2) The method of measurement and types of measuring equipment;
- (3) The expected results and tolerances permitted to meet the acceptable standards and objectives;
- (4) Suggested formats for recording the results of the measurements and tests; and
- (5) Some probable causes of nonconformance and methods for corrective action, where possible.

(b) Alternative methods of measurements that provide suitable alternative results shall be permitted with the concurrence of the Rural Utilities Service (RUS).

(c) For the purpose of this testing standard, a "measurement" shall be defined as an evaluation where quantitative data is obtained (e.g., resistance in ohms, structural return loss in decibels (dB), etc.) and a "test" shall be defined as an evaluation where no quantitative data is obtained (e.g., a check mark indicating conformance is usually the result of the test).

(d) The sequence of tests and measurements described in this standard have been prepared as a guide.

Variations from the sequence may be necessary on an individual application basis.

(e) There is some overlap in the methods of testing shown; also, the extent of each phase of testing may vary on an individual basis. The borrower shall determine the overall plan of testing, the need and extent of testing, and the responsibility for each phase of testing.

§ 1755.402 Ground resistance measurements.

(a) The resistance of the central office (CO) and the remote switching terminal (RST) ground shall be measured before and after it has been bonded to the master ground bar (MGB) where it is

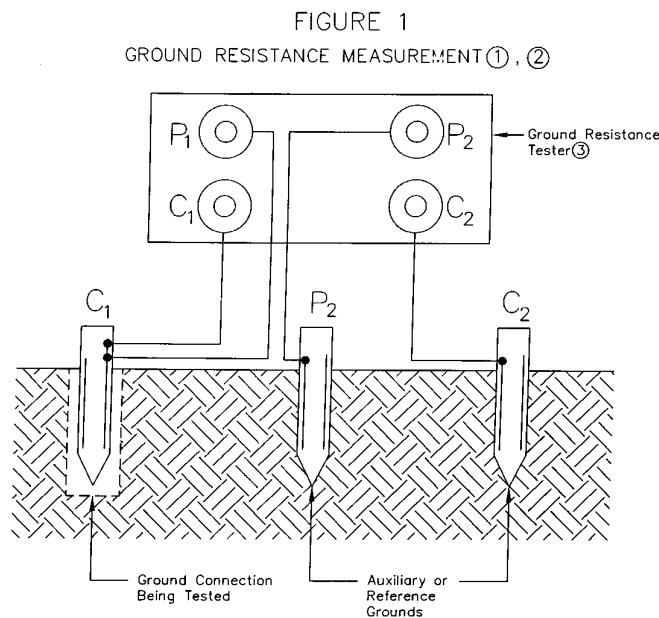
connected to the building electric service ground.

(b) The ground resistance of electronic equipment such as span line repeaters, carrier terminal equipment, concentrators, etc. shall be measured.

(c) Method of measurement. The connection of test equipment for the ground resistance measurement shall be as shown in Figure 1. Refer to RUS Bulletin 1751F-802, "Electrical Protection Grounding Fundamentals," for a comprehensive discussion of ground resistance measurements.

(d) Test equipment. The test equipment for making this measurement is shown in Figure 1 as follows:

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Notes:

- ①. Measurement procedure for COs, RSTs, and electronic equipment housings approximately 10 ft by 10 ft (3 m by 3m) or smaller shall be as follows: The minimum distance between the CO ground (C₁) being tested and C₂ = 100 ft (30.5 m). Take several measurements moving P₂ from 50 ft to 75 ft (15.2 m to 23 m) away from CO ground C₂. Resistance should initially rise then level off and then start rising again. The value to record for CO ground resistance is the value where it levels off which usually should occur with P₂ at 62 % of the distance between the CO ground and C₂.
- ②. Measurement procedure for COs, RSTs, and electronic equipment housings larger than 10 ft by 10 ft (3 m by 3 m) shall be in accordance with the test equipment manufacturer's instructions.
- ③. Dynatel Research—Vibroground, General Radio—Megger Bridge, Associate Research—Megohm Meter or equivalent.

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(e) Applicable results. (1) For the CO and RST, the resistance after the bond has been made to the MGB electric service ground shall not exceed 5 ohms. Where the measured ground resistance exceeds 5 ohms, the borrower shall determine what additional grounding, if any, shall be provided.

(2) For electronic equipment, the ground resistance shall not exceed 25 ohms. Where the measured ground resistance exceeds 25 ohms, the borrower shall determine what

additional grounding, if any, shall be provided.

(3) When ground resistance measurements exceed the ground resistance requirements of paragraphs (e)(1) and (e)(2) of this section, refer to RUS Bulletin 1751F-802, "Electrical Protection Grounding Fundamentals," for suggested methods of reducing the ground resistance.

(f) Data record. Results of the CO and RST ground resistance measurements shall be recorded. A suggested format

similar to Format I, Outside Plant Acceptance Tests—Subscriber Loops, in § 1755.407 or a format specified in the applicable construction contract may be used. Results of the electronic equipment ground resistance measurements shall be recorded. A suggested format similar to Format II, Outside Plant Acceptance Tests—Trunk Circuits, in § 1755.407 or a format specified in the applicable construction contract may be used. Data showing approximate moisture content of the soil

at the time of measurement, the temperature, the type of soil and a description of the test equipment used shall also be included.
 (g) Probable causes for nonconformance. Refer to RUS Bulletin 1751F-802, "Electrical Protection Grounding Fundamentals," and Telecommunications Engineering and Construction Manual (TE&CM) Section 810, "Electrical Protection of Electronic Analog and Digital Central Office Equipment," for possible causes of nonconformance and suggested methods for corrective action.

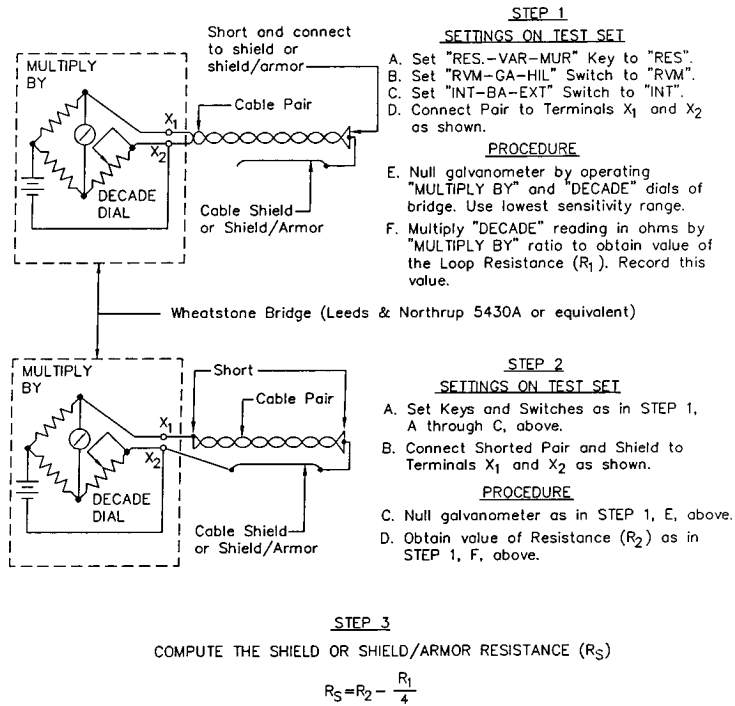
§1755.403 Copper cable telecommunications plant measurements.
 (a) *Shield or shield/armor continuity.*
 (1) Tests and measurements shall be made to ensure that cable shields or shield/armors are electrically continuous. There are two areas of concern. The first is shield or shield/

armor bonding within a pedestal or splice and the second is shield or shield/armor continuity between pedestals or splices.
 (2) Measurement techniques outlined here for verification of shield or shield/armor continuity are applicable to buried cable plant. Measurements of shield continuity between splices in aerial cable plant should be made prior to completion of splicing. Conclusive results cannot be obtained on aerial plant after all bonds have been completed to the supporting strand, multigrounded neutral, etc.
 (3) Method of measurement. (i) The shield or shield/armor resistance measurements shall be made between pedestals or splices using either a Wheatstone bridge or a volt-ohm meter. For loaded plant, measurements shall be made on cable lengths that do not exceed one load section. For nonloaded

plant, measurements shall be made on cable lengths that do not exceed 5,000 feet (ft) (1,524 meters (m)). All bonding wires shall be removed from the bonding lugs at the far end of the cable section to be measured. The step-by-step measurement procedure shall be as shown in Figure 2.
 (ii) Cable shield or shield/armor continuity within pedestals or splices shall be measured with a cable shield splice continuity test set. The step-by-step measurement procedure outlined in the manufacturer's operating instructions for the specific test equipment being used shall be followed.

(4) Test equipment. (i) The test equipment for measuring cable shield or shield/armor resistance between pedestals or splices is shown in Figure 2 as follows:
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FIGURE 2
 SHIELD OR SHIELD/ARMOR RESISTANCE MEASUREMENT



BILLING CODE 3410-15-P
 (ii) A cable shield splice continuity tester shall be used to measure shield or shield/armor continuity within pedestals or splices.

(5) Applicable results. (i) The shield or shield/armor resistance per 1000 ft and per kilometer (km) for cable diameters and types of shielding

materials are given in Table 1 (English Units) and Table 2 (Metric Units), respectively, as follows:

TABLE 1.—SHIELD RESISTANCE @ 68 °F (20 °C) CABLE DIAMETERS VERSUS SHIELD TYPES (ENGLISH UNITS)

Outside diameter inches (inch)	Nominal resistance ohm/1000 ft					
	A	B	C	D	E	F
0.40–0.49	0.77	1.54	1.65	1.96	2.30	5.51

TABLE 1.—SHIELD RESISTANCE @ 68 °F (20 °C) CABLE DIAMETERS VERSUS SHIELD TYPES (ENGLISH UNITS)—
Continued

Outside diameter inches (inch)	Nominal resistance ohm/1000 ft					
	A	B	C	D	E	F
0.50–0.59	0.64	1.28	1.37	1.63	1.91	4.58
0.60–0.69	0.51	1.03	1.10	1.31	1.53	3.67
0.70–0.79	0.44	0.88	0.94		1.31	3.14
0.80–0.89	0.38	0.77	0.82		1.14	2.74
0.90–0.99	0.35	0.69	0.74		1.03	2.47
1.00–1.09	0.31	0.62	0.66		0.92	2.20
1.10–1.19	0.28	0.56	0.60		0.84	2.00
1.20–1.29	0.26	0.51	0.55		0.77	1.84
1.30–1.39	0.24	0.48	0.51		0.71	1.70
1.40–1.49	0.22	0.44	0.47		0.65	1.57
1.50–1.59	0.21	0.41	0.44		0.61	1.47
1.60–1.69	0.19	0.38	0.41		0.57	1.37
1.70–1.79	0.18	0.37	0.39		0.54	1.30
1.80–1.89	0.17	0.35	0.37		0.51	1.24
1.90–1.99	0.16	0.33	0.35		0.49	1.17
2.00–2.09	0.15	0.31	0.33		0.46	1.10
2.10–2.19	0.15	0.29	0.31		0.43	1.03
2.20–2.29	0.14	0.28	0.30		0.42	1.00
2.30–2.39	0.14	0.27	0.29		0.40	0.97
2.40–2.49	0.13	0.25	0.27		0.38	0.90
2.50–2.59	0.12	0.24	0.26		0.36	0.87
2.60–2.69	0.12	0.23	0.25		0.35	0.83
2.70–2.79	0.11	0.22	0.24		0.33	0.80
2.80–2.89	0.11	0.22	0.24		0.33	0.80
2.90–2.99	0.11	0.22	0.23		0.32	0.77
3.00–3.09	0.10	0.21	0.22		0.31	0.73
3.10–3.19	0.10	0.20	0.21		0.29	0.70
3.20–3.29	0.10	0.20	0.21		0.29	0.70
3.30–3.39	0.09	0.19	0.20		0.28	0.67
3.40–3.49	0.09	0.18	0.19		0.26	0.63
3.50–3.59	0.09	0.18	0.19		0.26	0.63
3.60–3.69	0.08	0.17	0.18		0.25	0.60
3.70–3.79	0.08	0.17	0.18		0.25	0.60
3.80–3.89	0.08	0.16	0.17		0.24	0.57
3.90–3.99	0.08	0.16	0.17		0.24	0.57
4.00–4.99	0.07	0.15	0.16		0.22	0.53

Where:

Column A—10 mil Copper shield.

Column B—5 mil Copper shield.

Column C—8 mil Coated Aluminum and 8 mil Coated Aluminum/6 mil Coated Steel shields.

Column D—7 mil Alloy 194 shield.

Column E—6 mil Alloy 194 and 6 mil Copper Clad Stainless Steel shields.

Column F—5 mil Copper Clad Stainless Steel and 5 mil Copper Clad Alloy Steel shields.

TABLE 2.—SHIELD RESISTANCE @ 68°F (20°C) CABLE DIAMETERS VERSUS SHIELD TYPES (METRIC UNITS)

Outside diameter millimeters (mm)	Nominal resistance ohm/km					
	A	B	C	D	E	F
10.2–12.5	2.53	5.05	5.41	6.43	7.55	18.08
12.7–15.0	2.10	4.20	4.49	5.35	6.27	15.03
15.2–17.5	1.67	3.38	3.61	4.30	5.02	12.04
17.8–20.1	1.44	2.89	3.08		4.30	10.30
20.3–22.6	1.25	2.53	2.69		3.74	8.99
22.9–25.1	1.15	2.26	2.43		3.38	8.10
25.4–27.7	1.02	2.03	2.16		3.02	7.22
27.9–30.2	0.92	1.84	1.97		2.76	6.56
30.5–32.8	0.85	1.67	1.80		2.53	6.04
33.0–35.3	0.79	1.57	1.67		2.33	5.58
35.6–37.8	0.72	1.44	1.54		2.13	5.15
38.1–40.4	0.69	1.34	1.44		2.00	4.82
40.6–42.9	0.62	1.25	1.34		1.87	4.49
43.2–45.5	0.59	1.21	1.28		1.77	4.26
45.7–48.0	0.56	1.15	1.21		1.67	4.07
48.3–50.5	0.52	1.08	1.15		1.61	3.84
50.8–53.1	0.49	1.02	1.08		1.51	3.61
53.3–55.6	0.49	0.95	1.02		1.41	3.38
55.9–58.2	0.46	0.92	0.98		1.38	3.28
58.4–60.7	0.46	0.89	0.95		1.31	3.18

TABLE 2.—SHIELD RESISTANCE @ 68°F (20°C) CABLE DIAMETERS VERSUS SHIELD TYPES (METRIC UNITS)—Continued

Outside diameter millimeters (mm)	Nominal resistance ohm/km					
	A	B	C	D	E	F
61.0–63.2	0.43	0.82	0.89		1.25	2.95
63.5–65.8	0.39	0.79	0.85		1.18	2.85
66.0–68.3	0.39	0.75	0.82		1.15	2.72
68.6–70.9	0.36	0.72	0.79		1.08	2.62
71.1–73.4	0.36	0.72	0.79		1.08	2.62
73.7–75.9	0.36	0.72	0.75		1.05	2.53
76.2–78.5	0.33	0.69	0.72		1.02	2.39
78.7–81.0	0.33	0.66	0.69		0.95	2.30
81.3–83.6	0.33	0.66	0.69		0.95	2.30
83.6–86.1	0.29	0.62	0.66		0.92	2.20
86.4–88.6	0.29	0.59	0.62		0.85	2.07
88.9–91.2	0.29	0.59	0.62		0.85	2.07
91.4–93.7	0.26	0.56	0.59		0.82	1.97
94.0–96.3	0.26	0.56	0.59		0.82	1.97
96.5–98.8	0.26	0.52	0.56		0.79	1.87
99.1–101.3	0.26	0.52	0.56		0.79	1.87
101.6–103.9	0.23	0.49	0.52		0.72	1.74

Where:

Column A—10 mil Copper shield.

Column B—5 mil Copper shield.

Column C—8 mil Coated Aluminum and 8 mil Coated Aluminum/6 mil Coated Steel shields.

Column D—7 mil Alloy 194 shield.

Column E—6 mil Alloy 194 and 6 mil Copper Clad Stainless Steel shields.

Column F—5 mil Copper Clad Stainless Steel and 5 mil Copper Clad Alloy Steel shields.

(ii) All values of shield and shield/armor resistance provided in Tables 1 and 2 in paragraph (a)(5)(i) of this section are considered approximations. If the measured value corrected to 68°F (20°C) is within ± 30 percent (%) of the value shown in Table 1 or 2, the shield and shield/armor shall be assumed to be continuous.

(iii) To correct the measured shield resistance to the reference temperature of 68°F (20°C) use the following formulae:

$$R_{68} = R_t / [1 + A(t - 68)] \text{ for English Units}$$

$$R_{20} = R_t / [1 + A(t - 20)] \text{ for Metric Units}$$

Where:

R_{68} = Shield resistance corrected to 68°F in ohms.

R_{20} = Shield resistance corrected to 20°C in ohms.

R_t = Shield resistance at measurement temperature in ohms.

A = Temperature coefficient of the shield tape.

t = Measurement temperature in °F or (°C).

(iv) The temperature coefficient (A) for the shield tapes to be used in the formulae referenced in paragraph (a)(5)(iii) of this section is as follows:

(A) 5 and 10 mil copper = 0.0021 for English units and 0.0039 for Metric units;

(B) 8 mil coated aluminum and 8 mil coated aluminum/6 mil coated steel = 0.0022 for English units and 0.0040 for Metric units;

(C) 5 mil copper clad stainless steel and 5 mil copper clad alloy steel =

0.0024 for English units and 0.0044 for Metric units;

(D) 6 mil copper clad stainless steel = 0.0019 for English units and 0.0035 for Metric units; and

(E) 6 and 7 mil alloy 194 = 0.0013 for English units and 0.0024 for Metric units.

(v) When utilizing shield continuity testers to measure shield and shield/armor continuity within pedestals or splices, refer to the manufacturer's published information covering the specific test equipment to be used and for anticipated results.

(6) Data record. Measurement data from shield continuity tests shall be recorded together with anticipated Table 1 or 2 values (See paragraph (a)(5)(i) of this section.) in an appropriate format to permit comparison. The recorded data shall include specific location, cable size, cable type, type of shield or shield/armor, if known, etc.

(7) Probable causes for nonconformance. Among probable causes for nonconformance are broken or damaged shields or shield/armors, bad bonding harnesses, poorly connected bonding clamps, loose bonding lugs, etc.

(b) *Conductor continuity.* After placement of all cable and wire plant has been completed and joined together in continuous lengths, tests shall be made to ascertain that all pairs are free from grounds, shorts, crosses, and opens, except for those pairs indicated as being defective by the cable manufacturer. The tests for grounds,

shorts, crosses, and opens are not separate tests, but are inherent in other acceptance tests discussed in this section. The test for grounds, shorts, and crosses is inherent when conductor insulation resistance measurements are conducted per paragraph (c) of this section, while tests for opens are inherent when tests are conducted for loop resistance, insertion loss, noise, or return loss measurements, per paragraph (d), (e), or (f) of this section. The borrower shall make certain that all defective pairs are corrected, except those noted as defective by the cable manufacturer in accordance with the marking provisions of the applicable cable and wire specifications. All defective pairs that are not corrected shall be reported in writing with details of the corrective measures attempted.

(c) *Dc insulation resistance (IR) measurement.* (1) IR measurements shall be made on completed lengths of insulated cable and wire plant.

(2) *Method of measurement.* (i) The IR measurement shall be made between each conductor and all other conductors, sheath, shield and/or shield/armor, and/or support wire electrically connected together and to the main distributing frame (MDF) ground. The measurement shall be made from the central office with the entire length of the cable under test and, where used with all protectors and load coils connected. For COs containing solid state arresters, the solid state arresters shall be removed before making the IR measurements. Field

mounted voice frequency repeaters, where used, may be left connected for the IR test but all carrier frequency equipment, including carrier repeaters and terminals, shall be disconnected. Pairs used to feed power remote from the CO shall have the power

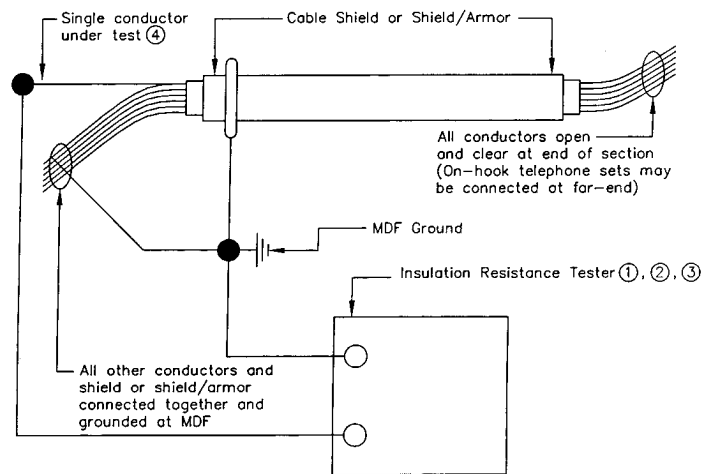
disconnected and the tip and ring conductors shall be opened before making IR tests. All conductors shall be opened at the far end of the cable being measured.

(ii) IR tests are normally made from the MDF with all CO equipment

disconnected at the MDF, but this test may be made on new cables at field locations before they are spliced to existing cables. The method of measurement shall be as shown in Figure 3 as follows:

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FIGURE 3
DC INSULATION RESISTANCE MEASUREMENT



Notes:

- ① For hand cranked or battery operated Insulation Resistance Testers, the output voltage should not exceed 500 volts dc.
- ② For dc bridge type Megohmmeters, the voltage applied to the conductors under test should not exceed 250 volts dc when using instruments having adjustable test voltage levels.
- ③ Biddle CO.—Model BM 200, Associate Research—Model 263, General Radio—1864 Megohm Meter, or equivalent.
- ④ Repeat test for each conductor in cable.

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(iii) If the IR of the conductor cannot be measured because of breakdown of lightning arresters by the test voltage, the arrester units shall be removed and the conductor IR retested. If the IR then meets the minimum requirements, the conductor will be considered satisfactory. Immediately following the IR tests, all arrester units which have been removed shall be reinstalled.

(3) Test equipment. (i) IR measurements shall be made with either an insulation resistance test set or a direct current (dc) bridge type megohmmeter.

(ii) The IR test set shall have an output voltage not to exceed 500 volts dc and shall be of the hand cranked or battery operated type.

(iii) The dc bridge type megohmmeter, which may be alternating current (ac) powered, shall have scales and multiplier which make it possible to accurately read IR from 1 megohm to 1

gigohm. The voltage applied to the conductors under test shall not exceed "250 volts dc" when using an instrument having adjustable test voltage levels. This will help to prevent breakdown of lightning arresters.

(4) Applicable results. (i) For all new insulated cable or wire facilities, the expected IR levels are normally greater than 1,000 to 2,000 megohm-mile (1,609 to 3,218 megohm-km). A value of 500 megohm-mile (805 megohm-km) at 68°F (20°C) shall be the minimum acceptable value of IR. IR varies inversely with the length and the temperature.

(ii) The megohm-mile (megohm-km) value for a conductor may be computed by multiplying the actual scale reading in megohms on the test set by the length in miles (km) of the conductor under test.

(iii) The objective insulation resistance may be determined by dividing 500 by the length in miles (805 by the length in km) of the cable or wire

conductor being tested. The resulting value shall be the minimum acceptable meter scale reading in megohms.

(iv) Due to the differences between various insulating materials and filling compounds used in manufacturing cable or wire, it is impractical to provide simple factors to predict the magnitude of variation in insulation resistance due to temperature. The variation can, however, be substantial for wide excursions in temperature from the ambient temperature of 68°F (20°C).

(v) Borrowers should be certain that tip and ring IR measurements of each pair are approximately the same. Borrowers should also be certain that IR measurements are similar for cable or wire sections of similar length and cable or wire type. If some pairs measure significantly lower, borrowers should attempt to improve these pairs in accordance with cable manufacturer's recommendations.

Note: Only the megohm-mile (megohm-km) requirement shall be cause for rejection, not individual measurement differences.

(5) Data record. The measurement data shall be recorded. Suggested formats similar to Format I, Outside Plant Acceptance Tests—Subscriber Loops, or Format II, Outside Plant Acceptance Tests—Trunk Circuits, in § 1755.407 or formats specified in the applicable construction contract may be used.

(6) Probable causes for nonconformance. (i) When an IR measurement is below 500 megohm-mile (805 megohm-km), the cable or wire temperature at the time of testing must then be taken into consideration. If this temperature is well above 68°F (20°C), the measurement shall be disregarded and the cable or wire shall be remeasured at a time when the temperature is approximately 68°F (20°C). If the result is then 500 megohm-mile (805 megohm-km) or greater, the cable or wire shall be considered satisfactory.

(ii) Should the cable or wire fail to meet the 500 megohm-mile (805 megohm-km) requirement when the temperature is known to be approximately 68°F (20°C) there is not yet justification for rejection of the cable or wire. Protectors, lightning arresters, etc., may be a source of low insulation

resistance. These devices shall be removed from the cable or wire and the cable or wire IR measurement shall be repeated. If the result is acceptable, the cable or wire shall be considered acceptable. The removed devices which caused the low insulation resistance value shall be identified and replaced, if found defective.

(iii) When the cable or wire alone is still found to be below the 500 megohm-mile (805 megohm-km) requirement after completing the steps in paragraph (c)(6)(i) and/or paragraph (c)(6)(ii) of this section, the test shall be repeated to measure the cable or wire in sections to isolate the piece(s) of cable or wire responsible. The cable or wire section(s) that is found to be below the 500 megohm-mile (805 megohm-km) requirement shall be either repaired in accordance with the cable or wire manufacturer's recommended procedure or shall be replaced as directed by the borrower.

(d) *Dc loop resistance and dc resistance unbalance measurement.* (1) When specified by the borrower, dc loop resistance and dc resistance unbalance measurements shall be made on all cable pairs used as trunk circuits. The dc loop resistance and dc resistance unbalance measurements shall be made between CO locations. Measurements

shall include all components of the cable path.

(2) Dc loop resistance and dc resistance unbalance measurements shall be made on all cable pairs used as subscriber loop circuits when:

- (i) Specified by the borrower;
- (ii) A large number of long loops terminate at one location (similar to trunk circuits); or
- (iii) Circuit balance is less than 60 dB when computed from noise measurements as described in paragraph (e) of this section.

(3) Dc resistance unbalance is controlled to the maximum possible degree by the cable specification. Allowable random unbalance is specified between tip and ring conductors within each reel. Further random patterns should occur when the cable conductor size changes. Cable meeting the unbalance requirements of the cable specification may under some conditions result in unacceptable noise levels as discussed in paragraph (d)(6)(iii) of this section.

(4) Method of measurement. The method of measurement shall be as detailed in Figures 4 and 5.

(5) Test equipment. The test equipment is shown in Figures 4 and 5 as follows:

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FIGURE 4
DC LOOP RESISTANCE MEASUREMENT

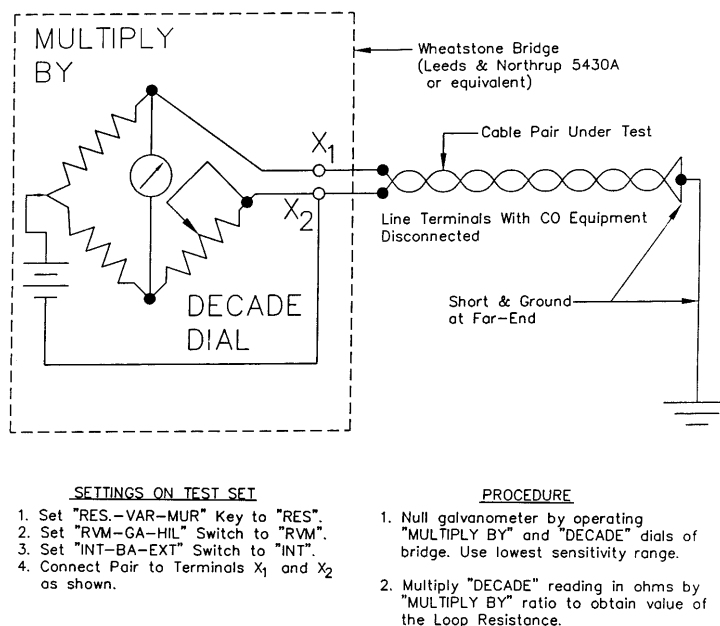
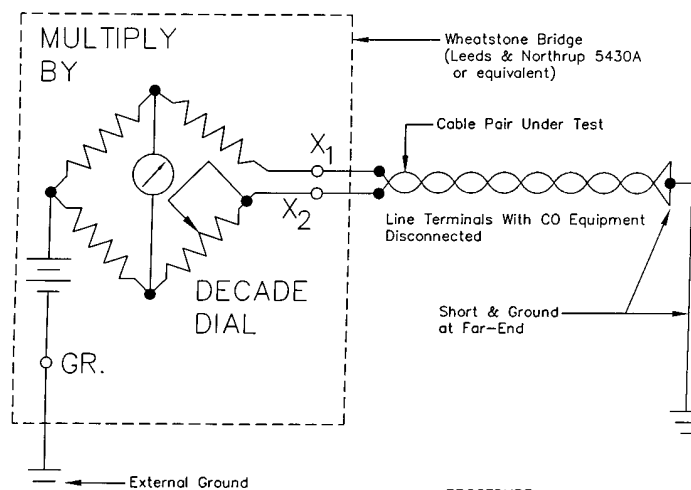


FIGURE 5
DC LOOP RESISTANCE UNBALANCE MEASUREMENT



SETTINGS ON TEST SET

1. Connect Terminals X_1 & X_2 as shown.
2. Set "RES.-VAR-MUR" Key to "VAR".
3. "MULTIPLY BY" Switch to 1/1.
4. Set "RVM-GA-HIL" Switch to "RVM".
5. Set "INT-BA-EXT" Switch to "INT".

PROCEDURE

1. Null galvanometer by operating "MULTIPLY BY" and "DECADE" dials of bridge. Use lowest sensitivity range.
2. If continuously varying 1, 10, or 100 ohm switches from 1 to 999 ohms produces a deflection consistently to the left on the galvanometer, reverse the conductors of the cable pair under test to the X_1 & X_2 terminals of the bridge.
3. Vary 1, 10, or 100 ohm switches again until deflection approaches zero. Read "DECADE" dial for Resistance Unbalance in ohms.

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(6) Applicable results. (i) The measured dc loop resistance shall be within $\pm 5\%$ of the calculated dc loop resistance when corrected for temperature.

(ii) The calculated dc loop resistance is computed as follows:

(A) Multiply the length of each different gauge by the applicable resistance per unit length as shown in Table 3 as follows:

TABLE 3.—DC LOOP RESISTANCE @ 68°F (20°C)

American wire gauge (AWG)	Loop resistance	
	Ohms/1000 ft	Ohms/km
19	16.1	52.8
22	32.4	106.3
24	51.9	170.3
26	83.3	273.3

(B) Add the individual resistances for each gauge to give the total calculated dc loop resistance at a temperature of 68°F (20°C).

(C) Correct the total calculated dc loop resistance at the temperature of 68°F (20°C) to the measurement temperature by the following formulae:

$$R_t = R_{68} \times [1 + 0.0022 \times (t - 68)] \text{ for English Units}$$

$$R_t = R_{20} \times [1 + 0.0040 \times (t - 20)] \text{ for Metric Units}$$

Where:

R_t = Loop resistance at the measurement temperature in ohms.

R_{68} = Loop resistance at a temperature of 68°F in ohms.

R_{20} = Loop resistance at a temperature of 20°C in ohms.

t = Measurement temperature in °F or (°C).

(D) Compare the calculated dc loop resistance at the measurement temperature to the measured dc loop resistance to determine compliance with the requirement specified in paragraph (d)(6)(i) of this section.

(iii) Resistance varies directly with temperature change. For copper conductor cables, the dc resistance changes by $\pm 1\%$ for every $\pm 5^\circ\text{F}$ (2.8°C) change in temperature from 68°F (20°C).

(iv) The dc resistance unbalance between the individual conductors of a pair shall not exceed that value which will result in a circuit balance of less than 60 dB when computed from noise measurements as described in paragraph (e) of this section. It is impractical to establish a precise limit for overall circuit dc resistance unbalance due to the factors controlling its contribution to

circuit noise. These factors include location of the resistance unbalance in relation to a low impedance path to ground (close to the central office) and the magnitude of unbalance in short lengths of cable making up the total circuit length. The objective is to obtain the minimum unbalance throughout the entire circuit when it is ascertained through noise measurements that dc resistance unbalance may be contributing to poor cable balance.

(v) Pairs with poor noise balance may be improved by reversing tip and ring conductors of pairs at cable splices. Where dc resistance unbalances are systematic over the total trunk circuit or loop circuit length, tip and ring reversals may be made at frequent intervals. Where the unbalances are concentrated in a shorter section of cable, only one tip and ring reversal should be required. Concentrated dc resistance unbalance produces maximum circuit noise when located adjacent to the central office. Concentrated dc resistance unbalance will contribute to overall circuit noise at a point approximately two-thirds ($\frac{2}{3}$) of the distance to the subscriber. All deliberate tip and ring reversals shall be tagged and identified to prevent plant personnel from removing the reversals when resplicing these connections in

the future. The number of tip and ring reversals shall be held to a minimum.

(vi) A systematic dc resistance unbalance can sometimes be accompanied by other cable parameters that are marginal. Among these are pair-to-pair capacitance unbalance, capacitance unbalance-to-ground, and 150 kilohertz (kHz) crosstalk loss. Engineering judgment has to be applied in each case. Rejection of cable for excessive dc resistance unbalance shall only apply to a single reel length, or shorter.

(7) Data record. The measurement data for dc loop resistance and dc resistance unbalance shall be recorded. Suggested formats similar to Format I for subscriber loops and Format II for trunk circuits in § 1755.407 or formats specified in the applicable construction contract may be used.

(8) Probable causes for nonconformance. Dc loop resistance and dc resistance unbalance are usually the result of the resistance of individual conductors used in the manufacture of the cable. Resistance unbalance can be

worsened by defective splicing of the conductors (splicing connectors, improper crimping tool, etc.).

(e) *Subscriber loop measurement (loop checking)*. (1) When specified by the borrower, insertion loss and noise measurements shall be performed on subscriber loops after connection of a line circuit to the loop by the one person method using loop checking equipment from the customer access location. For this method, the central office should be equipped with a 900 ohm plus two microfarad quiet termination and a milli watt generator having the required test frequencies; or a portable milli watt generator having the desired frequencies may be used, especially, where several small offices are involved.

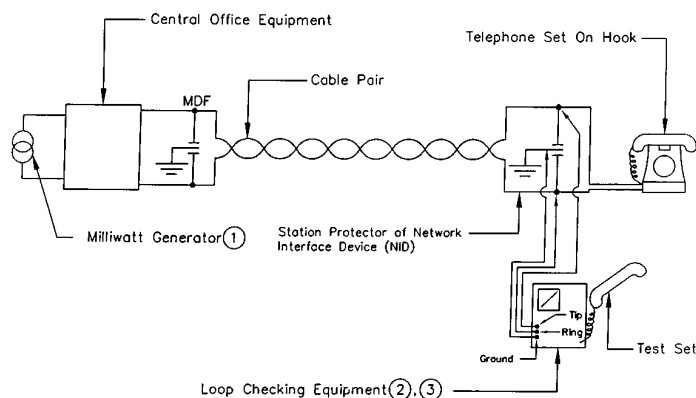
(2) At a minimum, insertion loss and frequency response of subscriber loop plant shall be measured at 1,000, 1,700, 2,300, and 2,800 Hertz (Hz). When additional testing frequencies are desired, the additional frequencies shall be specified in the applicable construction contract.

(3) Measurements of insertion loss and noise shall be made on five percent or more of the pairs. A minimum of five pairs shall be tested on each route. Pairs shall be selected on a random basis with greater consideration in the selection given to the longer loops. Consideration shall be given to measuring a large percentage, up to 100 percent, of all loops.

(4) Method of measurement—(i) *Insertion loss*. The step-by-step measurement procedure shall be as shown in Figure 6. The output level of the milli watt generator tones shall be determined prior to leaving the CO. This shall be accomplished by dialing the milli watt generator number from a spare line at the MDF and measuring with the same equipment to be used in the tests at customer access locations. The output levels shall be recorded for reference later. Insertion loss measurements shall be made across the tip and ring terminals of the pair under test. Figure 6 is as follows:

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FIGURE 6
INSERTION LOSS AND FREQUENCY RESPONSE MEASUREMENT
AT SUBSCRIBER LOCATION USING LOOP CHECKING EQUIPMENT



Calibration

1. Before leaving CO connect Loop Checking equipment to idle line at MDF.
 - A. Dial number of Milli watt Generator.
 - B. Read and record output level of all tones in dBm for reference.

Notes:

- ① H.P.-204B, H.P.-204C, General Radio-1335, or equivalent.
- ② N.E.C.-125, N.E.C.-37B, Wilcom-136, Wilcom-336, Wilcom-337, or equivalent.
- ③ Do not leave test equipment connected and exposed to ringing voltage of incoming call. Ringing voltage could damage test equipment.

Measurement Procedure

1. Connect Loop Checking equipment at subscriber's NID as shown.
2. Dial number of Milli watt Generator at central office.
3. Verify by listening on the test set that the tones are being received.
4. Switch test set to Circuit Loss mode.
5. Read loss in dBm at each frequency.
6. Record results of loss at each frequency.
7. Subtract the output levels observed at the CO for each tone by the values observed at the subscriber location. The resultant values are the Insertion Loss.
8. Disconnect leads of test equipment from NID when tests are completed.

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(ii) *Noise*. The step-by-step measurement procedure shall be as shown in Figure 7. Prior to leaving the

CO for testing, dial the 900 ohm plus two microfarad quiet termination from a spare pair and measure the termination to determine that it actually is quiet.

Circuit noise (noise-metallic) shall be measured at the customer access location across the tip and ring terminals of the pair under test. Power

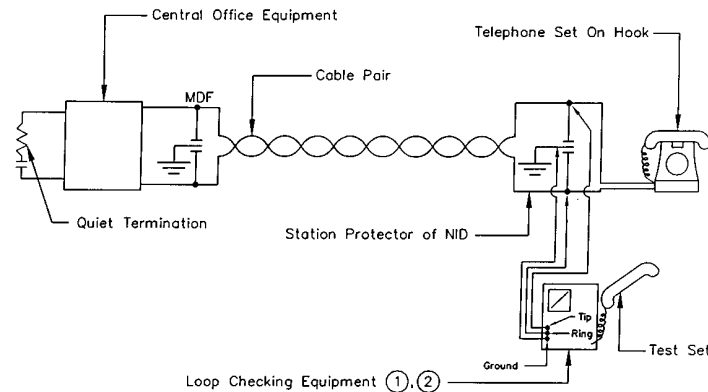
influence (direct reading with loop checking equipment) shall be measured at the customer access location from tip and ring conductors-to-ground (this connection is completed via the test

unit). The power influence measurement includes the entire talking connection from the quiet termination to the customer. (That is, the power influence measurement includes all the

CO equipment which normally makes up the connection.) Figure 7 is as follows:

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FIGURE 7
NOISE MEASUREMENT AT SUBSCRIBER LOCATION
USING LOOP CHECKING EQUIPMENT



Calibration

1. Before leaving CO connect Loop Checking equipment to idle line at MDF (no outside plant attached).
- A. Dial number of Quiet Termination.
- B. Read and record Circuit Noise in dBnc.

Note:

- ① N.E.C.-125, N.E.C.-37B, Wilcom-136, Wilcom-336, Wilcom-337, or equivalent.
- ② Do not leave test equipment connected and exposed to ringing voltage of incoming call. Ringing voltage could damage test equipment.

Measurement Procedure

1. Connect Loop Checking equipment at subscriber's NID as shown.
2. Dial number of Quiet Termination in central office.
3. Switch test set to Circuit Noise (NM) mode.
4. Read and record Circuit Noise value in dBnc.
5. Switch test set to Power Influence (PI) mode.
6. Read and record Power Influence value in dBnc.
7. Compute and record apparent Balance (Balance = PI - NM).
8. Disconnect leads of test equipment from NID when tests are completed.

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(5) Test equipment. (i) Loop checking equipment which is available from several manufacturers may be used for these measurements. The equipment should have the capability of measuring loop current, insertion loss, circuit noise (NM) and power influence (PI). The test equipment manufacturer's operating instructions shall be followed.

(ii) There should be no measurable transmission loss when testing through loop extenders.

(6) Applicable results—(i) *Insertion loss*. (A) For D66 loaded cables (a specific loading scheme using a 66 millihenry inductor spaced nominally at 4,500 ft [1,371 m] intervals) measured at a point one-half section length beyond the last load point, the measured nonrepeated insertion loss shall be within $\pm 10\%$ at 1000, 1700, 2300, and 2800 Hz, $\pm 15\%$ at 3400 Hz and $\pm 20\%$ at 4000 Hz of the calculated insertion loss at the same frequencies and temperature.

(B) For H88 loaded cables (a specific loading scheme using an 88 millihenry inductor spaced nominally at 6,000 ft [1,829 m] intervals) measured at a point one-half section length beyond the last load point, the measured nonrepeated insertion loss shall be within $\pm 10\%$ at 1000, 1700, and 2300 Hz, $\pm 15\%$ at 2800 Hz, and $\pm 20\%$ at 3400 Hz of the calculated insertion loss at the same frequencies and temperature.

(C) For nonloaded cables, the measured insertion loss shall be within $\pm 10\%$ at 1000, 1700, 2300, and 2800 Hz, $\pm 15\%$ at 3400 Hz and $\pm 20\%$ at 4000 Hz of the calculated insertion loss at the same frequencies and temperature.

(D) For loaded cables, the calculated loss at each desired frequency shall be computed as follows:

(1) Multiply the length in miles (km) of each different gauge in the loaded portion of the loop (between the office and a point one-half load section beyond the furthest load point) by the applicable decibel (dB)/mile (dB/km) value shown in Table 4 or 5. This loss

represents the total loss for each gauge in the loaded portion of the loop;

(2) Multiply the length in miles (km) of each different gauge in the end section or nonloaded portion of the cable (beyond a point one-half load section beyond the furthest load point) by the applicable dB/mile (dB/km) value shown in Table 6. This loss represents the total loss for each gauge in the nonloaded portion of the loop; and

(3) The total calculated insertion loss is computed by adding the individual losses determined in paragraphs (e)(6)(i)(D)(1) and (e)(6)(i)(D)(2) of this section.

(E) For nonloaded cables, the calculated loss at each desired frequency shall be computed by multiplying the length in miles (km) of each different gauge by the applicable dB/mile (dB/km) value shown in Table 6 and then adding the individual losses for each gauge to determine the total calculated insertion loss for the nonloaded loop.

(F) The attenuation information in Tables 4, 5, and 6 are based on a cable temperature of 68°F (20°C). Insertion loss varies directly with temperature. To convert measured losses for loaded cables to a different temperature, use the

following value for copper conductors: For each $\pm 5^\circ\text{F}$ ($\pm 2.8^\circ\text{C}$) change in the temperature from 68°F (20°C), change the insertion loss at any frequency by $\pm 1\%$. To convert measured losses for nonloaded cables to a different

temperature, use the following value for copper conductors: For each $\pm 10^\circ\text{F}$ ($\pm 5.6^\circ\text{C}$) change in the temperature from 68°F (20°C), change the insertion loss at any frequency by $\pm 1\%$. Tables 4, 5, and 6 are as follows:

TABLE 4.—FREQUENCY ATTENUATION @ 68°F (20°C) D66 LOADED EXCHANGE CABLES 83 NANOFARAD (NF)/ MILE (52 NF/KM) (SEE NOTE)

Frequency (Hz)	Attenuation dB/mile (dB/km) AWG			
	19	22	24	26
200	0.41 (0.26)	0.67 (0.42)	0.90 (0.56)	1.21 (0.75)
400	0.43 (0.26)	0.77 (0.48)	1.09 (0.68)	1.53 (0.95)
600	0.44 (0.27)	0.80 (0.49)	1.17 (0.73)	1.70 (1.06)
800	0.44 (0.27)	0.81 (0.50)	1.21 (0.75)	1.80 (1.12)
1000	0.44 (0.27)	0.82 (0.51)	1.23 (0.76)	1.86 (1.15)
1200	0.45 (0.28)	0.83 (0.52)	1.24 (0.77)	1.91 (1.19)
1400	0.45 (0.28)	0.83 (0.52)	1.26 (0.78)	1.94 (1.20)
1600	0.45 (0.28)	0.84 (0.52)	1.26 (0.78)	1.96 (1.22)
1800	0.45 (0.28)	0.84 (0.52)	1.27 (0.78)	1.98 (1.23)
2000	0.46 (0.29)	0.85 (0.53)	1.28 (0.79)	1.99 (1.24)
2200	0.46 (0.29)	0.85 (0.53)	1.29 (0.80)	2.01 (1.25)
2400	0.47 (0.29)	0.86 (0.53)	1.30 (0.81)	2.02 (1.26)
2600	0.47 (0.29)	0.87 (0.54)	1.31 (0.81)	2.04 (1.27)
2800	0.48 (0.30)	0.88 (0.55)	1.32 (0.82)	2.07 (1.29)
3000	0.49 (0.30)	0.89 (0.55)	1.34 (0.83)	2.10 (1.30)
3200	0.50 (0.31)	0.91 (0.57)	1.36 (0.84)	2.13 (1.32)
3400	0.52 (0.32)	0.93 (0.58)	1.40 (0.87)	2.19 (1.36)
3600	0.54 (0.34)	0.97 (0.60)	1.45 (0.90)	2.26 (1.40)
3800	0.57 (0.35)	1.02 (0.63)	1.52 (0.94)	2.36 (1.47)
4000	0.62 (0.38)	1.10 (0.68)	1.63 (1.01)	2.53 (1.57)

NOTE: Between end-section lengths of 2,250 ft (686 m) for D66 loading.

TABLE 5.—FREQUENCY ATTENUATION @ 68°F (20°C) H88 LOADED EXCHANGE CABLES 83 NF/ MILE (52 NF/KM) (SEE NOTE)

Frequency (Hz)	Attenuation dB/mile (dB/km) AWG			
	19	22	24	26
200	0.40 (0.25)	0.66 (0.41)	0.90 (0.56)	1.20 (0.75)
400	0.42 (0.26)	0.76 (0.47)	1.08 (0.67)	1.53 (0.95)
600	0.43 (0.27)	0.79 (0.49)	1.16 (0.72)	1.70 (1.06)
800	0.43 (0.27)	0.80 (0.50)	1.20 (0.75)	1.80 (1.12)
1000	0.43 (0.27)	0.81 (0.50)	1.23 (0.76)	1.86 (1.15)
1200	0.44 (0.27)	0.82 (0.51)	1.24 (0.77)	1.91 (1.19)
1400	0.44 (0.28)	0.82 (0.51)	1.25 (0.78)	1.94 (1.20)
1600	0.44 (0.27)	0.83 (0.52)	1.26 (0.78)	1.97 (1.22)
1800	0.45 (0.28)	0.84 (0.52)	1.28 (0.79)	1.99 (1.24)
2000	0.46 (0.29)	0.85 (0.53)	1.29 (0.80)	2.02 (1.26)
2200	0.47 (0.29)	0.86 (0.53)	1.31 (0.81)	2.06 (1.28)
2400	0.48 (0.30)	0.89 (0.55)	1.34 (0.83)	2.10 (1.30)
2600	0.50 (0.31)	0.92 (0.57)	1.39 (0.86)	2.18 (1.35)
2800	0.53 (0.33)	0.97 (0.60)	1.47 (0.91)	2.29 (1.42)
3000	0.59 (0.37)	1.07 (0.66)	1.60 (0.99)	2.48 (1.54)
3200	0.71 (0.44)	1.26 (0.78)	1.87 (1.16)	2.86 (1.78)
3400	1.14 (0.71)	1.91 (1.19)	2.64 (1.64)	3.71 (2.30)
3600	4.07 (2.53)	4.31 (2.68)	4.65 (2.90)	5.30 (3.29)
3800	6.49 (4.03)	6.57 (4.08)	6.72 (4.18)	7.06 (4.39)
4000	8.22 (5.11)	8.27 (5.14)	8.36 (5.19)	8.58 (5.33)

NOTE: Between end-section lengths of 3,000 ft (914 m) for H88 loading.

TABLE 6.—FREQUENCY ATTENUATION @ 68°F (20°C) NONLOADED EXCHANGE CABLES 83 nF/ MILE (52 nF/km)

Frequency (Hz)	Attenuation dB/mile (dB/km) AWG			
	19	22	24	26
200	0.58 (0.36)	0.82 (0.51)	1.03 (0.64)	1.30 (0.81)
400	0.81 (0.51)	1.15 (0.71)	1.45 (0.90)	1.84 (1.14)
600	0.98 (0.61)	1.41 (0.87)	1.77 (1.10)	2.26 (1.40)
800	1.13 (0.70)	1.62 (1.01)	2.04 (1.27)	2.60 (1.61)

TABLE 6.—FREQUENCY ATTENUATION @ 68°F (20°C) NONLOADED EXCHANGE CABLES 83 nF/ MILE (52 nF/km)—Continued

Frequency (Hz)	Attenuation dB/mile (dB/km) AWG			
	19	22	24	26
1000	1.25 (0.78)	1.80 (1.12)	2.28 (1.42)	2.90 (1.80)
1200	1.36 (0.84)	1.97 (1.22)	2.50 (1.55)	3.17 (1.97)
1400	1.46 (0.91)	2.12 (1.32)	2.69 (1.67)	3.42 (2.12)
1600	1.55 (0.96)	2.26 (1.40)	2.87 (1.78)	3.65 (2.27)
1800	1.63 (1.01)	2.39 (1.48)	3.04 (1.89)	3.87 (2.40)
2000	1.71 (1.06)	2.51 (1.56)	3.20 (1.99)	4.08 (2.53)
2200	1.78 (1.11)	2.62 (1.63)	3.35 (2.08)	4.27 (2.65)
2400	1.85 (1.15)	2.73 (1.70)	3.49 (2.17)	4.45 (2.76)
2600	1.91 (1.19)	2.83 (1.76)	3.62 (2.25)	4.63 (2.88)
2800	1.97 (1.22)	2.93 (1.82)	3.75 (2.33)	4.80 (2.98)
3000	2.03 (1.26)	3.02 (1.88)	3.88 (2.41)	4.96 (3.08)
3200	2.08 (1.29)	3.11 (1.93)	4.00 (2.48)	5.12 (3.18)
3400	2.13 (1.32)	3.19 (1.98)	4.11 (2.55)	5.27 (3.27)
3600	2.18 (1.35)	3.28 (2.04)	4.22 (2.62)	5.41 (3.36)
3800	2.22 (1.38)	3.36 (2.09)	4.33 (2.69)	5.55 (3.45)
4000	2.27 (1.41)	3.43 (2.13)	4.43 (2.75)	5.69 (3.53)

(G) For loaded subscriber loops, the 1 kHz loss shall be approximately 0.45 dB per 100 ohms of measured dc loop resistance. This loss shall be the measured loss less the net gain of any voice frequency repeaters in the circuit. Testing shall also be conducted to verify that the loss increases gradually as the frequency increases. The loss on H88 loaded loops should be down only slightly at 2.8 kHz but drop rapidly above 2.8 kHz. The loss on D66 loaded loops shall be fairly constant to about 3.4 kHz and there shall be good response at 4.0 kHz. When voice frequency repeaters are in the circuit there will be some frequency weighting in the build-out network and the loss at the higher frequencies will be greater than for nonrepeated loops.

(H) For nonloaded subscriber loops, the 1 kHz loss shall be approximately 0.9 dB per 100 ohms of measured dc loop resistance. Testing shall also be conducted to verify that the loss is approximately a straight line function with no abrupt changes. The 3 kHz loss should be approximately 70% higher than the 1 kHz loss.

(ii) *Noise*. The principal objective related to circuit noise (noise-metallic) and the acceptance of new plant is that circuit noise levels be 20 dBnc or less [decibels above reference noise, C-message weighted (a weighting derived from listening tests, to indicate the relative annoyance or speech impairment by an interfering signal of frequency (f) as heard through a "500-type" telephone set)]. For most new, properly installed, plant construction, circuit noise will usually be considerably less than 20 dBnc unless there are unusually long sections of telephone plant in parallel with electric power facilities and/or power influence

of paralleling electric facilities is abnormally high. When circuit noise is 20 dBnc or less, the loop plant shall be considered acceptable. When measured circuit noise is greater than 20 dBnc, loop plant shall still be considered acceptable providing circuit balance (power influence reading minus circuit noise readings) is 60 dB or greater and power influence readings are 85 dBnc or greater. When circuit noise is greater than 20 dBnc and circuit balance is less than 60 dB and/or power influence is less than 85 dBnc, loop plant shall not be considered acceptable and the loop plant shall be remedied to make circuit balance equal to or greater than 60 dB.

(7) Data record. Measurement data shall be recorded. A suggested format similar to Format I for subscriber loops in § 1755.407 or a format specified in the applicable construction contract may be used.

(8) Probable causes for nonconformance. (i) *Insertion loss*. Some of the more common causes for failing to obtain the desired results may be due to reversed load coil windings, missing load coils, bridge taps between load coils, load coil spacing irregularities, excessive end sections, cables having high or low mutual capacitance, load coils having the wrong inductance, load coils inadvertently installed in nonloaded loops, moisture or water in cable, split pairs, and improperly spliced connections. The above factors can occur singularly or in combination. Experience to date indicates that the most common problems are missing load coils, reversed load coil windings or bridge taps.

(ii) *Noise*. Some of the common causes for failing to obtain the desired results may be due to high power

influence from paralleling electrical power systems, poor telephone circuit balance, discontinuous cable shields, inadequate bonding and grounding of cable shields, high capacitance unbalance-to-ground of the cable pairs, high dc loop resistance unbalance, dc loop current less than 20 milliamperes, etc. The above factors can occur singularly or in combination. See TE&CM Section 451, Telephone Noise Measurement and Mitigation, for steps to be taken in reducing telecommunications line noise.

(f) *One-person open circuit measurement (subscriber loops)*. (1) When specified by the borrower, open circuit measurements shall be made on all loaded and nonloaded subscriber loops upon completion of the cable work to verify that the plant is free from major impedance irregularities.

(2) For loaded loops, open circuit measurements shall be made using one of the following methods:

(i) Impedance or pulse return pattern, with cable pair trace compared to that of an artificial line of the same length and gauge. For best results, a level tracer or fault locator with dual trace capability is required;

(ii) Return loss using a level tracer, with cable pair compared to an artificial line of the same length and gauge connected in lieu of a Precision Balance Network (PBN). This method can be made with level tracers having only single trace capability; or

(iii) Open circuit structural return loss using a level tracer. This method can be made with level tracer having only single trace capability.

(3) Of the three methods suggested for loaded loops, the method specified in paragraph (f)(2)(ii) of this section is the preferred method because it can yield

both qualitative and quantitative results. The methods specified in paragraphs (f)(2)(i) and (f)(2)(iii) of this section can be used as trouble shooting tools should irregularities be found during testing.

(4) For nonloaded loops, open circuit measurements shall be made using the method specified in (f)(2)(i) of this section.

(5) Method of measurement. Open circuit measurements shall be made at the CO on each loaded and nonloaded pair across the tip and ring terminals of the pair under test. All CO equipment shall be disconnected at the MDF for this test. For loaded loops containing voice frequency repeaters installed in the CO or field mounted, the open circuit measurement shall be made after the repeaters have been disconnected. Where field mounted repeaters are used, the open circuit measurement shall be made at the repeater location in both directions.

(i) *Impedance or pulse return pattern.* The step-by-step measurement procedure using the impedance or pulse return pattern for loaded and nonloaded

loops shall be as shown in Figure 8. An artificial line of the same makeup as the cable to be tested shall be set up. The traces of the impedance or pulse return pattern from the cable pair and the artificial line shall be compared and should be essentially identical. If the impedance or pulse return traces from the cable pair are different than the artificial line trace, cable faults are possible. When the cable pair trace indicates possible defects, the defects should be identified and located. One method of identifying and locating defects involves introducing faults into the artificial line until its trace is identical with the cable trace.

(ii) *Return loss balanced to artificial line.* The step-by-step measurement procedure using the return loss balanced to artificial line for loaded loops shall be as shown in Figure 9. An artificial line of the same makeup as the cable to be tested shall be set up. The artificial line is connected to the external network terminals of the test set. The cable pair under test is compared to this standard. When

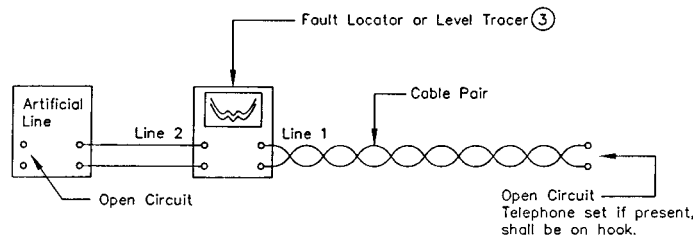
defects are found, they should be identified and located by introducing faults into the artificial line. This is more difficult than with the method referenced in paragraph (f)(5)(i) of this section since this measurement is more sensitive to minor faults and only a single trace is used.

(iii) *Open circuit structural return loss using level tracer.* The step-by-step measurement procedure using the level tracer for loaded loops shall be as shown in Figure 10. The cable pair is compared to a PBN.

(6) Test equipment. Equipment for performing these tests is shown in Figures 8 through 10. For loaded loops, artificial loaded lines must be of the same gauge and loading scheme as the line under test. For nonloaded loops, artificial nonloaded lines must be of the same gauge as the line under test. Artificial lines should be arranged using switches or other quick connect arrangements to speed testing and troubleshooting. Figures 8 through 10 are as follows:

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FIGURE 8
ONE-PERSON OPEN CIRCUIT MEASUREMENT
IMPEDANCE OR PULSE RETURN PATTERN



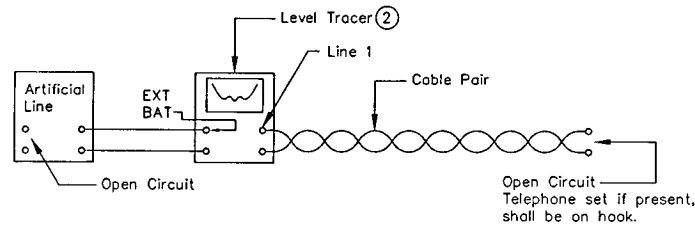
Measurement Procedure

1. Set up Artificial Line to same make-up [Length & Gauge(s)] as the cable pair.
2. Connect to test set (See Note ①).
3. Connect cable pair to test set (See Note ①).
4. Compare traces of Artificial Line and cable pair ②. They should be essentially identical. Differences indicate cable faults.
5. Location and type of fault may be determined by introducing faults in the Artificial Line until its trace is identical to that of the cable pair.

Notes:

- ①. Terminals to which cable pair and artificial line are attached shall be determined from the manufacturer's operating instructions. Proper settings for various switches and adjustments on the test set shall also be determined from the same source.
- ②. With test sets having trace storage capability only one set of terminals need be used. Connect Artificial Line to test set, store trace and disconnect line. Connect cable pair and compare trace to stored trace. To identify fault, store cable pair trace and connect Artificial Line. Introduce faults in the Artificial Line until traces are identical.
- ③. N.E.C.-17A, Biddle-CME110A-1, Dolcom-490, Tektronix-1503, Wilcom-T195, Wilcom-T132, or equivalent.

FIGURE 9
ONE-PERSON OPEN CIRCUIT MEASUREMENT
RETURN LOSS BALANCED TO ARTIFICIAL LINE



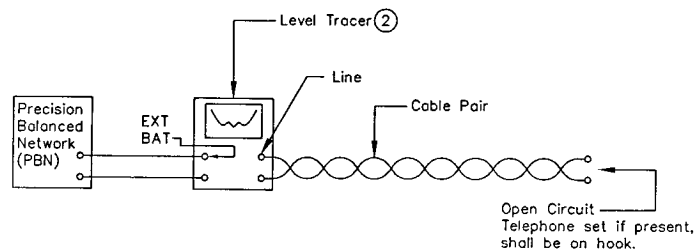
Measurement Procedure

1. Connect the test equipment and cable pair under test as shown above (See Note 1). Set up Artificial Line to same make-up [Length & Gauge(s)] as the cable pair.
2. Observe Return Loss from 200 to 3500 Hz (D66) or 200 to 3000 Hz (H88) noting maximum and minimum values. Note the value and frequency of the poorest (Lowest Numerical Value) SRL. (SRL becomes better as the readings become more negative). Record this value and frequency.

Notes:

- ① Terminals to which cable pair and Artificial Line are attached shall be determined from the manufacturer's operating instructions. Proper settings for various switches and adjustments on the test set shall also be determined from the same source.
- ② Wilcom-T132, Wilcom-T195, or equivalent.

FIGURE 10
ONE-PERSON OPEN CIRCUIT MEASUREMENT
STRUCTURAL RETURN LOSS USING LEVEL TRACER



Measurement Procedure

1. Connect the test equipment and cable pair under test as shown above (See Note ①). Set gauge of PBN for: Single Gauge — Same gauge as cable being measured; Mixed Gauge — Most predominant gauge adjacent to test set.
2. Observe Return Loss between 1000 and 3500 Hz (D66) or 1000 and 3000 Hz (H88) observing maximum and minimum values. Note the value and frequency of the poorest (Lowest Numerical Value) SRL. Single Gauge: Record this value. Mixed Gauge: Change gauge of PBN and note if SRL becomes better. (SRL becomes better as readings become more negative). If it does, record this value and frequency; if not, record value obtained with original gauge setting. (Varying gauge will be necessary, depending on actual cable layout, to obtain best SRL).

Notes:

- ① Terminals to which cable pair and Artificial Line are attached shall be determined from the manufacturer's operating instructions. Proper settings for various switches and adjustments on the test set shall also be determined from the same source.
- ② Wilcom-T132, Wilcom-T195, or equivalent.

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(7) Applicable results. (i) For loaded and nonloaded loops, the two traces in the pulse return pattern or impedance method (paragraph (f)(5)(i) of this section) shall be essentially identical. The degree of comparison required of

the two traces is to be determined by experience.

(ii) For loaded loops, results for return loss measurements using a level tracer, with artificial line, in lieu of a PBN (paragraph (f)(5)(ii) of this section) shall meet the following requirements:

(A) For D66 and H88 loaded cables the structural return loss (SRL) values shall range between 28 and 39 dB, respectively, at the critical frequency of structural return loss (CFSRL) within the pass band of the loading system being used. The minimum SRL value for

uniform gauge shall be 25 dB CFSRL. These SRL values apply for loaded cables of uniform gauge for the entire length of the subscriber loop circuit. Subscriber loop circuits shall meet the loading spacing deviations and the cable mutual capacitance requirements in the applicable RUS cable specifications;

(B) For mixed gauge loaded cables the SRL values shall be 25 and 27 dB CFSRL, respectively, and the minimum SRL value shall be 22 dB CFSRL; and

(C) The two traces in the pulse return pattern should be essentially identical. The degree of comparison required of the two traces is determined by experience.

(iii) For loaded loops, the results of open circuit structural return loss measurements using a level tracer (paragraph (f)(5)(iii) of this section) shall meet the following requirements. For D66 and H88 loaded cables with uniform or mixed gauges, the worst value allowed for measured open circuit structural return loss between 1,000–3,500 Hz and 1,000–3,000 Hz, respectively, shall be approximately 0.9 dB (round trip) for each 100 ohms outside plant dc loop resistance including the resistance of the load coils. The value of 0.9 dB per 100 ohms for the round trip loss remains reasonably accurate as long as:

(A) The subscriber end section of the loaded pair under test is approximately 2,250 ft (685 m) for D66 loading or 3,000 ft (914 m) for H88 loading in length; and

(B) The one-way 1,000 Hz loss does not exceed 10 dB.

(iv) For loaded loops, the measured value of open circuit structural return loss can only be as accurate as the degree to which the dc loop resistance of the loaded pair under test is known. Most accurate results shall be obtained when the dc loop resistance is known by actual measurements as described in paragraph (d) of this section. Furthermore, where the dc loop resistance is measured at the same time as the open circuit structural return loss, no correction for temperature is needed because the loss is directly proportional to the loop resistance. Where it is not practical to measure the dc loop resistance, it shall be calculated and corrected for temperature as specified in paragraph (d)(6)(ii) of this section. When measuring existing plant, care shall be taken to verify the accuracy of the records, if they are used for the calculation of the dc loop resistance. For

buried plant, the temperature correction shall be based at the normal depth of the cable in the ground. (Temperature can be measured by boring a hole to cable depth with a ground rod, placing a thermometer in the ground at the cable depth, and taking and averaging several readings during the course of the resistance measurements.) For aerial cable it shall be based on the temperature inside the cable sheath.

(v) For loaded loops, the best correlation between the measured and the expected results shall be obtained when the cable is of one gauge, one size, and the far end section is approximately 2,250 ft (685 m) for D66 loading or 3,000 ft (914 m) for H88 loading. Mixing gauges and cable sizes will result in undesirable small reflections whose frequency characteristics and magnitude cannot be accurately predicted. In subscriber loop applications, cable gauge may be somewhat uniform but the cable pair size most likely will not be uniform as cable pair sizes taper off toward the customer access location and a downward adjustment of 1 dB of the allowed value shall be acceptable. "Long" end sections (as defined in TE&CM Section 424, "Guideline for Telecommunications Subscriber Loop Plant") lower the expected value, a further downward adjustment of 3 dB in the allowed value shall be acceptable.

(vi) For loaded loops, the limiting factor when making open circuit structural return loss measurements is when the 1,000 Hz one-way loss of the loaded cable pair under test becomes 10 dB or greater; it becomes difficult to detect the presence of irregularities beyond the 10 dB point on the loop. To overcome this difficulty, loaded loops having a one-way loss at 1,000 Hz greater than 10 dB shall be opened at some convenient point (such as a pedestal or ready access enclosure) and loss measurements at the individual portions measuring less than 10 dB one-way shall be made separately. When field mounted voice frequency repeaters are used, the measurement shall be made at the repeater location in both directions.

(8) Data record. (i) When performing a pulse return pattern or impedance open circuit measurement on loaded and nonloaded loops, a "check mark" indicating that the pair tests good or an "X" indicating that the pair does not test good shall be recorded in the SRL column. A suggested format similar to

Format I for subscriber loops in § 1755.407 or a format specified in the applicable construction contract may be used.

(ii) When performing open circuit return loss measurements using the return loss balanced to an artificial line or return loss using a level tracer on loaded loops, the value of the poorest (lowest numerical value) SRL and its frequency in the proper column between 1,000 and 3,500 Hz for D66 loading or between 1,000 and 3,000 Hz for H88 loading shall be recorded. A suggested format similar to Format I for subscriber loops in § 1755.407 or a format specified in the applicable construction contract may be used.

(9) Probable causes for nonconformance. Some of the more common causes for failing to obtain the desired results may be due to reversed load coil windings, missing load coils, bridge taps between load coils, load coil spacing irregularities, excessive end sections, cables having high or low mutual capacitance, load coils inadvertently installed in nonloaded loops, moisture or water in the cable, load coils having the wrong inductance, split pairs, and improperly spliced connectors. The above can occur singularly or in combination. Experience to date indicates that the most common problems are missing load coils, reversed load coil windings or bridge taps.

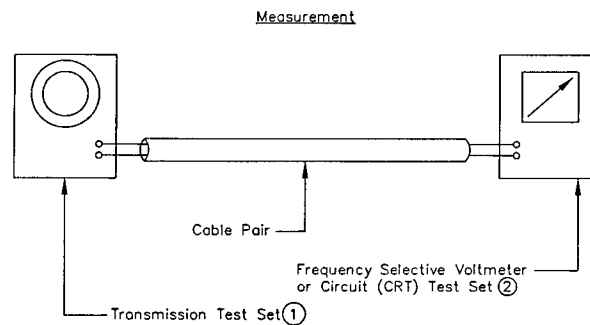
(g) *Cable insertion loss measurement (carrier frequencies).* (1) When specified by the borrower, carrier frequency insertion loss measurements shall be made on cable pairs used for T1, T1C, and/or station carrier systems. Carrier frequency insertion loss shall be made on a minimum of three pairs. Select at least one pair near the outside of the core unit layup. If the three measured pairs are within 10% of the calculated loss in dB corrected for temperature, no further testing is necessary. If any of the measured pairs of a section are not within 10% of the calculated loss in dB, all pairs in that section used for carrier transmission shall be measured.

(2) Method of measurement. The step-by-step method of measurement shall be as shown in Figure 11.

(3) Test equipment. The test equipment is shown in Figure 11 as follows:

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FIGURE 11
CARRIER FREQUENCY INSERTION LOSS MEASUREMENT
CABLE FACILITIES



Measurement Procedure

- ① Connect the transmission test set to one end of the length of cable to be measured and either the frequency selective voltmeter (FSVM) or CRT test set to the other end as shown.
- ② Record the Insertion Loss in dB of the cable at each specified frequency.
- ③ The measured Insertion Loss of the cable should be within ± 10 percent of the calculated loss in dB when the loss is corrected for temperature.
- ④ Transmission test sets having an impedance between 100 and 135 ohms on the cable side are acceptable.

Notes:

- ① H.P.—204B, H.P.—204C, H.P.—355, Siemens—W2057, or equivalent.
- ② Wilcom—T136, Wilcom—T336, Wilcom—T337, Wilcom—T132B, Siemens—D2057, or equivalent.

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(4) Applicable results. (i) The highest frequency to be measured is determined by the type of carrier system. For T1 type carrier, the highest frequency is normally 772 kHz. For T1C type carrier, the highest frequency is normally 1576

kHz. The highest frequency to be measured for station carrier is 140 kHz.

(ii) The measured insertion loss of the cable shall be within $\pm 10\%$ of the calculated loss in dB when the loss is corrected for temperature.

(iii) The calculated insertion loss is computed as follows:

(A) Multiply the length of each different gauge by the applicable dB per unit length as shown in Table 7 or 8 as follows:

TABLE 7.—CABLE ATTENUATION @ 68°F (20°C) FILLED CABLES—SOLID INSULATION

Frequency (kHz)	Attenuation dB/mile (dB/km) gauge (AWG)			
	19	22	24	26
10	2.8 (1.7)	4.8 (2.9)	6.4 (3.9)	8.5 (5.3)
20	3.2 (2.0)	5.8 (3.6)	8.2 (5.1)	11.2 (6.9)
40	3.6 (2.2)	6.5 (4.0)	9.6 (6.0)	13.9 (8.6)
60	4.0 (2.5)	6.9 (4.2)	10.3 (6.4)	15.2 (9.4)
80	4.5 (2.8)	7.3 (4.5)	10.7 (6.6)	16.0 (9.9)
100	4.9 (3.0)	7.7 (4.7)	11.1 (6.8)	16.5 (10.2)
112	5.2 (3.2)	8.0 (4.9)	11.3 (7.0)	16.8 (10.5)
120	5.4 (3.3)	8.1 (5.0)	11.5 (7.1)	17.0 (10.6)
140	5.8 (3.6)	8.6 (5.3)	11.9 (7.4)	17.4 (10.8)
160	6.2 (3.8)	9.0 (5.6)	12.3 (7.6)	17.8 (11.1)
180	6.6 (4.1)	9.5 (5.9)	12.7 (7.9)	18.2 (11.3)
200	7.0 (4.3)	10.0 (6.2)	13.2 (8.2)	18.6 (11.5)
300	8.7 (5.4)	12.2 (7.5)	15.4 (9.6)	20.6 (12.8)
400	10.0 (6.2)	14.1 (8.8)	17.7 (11.0)	22.9 (14.2)
500	11.2 (6.9)	15.9 (9.8)	19.8 (12.3)	25.2 (15.6)
600	12.2 (7.5)	17.5 (10.9)	21.8 (13.6)	27.4 (17.0)
700	13.2 (8.2)	19.0 (11.8)	23.6 (14.7)	29.6 (18.4)
772	13.8 (8.5)	19.9 (12.4)	24.8 (15.4)	31.4 (19.5)
800	14.2 (8.8)	20.1 (12.5)	27.4 (17.1)	31.7 (19.7)
900	14.8 (9.2)	21.6 (13.4)	29.0 (18.0)	33.8 (21.0)
1000	15.8 (9.8)	22.7 (14.1)	31.1 (19.3)	35.9 (22.3)
1100	16.4 (10.2)	23.8 (14.8)	32.7 (20.3)	38.0 (23.6)
1200	17.4 (10.8)	24.8 (15.4)	34.3 (21.3)	40.0 (24.9)
1300	17.9 (11.1)	25.9 (16.1)	35.4 (22.0)	41.7 (25.9)
1400	19.0 (11.8)	26.9 (16.7)	37.0 (23.0)	43.3 (26.9)
1500	19.5 (12.1)	28.0 (17.4)	38.0 (23.6)	44.3 (27.6)

TABLE 7.—CABLE ATTENUATION @ 68°F (20°C) FILLED CABLES—SOLID INSULATION—Continued

Frequency (kHz)	Attenuation dB/mile (dB/km) gauge (AWG)			
	19	22	24	26
1576	20.1 (12.4)	29.0 (18.0)	39.0 (24.3)	44.4 (28.2)

TABLE 8.—CABLE ATTENUATION @ 68°F (20°C) FILLED CABLES—EXPANDED INSULATION

Frequency (kHz)	Attenuation dB/mile (dB/km) gauge (AWG)			
	19	22	24	26
10	3.0 (1.8)	4.9 (3.0)	6.5 (4.0)	8.6 (5.3)
20	3.5 (2.1)	6.0 (4.1)	8.5 (5.2)	11.5 (7.1)
40	4.0 (2.5)	7.0 (4.3)	10.2 (6.3)	14.4 (8.9)
60	4.5 (2.8)	7.5 (4.6)	11.1 (6.8)	16.0 (9.9)
80	5.2 (3.3)	7.9 (4.9)	11.3 (6.9)	16.2 (10.1)
100	5.8 (3.6)	8.4 (5.2)	11.6 (7.2)	16.4 (10.2)
112	6.0 (3.8)	8.8 (5.4)	11.9 (7.4)	16.6 (10.3)
120	6.2 (3.9)	9.0 (5.6)	12.1 (7.5)	16.9 (10.5)
140	6.6 (4.1)	9.5 (5.9)	12.7 (7.9)	17.2 (10.7)
160	6.9 (4.3)	10.0 (6.2)	13.2 (8.2)	17.4 (10.8)
180	7.4 (4.6)	10.6 (6.6)	13.7 (8.5)	17.9 (11.1)
200	7.9 (4.9)	11.1 (6.9)	14.2 (8.8)	18.5 (11.5)
300	9.5 (5.9)	13.2 (8.2)	16.8 (10.5)	21.6 (13.4)
400	11.1 (6.9)	15.3 (9.5)	19.5 (12.1)	24.3 (15.1)
500	12.1 (7.5)	17.9 (11.1)	22.2 (13.8)	27.4 (17.1)
600	13.7 (8.5)	19.5 (12.1)	24.3 (15.1)	29.6 (18.4)
700	14.8 (9.2)	21.1 (13.1)	26.4 (16.4)	32.2 (20.0)
772	15.3 (9.5)	21.6 (13.4)	27.4 (17.1)	33.8 (21.0)
800	15.8 (9.8)	22.2 (13.8)	28.0 (17.4)	34.4 (21.3)
900	17.0 (10.5)	23.8 (14.8)	29.6 (18.4)	36.4 (22.6)
1000	17.4 (10.8)	24.8 (15.4)	31.1 (19.3)	38.5 (23.9)
1100	17.9 (11.1)	26.4 (16.4)	33.3 (20.7)	40.6 (25.3)
1200	19.0 (11.8)	27.4 (17.1)	34.3 (21.3)	42.2 (26.2)
1300	19.5 (12.1)	28.5 (17.7)	35.9 (22.3)	43.8 (27.2)
1400	20.1 (12.5)	29.6 (18.4)	37.0 (23.0)	45.9 (28.5)
1500	20.6 (12.8)	30.6 (19.0)	38.5 (23.9)	47.5 (29.5)
1576	21.6 (13.4)	31.1 (19.3)	39.1 (24.3)	48.6 (30.2)

(B) Add the individual losses for each gauge to give the total calculated insertion loss at a temperature of 68°F (20°C).

(C) Correct the total calculated insertion loss at the temperature of 68°F (20°C) to the measurement temperature by the following formulae:

$$A_t = A_{68} \times [1 + 0.0012 \times (t - 68)] \text{ for English Units}$$

$$A_t = A_{20} \times [1 + 0.0022 \times (t - 20)] \text{ for Metric Units}$$

Where:

A_t = Insertion loss at the measurement temperature in dB.

A_{68} = Insertion loss at a temperature of 68°F in dB.

A_{20} = Insertion loss at a temperature of 20°C in dB.

t = Measurement temperature in °F or (°C); and

(D) Compare the calculated insertion loss at the measurement temperature to the measured insertion loss to determine compliance with the requirement specified in paragraph (g)(4)(ii) of this section. (Note: Attenuation varies directly with temperature. For each ±10°F (5.6°C) change in temperature increase or decrease the attenuation by ±1%.)

(iv) If the measured value exceeds the ±10% allowable variation, the cause shall be determined and corrective action shall be taken to remedy the problem.

(5) Data record. Results of carrier frequency insertion loss measurements for station, T1, and/or T1C type carrier

shall be recorded. Suggested formats similar to Format III, Outside Plant Acceptance Tests—T1 or T1C Carrier Pairs, and Format IV, Outside Plant Acceptance Tests—Station Carrier Pairs, in § 1755.407 or formats specified in the applicable construction contract may be used.

(6) Probable causes for nonconformance. If the measured loss is low, the cable records are likely to be in error. If the measured loss is high, there may be bridge taps, load coils or voice frequency build-out capacitors connected to the cable pairs or the cable records may be in error. Figures 12 and 13 are examples that show the effects of bridge taps and load coils in the carrier path. Figures 12 and 13 are as follows:

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FIGURE 12
EFFECTS OF BRIDGE TAPS ON ATTENUATION

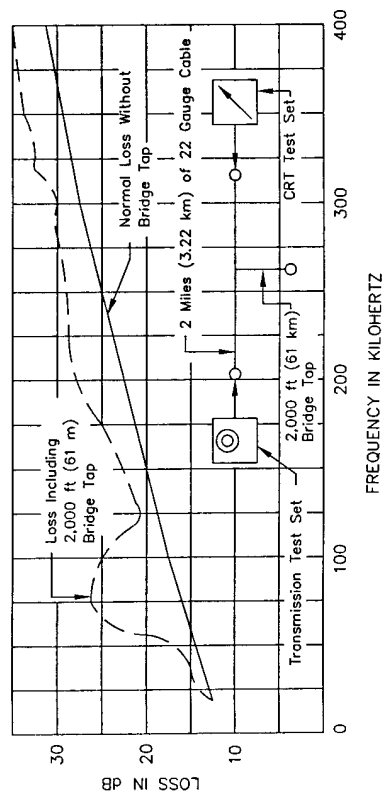
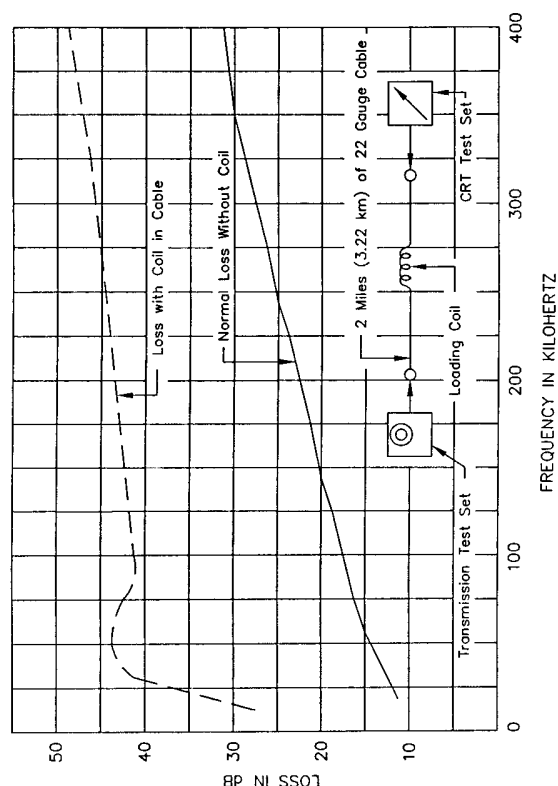


FIGURE 13
EFFECTS OF LOADING COILS ON ATTENUATION



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§ 1755.404 Fiber optic cable telecommunications plant measurements.

(a) *Armor continuity.* (1) Tests and measurements shall be made to ensure that the armor of fiber optic cables is continuous. There are two areas of concern. The first is armor bonding within a splice and the second is armor continuity between splices.

(2) Measurement techniques outlined here for verification of armor continuity are applicable to buried fiber optic cable plant. Measurements of armor continuity between splices in aerial, armored, fiber optic cable should be made prior to completion of splicing. Conclusive results cannot be obtained on aerial plant after all bonds have been completed to the supporting strand, multigrounded neutral, etc.

(3) *Method of measurement.* Armor continuity within splices shall be measured with a cable shield splice continuity test set. The step-by-step measurement procedure outlined in the manufacturer's operating instructions for the specific test equipment being used shall be followed.

(4) *Test equipment.* A cable shield splice continuity tester shall be used to

measure armor continuity within splices.

(5) *Applicable results.* When utilizing shield continuity testers to measure armor continuity within splices, refer to the manufacturer's published information covering the specific test equipment to be used and for anticipated results.

(6) *Data record.* Measurement data from armor continuity tests shall be recorded together with anticipated values in an appropriate format to permit comparison. The recorded data shall include specific location, cable size, and cable type, if known, etc.

(7) *Probable causes for nonconformance.* Among probable causes for nonconformance are broken or damaged armors, bad bonding harnesses, poorly connected bonding clamps, loose bonding lugs, etc.

(b) *Fiber optic splice loss measurement.* (1) After placement of all fiber optic cable plant has been completed and spliced together to form a continuous optical link between end termination points, splice loss measurements shall be performed on all field and central office splice points.

(2) *Method of measurement.* (i) Field splice loss measurements shall be made

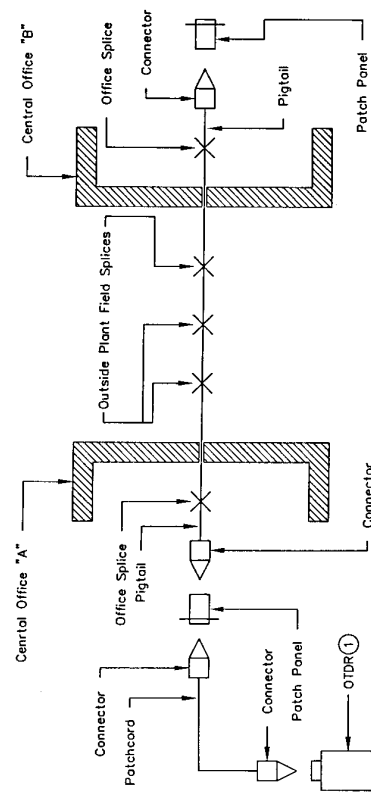
between the end termination points at 1310 and/or 1550 nanometers for single mode fibers and in accordance with Figure 14. Two splice loss measurements shall be made between the end termination points. The first measurement shall be from termination point A to termination point B. The second measurement shall be from termination point B to termination point A.

(ii) *CO splice loss measurements* shall be made at 1310 and/or 1550 nanometers for single mode fibers and in accordance with Figure 15. Two splice loss measurements shall be made between the end termination points. The first measurement shall be from termination point A to termination point B. The second measurement shall be from termination point B to termination point A.

(3) *Test equipment.* The test equipment is shown in Figures 14 and 15. The optical time domain reflectometer (OTDR) used for the testing should have dual wave length capability. Figures 14 and 15 are as follows:

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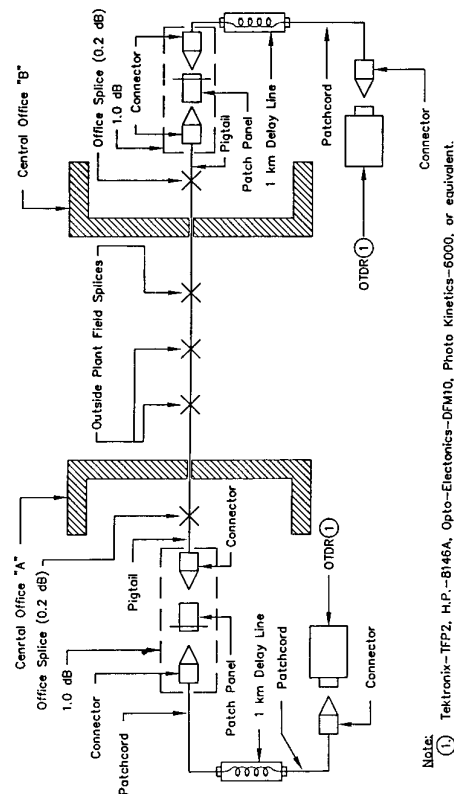
FIGURE 14
FIBER OPTIC FIELD SPLICE LOSS MEASUREMENT



Note:

- ① Tektronix-TFP2, H.P.-8146A, Opto-Electronics-DEM10, Photo Kinetics-6000, or equivalent.

FIGURE 15
FIBER OPTIC CENTRAL OFFICE SPLICE LOSS MEASUREMENT



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(4) Applicable results. (i) The splice loss for each single mode field splice

shall be the bi-directional average of the two OTDR readings. To calculate the actual splice loss, substitute the OTDR

readings maintaining the sign of the loss (+) or apparent gain (-) into the following equation:

$$\text{Actual Splice Loss (dB)} = \frac{\text{OTDR Reading From A to B} + \text{OTDR Reading From B to A}}{2}$$

(ii) When specified in the applicable construction contract, the splice loss of each field splice at 1310 and/or 1550 nanometers shall not exceed the limit specified in the contract.

(iii) When no limit is specified in the applicable construction contract, the splice loss of each field splice shall not exceed 0.2 dB at 1310 and/or 1550 nanometers.

(iv) The splice loss for each single mode CO splice shall be the bi-directional average of the two OTDR reading. To calculate actual splice loss, substitute the OTDR reading, maintaining the sign of the loss (+) or apparent gain (-), into the equation specified in paragraph (b)(4)(i) of this section.

(v) When specified in the applicable construction contract, the splice loss of each central office splice at 1310 and/or 1550 nanometers shall not exceed the limit specified in the contract.

(vi) When no limit is specified in the applicable construction contract, the splice loss of each central office splice shall not exceed 1.2 dB at 1310 and/or 1550 nanometers.

(5) Data record. The measurement data shall be recorded. A suggested format similar to Format V, Outside Plant Acceptance Test—Fiber Optic Telecommunications Plant, in § 1755.407 or a format specified in the applicable construction contract may be used.

(6) Probable causes for nonconformance. When the results of the splice loss measurements exceed the specified limits the following factors should be checked:

- (i) Proper end preparation of the fibers;
- (ii) End separation between the fiber ends;
- (iii) Lateral misalignment of fiber cores;

(iv) Angular misalignment of fiber cores;

(v) Fresnel reflection;

(vi) Contamination between fiber ends;

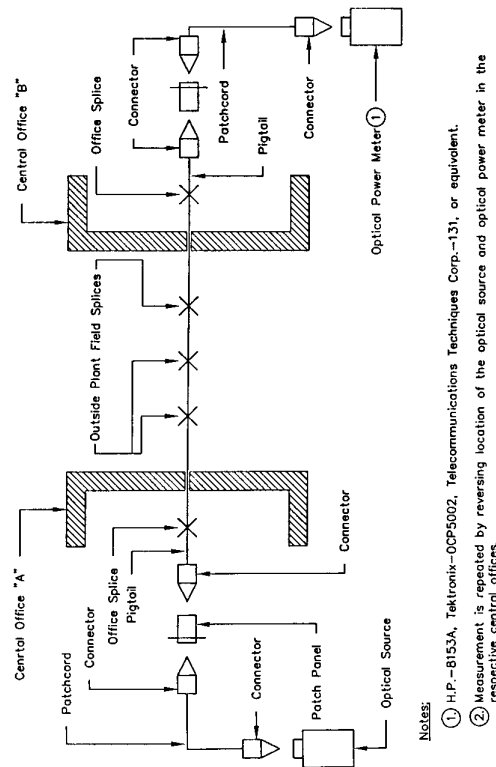
(vii) Core deformation; or

(viii) Mode-field diameter mismatch.

(c) *End-to-end attenuation measurement.* (1) After placement of all fiber optic cable plant has been completed and spliced together to form a continuous optical link between end termination points, end-to-end attenuation measurements shall be performed on each optical fiber within the cable.

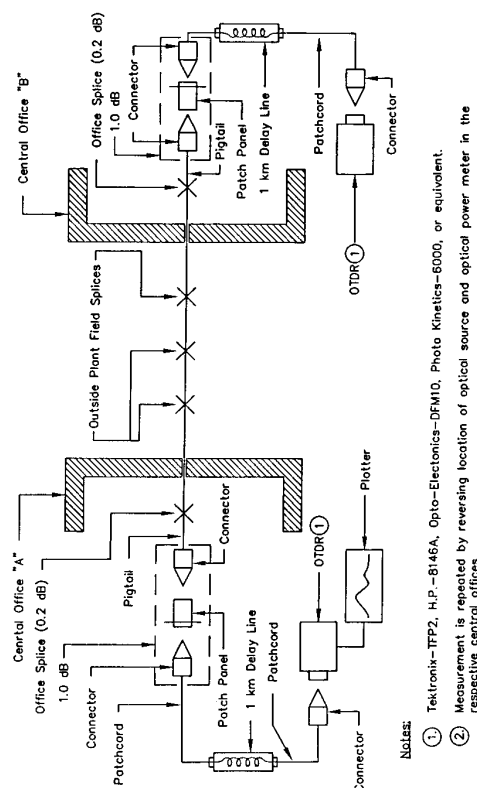
(2) Method of measurement. For single mode fibers, the end-to-end attenuation measurements of each optical fiber at 1310 and/or 1550 nanometers in each direction between end termination points shall be performed in accordance with Figure 16.

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FIGURE 17
END-TO-END FIBER OPTIC SIGNATURE MEASUREMENT
SHOWING MEASUREMENT IN ONE DIRECTION ONLY ②



BILLING CODE 3410-15-C

(4) Applicable results. The appearance of each optical fiber between end termination points.

(5) Data record. Plot the trace of each optical fiber and retain as a permanent record for future comparison if needed.

(6) Probable causes for nonconformance. None.

§ 1755.405 Voiceband data transmission measurements.

(a) The data transmission measurements listed in this section shall be used to determine the acceptability of trunk and nonloaded subscriber loop circuits for data modem transmission.

(b) Signal-to-C notched noise (S/CNN) measurement. (1) When specified by the borrower, S/CNN measurements shall be made on trunk circuits and nonloaded subscriber loops. For trunk circuits, the measurement shall be made between CO locations. For nonloaded subscriber loops, the measurement shall be made from the CO to the station protector of the NID at the customer's access location.

(2) S/CNN is the logarithmic ratio expressed in dB of a 1,004 Hz holding tone signal compared to the C-message weighted noise level. S/CNN is one of the most important transmission parameters affecting the performance of

data transmission because proper modem operation requires low noise relative to received power level. Since modulated carriers are used in data communication systems, noise measurements need to be performed with power on the connection to activate equipment having signal-level-dependent noise sources. For 4 kHz channels, a 1,004 Hz holding tone is used to activate the signal-dependent equipment on the channel or connection.

(3) Method of measurement. The S/CNN measurement shall be made using a 1,004 Hz holding tone at -13 dBm0 (decibels relative to one milliwatt, referred to a zero transmission level point) and performed in accordance with American National Standards Institute (ANSI) T1.506-1989, Telecommunications—Switched Exchange Access Network Transmission Specifications, and American National Standards Institute/Institute of Electrical and Electronics Engineers (ANSI/IEEE) 743-1984(R 1993), Standard Methods and Equipment for Measuring the Transmission Characteristics of Analog Voice Frequency Circuits. The ANSI T1.506-1989, Telecommunications—Switched Exchange Access Network Transmission Specifications is incorporated by

reference in accordance with 5 U.S.C. 522(a) and 1 CFR part 51. Copies of ANSI T1.506-1989 are available for inspection during normal business hours at RUS, room 2845, U.S. Department of Agriculture, Washington, DC 20250-1598 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies are available from ANSI, Customer Service, 11 West 42nd Street, New York, New York 10036, telephone number (212) 642-4900. The ANSI/IEEE 743-1984(R 1993), Standard Methods and Equipment for Measuring the Transmission Characteristics of Analog Voice Frequency Circuits is incorporated by reference in accordance with 5 U.S.C. 522(a) and 1 CFR part 51. Copies of ANSI/IEEE 743-1984(R 1993) are available for inspection during normal business hours at RUS, room 2845, U.S. Department of Agriculture, Washington, DC 20250-1598 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies are available from ANSI, Customer Service, 11 West 42nd Street, New York, New York 10036, telephone number (212) 642-4900.

Note: The incorporation by reference and availability of inspection copies are pending

approval by the Office of the Federal Register.

(4) Test equipment. The equipment for performing the measurement shall be in accordance with ANSI/IEEE 743–1984 (R 1993).

(5) Applicable results. The S/CNN for both trunk and nonloaded subscriber loop circuits shall not be less than 31 dB.

(6) Data record. The measurement data shall be recorded. Suggested formats similar to Format VI, Voiceband Data Transmission Tests—Nonloaded Subscriber Loops, and Format VII, Voiceband Data Transmission Tests—Trunk Circuits, in § 1755.407 or formats specified in the applicable construction contract may be used.

(7) Probable causes for nonconformance. Some of the causes for failing to obtain the desired results may be due to excessive harmonic distortion, quantizing noise, phase and amplitude jitter, and loss in digital pads used for level settings.

(c) Signal-to-intermodulation distortion (S/IMD) measurement. (1) When specified by the borrower, S/IMD measurements shall be made on trunk circuits and nonloaded subscriber loops. For trunk circuits, the measurement shall be made between CO locations. For nonloaded subscriber loops, the measurement shall be made from the CO to the station protector of the NID at the customer's access location.

(2) S/IMD is a measure of the distortion produced by extraneous frequency cross products, known as intermodulation products, when a multi-tone signal is applied to a system.

(3) Intermodulation distortion (IMD) is caused by system nonlinearities acting upon the harmonic frequencies produced from an input of multiple tones. The products resulting from IMD can be more damaging than noise in terms of producing data transmission errors.

(4) IMD is measured as a signal to distortion ratio and is expressed as the logarithmic ratio in dB of the composite power of four resulting test frequencies to the total power of specific higher order distortion products that are produced. The higher order products are measured at both the 2nd order and 3rd order and are designated R2 and R3, respectively. The four frequency testing for IMD is produced with four tones of 857, 863, 1,372, and 1,388 Hz input at a composite power level of –13 dBm0.

(5) Method of measurement. The S/IMD measurement shall be performed in accordance with ANSI T1.506–1989 and ANSI/IEEE 743–1984 (R 1993).

(6) Test equipment. The equipment for performing the measurement shall be

in accordance with ANSI/IEEE 743–1984 (R 1993).

(7) Applicable results. The 2nd order (R2) S/IMD for both trunk and nonloaded subscriber loop circuits shall not be less than 40 dB. The 3rd order (R3) S/IMD for both trunk and nonloaded subscriber loop circuits shall not be less than 40 dB.

(8) Data record. The measurement data shall be recorded. Suggested formats similar to Format VI for nonloaded subscriber loops and Format VII for trunk circuits in § 1755.407 or formats specified in the applicable construction contract may be used.

(9) Probable causes for nonconformance. Some of the causes for failing to obtain the desired results may be due to channel nonlinearities, such as compression and clipping, which cause harmonic and intermodulation distortion in a voiceband signal.

(d) Envelope delay distortion (EDD) measurement. (1) When specified by the borrower, EDD measurements shall be made on trunk circuits and nonloaded subscriber loops. For trunk circuits, the measurement shall be made between CO locations. For nonloaded subscriber loops, the measurement shall be made from the CO to the station protector of the NID at the customer's access location.

(2) EDD is a measure of the linearity or uniformity of the phase versus frequency characteristics of a transmission facility. EDD is also known as relative envelope delay (RED).

(3) EDD is specifically defined as the delay relative to the envelope delay at the reference frequency of 1,704 Hz. EDD is typically measured at two frequencies, one low and one high in the voiceband. The low frequency measurement is made at 604 Hz. The high frequency measurement is made at 2,804 Hz.

(4) Method of measurement. The EDD measurement shall be performed in accordance with ANSI T1.506–1989 and ANSI/IEEE 743–1984 (R 1993).

(5) Test equipment. The equipment for performing the measurement shall be in accordance with ANSI/IEEE 743–1984 (R 1993).

(6) Applicable results. The EDD for both trunk and nonloaded subscriber loop circuits at the low frequency of 604 Hz shall not exceed 1,500 microseconds. The EDD for both trunk and nonloaded subscriber loop circuits at the high frequency of 2,804 Hz shall not exceed 1,000 microseconds.

(7) Data record. The measurement data shall be recorded. Suggested formats similar to Format VI for nonloaded subscriber loops and Format VII for trunk circuits in § 1755.407 or

formats specified in the applicable construction contract may be used.

(8) Probable causes for nonconformance. Some of the causes for failing to obtain the desired results may be due to nonlinearity of the phase versus frequency characteristic of the transmission facility. This nonlinear phase versus frequency characteristic of the transmission facility causes the various frequency components to travel at different transit times which results in successively transmitted data pulses to overlap at the receive end. The overlapping of the pulses at the receive end results in distortion of the received signal. Excessive EDD on the transmission facility may be reduced using data modems with equalization or by conditioning the transmission line.

(e) Amplitude jitter (AJ) measurement.

(1) When specified by the borrower, AJ measurements shall be made on trunk circuits and nonloaded subscriber loops. For trunk circuits, the measurement shall be made between CO locations. For nonloaded subscriber loops, the measurement shall be made from the CO to the station protector of the NID at the customer's access location.

(2) AJ is any fluctuation in the peak amplitude value of a fixed tone signal at 1,004 Hz from its nominal value. AJ is expressed in peak percent amplitude modulation.

(3) AJ is measured in two separate frequency bands, 4–300 Hz and 20–300 Hz. The 4–300 Hz band is important for modems employing echo canceling capabilities. The 20–300 Hz band is used for modems that do not employ echo cancelers.

(4) Amplitude modulation can affect the error performance of voiceband data modems. The measurement of amplitude jitter indicates the total effect on the amplitude of the holding tone of incidental amplitude modulation and other sources including quantizing and message noise, impulse noise, gain hits, phase jitter, and additive tones such as single-frequency interference.

(5) Method of measurement. The AJ measurement shall be performed in accordance with ANSI T1.506–1989 and ANSI/IEEE 743–1984 (R 1993).

(6) Test equipment. The equipment for performing the measurement shall be in accordance with ANSI/IEEE 743–1984 (R 1993).

(7) Applicable results. The AJ for both trunk and nonloaded subscriber loop circuits in the 4–300 Hz frequency band shall not exceed 6%. The AJ for both trunk and nonloaded subscriber loop circuits in the 20–300 Hz frequency band shall not exceed 5%.

(8) Data record. The measurement data shall be recorded. Suggested formats similar to Format VI for

nonloaded subscriber loops and Format VII for trunk circuits in § 1755.407 or formats specified in the applicable construction contract may be used.

(9) Probable causes for nonconformance. Some of the causes for failing to obtain the desired results may be due to excessive S/CNN, impulse noise, and phase jitter.

(f) Phase jitter (PJ) measurement. (1) When specified by the borrower, PJ measurements shall be made on trunk circuits and nonloaded subscriber loops. For trunk circuits, the measurement shall be made between CO locations. For nonloaded subscriber loops, the measurement shall be made from the CO to the station protector of the NID at the customer's access location.

(2) PJ is any fluctuation in the zero crossings of a fixed tone signal (usually 1,004 Hz) from their nominal position in time within the voiceband. PJ is expressed in terms of either degrees peak-to-peak ($^{\circ}$ p-p) or in terms of a Unit Interval (UI). One UI is equal to 360° p-p.

(3) PJ measurements are typically performed in two nominal frequency bands. The frequency bands are 20–300 Hz band and either the 2–300 Hz band or the 4–300 Hz band. The 20–300 Hz band is important to all phase-detecting modems. The 4–300 Hz band or the 2–300 Hz band is important for modems employing echo canceling capabilities.

(4) Phase jitter can affect the error performance of voiceband data modems that use phase detection techniques. The measurement of phase jitter indicates the total effect on the holding tone of incidental phase modulation and other sources including quantizing and message noise, impulse noise, phase hits, additive tones such as single-frequency interference, and digital timing jitter.

(5) Method of measurement. The PJ measurement shall be performed in accordance with ANSI T1.506–1989 and ANSI/IEEE 743–1984(R 1993).

(6) Test equipment. The equipment for performing the measurement shall be

in accordance with ANSI/IEEE 743–1984 (R 1993).

(7) Applicable results. The PJ for both trunk and nonloaded subscriber loop circuits in the 4–300 Hz frequency band shall not exceed 6.5° p-p. The PJ for both trunk and nonloaded subscriber loop circuits in the 20–300 Hz frequency band shall not exceed 10.0° p-p.

(8) Data record. The measurement data shall be recorded. Suggested formats similar to Format VI for nonloaded subscriber loops and Format VII for trunk circuits in § 1755.407 or formats specified in the applicable construction contract may be used.

(9) Probable causes for nonconformance. Some of the causes for failing to obtain the desired results may be due to excessive S/CNN, impulse noise, and amplitude jitter.

(g) Impulse noise measurement. (1) When specified by the borrower, impulse noise measurements shall be made on trunk circuits and nonloaded subscriber loops. For trunk circuits, the measurement shall be made between CO locations. For nonloaded subscriber loops, the measurement shall be made from the CO to the station protector of the NID at the customer's access location.

(2) Impulse noise is a measure of the presence of unusually large noise excursions of short duration that are beyond the normal background noise levels on a facility. Impulse noise is typically measured by counting the number of occurrences beyond a particular noise reference threshold in a given time interval. The noise reference level is C-message weighted.

(3) Method of measurement. The impulse noise measurement shall be performed using a 1,004 Hz tone at -13 dBm0 and in accordance with ANSI T1.506–1989 and ANSI/IEEE 743–1984(R 1993).

(4) Test equipment. The equipment for performing the measurement shall be in accordance with ANSI/IEEE 743–1984 (R 1993).

(5) Applicable results. The impulse noise for both trunk and nonloaded subscriber loop circuits shall not exceed 65 dBrnC0 (decibels relative to one picowatt reference noise level, measured with C-message frequency weighting, referred to a zero transmission level point). The impulse noise requirement shall be based upon a maximum of 5 counts in a 5 minute period at equal to or greater than the indicated noise thresholds.

(6) Data record. The measurement data shall be recorded. Suggested formats similar to Format VI for nonloaded subscriber loops and Format VII for trunk circuits in § 1755.407 or formats specified in the applicable construction contract may be used.

(7) Probable causes for nonconformance. Some of the causes for failing to obtain the desired results may be due to excessive transient signals originating from the various switching operations.

§ 1755.406 Shield or armor ground resistance measurements.

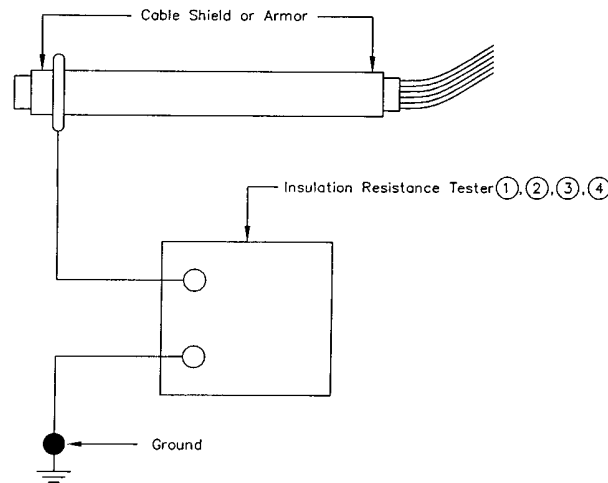
(a) Shield or armor ground resistance measurements shall be made on completed lengths of copper cable and wire plant and fiber optic cable plant.

(b) Method of measurement. (1) The shield or armor ground resistance measurement shall be made between the copper cable and wire shield and ground and between the fiber optic cable armor and ground, respectively. The measurement shall be made either on cable and wire lengths before splicing and before any ground connections are made to the cable or wire shields or armors. Optionally, the measurement may be made on cable and wire lengths after splicing, but all ground connections must be removed from the section under test.

(2) The method of measurement using either an insulation resistance test set or a dc bridge type megohmmeter shall be as shown in Figure 18 as follows:

BILLING CODE 3410–15–P

FIGURE 18
SHIELD OR ARMOR GROUND RESISTANCE MEASUREMENT



Notes:

- ① For hand cranked or battery operated Insulation Resistance Testers, the output voltage should not exceed 500 volts dc.
- ② For dc bridge type Megohmmeters, the voltage applied to the shield or armor under test should not be less than 250 volts dc nor greater than 1000 volts dc when using instruments having adjustable test voltage levels.
- ③ When the distance between test points results in a measurement beyond the range of the test equipment, extended range devices recommended by the test equipment manufacturer may be used to assist in making the measurement.
- ④ Biddle CO.—Model BM 200, Associate Research—Model 263, General Radio—1864 Megohm Meter, or equivalent.

BILLING CODE 3410-15-C

(c) Test equipment. (1) The shield or armor ground resistance measurements may be made using an insulation resistance test set, a dc bridge type megohmmeter, or a commercially available fault locator.

(2) The insulation resistance test set should have an output voltage not to exceed 500 volts dc and may be hand cranked or battery operated.

(3) The dc bridge type megohmmeter, which may be ac powered, should have scales and multipliers which make it possible to accurately read resistance values of 50,000 ohms to 10 megohms. The voltage that is applied to the shield or armor during the test should not be less than "250 volts dc" nor greater than "1,000 volts dc" when using an instrument having adjustable test voltage levels.

(4) Commercially available fault locators may be used in lieu of the above equipment, if the devices are capable of detecting faults having resistance values of 50,000 ohms to 10 megohms. Operation of the devices and method of locating the faults should be in accordance with manufacturer's instructions.

(d) Applicable results. (1) For all new copper cable and wire facilities and all new fiber optic cable facilities, the

shield or armor ground resistance levels normally exceed 1 megohm-mile (1.6 megohm-km) at 68°F (20°C). A value of 100,000 ohm-mile (161,000 ohm-km) at 68°F (20°C) shall be the minimum acceptable value of the shield or armor ground resistance.

(2) Shield or armor ground resistance varies inversely with length and temperature. In addition other factors which may affect readings could be soil conditions, faulty test equipment and incorrect test procedures.

(3) For the resistance test method and dc bridge type megohmmeter, the ohm-mile (ohm-km) value for the shield or armor ground resistance shall be computed by multiplying the actual scale reading in ohms on the test set by the length in miles (km) of the cable or wire under test.

(4)(i) The objective shield or armor ground resistance may be determined by dividing 100,000 by the length in miles (161,000 by the length in km) of the cable or wire under test. The resulting value is the minimum acceptable meter scale reading in ohms. Examples for paragraphs (d)(3) and (d)(4) of this section are as follows:

Equation 1. Test Set

$$\begin{aligned} \text{Scale Reading} \times \text{Length} &= \text{Resistance-} \\ \text{Length} \\ 75,000 \text{ ohms} \times 3 \text{ miles} &= 225,000 \end{aligned}$$

ohm-mile

$$(75,000 \text{ ohms} \times 4.9 \text{ km} = 367,000 \text{ ohm-km})$$

$$\text{Equation 2. } 100,000 \text{ ohm-mile} \div \text{Length} = \text{Minimum Acceptable Meter Scale Reading}$$

$$\begin{aligned} 100,000 \text{ ohm-mile} \div 3 \text{ miles} &= 33,333 \text{ ohms} \\ (161,000 \text{ ohm-km} \div 4.9 \text{ km} &= 32,857 \text{ ohms}) \end{aligned}$$

(ii) Since the 33,333 ohms (32,857 ohms) is the minimum acceptable meter scale reading and the meter scale reading was 75,000 ohms, the cable is considered to have met the 100,000 ohm-mile (161,000 ohm-km) requirement.

(5) Due to the differences between various jacketing materials used in manufacturing cable or wire and to varying soil conditions, it is impractical to provide simple factors to predict the magnitude of variation in shield or armor to ground resistance due to temperature. The variations can, however, be substantial for wide excursions in temperature from the ambient temperature of 68°F (20°C).

(e) Data record. The data shall be corrected to the length requirement of ohm-mile (ohm-km) and a temperature of 68°F (20°C) and shall be recorded on a form specified in the applicable construction contract.

(f) Probable causes for nonconformance. (1) When results of resistance measurements are below the 100,000 ohm-mile (161,000 ohm-km) requirement at 68°F (20°C), the jacket temperature, soil conditions, test equipment and method shall be reviewed before the cable or wire is considered a failure. If the temperature is approximately 68°F (20°C) and soil conditions are acceptable, and a reading of less than 100,000 ohm-mile (161,000 ohm-km) is indicated, check the calibration of the equipment; as well as, the test method. If the equipment was found to be out of calibration, recalibrate the equipment and remeasure the cable or wire. If the

temperature was 86°F (30°C) or higher, the cable or wire shall be remeasured at a time when the temperature is approximately 68°F (20°C). If the test was performed in unusually wet soil, the cable or wire shall be retested after the soil has reached normal conditions. If after completion of the above steps, the resistance value of 100,000 ohm-mile (161,000 ohm-km) or greater is obtained, the cable or wire shall be considered acceptable.

(2) When the resistance value of the cable or wire is still found to be below 100,000 ohm-mile (161,000 ohm-km) requirement after completion of the steps listed in paragraph (f)(1) of this section, the fault shall be isolated by

performing shield or armor ground resistance measurements on individual cable or wire sections.

(3) Once the fault or faults have been isolated, the cable or wire jacket shall be repaired in accordance with § 1755.200, RUS Standard for Splicing Copper and Fiber Optic Cables, or the entire cable or wire section may be replaced at the request of the borrower.

§ 1755.407 Data formats.

The following suggested formats listed in this section may be used for recording the test data:

BILLING CODE 3410-15-P

FORMAT 1

OUTSIDE PLANT ACCEPTANCE TESTS – SUBSCRIBER LOOPS

[illegible]

FORMAT III

OUTSIDE PLANT ACCEPTANCE TESTS – T1 or T1C CARRIER PAIRS

PROJECT: _____ Type of Proposed Carrier: _____ (Trunk – Subscriber)

LOCATION: From _____ to _____ (CO Name) Shield or Shield/Armor Continuity has been checked: _____

Aerial _____ Buried _____ Weather: _____ Temp.: _____ Date: _____ Sheet _____ of _____

CARRIER FREQUENCY INSERTION LOSS MEASUREMENTS ①

From _____ to _____		From _____ to _____	
Freq. ② (kHz)	Send Level (dBm)	Receive Level (dBm)	Measured Loss (dB)
20			
60			
100			
140			
180			
200			
300			
400			
600			
700			
772			
800			
1000			
1200			
1300			
1400			
1500			
1576			

Estimated ③ Loss (dB)

Measured Loss (dB)

Estimated ③ Loss (dB)

Notes: ① Refer to RUS T&CM 925 on How to Make Measurements. ② Go as high in frequency as required by contract. ③ From either Table 7 or 8 in Paragraph (g)(4)(iii)(A) of Section 1753.403; Correct loss for temperature.

FORMAT IV
OUTSIDE PLANT ACCEPTANCE TESTS — STATION CARRIER PAIRS

PROJECT: _____ Type of Proposed Carrier: _____ (Trunk — Subscriber)
 LOCATION: From _____ to _____ (Sub.) Shield or Shield/Armor Continuity has been checked: _____
 Aerial: _____ Buried: _____ Weather: _____ Temp.: _____ Date: _____ Sheet _____ of _____

CARRIER FREQUENCY INSERTION LOSS MEASUREMENTS ①

From _____ to _____				From _____ to _____			
Freq. (kHz)	Send Level (dBm)	Receive Level (dBm)	Measured Loss (dB)	Estimated Loss (dB)	Freq. (kHz)	Send Level (dBm)	Receive Level (dBm)
20					20		
60					60		
100					100		
112					112		
140					140		

From _____ to _____				From _____ to _____			
Freq. (kHz)	Send Level (dBm)	Receive Level (dBm)	Measured Loss (dB)	Estimated Loss (dB)	Freq. (kHz)	Send Level (dBm)	Receive Level (dBm)
20					20		
60					60		
100					100		
112					112		
140					140		

Notes:
 ① Refer to RUS T&CM 925 on How to Make Measurements.
 ② From either Table 7 or 8 in Paragraph (g)(4)(iii)(A) of Section 1755.403; correct loss for temperature.

FORMAT V
OUTSIDE PLANT ACCEPTANCE TESTS
FIBER OPTIC TELECOMMUNICATIONS PLANT

PROJECT: _____ Date of Test: _____
 TERMINATION POINT A: _____ Tester (Contractor): _____
 TERMINATION POINT B: _____ Tester (Engineer): _____
 Time Measured: _____ Tester (Borrower): _____
 Temperature: _____ Test Equip: _____
 Soil Type: _____ Moisture Content of Soil: _____

Route No.	Fiber No.	Length Miles or km	Splice Loss (dB)		End-to-End Attenuation (dB/km)	End-to-End Fiber Signature	
			FIELD	CO		Yes	No

Armor Continuity Data has been attached. Yes _____ No _____

VOICEBAND DATA TRANSMISSION TESTS – NONLOADED SUBSCRIBER LOOPS

[illegible]

these terms in the Report of the House of Representatives Committee on the Judiciary, H.R. No. 103-387, November 20, 1993. The relevant comments, found on pages 5 and 6 of the report, read:

The bill also provides a general waiver of all testing requirements for persons of any age who, because of "physical or developmental disability or mental impairment," could not reasonably be expected to pass the test. This is not intended to include conditions that are either temporary or that have resulted from an individual's illegal use of drugs.

An individual who is developmentally disabled is one who shows delayed development of a specific cognitive area of maturation, i.e., reading, language, or speech, resulting in intellectual functioning so impaired as to render the individual unable to participate in the normal testing procedures for naturalization. This is not an acquired disability, but one whose onset occurred prior to the 18th birthday. An individual who is mentally disabled is one for whom there is a primary impairment of brain function, generally associated with an organic basis upon which diagnosis is based, resulting in an impairment of intellectual functions, including memory, orientation or judgment. This definition does not include individuals whose mental disability is not the result of a physical disorder. An individual who is physically disabled is one who has a physical impairment that substantially limits a major life activity.

It is clear that the amendment to section 312 is to exempt only those individuals who, because of their disability, cannot demonstrate the requisite literacy and knowledge as required under section 312 of the Act.

On November 21, 1995, the Service provided policy guidance to its field offices with preliminary instructions for adjudication of naturalization applications based on the expanded exemptions provided under the Technical Corrections Act. The Service also provided preliminary definitions of the terms "developmental disability," "physical disability," and "mental impairment" following the language in H.R. No. 103-387. Applicants seeking disability waivers were required to submit medical evidence (e.g., a one-page certification from a designated civil surgeon) with their N-400, Application for Naturalization, supporting their claim of disability.

Amendment of Existing Regulation

In order to implement the changes to section 312 of the Act as mandated by the Technical Corrections Act, the Service is proposing to amend 8 CFR 312.1 and 312.2 to provide definitions of the terms "developmental disability," "physical disability," and "mental impairment," and to outline procedures for individuals who seek disability

exemption pursuant to section 312(b)(1) of the Act.

This proposed rule not only modifies the Service's current preliminary guidance to the field but also comports with existing Federal policies and regulations for implementing nondiscriminatory disability based programs as required under section 504 of the Rehabilitation Act of 1973, as amended by section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978, and 28 CFR part 39. This proposed rule also provides that an exemption will be granted only to those individuals with disabilities who, because of the nature of their disability, cannot demonstrate the required understanding of the English language and knowledge of American history and government.

The section 312(b) disability-exemption is not a blanket waiver from the testing requirements to be granted based solely on evidence of a disability. To interpret section 312(b) as a blanket exemption not only would have the tacit effect of perpetuating the negative stereotype that people with disabilities are unable to participate fully in mainstream activities, but also would be contrary to the requirements of section 504 of the Rehabilitation Act.

All waiver eligibility determinations will be based on individual assessments by civil surgeons or qualified individuals or entities designated by the Attorney General, who determine that the applicant has a disability that renders the individual unable to demonstrate the English proficiency or knowledge required by this part or renders the individual unable, even with reasonable modifications, to participate in the testing procedures for naturalization.

Pursuant to section 504 of the Rehabilitation Act of 1973, the Service will provide reasonable modifications in its testing procedures to enable naturalization applicants who have disabilities to participate in the process. Reasonable modifications may include providing wheelchair-accessible test sites, sign language interpreters, or brailled materials. In addition, modifications may be made in the test format or test administration procedures. An applicant will be deemed unable to participate in the testing procedures only in those situations where there are no reasonable modifications that would enable the applicant to participate.

It will be the responsibility of the disabled person applying for naturalization to provide the documentation necessary to substantiate

the claim for a disability-based exception. The Service has no desire for applicants with disabilities to submit extensive medical reports or medical background information regarding their condition. Since Service officers are not physicians and should not be placed in the position of making a medical determination, the Service is proposing use of civil surgeons for assessing the disability claimed by applicants. In addition, as reflected in the language of the proposed rule, the Service is considering use of qualified individuals or entities designated by the Attorney General to perform such assessments. The designees will review the necessary background medical reports, submitted by the applicant or the applicant's medical specialist. Civil surgeons not experienced in diagnosing developmental disabilities or other cognitive impairments shall be required to consult with professionals who are experienced in diagnosing cognitive impairments prior to making an eligibility determination. If the surgeon or designee is in agreement with the background information and has consulted with the necessary specialist, he or she will issue a one-page certification, verifying the existence of a disability as defined under 8 CFR 312.1(b)(3) and 312.2(b)(1), and attesting to the applicant's inability to participate in the testing procedures required under section 312 of the Act. The Service fully intends to work with the civil surgeons and other qualified individuals or entities in developing guidance and procedures for the preparation of the certification needed by an applicant with a disability for this particular exception.

Request for Comments

The Service is seeking public comments regarding this proposed rule. The Service is interested in public comment on the requirements for medical certifications. The Service also seeks public comment on the use of civil surgeons and on the circumstances under which the Service should consider use of qualified individuals or entities, other than civil surgeons, for disability determinations such as licensed physicians, other health care professionals, or other government or private entities designated by the Attorney General. It should also be noted that the Service is engaged in an additional revision of 8 CFR part 312. That revision will be issued as a proposed rule, also with a request for public comments.

Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by OMB under the Paperwork Reductions Act of 1995 (Pub. L. 104-13). Therefore, the agency solicits public comments on the revised information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

The Service, in calculating the overall burden this requirement will place upon the public, estimates that approximately 300,000 applicants may apply for an exemption from the requirements of section 312. The Service also estimates that it will take each applicant three (3) hours to obtain the necessary attestation for an exemption. This amounts to 900,000 total burden hours.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, the Service has submitted a copy of this proposed rule to OMB for its review of the revised information collection requirements. Other organizations and individuals interested in submitting comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to: Office of Information and Regulatory Affairs (OMB), 725 17th Street, NW, Washington, DC 20503, Attn: DOJ/INS Desk Officer, Room 10235.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it, certifies that the rule will not have a significant economic impact on a substantial number of small entities. This rule has been drafted in a way to minimize the economic impact that it has on small business while meeting its intended objectives.

Executive Order 12866

This rule is considered by the Department of Justice, Immigration and Naturalization Service, to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review. Under Executive Order 12866, section 6(a)(3) (B)-(D), this proposed rule has been submitted to the Office of Management and Budget for review. This rule is mandated by the 1994 Technical Corrections Act in order to afford certain disabled naturalization applicants an exemption from the educational requirements outlined in section 312 of the Immigration and Nationality Act.

Executive Order 12612

The regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 8 CFR Part 312

Citizenship and naturalization, Education.

Accordingly, part 312 of chapter I of title 8 of the Code of Federal Regulations is proposed to be amended as follows:

**PART 312—EDUCATIONAL
REQUIREMENTS FOR
NATURALIZATION**

1. The authority citation for part 312 continues to read as follows:

Authority: 8 U.S.C. 1103, 1423, 1443, 1447, 1448.

2. In § 312.1, paragraph (b)(3) is revised to read as follows:

§ 312.1 Literacy requirements.

* * * * *

(b) * * *

(3) The requirements of paragraph (a) of this section shall not apply to any person who is unable because of physical or developmental disability or mental impairment to demonstrate an understanding of the English language, as noted in paragraph (a) of this section. *Physical disability*, *developmental disability*, and *mental impairment* do not include conditions that are temporary or that have resulted from an individual's illegal drug use.

(i) For the purposes of this paragraph (b)(3), the term:

Developmental disability means an impairment, the onset of which precedes an individual's 18th birthday, that causes an individual to show delayed development of a specific cognitive area of maturation, i.e., reading, language or speech, resulting in intellectual functioning so impaired as to render an individual to be unable to demonstrate an understanding of the English language as required by this section, or that renders the individual unable to fulfill the requirements for English proficiency, even with reasonable modifications.

Mental impairment means a primary impairment of brain function, generally associated with an organic basis upon which the diagnosis is based, resulting in an impairment of intellectual functions such as memory, orientation, or judgment that causes an individual to be unable to demonstrate an understanding of the English language required by this section, or that renders the individual unable to fulfill the requirements for English proficiency, even with reasonable modifications. This definition does not include a mental impairment that is not the result of a physical disorder.

Physical disability means a physical impairment that substantially limits an individual's major life activities in a way that causes that individual to be unable to demonstrate an understanding of the English language required by this section, or that renders the individual unable to fulfill the requirements for English proficiency, even with reasonable modifications.

(ii) [Reserved]

* * * * *

3. Section 312.2 is amended by:

- Revising the last sentence of paragraph (a);

- Redesignating paragraph (b) as paragraph (c) and by

- Adding a new paragraph (b), to read as follows:

§ 312.2 Knowledge of history and government of the United States.

(a) * * * A person who is exempt from the literacy requirement under § 312.1(b) (1) and (2) must still satisfy this requirement.

(b) *Exceptions.* (1) The requirements of paragraph (a) of this section shall not apply to any person who is unable because of physical or developmental disability or mental impairment to demonstrate a knowledge and understanding of the fundamentals of the history, and of the principles and form of government of the United States. *Physical disability*, *developmental disability*, and *mental impairment* do not include conditions that are

temporary, or that have resulted from an individual's illegal drug use.

(i) For the purposes of this paragraph (b)(1), the term:

Developmental disability means an impairment, the onset of which precedes an individual's 18th birthday, that causes an individual to show delayed development of a specific cognitive area of maturation, i.e., reading, language or speech, resulting in intellectual functioning so impaired as to render the individual unable to demonstrate the knowledge required by this section or that renders the individual unable to participate in the testing procedures for naturalization, even with reasonable modifications.

Mental impairment means a primary impairment of brain function, generally associated with an organic basis upon which the diagnosis is based, resulting in an impairment of intellectual functions such as memory, orientation, or judgment that renders the individual unable to demonstrate the knowledge required by this section or that renders the individual unable to participate in the testing procedures for naturalization, even with reasonable modifications. This definition does not include a mental impairment that is not the result of a physical disorder.

Physical disability means a physical impairment that substantially limits an individual's major life activities in a way that renders the individual unable to demonstrate the knowledge required by this section or that renders the individual unable to participate in the testing procedures for naturalization, even with reasonable modifications.

(ii) [Reserved]

(2) *Medical certification.* All persons applying for naturalization and seeking an exemption from the requirements of § 312.1(a) and paragraph (a) of this section based on one of the enumerated disability exceptions must submit a certification from a designated civil surgeon (as defined in 42 CFR 34.2) or qualified individuals or entities designated by the Attorney General, attesting to the origin, nature, and extent of the person's medical condition as it relates to the disability exceptions noted under § 312.1(b)(3) and paragraph (b)(1) of this section. The certification shall be a letter-sized one-page document, signed and dated by the civil surgeon or qualified individuals or entities. The civil surgeon, in particular those not experts in diagnosing developmental disabilities or other cognitive impairments, shall consult with other qualified physicians and psychologists prior to providing a certification, and may require the person seeking a disability-based exception to furnish

evidence from a medical specialist or psychologist to support the person's claim of a qualifying disability. Any additional medical evidence required by a civil surgeon to assist in the evaluation shall only be for the use of the civil surgeon. The additional evidence shall not be attached to the civil surgeon's certification or filed with the applicant's application for naturalization as background or supporting documentation. An affidavit or attestation by the person, his or her relatives, or guardian on his or her medical condition is not a sufficient medical attestation for purposes of satisfying this requirement. The Service may consult with other Federal agencies in making its determination on whether an individual previously determined to be disabled by another Federal agency has a disability as defined in this section. This consultation may be used in lieu of the individual's medical certification.

* * * * *

Dated: August 23, 1996.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 96-22043 Filed 8-26-96; 11:52 am]

BILLING CODE 4410-10-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96-NM-145-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 737-100 and -200 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 737-100 and -200 series airplanes. This proposal would require replacing the aileron (lateral) control transfer mechanism with a new modified mechanism, or reworking the existing mechanism. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions specified by the proposed AD are intended to prevent unexpected, significant control wheel forces and reduced travel of a control wheel due to mechanical interference within the lateral control

system transfer mechanism during a jam override condition.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-145-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Don Kurle, Senior Engineer, Systems and Equipment Branch, ANM-130S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2798; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 96-NM-145-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-145-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania. The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team reviewed the service history and the design of the flight control systems of Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of certain design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Report Received by FAA

The FAA has received a report indicating that mechanical interference can occur within the aileron control transfer mechanism on Model 737 series airplanes. The aileron control transfer mechanism (lateral control system transfer mechanism) enables lateral (roll) control of the airplane to be retained through either the captain's control wheel or the first officer's control wheel in the event that a malfunction restricts motion of the other control wheel or its cable system. When control motion is restricted, the captain's control wheel independently controls the aileron system; the first officer's control wheel independently controls the spoiler system. The aileron or spoiler system can be operated when sufficient force to overcome the

resistance of a preloaded torsion spring in the aileron transfer mechanism is applied to the control wheel.

If mechanical interference occurs within the lateral control system transfer mechanism and one of the control wheels jams, the travel of the operable (non-jammed) control wheel may be limited to ± 100 degrees about the jam position, instead of the intended minimum available travel of ± 138 degrees. Additionally, the control wheel forces that are required to override a jam may be above normal. If the airplane is already banked or at a low altitude, or if the flightcrew does not respond rapidly enough to override the jam, such conditions, if not corrected, could result in an unexpected, significant control upset.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletin 27-1033, dated February 13, 1970, which describes procedures for either replacing the aileron (lateral) control transfer mechanism with a new modified mechanism (specified in the service bulletin as Procedure I), or reworking the existing mechanism (specified in the service bulletin as Procedure II). Accomplishment of the replacement or rework will enable the flightcrew to correct reduced travel of the control wheel or cable system due to a mechanical interference, and will allow increased travel of the operable control wheel in such cases.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require either replacing the aileron control transfer system, transfer mechanism with a new modified mechanism, or reworking the existing mechanism. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Explanation of Proposed Compliance Time

In developing an appropriate compliance time for the proposed actions, the FAA's intent is that it be performed during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. In addition, the FAA considered the availability of necessary parts. The FAA finds that 18 months corresponds

closely to the interval representative of most of the affected operators' normal maintenance schedules. The FAA considers that this interval will provide an acceptable level of safety.

Cost Impact

There are approximately 236 Model 737-100 and -200 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 157 airplanes of U.S. registry would be affected by this proposed AD.

For operators that elect to accomplish the proposed replacement, it would take approximately 20 work hours per airplane to accomplish it, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$15,343 per airplane. Based on these figures, the cost impact of the proposed replacement on U.S. operators is estimated to be \$16,543 per airplane.

For operators that elect to accomplish the proposed rework by using new components, it would take approximately 40 work hours to accomplish it, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$6,500. Based on these figures, the cost impact of the proposed rework (by using new components) on U.S. operators is estimated to be \$8,900 per airplane.

For operators that elect to accomplish the proposed rework by machine shop rework of the components, it would take approximately 70 work hours to accomplish it, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$1,450. Based on these figures, the cost impact of the proposed rework (by machine shop rework of the components) on U.S. operators is estimated to be \$5,650 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1)

is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 96–NM–145–AD.

Applicability: Model 737–100 and –200 series airplanes; as listed in Boeing Service Bulletin 27–1033, dated February 13, 1970; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent an unexpected, significant control upset due to mechanical interference within the lateral control system transfer mechanism, which could result in reduced travel of a control wheel and above normal control wheel forces during a jam override, accomplish the following:

(a) Within 18 months after the effective date of this AD: Accomplish the

requirements of either paragraph (a)(1) or (a)(2) of this AD, in accordance with Boeing Service Bulletin 27–1033, dated February 13, 1970.

(1) Replace the aileron control transfer mechanism, part number (P/N) 65–54200–4 or –5, with a new modified mechanism in accordance with Procedure I of the Accomplishment Instructions of the service bulletin. Or

(2) Rework the existing aileron control transfer mechanism, P/N 65–54200–4 or –5, in accordance with Procedure II of the Accomplishment Instructions of the service bulletin.

(b) As of the effective date of this AD, no person shall install an aileron control transfer mechanism having P/N 65–54200–4 or –5 unless it has been reworked in accordance with the requirements of paragraph (a)(2) of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–21877 Filed 8–23–96; 9:01 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 96–NM–146–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 737 series airplanes. This proposal would require replacement of the flow restrictors of the aileron and elevator power control units (PCU's) with new flow restrictors. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions

specified by the proposed AD are intended to prevent reduced roll and/or pitch rate control of the airplane and consequent increased pilot workload as a result of fragments from a deteriorated flow restrictor filter screen becoming lodged in the PCU.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–146–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Don Kurle, Senior Engineer, Systems and Equipment Branch, ANM–130S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2798; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped

postcard on which the following statement is made: "Comments to Docket Number 96-NM-146-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-146-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania.

The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team reviewed the service history and the design of the flight control systems of Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of certain design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Report Received by FAA

The FAA received a report indicating that, prior to its installation on a Model 737 series airplane, an aileron/elevator power control unit (PCU) failed a functional test for maximum rate capability. Investigation revealed that the PCU was contaminated at the main control valve. The source of this contamination was a filter screen from a flow restrictor. These filter screens were manufactured using a new forming process that results in deterioration of the screens when proof pressure is applied during functional testing.

If the filter screen deteriorates, fragments of the screen could migrate to the main control valve, the damping orifice, or the bypass valve. If a fragment lodges in the main control valve, one of the slides could jam or a control port could be blocked partially. A jammed slide could result in reduced hinge moment of the PCU and reduced rate capability of the elevator or aileron in one direction. A partially blocked control port could result in reduced aileron/spoiler or elevator maximum rate and, consequently, reduction of the airplane pitch or roll rate capability. Lodging of a fragment in the damping orifice could result in blockage of the orifice and consequent small amplitude aileron or elevator limit cycling on the ground.

Jamming of the bypass valve in the power-off (bypass) position could cause one PCU to remain unpowered. The other PCU will continue to function at its full capacity, but the total surface hinge moment and maximum airplane pitch or roll rate capability will be reduced. Subsequent loss of hydraulic power to the other PCU could result in manual reversion control of the elevator or ailerons.

Jamming of the bypass valve in the power-on position would have no effect on the operation of the system as long as both hydraulic systems remain powered. If the hydraulic system that powers the non-contaminated PCU is lost, the effect would be essentially the same as if a bypass valve jams in the bypass condition: one PCU will be unpowered, and the contaminated PCU will continue to function at its full capacity, but the total surface hinge moment and maximum airplane pitch or roll rate capability will be reduced. If the hydraulic system that powers the contaminated PCU is lost, the other PCU will continue to function at its full capacity. However, the maximum aileron/spoiler or elevator maximum rate would be reduced and, consequently, pitch or roll rate would be reduced because the contaminated PCU will not go into bypass mode.

Reduced roll and/or pitch rate control of the aileron could result in increased pilot workload.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Letter 737-SL-27-71-A, dated June 19, 1992, including Attachment 1, which describes procedures for replacement of the four flow restrictors, part number (P/N) JETA1875500D, on the aileron and elevator PCU's, P/N 65-45180-29, serial numbers 182 through 1297 inclusive,

with flow restrictors having P/N JETX0527100B.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require replacement of the flow restrictors of the aileron and elevator power control units (PCU's) with new flow restrictors. The actions would be required to be accomplished in accordance with the service letter described previously.

Explanation of Proposed Compliance Time

In developing an appropriate compliance time for the proposed replacement, the FAA's intent is that it be performed during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. In addition, the FAA considered the availability of necessary parts. The FAA finds that 18 months corresponds closely to the interval representative of most of the affected operators' normal maintenance schedules. The FAA considers that this interval will provide an acceptable level of safety.

Cost Impact

There are approximately 244 Model 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 146 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 12 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$2,960 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$537,280, or \$3,680 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore,

in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 96–NM–146–AD.

Applicability: Model 737 series airplanes equipped with an aileron or elevator power control unit (PCU) having part number (P/N) 65–45180–29, serial numbers 182 through 1297 inclusive; certificated in any category.

Note 1: Originally, aileron or elevator PCU's having P/N's and serial numbers identified in the applicability of this AD may have been installed on Model 737 series airplanes having line numbers 1793 through 2036 inclusive. In addition, some of these PCU's may have been used as spares; therefore, specific airplane line numbers equipped with such PCU's cannot be provided in this AD.

Note 2: PCU's having P/N 65–45180–29 consist of a PCU assembly having P/N 65–44761–21 plus associated hydraulic fittings. Both PCU P/N's 65–45180–29 and 65–44761–21 are serialized. PCU's subject to the requirements of this AD may be more easily identified using serial numbers for P/N 65–44761–21. The following serial numbers correspond to P/N 65–44761–21:

8549A,
8550A,
8552A,
8556A,
8557A,
8561A,
8563A through 8718A inclusive,
8720A through 8726A inclusive,
8728A through 8745A inclusive,
8749A,
8750A through 8758A inclusive,
8760A through 8873A inclusive,
8876A through 9004A inclusive,
9007A through 9012A inclusive,
9014A through 9040A inclusive,
9042A through 9066A inclusive,
9068A through 9340A inclusive,
9342A through 9388A inclusive,
9390A through 9529A inclusive,
9531A through 9676A inclusive, and
9678A through 9688A inclusive.

Note 3: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced roll and/or pitch rate control of the aileron and consequent increased pilot workload, accomplish the following:

(a) Within 18 months after the effective date of this AD, replace the four flow restrictors, part number (P/N) JETA1875500D, on the aileron and elevator power control units (PCU's), P/N 65–45180–29, serial numbers 182 through 1297 inclusive, with flow restrictors having P/N JETX0527100B, in accordance with Boeing Service Letter 737–SL–27–71–A, dated June 19, 1992, including Attachment 1.

(b) As of the effective date of this AD, no person shall install a flow restrictor having P/N JETA1875500D on an aileron or elevator PCU having P/N 65–45180–29, serial numbers 182 through 1297 inclusive, of any airplane.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR

21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 96–21878 Filed 8–23–96; 9:01 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 96–NM–147–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–100, –200, –300, –400, and –500 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Boeing Model 737–100, –200, –300, –400, and –500 series airplanes. This proposal would require operational tests of the standby rudder power control unit (PCU) to ensure correct operation of the rudder, and correction of any discrepancy found; and repetitive inspections to detect galling on the input shaft and bearing of the standby PCU, and replacement of the standby rudder actuator with a serviceable actuator, if necessary. This proposal also would require eventual replacement of the input bearing of the standby PCU with an improved bearing, which constitutes terminating action for the inspections to detect galling. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions specified by the proposed AD are intended to prevent corrosion of the servo valve and bypass valve sleeves of the standby PCU, and galling on the input shaft and bearing of the standby PCU, which could result in uncommanded movement of the rudder or increased pedal forces. These conditions, if not corrected, could result in reduced controllability of the airplane.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96–NM–147–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this

location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Kenneth W. Frey, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2673; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 96-NM-147-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-147-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design

Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania. The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team analyzed conclusions from previous reviews and analyses of the design of the flight control systems on Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of any design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Reports Received by FAA

The FAA received a report indicating that significant corrosion was found on the outer diameter and radial passages of both the servo valve and bypass valve sleeves of the standby rudder power control unit (PCU). Although the bypass valve was functional, the servo valve was seized, and the input ball of the input shaft was sheared. The slides removed from these valves also exhibited heavy corrosion deposits on the outer diameter surfaces and gray/black hydraulic fluid stains within the standby PCU. In addition, water was found in the PCU. The corrosion has been attributed to high moisture content in the standby PCU, which may have condensed in the PCU prior to installation and was not flushed out by hydraulic fluid cycling. Investigation of the fracture surface indicated that the fracture of the ball of the input shaft was caused by stress corrosion cracking. When the standby rudder system is powered, and the servo valve of the standby PCU is jammed in an off neutral position, uncommanded movement of the rudder could occur.

The FAA also received reports of galling on the input shaft and bearing of

the standby rudder PCU. Galling is defined as fretting or chafing of a mating surface by sliding contact with another surface or body. The friction between the sliding surfaces causes the material from one surface to be welded or deposited onto the other surface, which ultimately destroys the surface area, and forces an uncommanded motion of the rudder. In response to these reports, the airplane manufacturer increased the clearance between the input shaft and bearing. However, this change did not eliminate the galling condition. Further, some reported incidents of uncommanded yaw were traced to galling on the input shaft and bearing. Galling on the input shaft and bearing of the standby rudder PCU could result in increased rudder pedal forces and erratic operation of the yaw damper.

Uncommanded movement of the rudder due to corrosion of the servo valve and bypass valve sleeves of the standby rudder PCU, or increased rudder pedal forces and uncommanded motion of the rudder, due to galling on the input shaft and bearing of the standby PCU; if not corrected, could result in reduced controllability of the airplane.

FAA's Findings

In light of this information, the FAA finds that certain procedures and corrective actions must be accomplished to ensure correct operation of the rudder when the standby hydraulic system is powered, and to detect galling on the input shaft and bearing of the standby rudder PCU. In addition, the FAA finds that the input bearing of the standby PCU must be replaced eventually with an improved bearing. The FAA has determined that these actions are necessary to ensure the safety of the affected fleet.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Letter 737-SL-27-103, dated October 13, 1995, which describes procedures for repetitive operational tests to cycle hydraulic fluid through the standby rudder PCU and to ensure correct operation of the rudder when the standby hydraulic system is powered, and correction of any discrepancy found. Cycling of fluid through the standby rudder PCU will minimize the possibility of moisture collection and corrosion within the unit.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would

require repetitive operational tests to cycle hydraulic fluid through the standby rudder PCU and to ensure correct operation of the rudder when the standby hydraulic system is powered, and correction of any discrepancy found. The operational tests and correction of discrepancies would be required to be accomplished in accordance with the service letter described previously.

Additionally, the proposed AD would require repetitive inspections to detect galling on the input shaft of the standby rudder PCU, and replacement of the standby rudder actuator with a serviceable actuator, if necessary. The actions would be required to be accomplished in accordance with certain procedures specified in this proposed AD.

The proposed AD also would require eventual replacement of the input bearing of the standby rudder PCU with an improved bearing. Accomplishment of the replacement constitutes terminating action for the repetitive inspections to detect galling on the input shaft of the standby rudder PCU. The replacement would be required to be accomplished in accordance with a method approved by the FAA.

Explanation of Proposed Compliance Times

In developing an appropriate compliance time for the proposed operational tests, the FAA's intent is that the actions be performed during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. The FAA has determined that an interval of 250 hours time-in-service corresponds closely to the interval representative of most of the affected operators' regularly scheduled "A" checks. The FAA considers that this interval represents an interval in which the tests can be accomplished in a timely manner within the fleet and still maintain an adequate level of safety.

Similarly, in developing an appropriate compliance time for the proposed inspections to detect galling, the FAA's intent is that the inspections be accomplished during a regularly scheduled "C" check of the airplane. In addition, the FAA considered the availability of replacement standby rudder actuators that may be needed if galling is detected. The FAA finds that an interval of 3,000 hours time-in-service correlates with that representative of normal maintenance schedules and will provide an acceptable level of safety.

Cost Impact

There are approximately 2,830 Model 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,037 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 1 work hour per airplane to accomplish the proposed operational tests, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the proposed operational tests on U.S. operators is estimated to be \$62,220, or \$60 per airplane, per test cycle.

The FAA estimates that it would take approximately 2 work hours per airplane to accomplish the proposed inspections, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the proposed inspections on U.S. operators is estimated to be \$124,440, or \$60 per airplane, per inspection cycle.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

The FAA currently has no specific cost estimates associated with the proposed replacement of the input bearing, since the improved bearing has not been developed yet. The proposed compliance time of 3 years for this replacement should allow the time necessary for design of an acceptable replacement part, and should coincide with normal maintenance schedules, thereby minimizing the costs and schedule impact of such a change on operators. As indicated earlier in this preamble, the FAA specifically invites the submission of comments and other data regarding this economic aspect of the proposal.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44

FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 96–NM–147–AD.

Applicability: All Model 737–100, –200, –300, –400, and –500 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent uncommanded movement of the rudder or increased rudder pedal forces, and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 250 hours time-in-service after the effective date of this AD, and thereafter at intervals not to exceed 250 hours time-in-service: Perform an operational test to cycle hydraulic fluid through the standby rudder power control unit (PCU) and to ensure correct operation of the rudder when the standby hydraulic system is powered, in accordance with Boeing Service Letter 737–SL–27–103, dated October 13, 1995. Prior to

further flight, correct any discrepancy that is found, in accordance with the service letter.

(b) Within 3,000 hours time-in-service after the effective date of this AD, and thereafter at intervals not to exceed 3,000 hours time-in-service: Perform an inspection to detect galling on the input shaft and bearing of the standby rudder PCU by accomplishing paragraphs (b)(1) through (b)(10) of this AD.

(1) Shut off all hydraulic power.

(2) Gain access to the standby rudder actuator.

(3) Disconnect the input rod from the standby actuator.

(4) Using a push/pull spring scale (minimum +/- 10% accuracy at 1.0 pound; preferably one having a peak load memory function), push on the standby rudder actuator input lever with sufficient force to move the lever from the neutral position up to, but not touching, the aft stop. The scale must be contacting the input lever at approximately the clevis bolt centerline. While applying the load required to move the lever, the scale must be maintained at an angle perpendicular to the lever arm (not to exceed 20 degrees from perpendicular). The force required to move the input lever throughout this range of motion must not exceed one pound.

(5) Repeat the test specified in paragraph (b)(4) of this AD, moving the lever arm from the aft stop position up to the forward stop, but not touching. The force required to move the input lever throughout this range of motion must not exceed one pound.

(6) Repeat the test specified in paragraph (b)(4) of this AD, moving the lever arm from the forward stop position back to the neutral position. The force required to move the input lever throughout this range of motion must not exceed one pound.

(7) If the actuator force encountered during any of the procedures required by paragraph (b)(4), (b)(5), or (b)(6) of this AD exceeds one pound, prior to further flight, replace the standby rudder actuator with a serviceable actuator, and test the standby rudder actuator in accordance with the procedure specified in paragraph (b)(9) of this AD.

(8) If the actuator force encountered during any of the procedures required by paragraph (b)(4), (b)(5), or (b)(6) of this AD is one pound or less, prior to further flight, reconnect the input rod to the standby rudder actuator, and test the standby rudder actuator in accordance with the procedure specified in paragraph (b)(9) of this AD.

(9) Perform a functional test of the standby rudder actuator in accordance with Maintenance Manual 737-100/-200, Chapter 27-21-141, removal/installation (for Model 737-100 and -200 series airplanes); or maintenance Manual 737-300/-400/-500, Chapter 27-21-24, removal/installation (for Model 737-300, -400, and -500 series airplanes).

(10) Restore the airplane to its normal condition.

(c) Within 3 years after the effective date of this AD, replace the input bearing of the standby rudder PCU with an improved bearing in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Accomplishment of the replacement terminates the repetitive inspections required by paragraph (b) of this AD.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 96-21879 Filed 8-23-96; 9:01am]

BILLING CODE 4910-13-U

14 CFR Part 39

[Docket No. 96-NM-148-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 737-300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 737-300 series airplanes. This proposal would require an inspection to detect fatigue cracking, base trim, and upper flange over-trim of the pulley brackets of the aileron control cables. It also would require, if necessary, replacement of the pulley brackets with new pulley brackets, and replacement of the two button-head rivets with flush-head rivets. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions specified by the proposed AD are intended to prevent fatigue cracking or fracturing of the pulley brackets, which could result in slack in the cables and consequent reduced ability of the flightcrew to control the aileron.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-148-AD, 1601 Lind Avenue, SW.,

Renton, Washington 98055-4056.

Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Don Kurle, Senior Engineer, Systems and Equipment Branch, ANM-130S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2798; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 96-NM-148-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-148-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania. The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team reviewed the service history and the design of the flight control systems of Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of certain design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Report Received by FAA

The FAA has received a report indicating that some pulley brackets of the aileron control cables were trimmed to clear adjacent structure when the brackets were installed on the airplane during manufacture. In this case, the fatigue life of the pulley brackets can be compromised and the pulley brackets could crack or fracture. Fatigue cracking or fracturing of the pulley brackets, if not detected and corrected in a timely manner, could result in slack in the cables and consequent reduced ability of the flightcrew to control the aileron.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletin 737-27-1154, dated August 25, 1988, which describes procedures for a visual inspection to detect fatigue cracking, base trim, and upper flange over-trim of the pulley brackets of the aileron control cables. It also describes procedures for replacing the pulley brackets with new pulley brackets, and replacing the two button-head rivets with flush-head rivets, if

necessary. Installation of flush-head rivets will prevent interference between the pulley brackets and the adjacent structure.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require a visual inspection to detect fatigue cracking, base trim, and upper flange over-trim of the pulley brackets of the aileron control cables. It also would require, if necessary, replacement of the pulley brackets with new pulley brackets, and replacement of the two button-head rivets with flush-head rivets. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Explanation of Proposed Compliance Time

In developing an appropriate compliance time for the proposed inspection, the FAA's intent is that it be performed during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. In addition, the FAA considered the availability of replacement pulley brackets and rivets that may be needed if fatigue cracking, base trim, or upper flange over-trim is detected. The FAA finds that 18 months corresponds closely to the interval representative of most of the affected operators' normal maintenance schedules. The FAA considers that this interval will provide an acceptable level of safety.

Cost Impact

There are approximately 262 Model 737-300 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 169 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed inspection, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$10,140, or \$60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Should an operator be required to accomplish the necessary replacement of pulley brackets and rivets, it would

take approximately 15 work hours per airplane to accomplish those actions, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$713 per airplane. Based on these figures, the cost impact of any necessary replacement action is estimated to be \$1,613 per airplane.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing; Docket 96-NM-148-AD.

Applicability: Model 737-300 series airplanes; as listed in Boeing Service Bulletin 737-27-1154, dated August 25, 1988; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue cracking or fracturing of the pulley brackets, which could result in slack in the cables and consequent reduced ability of the flightcrew to control the aileron, accomplish the following:

(a) Within 18 months after the effective date of this AD: Perform a visual inspection to detect fatigue cracking, base trim, or upper flange over-trim of the pulley brackets, part number (P/N) 65C25555-3, 65C25555-501, or 69-73479-1, of the aileron control cables, in accordance with Boeing Service Bulletin 737-27-1154, dated August 25, 1988.

(b) If any cracking or over-trim of the pulley brackets is detected: Prior to further flight, replace the pulley brackets with new pulley brackets; and replace the two existing button-head rivets with flush-head rivets; in accordance with Boeing Service Bulletin 737-27-1154, dated August 25, 1988.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 96-21880 Filed 8-23-96; 9:01 am]

BILLING CODE 4910-13-U

14 CFR Part 39

[Docket No. 96-NM-149-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 737 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Boeing Model 737 series airplanes. This proposal would require revising the FAA-approved maintenance program to prohibit the use of pressure washing within the wheel well or on the landing gear and to prohibit the use of pumps and/or nozzles for washing wheel wells or the landing gear. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions specified by the proposed AD are intended to prevent corrosion of certain equipment due to the use of inappropriate pressure washing techniques. Corrosion of bearings, cables, electrical connectors, or other equipment in the main wheel well, if not detected and corrected in a timely manner, could result in reduced controllability of the airplane.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-149-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: David Herron, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2672; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the

proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 96-NM-149-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-149-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania. The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team reviewed the service history and the design of the

flight control systems of Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of certain design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Reports Received by FAA

The FAA has received reports indicating that inappropriate pressure washing techniques, such as the use of high pressure washing, have been used to clean equipment within the wheel wells of Model 737 series airplanes. High pressure washing of the bearings, cables, electrical connectors, and other equipment in the main wheel well can result in fluids (or additives in the fluids) being forced into these areas. Retention of fluid in these areas can result in the development of corrosion. Corrosion of bearings, cables, electrical connectors, or other equipment in the main wheel well, if not detected and corrected in a timely manner, could result in reduced controllability of the airplane.

FAA's Findings

The FAA finds that Model 737 series airplanes were not designed to withstand high pressure washing of the wheel wells and landing gears. The FAA concludes that these airplanes were designed to operate with contaminate buildup in the wheel wells and landing gears. In light of this, the FAA has determined that the FAA-approved maintenance program must be revised to prohibit the use of pressure washing within the wheel well or on the landing gear. Pressure washing is defined as the use of any fluid under pressure greater than 80 pounds per square inch, gauge (psig). The FAA also finds that the use of pumps and/or nozzles must be prohibited, since such use results in pressure greater than 80 psig.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require revising the FAA-approved maintenance program to prohibit the use of pressure washing within the wheel well or on the landing gear and to prohibit the use of pumps and/or nozzles for washing wheel wells or the landing gear.

Cost Impact

There are approximately 2,463 Model 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,040 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 5 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$312,000, or \$300 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 96–NM–149–AD.

Applicability: All Model 737 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent corrosion in the bearings, cables, electrical connectors, or other equipment in the main wheel well, which could result in reduced controllability of the airplane, accomplish the following:

(a) Within 90 days after the effective date of this AD, incorporate a revision into the FAA-approved maintenance program that prohibits the use of pressure washing within the wheel well or on the landing gear, and that prohibits the use of pumps and/or nozzles for washing wheel wells or the landing gear. Pressure washing is defined as the use of any fluid under pressure greater than 80 pounds per square inch, gauge (psig).

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,
Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 96–21881 Filed 8–23–96; 9:02 am]

BILLING CODE 4910-13-U

14 CFR Part 39**[Docket No. 96-NM-150-AD]****RIN 2120-AA64****Airworthiness Directives; Boeing Model 737-100, -200, -300, -400, and -500 Series Airplanes****AGENCY:** Federal Aviation Administration, DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Boeing Model 737-100, -200, -300, -400, and -500 series airplanes. This proposal would require an inspection of the aileron/elevator power control units (PCU's) and the rudder PCU to determine if reworked PCU manifold cylinder bores containing chrome plating are installed, and replacement of the cylinder bores with bores that have been reworked using the oversize method or the steel sleeve method, if necessary. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions specified by the proposed AD are intended to prevent a reduced rate of movement of the elevator, aileron, or rudder due to contamination of hydraulic fluid from chrome plating chips; such reduced rate of movement, if not corrected, could result in reduced controllability of the airplane.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-150-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Don Kurlle, Senior Engineer, Systems and Equipment Branch, ANM-130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (206) 227-2798; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION:**Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 96-NM-150-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-150-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania. The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team reviewed the service history and the design of the flight control systems of Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of certain design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Reports Received by FAA

The FAA has received reports indicating that the chrome plating separated from reworked cylinder bores of the aileron/elevator power control units (PCU's). Investigation revealed that a number of aileron/elevator and rudder PCU's were repaired using chrome plating on the aluminum cylinder bores. Separation of the chrome plating has occurred on several of these repaired units, which can result in contamination of hydraulic fluid from chrome plating chips. Such contamination could result in blocked or jammed valves in the rudder PCU, which could result in reduced movement capability of the rudder or partial or total deflection of the rudder. In addition, such contamination could result in scored piston seals or cylinder bores and consequent reduced performance of the aileron/elevator PCU's. A reduced rate of movement of the elevator, aileron, or rudder, if not corrected, could result in reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Letter 737-SL-27-30, dated April 1, 1985, which describes procedures for an inspection of the aileron/elevator PCU's and the rudder PCU to determine if reworked PCU manifold cylinder bores containing chrome plating are installed, and replacement of the cylinder bores with bores that have been reworked using the oversize method or the steel sleeve method, if necessary.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require an inspection of the aileron/elevator PCU's and the rudder PCU to determine if reworked PCU manifold

cylinder bores containing chrome plating are installed, and replacement of the cylinder bores with bores that have been reworked using the oversize method or the steel sleeve method, if necessary. The actions would be required to be accomplished in accordance with the service letter described previously.

Explanation of Proposed Compliance Time

In developing an appropriate compliance time for the proposed actions, the FAA's intent is that they be performed during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. In addition, the FAA considered the availability of necessary parts. In light of these considerations, the FAA has specified a compliance time of 18 months for accomplishment of the proposed inspection. The FAA finds that 18 months corresponds closely to the interval representative of most of the affected operators' normal maintenance schedules. The FAA considers that the proposed compliance time will provide an acceptable level of safety.

Cost Impact

There are approximately 2,675 Model 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,091 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 5 work hours per airplane to accomplish the proposed inspection, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$327,300, or \$300 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Should an operator be required to accomplish the necessary replacement, it would take approximately 18 work hours per airplane to accomplish, at an average labor rate of \$60 per work hour. Required parts will cost approximately \$15,800 per airplane. Based on these figures, the cost impact of any necessary replacement action is estimated to be \$16,880 per airplane.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 96-NM-150-AD.

Applicability: All Model 737-100, -200, -300, -400, and -500 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in

accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent a reduced rate of movement of the elevator, aileron, or rudder, which, if not corrected, could result in reduced controllability of the airplane, accomplish the following:

(a) Within 18 months after the effective date of this AD: Perform an inspection of the aileron and elevator PCU's, part number (P/N) 65-44761-(), and the rudder PCU, P/N 65-44681-(), to determine if reworked PCU manifold cylinder bores containing chrome plating are installed, in accordance with Boeing Service Letter 737-SL-27-30, dated April 1, 1985.

(b) If any reworked PCU manifold cylinder bores containing chrome plating are installed: Prior to further flight, replace the cylinder bores with bores that have been reworked using the oversize method or the steel sleeve method specified in Boeing Service Letter 737-SL-27-30, dated April 1, 1985. Accomplish the replacement in accordance with the service letter.

(c) As of the effective date of this AD, no person shall install a reworked PCU manifold cylinder bore containing chrome plating on an aileron or elevator PCU having P/N 65-44761-(), or on a rudder PCU having P/N 65-44681-(), of any airplane unless the cylinder bore has been reworked using the oversize method or the steel sleeve method specified in Boeing Service Letter 737-SL-27-30, dated April 1, 1985.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 96-21882 Filed 8-23-96; 9:02 am]

BILLING CODE 4910-13-U

14 CFR Part 39**[Docket No. 96-NM-151-AD]****RIN 2120-AA64****Airworthiness Directives; Boeing Model 737-100, -200, -300, -400, and -500 Series Airplanes****AGENCY:** Federal Aviation Administration, DOT.**ACTION:** Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Boeing Model 737-100, -200, -300, -400, and -500 series airplanes. This proposal would require repetitive tests to verify the integrity of the yaw damper coupler, and various follow-on actions. This proposal also would require a one-time inspection to determine the part number of the engage solenoid valve of the yaw damper, and replacement of the valve with a valve having a different part number, if necessary. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions specified by the proposed AD are intended to prevent sudden uncommanded yawing of the airplane due to potential failures within the yaw damper system, and consequent injury to passengers and crewmembers.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-151-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Commercial Flight Systems Group, Air Transport Systems Division, Honeywell Inc., Box 21111, Phoenix, Arizona 85036; and Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Hania Younis, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2764; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION:**Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 96-NM-151-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-151-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania. The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team reviewed the service history and the design of the flight control systems of Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of certain design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Reports Received by FAA

The FAA has received a number of reports of uncommanded yawing of Boeing Model 737 series airplanes. This condition may have been caused by one of two separate failures of the yaw damper system:

First, the rate gyroscope of the yaw damper coupler can fail as a result of wear of the rotor bearing. Such wear can cause increased vibration, which may be translated into brinnels (dents) in the gimbal bearings. This condition can cause faults in the gyroscope at certain input rates and consequent rudder kicks to the yaw damper authority.

Second, intermittent failures of the engage solenoid valve of the yaw damper on the rudder power control units (PCU's) could occur. Valves having certain part numbers have encapsulated electrical coils (i.e., the coils are coated with a thermoset epoxy moulding compound or similar material), which makes the valves less susceptible to damage and exposure to moisture. Corrosion could occur if the coils are exposed to moisture. Corrosion or damage of the coils could result in abrupt uncommanded rudder deflections.

These conditions, if not corrected, could result in sudden uncommanded yawing of the airplane and consequent injury to passengers and crewmembers.

FAA's Determinations

In light of this information, the FAA finds that certain procedures must be required to ensure the safety of the affected fleet. These procedures include tests to verify the integrity of the yaw damper coupler, and various follow-on actions (including tests to verify the integrity of the rate gyroscope of the yaw damper coupler; and removal, overhaul, replacement, repair, and reinstallation of the rate gyroscope), as necessary. The FAA has reviewed the procedures for accomplishment of these actions, which are contained in the documents described below:

1. Honeywell Component Maintenance Manual (CMM) 22-10-27, Revision 6, dated September 1, 1992. The CMM describes procedures for repetitive tests to verify the integrity of the yaw damper coupler; repair of the yaw damper coupler, if necessary; removal and reinstallation of the rate gyroscope of the yaw damper coupler; replacement of the rate gyroscope with a new part; and replacement of the yaw damper coupler with a new or serviceable coupler.

2. Sperry Overhaul Manual 24-09-20, RG1000 Miniature Rate Gyroscope, Part No. 2589124-902." The overhaul manual describes procedures for overhauling the rate gyroscope of the yaw damper coupler.

3. Honeywell Engineering Specification No. IT2589124, "Integrated Test Specification for Rate Gyroscope, Part Number 2589124-902," dated October 9, 1992. This document describes procedures for tests to verify the integrity of the rate gyroscope of the yaw damper coupler.

Additionally, the Boeing 737 Overhaul Manual specifies procedures for a one-time inspection of the engage solenoid valve of the yaw damper to determine the part number of the valve, and replacement of the valve with a valve having a different part number. The FAA finds that the accomplishment of these actions will adequately address intermittent failures of the engage solenoid valve. [Operators should note that Boeing In-Service Activities Report 95-03-2725-10, dated February 16, 1995 (for Model 737-100 and -200 series airplanes), or 95-04-2725-10, dated February 24, 1995 (for Model 737-300, -400, and -500 series airplanes), provide additional information concerning interchangeability of solenoid valve part numbers.]

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require repetitive tests to verify the integrity of the yaw damper coupler, and various follow-on actions. These actions would be required to be accomplished in accordance with the Honeywell CMM, the Honeywell engineering specification document, and the Sperry overhaul manual described previously.

The proposed AD also would require a one-time inspection to determine the part number of the engage solenoid valve of the yaw damper, and replacement of the valve with a valve having a different part number, if

necessary. These actions would be required to be accomplished in accordance with the Boeing 737 Overhaul Manual discussed previously.

Explanation of Proposed Compliance Times

In developing appropriate compliance times for the proposed actions, the FAA's intent is that they be performed during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. In addition, the FAA considered the availability of necessary parts. In light of these considerations, the FAA has specified compliance times of 3,000 hours time-in-service for accomplishment of the initial tests (and 6,000 hours time-in-service for the repetitive tests), and 18 months for accomplishment of the one-time inspection. The FAA finds that these intervals correspond closely to the intervals representative of most of the affected operators' normal maintenance schedules. The FAA considers that the proposed compliance times will provide an acceptable level of safety.

Interim Action

This proposed AD is considered to be interim action. The manufacturer has advised that it currently is developing a modification that will positively address the unsafe condition addressed by this AD. Once this modification is developed, approved, and available, the FAA may consider additional rulemaking.

Cost Impact

There are approximately 2,675 Model 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,091 airplanes of U.S. registry would be affected by this proposed AD.

The FAA estimates that it would take approximately 4 work hours per airplane to accomplish the proposed tests of the yaw damper coupler, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the proposed tests on U.S. operators is estimated to be \$261,840, or \$240 per airplane, per test.

The FAA estimates that it would take approximately 1 work hour per airplane to accomplish the proposed one-time inspection of the engage solenoid valve, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the proposed inspection on U.S. operators is estimated to be \$65,460, or \$60 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Should an operator be required to replace an engage solenoid valve of the yaw damper, it would take approximately 3 work hours to accomplish the replacement, at an average labor rate of \$60 per work hour. Required parts would cost approximately \$1,688 per airplane. Based on these figures, the cost impact of any necessary replacement of an engage solenoid valve is estimated to be \$1,868 per airplane.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 96-NM-151-AD.

Applicability: All Model 737-100, -200, -300, -400, and -500 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent sudden uncommanded yawing of the airplane due to potential failures within the yaw damper system, and consequent injury to passengers and crewmembers, accomplish the following:

(a) Within 3,000 hours time-in-service after the effective date of this AD, and thereafter at intervals not to exceed 6,000 hours time-in-service: Perform tests to verify the integrity of the yaw damper coupler, in accordance with procedures specified in the Honeywell Component Maintenance Manual 22-10-27, Revision 6, dated September 1, 1992.

(1) If the yaw damper coupler passes the tests, prior to further flight, remove the rate gyroscope in accordance with Section 4E, page 103, of the Honeywell Component Maintenance Manual; and perform tests to verify the integrity of the rate gyroscope, in accordance with procedures specified in Honeywell Engineering Specification No. IT2589124, "Integrated Test Specification for Rate Gyroscope, Part Number 2589124-902," dated October 9, 1992.

(i) If the rate gyroscope passes the tests, reinstall the rate gyroscope in accordance with Section 3F, page 504, of the Honeywell Component Maintenance Manual.

(ii) If the rate gyroscope fails the tests, prior to further flight, accomplish either paragraph (a)(1)(ii)(A) or (a)(1)(ii)(B) of this AD.

(A) Overhaul the rate gyroscope in accordance with Sperry Overhaul Manual 24-09-20, "RG1000 Miniature Rate Gyroscope, Part No. 2589124-902," and reinstall the rate gyroscope in accordance with Section 3F, page 504, of the Honeywell Component Maintenance Manual. Or

(B) Replace the rate gyroscope with a new part in accordance with Section 3F, page 504, of the Honeywell Component Maintenance Manual.

(2) If the yaw damper coupler fails the tests, prior to further flight, accomplish either paragraph (a)(2)(i) or (a)(2)(ii) of this AD.

(i) Repair the coupler in accordance with the Honeywell Component Maintenance Manual, and perform tests specified in

paragraph (a)(1) of this AD to verify the integrity of the rate gyroscope. Or

(ii) Replace the coupler with a new coupler, or with a serviceable coupler on which the integrity of the rate gyroscope has been verified in accordance with paragraph (a)(1) of this AD. Accomplish the replacement in accordance with procedures specified in the Honeywell Component Maintenance Manual.

(b) Within 18 months after the effective date of this AD: Perform a one-time inspection of the engage solenoid valve of the yaw damper to determine the P/N of the valve. If any valve having P/N 10-60881-1, -3, or -9 is installed, prior to further flight, replace it with a valve having P/N 10-60881-8 or -13. Accomplish the actions in accordance with Chapter 27-20-01 of the Boeing 737 Overhaul Manual.

Note 2: Boeing In-Service Activities Report 95-03-2725-10, dated February 16, 1995 (for Model 737-100 and -200 series airplanes), or 95-04-2725-10, dated February 24, 1995 (for Model 737-300, -400, and -500 series airplanes), provide additional information concerning interchangeability of solenoid valve part numbers.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96-21883 Filed 8-23-96; 9:03 am]

BILLING CODE 4910-13-U

14 CFR Part 39

[Docket No. 96-NM-152-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 737-100 and -200 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Boeing Model 737-100 and -200 series

airplanes. This proposal would require replacement of certain outboard and inboard wheel halves with improved wheel halves. This proposal also would require cleaning and inspecting certain outboard and inboard wheel halves for corrosion, missing paint in large areas, and cracks; and repair or replacement of the wheel halves with serviceable wheel halves, if necessary. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions specified by the proposed AD are intended to prevent failure of the wheel flanges, which could result in failure of the hydraulics systems, jammed flight controls, loss of electrical power, or other combinations of failures; and consequent reduced controllability of the airplane.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-152-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Allied Signal Aerospace Company, Bendix Wheels and Brakes Division, South Bend, Indiana 46624; and Bendix, Aircraft Brake and Strut Division, 3520 West Mestmoor Street, South Bend, Indiana 46624. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: David Herron, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (206) 227-2672; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 96-NM-152-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-152-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania. The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team reviewed the service history and the design of the flight control systems of Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of certain design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Reports Received by FAA

The FAA received a report indicating that failure of the wheel flanges can result in metallic debris impacting the hydraulics systems and other critical elements associated with control of the airplane that are within the proximity of the wheel. Such impact can result in failure of the hydraulics systems, jammed flight controls, loss of electrical power, or other combinations of failures. These conditions, if not corrected, could result in reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Bendix Service Information Letter (SIL) 392, Revision 1, dated November 15, 1979, which describes procedures for replacement of any outboard wheel half having serial number (S/N) H-999 and lower with an outboard wheel half having part number (P/N) 2607047; and replacement of any inboard wheel half having S/N H-1799 and lower with a wheel half having P/N 2607046. These replacements must be accomplished on airplanes equipped with a Bendix main wheel assembly having part number (P/N) 2601571-1, S/N B-5999 and lower. The improved wheel halves incorporate additional material that will ensure greater tolerance for corrosion and handling damage of the wheel.

The FAA also has reviewed and approved Allied Signal Service Bulletin No. 737-32-026, dated April 26, 1988, including Attachments 1 and 2. The service bulletin describes procedures for cleaning any outboard wheel half having P/N 2601454, S/N H0001 through H1049 inclusive, and any inboard wheel half having P/N 2601567, S/N H0001 through H1799 inclusive; inspecting the wheel halves for corrosion or missing paint in large areas, stripping or removing any paint, and removing any corrosion; and performing an eddy current inspection for cracks. These actions must be accomplished on airplanes equipped with a Bendix main wheel assembly having P/N 2601571, S/N B0001 through B5999 inclusive.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require replacement of certain outboard and inboard wheel halves with improved wheel halves. The proposed AD also would require cleaning and inspecting certain outboard and inboard wheel halves for corrosion, missing paint in large areas, and cracks; and

repair or replacement of the wheel halves with serviceable wheel halves, if necessary. Replacement of inboard and outboard wheel halves would be required to be accomplished in accordance with the SIL described previously. The cleaning and inspection would be required to be accomplished in accordance with the service bulletin described previously.

Explanation of Proposed Compliance Time

In developing an appropriate compliance time for the proposed actions, the FAA's intent is that it be performed during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. In addition, the FAA considered the availability of necessary parts. The FAA finds that 180 days corresponds closely to the interval representative of most of the affected operators' normal maintenance schedules. The FAA considers that this interval will provide an acceptable level of safety.

Cost Impact

There are approximately 634 Model 737-100 and -200 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 241 airplanes of U.S. registry would be affected by this proposed AD.

The FAA estimates that it would take approximately 4 work hours per airplane to accomplish the proposed replacement of wheel halves, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$20,212 per airplane. Based on these figures, the cost impact of the proposed replacement on U.S. operators is estimated to be \$4,928,932, or \$20,452 per airplane.

The FAA also estimates that it would take approximately 2 work hours per airplane to accomplish the proposed cleaning and inspection, and that the average labor rate is \$60 per work hour. Based on these figures, the cost impact of the proposed cleaning and inspection on U.S. operators is estimated to be \$28,920, or \$120 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

The FAA recognizes that the obligation to maintain aircraft in an airworthy condition is vital, but sometimes expensive. Because AD's require specific actions to address

specific unsafe conditions, they appear to impose costs that would not otherwise be borne by operators. However, because of the general obligation of operators to maintain aircraft in an airworthy condition, this appearance is deceptive. Attributing those costs solely to the issuance of this AD is unrealistic because, in the interest of maintaining safe aircraft, prudent operators would accomplish the required actions even if they were not required to do so by the AD.

A full cost-benefit analysis has not been accomplished for this proposed AD. As a matter of law, in order to be airworthy, an aircraft must conform to its type design and be in a condition for safe operation. The type design is approved only after the FAA makes a determination that it complies with all applicable airworthiness requirements. In adopting and maintaining those requirements, the FAA has already made the determination that they establish a level of safety that is cost-beneficial. When the FAA, as in this proposed AD, makes a finding of an unsafe condition, this means that the original cost-beneficial level of safety is no longer being achieved and that the proposed actions are necessary to restore that level of safety. Because this level of safety has already been determined to be cost-beneficial, a full cost-benefit analysis for this proposed AD would be redundant and unnecessary.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the

location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 96-NM-152-AD.

Applicability: All Model 737-100 and -200 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the wheel flanges, which could result in failure of the hydraulics systems, jammed flight controls, loss of electrical power, or other combinations of failures; and consequent reduced controllability of the airplane, accomplish the following:

(a) For airplanes equipped with a Bendix main wheel assembly having part number (P/N) 2601571-1, serial number (S/N) B-5999 or lower: Within 180 days after the effective date of this AD, accomplish the actions specified in paragraphs (a)(1) and (a)(2) of this AD, in accordance with Bendix Service Information Letter (SIL) 392, Revision 1, dated November 15, 1979.

(1) Remove any outboard wheel half having S/N H-999 or lower, and replace it with an outboard wheel half having P/N 2607047; and

(2) Remove any inboard wheel half having S/N H-1799 or lower, and replace it with a wheel half having P/N 2607046.

(b) For airplanes equipped with a Bendix main wheel assembly having P/N 2601571, S/N B0001 through B5999 inclusive, accomplish the following:

(1) Within 180 days after the effective date of this AD, and thereafter at each tire change, accomplish the actions specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this AD, in accordance with the Accomplishment Instructions of Allied Signal Service Bulletin No. 737-32-026, dated April 26, 1988, including Attachments 1 and 2.

(i) Clean any outboard wheel half having P/N 2601454, S/N H0001 through H1049 inclusive, and any inboard wheel half having P/N 2601567, S/N H0001 through H1799 inclusive; and

(ii) Inspect the wheel halves for corrosion or missing paint in large areas, strip or remove any paint, and remove any corrosion; and

(iii) Perform an eddy current inspection to detect cracks.

(2) If any cracking is found during the inspections required by this paragraph, prior to further flight, repair or replace the wheel halves with serviceable wheel halves in accordance with procedures specified in the Component Maintenance Manual.

(c) As of the effective date of this AD, no person shall install an outboard wheel half having S/N H-999 or lower, or an inboard wheel half having S/N H-1799 or lower, on a main wheel assembly having P/N 2601571, S/N B0001 through B5999 inclusive, on any airplane.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,
Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 96-21884 Filed 8-23-96; 9:03 am]

BILLING CODE 4910-13-U

14 CFR Part 39

[Docket No. 96-NM-153-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 737 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 737 series airplanes. This proposal would require modification of the aileron center spring and trim mechanism. This proposal is prompted by a review of the design of the flight control systems on Model 737 series airplanes. The actions specified by the proposed AD are intended to prevent jamming of the aileron control system during flight due to fracturing of the springs in the aileron centering units; this condition, if not corrected, could result in reduced lateral control of the airplane.

DATES: Comments must be received by October 24, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-153-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Don Kurle, Senior Engineer, Systems and Equipment Branch, ANM-130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington; telephone (206) 227-2798; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by

interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 96-NM-153-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 96-NM-153-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

In October 1994, the FAA organized a team to conduct a Critical Design Review (CDR) of the flight control systems installed on Boeing Model 737 series airplanes in an effort to confirm the continued operational safety of these airplanes. The formation of the CDR team was prompted by questions that arose following an accident involving a Model 737-200 series airplane that occurred near Colorado Springs, Colorado, and one involving a Model 737-300 series airplane that occurred near Pittsburgh, Pennsylvania. The CDR team's analysis of the flight control systems was performed independent of the investigations of these accidents, which are conducted by the National Transportation Safety Board (NTSB). The cause of the accidents has not yet been determined.

The CDR team was composed of representatives from the FAA, the NTSB, other U.S. government organizations, and foreign airworthiness authorities. The team reviewed the service history and the design of the flight control systems of Model 737 series airplanes. The team completed its review in May 1995. The recommendations of the team include various changes to the design of the flight control systems of these airplanes, as well as correction of certain design deficiencies. This proposed AD is one of nine rulemaking actions being issued by the FAA to address the recommendations of the CDR team.

Reports Received by FAA

The FAA received numerous reports indicating that fractured springs were found in the aileron centering units on Model 737 series airplanes. The cause of the fracturing has been attributed to fatigue cracking. A fractured spring can

result in degraded aileron feel at the control wheel. Two of these reports indicated that a fractured spring became lodged in a centering cam weight reduction hole when the control wheel was turned beyond 40 degrees. This condition, if not corrected, could result in jamming of the aileron control system; jamming of the aileron control system during flight could result in reduced lateral control of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletin 737-27-1155, dated October 26, 1989; as revised by Notices of Status Change No. 737-27-1155NSC1, dated January 25, 1990, No. 737-27-1155NSC2, dated February 15, 1990, and No. 737-27-1155NSC3, dated May 17, 1990; which describe procedures for modification of the aileron center spring and trim mechanism. The modification involves the following:

- for Groups 1 and 2 airplanes, replacing the aileron centering springs with improved springs that are corrosion resistant and more durable;
- for Groups 1 and 2 airplanes, plugging a weight reduction hole in the feel cam to prevent foreign materials from lodging in the mechanism; and
- for Group 1 airplanes only, replacing the eyebolts of the centering spring attachment with new eyebolts that have extended arms to prevent a fractured centering spring from lodging in or behind the feel cam.

Accomplishment of these actions will improve the reliability of the aileron centering spring and trim mechanism.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require modification of the aileron center spring and trim mechanism. The actions would be required to be accomplished in accordance with the service bulletin and Notice of Status Change described previously.

Explanation of Proposed Compliance Time

In developing an appropriate compliance time for the proposed modification, the FAA's intent is that it be performed during a regularly scheduled maintenance visit for the majority of the affected fleet, when the airplanes would be located at a base where special equipment and trained personnel would be readily available, if necessary. In addition, the FAA

considered the availability of necessary parts. The FAA finds that 18 months corresponds closely to the interval representative of most of the affected operators' normal maintenance schedules. The FAA considers that this interval will provide an acceptable level of safety.

Cost Impact

There are approximately 1,631 Model 737 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 830 airplanes of U.S. registry would be affected by this proposed AD.

The FAA estimates that 485 Group 1 airplanes would be affected by this proposed AD. For Group 1 airplanes, the FAA estimates that it would take approximately 2 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$707 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators of Group 1 airplanes is estimated to be \$401,095, or \$827 per airplane.

The FAA estimates that 345 Group 2 airplanes would be affected by this proposed AD. For Group 2 airplanes, the FAA estimates that it would take approximately 2 work hours per airplane to accomplish the proposed actions, and that the average labor rate is \$60 per work hour. Required parts would cost approximately \$224 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators of Group 2 airplanes is estimated to be \$118,680, or \$344 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT

Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 96-NM-153-AD.

Applicability: Model 737 series airplanes; as listed in Boeing Service Bulletin 737-27-1155, dated October 26, 1989; as revised by Notices of Status Change No. 737-27-1155NSC1, dated January 25, 1990, No. 737-27-1155NSC2, dated February 15, 1990, and No. 737-27-1155NSC3, dated May 17, 1990; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent jamming of the aileron control system during flight, which could result in reduced lateral control of the airplane, accomplish the following:

(a) Within 18 months after the effective date of this AD, accomplish the requirements of paragraphs (a)(1), (a)(2), and (a)(3) of this AD, as applicable, in accordance with Boeing

Service Bulletin 737-27-1155, dated October 26, 1989; as revised by Notice of Status Change No. 737-27-1155NSC1, dated January 25, 1990, and Notice of Status Change No. 737-27-1155NSC2, dated February 15, 1990, and Notice of Status Change No. 737-27-1155NSC3, dated May 17, 1990.

(1) For Groups 1 and 2 airplanes: Replace the aileron centering springs, part number (P/N) 69-39429-2, with improved springs, P/N 69-39429-3, in accordance with the service bulletin and Notices of Status Change.

(2) For Groups 1 and 2 airplanes: Install a two-piece plug, P/N 69-78072-1, in the weight reduction hole in the feel cam in accordance with the service bulletin and Notices of Status Change.

(3) For Group 1 airplanes: Replace the two eyebolts, P/N 69-39423-1, of the aileron centering spring attachment with new eyebolts, P/N 69-74646-1, in accordance with the service bulletin and Notices of Status Change.

(b) As of the effective date of this AD, no person shall install the items specified in paragraphs (b)(1) and (b)(2) of this AD on any airplane, as specified:

(1) For Groups 1 and 2 airplanes: Aileron centering springs having P/N 69-39429-2 shall not be installed.

(2) For Group 1 airplanes: Eyebolts, P/N 69-39423-1, of the aileron centering spring attachment shall not be installed.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 21, 1996.

Ronald T. Wojnar,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96-21885 Filed 8-23-96; 9:03 am]

BILLING CODE 4910-13-U

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 232 and 240

[Release No. 34-37595; File No. S7-21-96]
RIN 3235-AG99

Lost Securityholders

AGENCY: Securities and Exchange Commission.

ACTION: Notice of Proposed Rulemaking and Request for Comments.

SUMMARY: The Securities and Exchange Commission ("Commission") is publishing for comment proposed Rule 17Ad-17 and proposed Rule 17a-24 which are designed to address the problem of "lost securityholders." Rule 17Ad-17 would require transfer agents to conduct searches in an effort to locate lost securityholders. Rule 17a-24 would allow the Commission to gather data related to lost securityholders and to provide it to information distributors or others. The Commission also is seeking comments on the extent to which further regulatory or remedial steps are necessary, including whether the Commission should operate a national database for lost securityholders.

DATES: Comments should be received on or before October 28, 1996.

ADDRESSES: Interested persons should submit three copies of their written data, views, and opinions to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington D.C. 20549. Comments also may be submitted electronically at the following E-mail address: rule-comments@sec.gov. All comment letters should refer to File No. S7-21-96; this file number should be included on the subject line if E-mail is used. Comment letters will be available for public inspection and copying at the Commission's public reference room, 450 Fifth St., N.W., Washington D.C. 20549. Electronically submitted comment letters will be posted on the Commission's Internet Web site (<http://www.sec.gov>).

FOR FURTHER INFORMATION CONTACT: Jerry W. Carpenter, Assistant Director; Christine Sibille, Senior Counsel; or Michele Bianco, Attorney; at 202/942-4187, Office of Risk Management and Control, Mail Stop 5-1, Division of Market Regulation, Securities and Exchange Commission, Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION:

I. Introduction and Summary

From time to time, issuers lose contact with some of their securityholders ("lost securityholders"). Loss of contact may result from a change in the securityholder's address or a transfer of beneficial ownership (e.g., through inheritance). As a result, these securityholders do not receive principal, dividend, or interest distributions to which they are entitled, and their property is at risk of being deemed

abandoned under state escheat laws.¹ At a point in time established under the applicable escheat law, the custodians of these assets must turn them over to the appropriate state unclaimed property administrator. In some states, that can occur in as few as three years after the custodian loses contact with the securityholder.² Transfer agents, as the primary custodians of the records that determine the ownership of securities and the entitlement to corporate distributions, can reduce significantly the number of lost securityholders by maintaining accurate records and by promptly initiating corrective measures when records no longer reflect the current status of a securityholder.³

Some transfer agents already take meaningful steps to prevent the loss of contact with securityholders and to reestablish contact after it has been lost. However, the Commission is concerned that some transfer agents may not be making sufficient use of currently available technology to locate securityholders with whom contact has been lost.

To address this problem, the Commission is seeking comment on several proposals. Proposed Rule 17Ad-17 would require that transfer agents take certain minimum steps to locate the correct address of each securityholder in their master securityholder files as well as require them to take such additional steps as are reasonable. Transfer agents would be required at a minimum to make two good faith attempts to locate lost securityholders before turning assets over to an unclaimed property administrator. These searches would be made at no cost to the securityholder.

¹ See House Committee on Small Business, 103d Cong., 2nd Sess., Report on Business Opportunities and Technology (1993); Letter from Richard Breeden, Chairman, Commission, to Ron Wyden, Chairman, Committee on Small Business, U.S. House of Representatives (February 22, 1993); Letter from Arthur Levitt, Chairman, Commission, to Ron Wyden, Chairman, Committee on Small Business, U.S. House of Representatives (October 29, 1993).

² In some states, an investor's failure to vote or to communicate with the issuer during a period of five successive years, even if no communication from the investor has been required, can become the basis for constructive abandonment. See, e.g., Letter from John K. Dalton, Associate Counsel, State of New York Office of the State Comptroller, to the Division of Market Regulation ("Division") (December 12, 1994).

³ Other financial institutions, such as registered broker-dealers, also may maintain records of securities ownership on behalf of customers for which they hold assets. In such instances, the transfer agent has recorded the financial institution as the owner in its account records, and the financial institution's customer account records will identify the beneficial owner of the securities. The Commission understands that such financial institutions have a lower incidence of lost securityholders. Letter from Judith Poppalardo, Assistant General Counsel, Securities Industry Association ("SIA"), to Division (June 7, 1996).

The Commission believes that this requirement should help reduce the number of lost securityholders and the escheatment of investor assets.

The Commission preliminarily believes that imposing an affirmative obligation on transfer agents to search for lost securityholders is in the public interest and would enhance investor protection. The Commission recognizes that regulatory obligations impose financial burdens and that the costs of complying with proposed Rule 17Ad-17 may fall upon transfer agents or indirectly on issuers. In proposing specific requirements, the Commission has attempted to minimize compliance costs. Also, decreasing the number of lost securityholders should reduce the costs to transfer agents and issuers of complying with state escheat laws.

The Commission also is proposing Rule 17a-24 to gather data related to lost securityholders that would be available to information distributors and others. Under this rule, the Commission would require entities that hold assets for investors, such as transfer agents and broker-dealers, to file electronically with the Commission certain lost securityholder information. The Commission would make such data available to private entities which could establish information services that could be accessed by investors to determine if they have been reported as lost.

As discussed more fully below, the Commission is also soliciting comment on the concept of a national database of lost securityholders to be operated by the Commission in order to facilitate the ability of lost securityholders to reestablish contact with issuers and transfer agents.

In summary, the proposals would:

- Establish a definition of lost securityholder.
- Require transfer agents to search for lost securityholders at no cost to the securityholders using at least one information database.
- Require certain entities that hold assets for securityholders to file with the Commission certain information pertaining to lost securityholders.
- Solicit comment on the establishment of a national lost securityholder database to be maintained by the Commission.

II. Transfer Agent Responsibilities to Maintain Accurate Records and to Locate Lost Securityholders

A. Maintenance of Master Securityholder Files

Rule 17Ad-10 under the Securities Exchange Act of 1934 ("Exchange Act")⁴ requires every recordkeeping

⁴ 17 CFR 240.17Ad-10.

transfer agent⁵ to maintain and keep current an accurate master securityholder file⁶ that contains the minimum appropriate "certificate detail" for all securities transferred, purchased, redeemed, or issued and to which the transfer agent must post debits and credits. Certificate detail is defined by Rule 17Ad-9(a) to include information such as the securityholder's registration (including name), address of the securityholder, the size of the position, and other information used to identify the securities and the securityholder.⁷

The Commission believes that an accurate master securityholder file is one of the most basic steps in addressing the lost securityholder problem. Therefore, the Commission believes that recording of patently inadequate or inaccurate certificate detail to the master securityholder files is inconsistent with Rule 17Ad-10. For example, recording an address of "New York, New York" without a street address will almost certainly result in the return by the U.S. Postal Service as undeliverable of all correspondence sent to such address. Thus, in most cases a transfer agent should not post to the master securityholder files items it receives for transfer that contain a patently incorrect address or items that do not contain a complete address⁸ and should return such transfer request to the presenter without effecting the transfer.⁹

⁵ 17 CFR 240.17Ad-9(h) defines recordkeeping transfer agent as the registered transfer agent that maintains and updates the master securityholder file.

⁶ 17 CFR 240.17Ad-10(b) requires every recordkeeping transfer agent to maintain and keep current an accurate master securityholder file and subsidiary files. If there is a record difference, the master securityholder file and subsidiary files must accurately represent all relevant debits and credits until the record difference is resolved. The recordkeeping transfer agent must exercise diligent and continuous attention to resolve all record differences. See also 17 CFR 240.17Ad-9(b).

⁷ 17 CFR 240.17Ad-9(a).

⁸ Transfer agents should use their experience in their reviews for adequacy of addresses contained in items submitted for transfer. For example, the absence of a street address in some rural areas and small towns may not render an address incomplete or inadequate. Accordingly, posting such certificate detail may not violate Rule 17Ad-10.

⁹ The Commission understands that there are situations where rejecting a transfer request because of an incomplete address may result in financial harm to the investor (e.g., when a transfer request is received near or on a record date or in connection with a tender or an exchange offer). Letter from Michael Foley, President, The Securities Transfer Association ("STA"), to the Division (May 26, 1994). In such situations, the Commission believes that a transfer agent should have the flexibility to follow the general practice of accepting the transfer request and using the address of the presenting financial intermediary in care of the securityholder before seeking an accurate address.

B. Current Transfer Agent Practices Regarding Lost Securityholders

Currently, most transfer agents rely on the standards contained in Rule 14a-3(e)(2) under the Exchange Act to determine when to code as "lost" the accounts of securityholders whose correspondence has been returned as "undeliverable" because of an incorrect or insufficient address.¹⁰ That rule provides that unless otherwise required by state law, the obligation to mail an annual report or proxy statement to a securityholder is suspended if (1) an annual report and a proxy statement for two consecutive annual meetings, or (2) all payments of dividends or interest on securities sent by first class mail (of which there has been at least two payments) during a twelve month period which have been mailed to such securityholder's address have been returned as undeliverable.

Generally, the first time a distribution check is returned as undeliverable, a transfer agent will place the returned check in another specially marked (e.g., color-coded) envelope and will remail the distribution check to the registered owner at the same address ("re-mailing procedure").¹¹ If the re-mailing is returned, the issuer or the transfer agent will hold the check until the next distribution payment. This re-mailing procedure may be repeated if the next distribution payment or other issuer correspondence is returned as undeliverable. If two consecutive distribution payment mailings are returned as undeliverable, the transfer agent will code the securityholder's account as undeliverable (i.e., the securityholder is "lost") and will hold any further distributions and communications to the securityholder. Some transfer agents also conduct a mass mailing at the end of each year to all securityholders whose accounts they deem to be undeliverable.

After two consecutive mailings are returned as undeliverable, some transfer agents conduct searches for the securityholder by using information databases.¹² In addition to information

¹⁰ 17 CFR 240.14a-3(e)(2).

¹¹ Transfer agents use this second mailing to test the possibility that the first mailing did not reach the intended recipient because of an error by the postal service. The second mailing also can be used to generate a better or current address by requesting an address correction from the postal service. Letter from Michael Foley, President, STA, to the Division (May 26, 1994). Transfer agents have estimated the success rate for this re-mailing from less than 10% to 50%. See, e.g., Letters from Charles Rossi, Boston EquiServe, to the Division (February 26, 1996) and from Anthony J. Calcagni, Harris Trust and Savings Bank, to the Division (February 23, 1996).

¹² Many transfer agents and corporate issuers that conduct the transfer functions for their own securities currently use vendor-maintained,

databases, transfer agents also use various other methods in their attempts to obtain the current addresses of lost securityholders.¹³ However, not all transfer agents take such actions to search for lost securityholders.

C. Proposed Rule 17Ad-17

The Commission is proposing Rule 17Ad-17 under the Exchange Act to require transfer agents to conduct searches for securityholders once the transfer agents have determined that a securityholder is lost. The proposed rule would require each recordkeeping transfer agent to exercise reasonable care to locate the correct address of lost securityholders, and would establish minimum search requirements.¹⁴ However, the rule would not impose on transfer agents an absolute obligation actually to locate each lost securityholder.

1. Definition of Lost Securityholder

For purposes of Rule 17Ad-17, a securityholder will be classified as a lost securityholder when two items of correspondence,¹⁵ such as distribution payments, that were sent by first class mail at least three months apart, have been returned as undeliverable. Because at times transfer agents receive change of address notifications soon after the mailing and subsequent return of a distribution payment, a three month period will be required to have elapsed between the two correspondences. If and when a transfer agent receives a

computer databases to assist them in searching for lost securityholders. Letters from Michael Foley, President, STA, to the Division (May 26, 1994), and Anthony F. Fireman, President, Corporate Transfer Agents Association, Inc. ("CTAA"), to the Division (April 25, 1994). These searches are usually based on name, address, or social security number. Many professional transfer agents (e.g., transfer agents that perform transfer functions for issuers for a fee) also have the capability to perform searches by taxpayer identification number for issuers that are willing to pay an additional fee. In addition to using vendor-maintained information databases (e.g., credit bureaus), some transfer agents and corporate issuers employ the services of the Social Security Administration ("SSA") or the Internal Revenue Service ("IRS") in an attempt to contact the lost securityholder.

¹³ Among others, these methods include using CD-ROM technology for searching telephone directories, and inquiring at the bank where previously endorsed distribution checks were presented to learn if the bank has a current address. See also, Guttman, *Modern Securities Transfers*, ¶ 16.04 (3rd ed. 1987), noting that other methods include, but are not limited to, (i) checking all past correspondence with the registered owner, (ii) checking the source of transfer instructions for a proper address (for example, the broker through whom the securities had been acquired by the registered owner), and (iii) contacting the occupant of the premises of the last-known address for a forwarding address.

¹⁴ See *supra* note 5 for a definition of recordkeeping transfer agent.

¹⁵ The re-mailing of the same correspondence does not constitute a second item of correspondence.

new address for a lost securityholder, either directly from the securityholder or through the transfer agent's efforts, the securityholder will no longer be classified as lost.¹⁶

The Commission requests comments on whether the proposed standards for classifying a lost securityholder is appropriate or whether a different standard should be employed. For example, is the three month period between the mailing of two correspondences an appropriate time period?

2. Transfer Agents' Search Requirements

Rule 17Ad-17 would require every recordkeeping transfer agent whose master securityholder file includes accounts of lost securityholders to search an information database for such securityholders' current address. The transfer agent's initial search for the securityholder must be based on either name, if reasonably likely to locate the lost securityholder, or taxpayer identification number (typically an individual's social security number) using at least one information database. The search must be conducted within three months of the securityholder being classified as lost. If the lost securityholder is not found on the initial search, the transfer agent also must conduct a second search for the lost securityholder between one year and eighteen months after the initial search. This search is intended to identify address changes that were added to the database after the time of the earlier search. The transfer agent must conduct these searches without charge to the lost securityholder.

The Commission understands that database searches generally are considered a cost-effective way in which to locate lost securityholders. The Commission requests comment with respect to the potential costs of proposed Rule 17Ad-17 and its potential effectiveness in addressing the lost securityholder issue. The Commission requests commenters to submit specific data on costs involved in utilizing various vendors' information databases and costs involved in using other methods in an effort to locate lost securityholders. The Commission also requests comment on whether there are other entities that maintain ownership records such as

broker-dealers, that should also have search requirements.¹⁷

In conducting an information database search, should a transfer agent have the option as proposed of conducting a search using either the names or taxpayer identification numbers of the lost securityholders or should the transfer agent be required to conduct a search using taxpayer identification numbers? The Commission understands that conducting searches using the taxpayer identification numbers may be more costly than a search using lost securityholders' names, but searches using taxpayer identification numbers may be more effective in locating lost securityholders.

Should the requirement to search for lost securityholders apply only where the transfer agent is holding assets over some de minimis amount? A de minimis threshold would avoid a situation where a transfer agent would be required to expend funds in excess of the amount at risk of escheating.

The Commission also is requesting comment on the time frames within which a search must be made. The purpose of the three month time frame is to require a transfer agent to search within a short period of time after the securityholder becomes lost, because generally chances of locating a lost securityholder are better the sooner a search is initiated. However, if the search is conducted too soon, there may not be an opportunity for the information databases to be updated with the securityholder's new address. Further, the three month period will permit transfer agents to conduct searches on a quarterly basis, which may be more cost-effective. The period between the first and the second search, one year to eighteen months, is intended to provide sufficient time for a lost securityholder's new address to appear in an information database subsequent to the first search.

Comments also are requested on whether the rule should include (1) a requirement that transfer agents periodically assess the effectiveness and appropriateness of the search procedures and technology they employ, and/or (2) a requirement that transfer agents' search procedures meet a performance-based standard based on success in locating lost securityholders.

3. Definition of Information Database

For purposes of Rule 17Ad-17, an information database would be defined

as any automated database service that (1) contains addresses of United States residents including addresses in the geographic area in which the lost securityholder's last known address is located, (2) covers a reasonably broad geographic area, (3) is indexed by the search criterion used by the transfer agent (e.g., name or taxpayer identification number), and (4) is updated at least four times a year.¹⁸ The Commission requests comments on these criteria. Comment is also sought on whether instead of setting forth specific criteria for an acceptable database, the rule should require transfer agents to use technology reasonably designed to locate a lost securityholder.

4. Use of Professional Search Firms to Meet Search Requirements

Currently, some transfer agents rely on professional search firms that charge lost securityholders a fee for locating the lost securityholders' assets instead of using database services.¹⁹ Under proposed Rule 17Ad-17, the use of such firms as the method of locating a lost securityholder would satisfy the transfer agent's search obligation only if the securityholder would not be charged a fee as the result of a successful search. Therefore, the use of a professional search firm that charges the securityholder a fee for recovering his or her assets would be permissible only after the transfer agent has conducted the required two information database searches described above.

Comment is sought on the extent to which transfer agents currently employ professional search firms and on any problems or concerns that arise from their use. Specifically, the Commission

¹⁸ Some examples of vendors of information databases that satisfy these criteria are credit bureaus, the SSA, and the IRS.

¹⁹ The CTAA stated that some of its members utilize professional search firms which generally have extensive search methods. The CTAA believes that the decision to use a professional search firm should be an independent one made by the transfer agent or issuer taking into consideration potential cost to either the issuer or the securityholder. Letter from Anthony F. Fireman, President, CTAA, to the Division (April 25, 1994). The National Association of Unclaimed Property Administrators ("NAUPA") has informed the Commission that transfer agents should use caution when employing information vendors because many such vendors are also in the business of contacting lost securityholders and charging them a fee, which may be between 30% and 50% of the value of the distributions, for information about the distributions. While NAUPA supports the use of all available methods of facilitating transfer agents' searches, it is concerned about any search effort that causes a shareholder to lose a substantial portion of the value of the property and believes that such firms should be used only as a last resort and not as a routine method to find lost securityholders. Letter from Dawn E. Rockey, Second Vice President, NAUPA, to the Division (April 29, 1994).

¹⁶ While not specifically required by the proposed rule, the Commission encourages transfer agents to take steps that may prevent securityholders from becoming "lost." In particular, the remailing procedure described in the text above and the procedures described in footnote 13 appear to be effective methods of correcting misdeliveries of mail and other delivery problems. Such early measures may prove especially beneficial because the "trail" of the securityholder may still be fresh.

¹⁷ The Commission understands that many broker-dealers currently conduct searches for missing customers. Letter from Judith Poppalardo, Assistant General Counsel, SIA, to Division (June 7, 1996).

requests comment on whether the limitation contained in the proposed rule, prohibiting charging the shareholder for use of such firms until after a transfer agent has conducted the two prescribed searches using an information database, is appropriate.

5. Verification of Shareholder Identity

Although a careful search is unlikely to result in an erroneous match of a lost securityholder and the information obtained from an information database, information databases are not 100% accurate. Thus, in order to guard against delivery of distributions to an incorrect recipient, the Commission strongly suggests that transfer agents verify that the person at the newly obtained address is its lost shareholder before disbursing securities or funds.²⁰ Among other methods, verification could consist of confirming the shareholder's taxpayer identification number and former address.

6. Recordkeeping Requirements

Proposed Rule 17Ad-17 will require that all recordkeeping transfer agents maintain records necessary to demonstrate their compliance with the requirements of the rule. At a minimum, transfer agents should document the date a securityholder was classified as lost and the date a database search was conducted for such securityholder. The Commission also is proposing an amendment to Rule 17Ad-7 under the Exchange Act to require that transfer agents maintain the records required by the proposed rule for a period of not less than three years with the first year in an easily accessible place.

²⁰ The STA notes that currently most transfer agents send a search letter to the new address obtained from an information database in order to obtain additional information to assure that the shareholder and the new addressee are the same person. However, for small money values, some transfer agents automatically update their records and forward lost distributions to the address obtained from the information database. The STA believes that transfer agents should establish contact with the shareholder at the new address before releasing distributions. Letter from Michael Foley, President, STA, to the Division (May 26, 1994). The CTAA states that many transfer agents and issuers currently require the person at the new address to confirm the shareholder's taxpayer identification number and former address before issuing a check for past dividend or interest distributions. The CTAA also states that when an estate is being probated, most transfer agents or issuers will issue the check in the name of the deceased so that the personal representative or trustee of the estate is required to use legal documents to cash the check. Letter from Anthony F. Fireman, President, CTAA, to the Division (April 25, 1994).

III. Collection of Lost Securityholder Data

A. Proposed Rule 17a-24—Background

As discussed further in Section IV below, the Commission has been urged to support the establishment of a national lost securityholder database. In the alternative, the Commission is proposing to facilitate the gathering of data related to lost securityholders to provide access to the information by information distributors or others, including individuals.

The Commission proposes to collect information on lost securityholders²¹ from entities such as transfer agents and broker-dealers that hold assets for investors, and to make such information available to private entities which could establish databases accessible by the public. For example, a distributor could obtain this information from the Commission and charge a fee to persons who inquire about whether they have been reported as lost. The inquirer could then contact the reporting entity or otherwise take steps to recover the property. The Commission requests comment as to whether it would be economically feasible for communication vendors to develop a lost securityholders database and to make the information available to the general public at a reasonable cost.

B. Definition of Recordkeeper

The filing requirements under proposed Rule 17a-24 would apply to any entity defined by that rule as a recordkeeper. The proposed rule defines the term recordkeeper to mean (1) a member of a national securities exchange, a registered broker or dealer, or a registered municipal securities dealer which maintains records of securities received, acquired, held, or carried by or on behalf of such entity for the account of any securityholder, or (2) a recordkeeping transfer agent. Exchange members and broker-dealers carry accounts for others, which may include retail investors, institutional investors, or other broker-dealers.²² Recordkeeping transfer agents maintain records of ownership on behalf of issuers.

The Commission seeks comment concerning the scope of this definition. Should any other entities, such as investment advisors, be included within

the definition of recordkeeper? Does the proposed definition cover entities that should not be deemed recordkeepers because they do not typically have lost securityholders?

C. Recordkeeper Filing Requirements

Proposed Rule 17a-24 will require each recordkeeper to file electronically with the Commission on or before May 31 of each year information on all lost securityholders contained in such recordkeeper's records as of May 1 of such year.²³ With the same filing date for all filers, the Commission could easily compile all the submissions into one file for downloading.

The filing would include the identity of the reporting recordkeeper, a contact name and telephone number at the recordkeeper, and the period covered by the report. In an effort to protect confidentiality, the report contents would consist solely of a list of taxpayer identification numbers of lost securityholders contained in the recordkeeper's records.²⁴ No names, number of shares, or dollar amounts would be provided.

The Commission requests comment on the feasibility of the filing requirement under the proposed rule. A private entity that wants to establish a database would only need to download the information once a year from the Commission. Is an annual filing sufficient? Should more frequent submissions be required? Should filers submit such information concerning all lost securityholders, securityholders who have been lost for some specified time period, or lost securityholders after a specific occurrence, such as after the two database searches required under proposed Rule 17Ad-17 have been conducted? Should filers be required to file information with the Commission indicating that a securityholder has been found? If so, how soon after the securityholder is found? In addition to the costs they currently incur in providing information on lost property to state unclaimed property administrators, what costs would filers incur in providing the requested information to the Commission?

The Commission also requests comment on whether the privacy of lost securityholders will be compromised by filers providing the required taxpayer identification numbers.²⁵ Would information other than taxpayer

²¹ The rule would include a definition of the term lost securityholder that is consistent with the definition under proposed Rule 17Ad-17.

²² Exchange members and broker-dealers which carry accounts for others are frequently listed on the books of issuers, clearing agencies, or financial intermediaries as the holder of a security. These exchange members or broker-dealers know the identity of the entity for which they hold the security.

²³ The annual filing would include information on a lost securityholder even if the securityholder was reported as lost in the previous year's filing.

²⁴ The Commission understands that some professional search firms have databases that can identify an individual's name based on a social security number.

²⁵ *Supra* note 24.

identification numbers provide greater privacy protection and still accomplish the stated goals? For example, would the gathering of specific information about a lost securityholder (e.g., the lost securityholder's name, last known city and state) be an effective means of addressing the problem while presenting fewer privacy concerns?²⁶ Are there any other steps that should be taken to protect securityholders' privacy? Should information on the lost securityholder's assets (e.g., the issues and the CUSIP numbers) be included, and would the inclusion of such information serve any useful function so as to override any privacy concerns?

D. Method of Filing

The Commission believes that two methods of electronic filing are feasible. First, recordkeepers could utilize the Commission's Electronic Data Gathering Analysis and Retrieval System ("EDGAR") to submit their filings in accordance with current Commission rules.²⁷ The Commission is proposing the use of the EDGAR system in an effort to employ available technology to facilitate the objectives of the proposed rule. EDGAR filings generally are made through a dial-up connection to the Commission's host equipment and transmitted using Commission supplied, personal computer based software called EDGARLink. Therefore, the cost to recordkeepers should be limited to a long distance telephone call.

In addition to built-in communications and data compression capability, EDGARLink contains features which help EDGAR filers create and prevalidate their submission prior to making a transmission. Use of the EDGAR system also would enable the Commission to validate the identity of the submitter, the type of submission, and whether the filing meets certain minimal format requirements.

As an alternative to filing through the EDGAR system, filings could be submitted to the Commission through the Internet.²⁸ Under this approach, the same document structure required for EDGAR could be used. However, the filer would not receive validation of the filing, and there would be no validation

for header accuracy or format compliance. The cost may be somewhat higher because entities would be required to obtain access to the Internet either directly through a provider or through use of a service which would file on their behalf.

Comments are requested on whether the EDGAR system or the Internet would be the better vehicle for the submission of such information. Commenters are requested to provide specific alternative cost estimates for compliance using both systems. Are there limits on the ability of smaller transfer agents and broker-dealers to submit this information due to their level of automation?

E. Dissemination of Information

The Commission anticipates that the information filed under proposed Rule 17a-24 could be disseminated as part of the existing EDGAR data dissemination stream. Alternatively, the Commission could provide access to the data on its Internet Web site. On the Internet Web site, any entity or individual could download the information submitted to the Commission for whatever reason(s) it deemed appropriate. The Commission requests comment on the costs and benefits associated with this proposal. Does the release of this information to any outside party create the possibility of fraud, and if so, is there some method to eliminate this possibility?

Alternatively, should the Commission limit access to the information collected with respect to lost securityholders? For example, should dissemination of the information be limited to information vendors that agree to restrict the use and protect the confidentiality of the information?

F. Proposed Recordkeeping Requirements

The proposed rule would require every recordkeeper to maintain such records necessary to demonstrate compliance with the requirements set forth in this rule. The proposed rule also would provide that such records must be maintained for a period of not less than three years, the first year in an easily accessible place. Comment is requested as to the feasibility of this requirement.

IV. Commission Supported Database

As an alternative to the data collection proposed in Section III above, it has been suggested that the Commission should directly support the establishment of a national lost securityholder database which would be analogous to the database used in the Commission's lost and stolen securities

program.²⁹ Such a database would contain information such as the names and/or taxpayer identification number of lost securityholders. Information would be required to be submitted to the database by entities that are required to make other filings with the Commission (e.g., issuers, transfer agents, and broker-dealers).³⁰ All securities and funds of lost securityholders would continue to be held by the issuers, transfer agents, or broker-dealers. The database would be accessible by telephone or by computer linkage by shareholders or any other interested party. A user fee (i.e., a small charge for each inquiry) would be used to fund the operation of the database. The register could be searched by using a securityholder's name or taxpayer identification number and would reveal whether an entity is holding securities or funds for the securityholder. However, the register would not disclose the value of the assets being held.

Alternatively, it has been suggested that the Commission could directly maintain and operate a lost securityholder database utilizing the Commission's Internet Web site. Similar to the above proposal, transfer agents, issuers, and broker-dealers would be required to submit information concerning lost securityholders to the Commission. Individuals would have access to the database through the Internet.³¹

Recently, the National Association of Unclaimed Property Administrators ("NAUPA") advised the Commission that it is in the process of developing a national database of lost securityholders.³² NAUPA indicated that most, if not all, of the states that belong to the association will provide names and last known addresses to its centralized database. The NAUPA database will be accessible by any

²⁹ Letter from Robert N. Shamansky, Benesch, Friedlander, Coplan & Aronoff, to the Division (May 16, 1994).

³⁰ Specifically, the proposal suggests that an issuer, transfer agent, or broker-dealer enroll each lost securityholder on an expanded version of the register which is maintained for the Commission by the Securities Information Center for information on lost and stolen securities. Letter from Robert N. Shamansky (May 16, 1994).

³¹ This proposal differs from the proposal discussed under Section III above in terms of the level of Commission involvement in developing and running the database. In addition, the Commission might need to institute a small charge for each search to cover the costs of development and operations. Furthermore, it might take longer to implement this proposal due to the complexities of such a database.

³² Letter from Randall A. Ross, President, NAUPA, to Steven M. H. Wallman, Commissioner, Commission (January 18, 1996). NAUPA members represent fifty jurisdictions which have unclaimed property laws.

²⁶ Listing lost shareholders by name may allow for greater privacy because of the potential for multiple individuals to have the same name while a social security number will identify one specific individual.

²⁷ 17 CFR 202.7(b). As set forth in part VIII below, the Commission is proposing to amend 17 CFR 232.101, which specifies mandated electronic submissions, to include filings under proposed Rule 17a-24.

²⁸ If this alternative is adopted it would be necessary to amend 17 CFR 202.7 and 17 CFR 232.101 to reflect the use of the Internet for these submissions.

person through the Internet for a nominal fee, which will be used to maintain the database. NAUPA believes that a centralized database managed by states is an effective way to return property to rightful owners because states have considerable expertise in administering unclaimed property programs and locating missing owners. However, the Commission notes that NAUPA's database would not list a lost securityholder until such securityholder's assets had escheated to a state.

The Commission requests comment on the establishment of a national lost securityholder database. Specifically, the Commission seeks comment on whether such a database would be of significant benefit to investors and the cost-effectiveness of such a database, particularly in light of the potential impact of proposed Rule 17Ad-17. Comments should also contrast the benefits of a national database with the data collection concept proposed in Section III.

Commenters favoring a database should discuss, among other things, (i) the entity best suited to administer the database, (ii) the appropriate frequency of submission of information, (iii) the allocation of costs to maintain and to operate the database, (iv) methods of access to the database, and (v) the potential necessity for and design of safeguards to prevent unauthorized access into the database and to prevent fraud. In addition to the issues cited above, the Commission is interested in obtaining comment with respect to potential privacy concerns arising from the dissemination of financial information via the Internet. The Commission also requests comment on whether the NAUPA database or other available databases would be an adequate mechanism to address the lost securityholder problem.³³

V. Initial Regulatory Flexibility Analysis

Section 603(a)³⁴ of the Administrative Procedure Act, as amended by the Regulatory Flexibility Act (the

"Flexibility Act")³⁶ generally requires the Commission to undertake a Regulatory Flexibility Act Analysis of all proposed rules or proposed rule amendments to determine the impact of such rulemaking on "small entities."³⁷ Approximately 470 registered transfer agents qualify as "small entities" for purposes of the Flexibility Act and would be subject to the requirements of proposed Rules 17a-24 and 17Ad-17. Of the approximately 650 registered broker-dealers that would be classified as recordkeepers under proposed Rule 17a-24, approximately 85 are small entities.

The Commission has prepared an Initial Regulatory Flexibility Analysis ("IRFA") pursuant to the requirements of the Flexibility Act, regarding the proposed rules. The IRFA notes that the proposed rules are intended to reduce the number of securityholders with whom contact is lost and to address the associated problems of undeliverable dividend and interest distributions by establishing standards for transfer agents with respect to their obligation to conduct searches in an effort to locate such securityholders and by facilitating

³⁶ 17 Pub. L. No. 96-354 (September 19, 1980), 94 Stat. 1164, reprinted in (1980) U.S. Code Cong. & Ad. News 1169.

³⁷ Although section 601(b) of the Flexibility Act defines the term "small entity" the statute permits agencies to formulate their own definitions. The Commission published final definitions of the term "small business" and "small organization" in Securities Exchange Act Release No. 6380 (February 4, 1982), 47 FR 5215. Section 240.0-10(h) defines a small transfer agent for purposes of the Flexibility Act as follows:

For purposes of the Commission rulemaking in accordance with the provisions of Chapter Six of the Administrative Procedure Act (5 U.S.C. 601 et seq.) and unless otherwise defined for purposes of a particular rulemaking proceeding, the term "small business" or "small organization" shall . . .

(c) When used with reference to a broker or dealer, mean a broker or dealer that:

(1) Had total capital (net worth plus subordinated liabilities) of less than \$500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to § 240.17a-5(d) or, if not required to file such statements, a broker or dealer that had total capital (net worth plus subordinated liabilities) of less than \$500,000 on the last business day of the preceding fiscal year (or in the time that it has been in business, if shorter); and

(2) Is not affiliated with any person (other than a natural person) that is not a small business or small organization as defined in this section; . . .

(h) When used with reference to a transfer agent, mean a transfer agent that:

(1) Received less than 500 items for transfer and less than 500 items for processing during the preceding six months (or in the time that it has been in business, if shorter);

(2) Maintained master shareholder files that in the aggregate contained less than 1,000 shareholder accounts or was the named transfer agent for less than 1,000 shareholder accounts at all times during the preceding fiscal year (or in the time that it has been in business, if shorter); and

(3) Is not affiliated with any person (other than a natural person) that is not a small business or small organization under this section.

the collection of data related to lost securityholders to permit information distributors or others the opportunity to establish databases in whatever form is most cost efficient. Proposed Rule 17Ad-17 establishes a single standard for all transfer agents regardless of size and is not anticipated to have any significant economic impact on small entities. Similarly, proposed Rule 17a-24 sets forth a uniform filing requirement for all recordkeepers and is not anticipated to have any significant economic impact on the small entities subject to the rule.

A. Rule 17Ad-17

Some registered transfer agents will not incur significant additional compliance costs because they currently use an information database to search for lost securityholders. Thus, the proposed requirements will have a practical effect only on transfer agents that do not presently conduct searches using an information database. The Commission estimates that even for such transfer agents, the cost of compliance with proposed Rule 17Ad-17 will be small.³⁸ In addition, because a transfer agent's cost of compliance generally will be based upon the quantity of lost securityholders it must attempt to locate, small transfers agents should not, on average, bear disproportionately high compliance costs. On average, compliance costs should be roughly proportional to the number of securityholder records maintained by the transfer agent. Some database vendors may charge discounted rates for bulk searches, which could inure to the benefit of larger transfer agents. However, such discounts are small, and thus they should not disadvantage small transfer agents significantly.

The proposed rule will impose on transfer agents an additional recordkeeping requirement. The requirement has been broadly drafted to provide transfer agents with sufficient flexibility to minimize recordkeeping costs. Specifically, proposed Rule 17Ad-17 will require that all recordkeeping transfer agents maintain records necessary to demonstrate their compliance with the rule's requirements. The Commission also is proposing an amendment to Rule 17Ad-7 to require that transfer agents maintain the records required by the proposed rule for a period of not less than three

³⁸ Based upon information supplied to the Commission by transfer agents, vendors other than the SSA and the IRS typically charge \$.95 to \$1.75 per account for lost securityholder searches. The charge for searches conducted through the SSA and IRS using securityholder social security or tax identification numbers is \$3.00 per account.

³³ The Commission notes that in April of 1994, Indiana placed all of its unclaimed property information on the Internet. Since going on-line, Indiana has received approximately six additional calls per week; however, professional search firms (i.e., entities employed by corporate issuers to locate lost securityholders and that charge lost securityholders a percentage of their assets for such efforts) account for about sixty percent of the additional calls. Very recently, Wyoming also placed its unclaimed property information on the Internet.

³⁴ 5 U.S.C. 603(a).

³⁵ 5 U.S.C. 551, et seq.

years, the first year in an easily accessible place.

The Commission considered various alternatives to the proposed rule and found no alternatives consistent with the proposed rule's objective and the Commission's statutory mandate.³⁹ However, as set forth in Section II.B. above, the Commission is seeking comment on alternative search and reasonable care standards including (i) a requirement that transfer agents use technology reasonably designed to locate a lost securityholder instead of following specific guidelines as to what constitutes an acceptable database, (ii) a requirement that transfer agents periodically assess the effectiveness and appropriateness of the search procedures and technology they employ, and/or (iii) a requirement that transfer agents' satisfaction of their reasonable care obligations be based upon their search procedures meeting a performance-based standard based on success in locating lost securityholders.

B. Rule 17a-24

Proposed Rule 17a-24 will impose some additional compliance costs upon all registered transfer agents and such registered broker-dealers that fall within the definition of recordkeeper under the rule. However, the Commission estimates that the cost of compliance with proposed Rule 17a-24 will be small⁴⁰ and that the impact of the rule

upon recordkeepers' operations will be insignificant, regardless of the recordkeepers' size.

The proposed rule will impose on registered transfer agents and broker-dealers an additional recordkeeping requirement. The requirement has been broadly drafted to provide transfer agents and broker-dealers with sufficient flexibility to minimize recordkeeping costs. Specifically, proposed Rule 17a-24 will require that all recordkeepers under the proposed rule maintain records necessary to demonstrate their compliance with the rule's requirements. The Commission also is requiring that transfer agents maintain the records required by the proposed rule for a period of not less than three years, the first year in an easily accessible place.

The Commission considered various alternatives to the proposed rule and preliminarily concluded that Rule 17a-24 best fulfilled the proposed rule's objective and the Commission's statutory mandate.⁴¹ However, as set forth in Section IV above, the Commission is seeking comment on alternative information databases.

Commenters are encouraged to comment on any aspect of the analysis. Such comments will be considered in the preparation of the Final Regulatory Flexibility Analysis if the proposed rule is adopted. A copy of the Analysis may be obtained by contacting Michele Bianco, Attorney, Division of Market Regulation, U.S. Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC. 20549 at 202/942-4187.

VI. Paperwork Reduction Act

Certain provisions of proposed Rule 17Ad-17 and proposed Rule 17a-24 may contain "collection of information" requirements within the meaning of the Paperwork Reduction Act of 1995,⁴² and the Commission has submitted them to the Office of Management and Budget for review in accordance with 44 U.S.C.

approximately \$10.00 per year for the cost of a long distance telephone call.

⁴¹ As noted in footnote 37 above, the Commission considered (i) the establishment of a national database to which transfer agents would be required to submit the names of all lost securityholders and (ii) the effects of a database to be established by the National Association of Unclaimed Property Administrators and populated with information provided by the states that will include the names of all persons whose property has escheated to the states. With respect to the first alternative, the Commission believes that private vendors will be able to establish an effective database more quickly than the Commission. As previously noted with respect to the second alternative, lost securityholders would be deprived of their assets for a longer period of time because their names would not be included in the database until their assets had escheated to the state.

⁴² 44 U.S.C. 3501 et seq.

3507(d). The titles for the collection of information are: "Proposed Rule 17Ad-17 (Transfer Agents' Obligation to Search for Lost Securityholders)" and "Proposed Rule 17a-24 (Data Collection for Private Databases)."

The collection of information under proposed Rule 17Ad-17 and under proposed Rule 17a-24 is intended to facilitate greater accuracy of transfer agents' and broker-dealers' records. The collection of information is necessary to enable recordkeeping transfer agents, as the usual custodians of the records that determine the ownership of securities and the entitlement to corporate distributions, and broker-dealers, as holders of customer assets, to reduce significantly the number of lost securityholders.

Under the proposed rules, transfer agents and broker-dealers may use any appropriate method (e.g., through computerized or manual means) to collect the names of the lost securityholders. Under proposed Rule 17Ad-17, information must be submitted by transfer agents to a database service that is automated. Broker-dealers and transfer agents must submit information to the Commission pursuant to proposed Rule 17a-24 through computerized means. The information required to be collected by Rule 17Ad-17 and Rule 17a-24 (*i.e.*, the taxpayer identification numbers of lost securityholders) generally is already maintained by registered transfer agents and broker-dealers. Therefore, the Commission anticipates that the increased costs imposed by the rules will be relatively minimal.⁴³

The proposed rules also require that all recordkeeping transfer agents (and all recordkeepers with respect to

⁴³ The cost of compliance with proposed Rule 17Ad-17 will depend on the number of undeliverable accounts at each transfer agent. Based upon the information received from transfer agents and broker-dealers, the Commission believes there will be approximately 250,000 securityholders lost annually by all transfer agents. The Commission estimates that approximately \$3.00 will be spent per account (comprised of approximately \$1.00 for each of two searches and approximately \$1.00 in increased administrative costs for downloading and forwarding the information). Therefore, the estimated total annual cost for all transfer agents is \$750,000.

The cost of compliance with proposed Rule 17a-24 should be a minimal amount comprised of the cost of a long distance telephone call and administrative costs. Transfer agents and broker-dealers will be required to make an annual electronic filing. Filing capability through EDGAR should not require any significant start-up expense. The Commission estimates a long distance telephone charge of approximately \$10.00 per year and an additional administrative cost of approximately \$50.00 per year for downloading and forwarding the information. Thus, at a total cost of approximately \$60.00 per year for each recordkeeper, the total annual cost for all recordkeepers is estimated to be \$129,000.

³⁹ Among other things, the Commission considered (i) the establishment of a national database to which transfer agents would be required to submit the names of all lost securityholders and (ii) the effects of a database to be established by the National Association of Unclaimed Property Administrators and populated with information provided by the states that will include the names of all persons whose property has escheated to the states. In both instances, securityholders would need to take affirmative action to discover the existence of their lost assets. Because many if not most lost securityholders are unaware that they have property which is considered undeliverable and escheatable, many would not realize the importance of accessing the database. With respect to the first alternative, many of the same costs would be incurred by transfer agents because they would need to submit the names of the lost securityholders to the national database rather than to a database service. With respect to the second alternative, lost securityholders would be deprived of their assets for a longer period of time because their names would not be included in the database until their assets had escheated to the state. However, the Commission believes that it may be beneficial to pursue one of the alternatives as an additional mechanism for locating lost securityholders in conjunction with the proposed rule.

⁴⁰ Establishing filing capability through EDGAR should not require any expenditure by recordkeepers because the Commission supplies the necessary software. Even if the small entity does not currently have computer capability, the entity should be able to find a service provider to file on its behalf for a small charge. The Commission estimates an additional administrative cost of approximately \$50.00 per year for gathering and transmission of the required information and

proposed Rule 17a-24) maintain records necessary to demonstrate their compliance with the rules' requirements. This recordkeeping requirement is intended to provide transfer agents and broker-dealers with sufficient flexibility to record and to maintain necessary information in a manner that minimizes recordkeeping costs. The Commission will require that transfer agents (and all recordkeepers with respect to proposed Rule 17a-24) maintain the records required by the proposed rules for a period of not less than three years, the first year in an easily accessible place.

The Commission does not anticipate that the collection of information will result in any significant burden to transfer agents or broker-dealers. The likely respondents to the proposed collection of information under proposed Rule 17Ad-17 will be the approximately 1500 registered transfer agents. The likely respondents to the proposed collection of information under proposed Rule 17a-24 will be the approximately 1500 transfer agents and approximately 650 of the registered broker-dealers. The Commission estimates registered transfer agents will devote approximately five hours per year⁴⁴ to providing information on lost securityholders to third party database vendors, totalling 7,500 hours industry-wide. The Commission estimates registered transfer agents and broker-dealers will devote approximately two hours per year to make the required annual filing under proposed Rule 17a-24, totalling 4300 hours industry-wide.⁴⁵

The collection of information under proposed Rule 17Ad-17 and proposed Rule 17a-24 would be mandatory. Any information collected pursuant to proposed Rule 17Ad-17 or proposed Rule 17a-24 would not be confidential. Unless a valid Office of Management and Budget ("OMB") control number is displayed, for Commission may not sponsor or conduct or require response to an information collection.

Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments to—

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Persons desiring to submit comments on the collection of information requirements should direct them to the Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503, and should also send a copy of their comments directly to the Commission. OMB is required to make a decision concerning the collections of information between thirty and sixty days after publication, so a comment to OMB is best assured of having its full effect if OMB receives it within thirty days of publication.

VII. Burden on Competition

The Commission believes that the proposed rules will not have a significant impact on transfer agent or broker-dealer competition. Under proposed Rule 17Ad-17, all transfer agents will be subject to the same specified minimum standard for reasonable care in attempting to locate securityholders with whom contact has been lost. Similarly, proposed Rule 17a-24 will require all transfer agents and broker-dealers to submit the same information to the Commission.

The cost of compliance with proposed Rule 17Ad-17 is minimal.⁴⁶ For many transfer agents that currently conduct securityholder searches using an information database, proposed Rule 17Ad-17 will pose no additional cost. Because a transfer agent's cost of compliance generally is based upon the number of securityholders it must attempt to locate, transfers agents regardless of their size and exercising comparable care should incur comparable relative costs. On average, compliance costs should be roughly proportional to the number of securityholder records maintained by the transfer agent. In addition, the extent of the effort required by a transfer agent to meet its reasonable care obligations will require a balancing of cost against the value of assets at issue. Accordingly, larger transfer agents which are likely to have a greater proportion of accounts of considerable value, often will be required to take

more extensive measures and incur greater costs in meeting their reasonable care obligations under proposed Rule 17Ad-17.

With respect to proposed Rule 17a-24, the cost of compliance also should be minimal.⁴⁷ While the cost to each entity will be approximately the same regardless of the entities' size (i.e., the number of lost securityholders should not affect significantly the amount of time it takes to collect the information and to transmit it to the Commission), the total cost to each entity should be so limited as to not raise competition concerns.

VIII. Text of the Amendments

List of Subjects

17 CFR Part 232

Reporting and recordkeeping requirements; Securities.

17 CFR Part 240

Transfer agents; Broker-dealers; Reporting and recordkeeping requirements; Securities.

For the reasons set out in the preamble, the Commission proposes to amend Chapter II of Title 17 of the Code of Federal Regulations as follows:

PART 232—REGULATION S-T— GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll(d), 79t(a), 80a-8, 80a-29, 80a-30 and 80a-37.

2. By amending § 232.101 paragraph (a)(1)(iv) by revising the phrase "format; and" to read "format;"

3. By amending § 232.101 paragraph (a)(1)(v) by revising the phrase "et seq.;" to read "et seq.;" and".

4. By adding paragraph (a)(1)(vi) to § 232.101 to read as follows:

§ 232.101 Mandated electronic submissions and exceptions.

(a) * * *

(1) * * *

(vi) Documents filed with the Commission pursuant to § 240.17a-24 of this chapter.

* * * * *

5. By amending § 232.101(c)(11) by revising the phrase "Regulation;" to read "Regulation, other than those filed with the Commission pursuant to § 240.17a-24 of this chapter;"

⁴⁴ Transfer agents will need to submit this information to a database a maximum of four times a year to insure that a search is made within three months of a securityholder becoming lost. Each download and forwarding of information should take approximately 1.2 hours.

⁴⁵ Recordkeepers will submit information once a year. Each download and transmission of information should take approximately two hours.

⁴⁶ *Supra* note 43.

⁴⁷ *Supra* note 43.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

6. The authority citation for part 240 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78i, 78j, 78l, 78m, 78n, 78o, 78p, 78q, 78s, 78w, 78x, 78ll(d), 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

7. By adding § 240.17a–24 to read as follows:

§ 240.17a–24 Reports of Lost Securityholders.

(a) Each recordkeeper shall file electronically with the Commission on or before May 31 of each year a list of the taxpayer identification numbers (*e.g.*, social security number or employer identification number) of all lost securityholders for which such recordkeeper maintains records of ownership interests as of May 1 of such year. The list of lost securityholders shall include the name and telephone number of the appropriate person to contact at the recordkeeper.

(b) For purposes of this section:

(1) *Lost securityholder* means the holder of record of a security or any person from whom or on whose behalf a recordkeeper has received, has acquired, holds, or carries securities;

(i) To whom two separate items of correspondence that were sent by first class mail by the recordkeeper at least three months apart have been returned as undeliverable; and

(ii) For whom the recordkeeper has not received information regarding the securityholder's new address.

(2) *Recordkeeper* means:

(i) A member of a national securities exchange, a registered broker or dealer, or a registered municipal securities dealer which maintains records of securities received, acquired, held, or carried by or on behalf of such entity for the account of any securityholder; or

(ii) A recordkeeping transfer agent as defined in § 240.17Ad–9(h).

(c) Every recordkeeper shall maintain such records necessary to demonstrate compliance with the requirements set forth in this section. Such records shall be maintained for a period of not less than three years, the first year in an easily accessible place.

8. By amending § 240.17Ad–7 by adding paragraph (i) to read as follows:

§ 240.17Ad–7 Record retention.

* * * * *

(i) The records required by § 240.17Ad–17(c) shall be maintained for a period of not less than three years,

the first year in an easily accessible place.

9. By adding § 240.17Ad–17 to read as follows:

§ 240.17Ad–17 Transfer agents' obligation to search for lost securityholders.

(a)(1) Every recordkeeping transfer agent whose master securityholder file includes accounts of lost securityholders shall exercise reasonable care to ascertain the correct address of such securityholders. In exercising reasonable care to ascertain for its master securityholder file such lost securityholders' current address, each recordkeeping transfer agent shall conduct two database searches using at least one information database service. The transfer agent shall search by name (if reasonably likely to locate the securityholder) or taxpayer identification number (*e.g.*, social security number or employer identification number). Such database searches must be conducted without charge to a lost securityholder and with the following frequency:

(i) Within three months of such securityholder becoming a lost securityholder; and

(ii) Between one year and eighteen months after the transfer agent's first search for such lost securityholder.

(2) A transfer agent may not use a search method or service to establish contact with lost securityholders that results in a charge to a lost securityholder prior to completing the searches set forth in paragraphs (a)(1)(i) and (a)(1)(ii) of this section.

(b) For purposes of this section:

(1) *Information database service* means any automated database service that:

(i) Contains addresses of United States residents including addresses in the geographic area in which the lost securityholder's last known address is located;

(ii) Covers a reasonably broad geographic area;

(iii) Is indexed by name or taxpayer identification number; and

(iv) Is updated at least four times a year.

(2) *Lost securityholder* means a securityholder:

(i) To whom two separate items of correspondence that were sent by first class mail at least three months apart have been returned as undeliverable; and

(ii) For whom the transfer agent has not received information regarding the securityholder's new address.

(c) Every recordkeeping transfer agent shall maintain such records necessary to demonstrate compliance with the requirements set forth in this section.

Dated: August 22, 1996.

By the Commission.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 96–21892 Filed 8–27–96; 8:45 am]

BILLING CODE 8010–10–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 920

[MD–040]

Maryland Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Maryland regulatory program (hereinafter the “Maryland program”) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to the Maryland statutes pertaining to permit revocation, reinstatement, and reissuance. The amendment is intended to revise the Maryland program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., [e.d.t.] September 27, 1996. If requested, a public hearing on the proposed amendment will be held on September 23, 1996. Requests to speak at the hearing must be received by 4:00 p.m., [e.d.t.], on September 12, 1996.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to George Rieger, Field Branch Chief, at the address listed below.

Copies of the Maryland program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Appalachian Regional Coordinating Center.

George Rieger, Field Branch Chief,
Appalachian Regional Coordinating
Center, Office of Surface Mining
Reclamation and Enforcement, 3

Parkway Center, Pittsburgh, PA 15220. Telephone: (412) 937-2849. Maryland Bureau of Mines, 160 South Water Street, Frostburg, Maryland 21532. Telephone: (301) 689-4136.

FOR FURTHER INFORMATION CONTACT: George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Telephone: (412) 937-2849.

SUPPLEMENTARY INFORMATION:

I. Background on the Maryland Program

On February 18, 1982, the Secretary of the Interior approved the Maryland program. Background information on the Maryland program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the February 18, 1982, Federal Register (47 FR 7214). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 920.15 and 920.16.

II. Description of the Proposed Amendment

By letter dated August 5, 1996 (Administrative Record No. MD-575-00) Maryland submitted a proposed amendment to its program pursuant to SMCRA at its own initiative. House Bill 1124 enacted on May 14, 1996, revises the provisions of Chapter 522 of the Annotated Code of Maryland (Code) that pertain to surface coalmining. Specifically, Maryland proposes to authorize the reinstatement of a revoked permit in order to reissue all or part of the permit to another qualified operator. The new operator must submit certain information prior to obtaining a reissued permit. The operator of a revoked permit forfeits all rights and claims to the permit.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Maryland program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Appalachian Regional Coordinating Center will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to speak at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., [e.d.t.] on September 12, 1996. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. Persons in the audience who have not been scheduled to speak, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Public Meeting

If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language

of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the date and assumptions for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose a cost of \$100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 920

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 20, 1996.

Ronald C. Recker,

*Acting Regional Director, Appalachian
Regional Coordinating Center.*

[FR Doc. 96-21862 Filed 8-27-96; 8:45 am]

BILLING CODE 4310-05-M

30 CFR Part 943

[SPATS No. TX-017-FOR]

Texas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed Rule; Reopening and extension of public comment period on proposed amendment.

SUMMARY: OSM is announcing receipt of revisions pertaining to a previously proposed amendment to the Texas regulatory program (hereinafter, the "Texas program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions of Texas' proposed rules pertain to exemption for coal extraction incidental to the extraction of other minerals; surface water information; protection of hydrologic balance; permitting; siltation structures; impoundments; revegetation; definitions; lands unsuitable for mining; areas designated by act of congress; prime farmland; notices of violation, hydrology and geology requirements; use of explosives; bond release; assessment of civil penalties; and individual civil penalties. Texas also proposed nonsubstantive changes in wording, numbering, and punctuation of its rules. The amendment is intended to revise the State program to be consistent with the corresponding Federal regulations.

This notice sets forth the times and locations that the Texas program and revisions to the proposed amendment to that program are available for public inspection, and the reopened comment period during which interested persons may submit written comments on the proposed amendment.

DATES: Written comments must be received by 4:00 p.m., c.d.t., September 27, 1996.

ADDRESSES: Written comments should be mailed or hand delivered to Mr. Jack R. Carson, Acting Director, Tulsa Field Office, at the address listed below.

Copies of the Texas program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free

copy of the proposed amendment by contacting OSM's Tulsa Field Office.

Jack R. Carson, Acting Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma, 74135-6547, Telephone: (918) 581-6430.

Railroad Commission of Texas, Surface Mining and Reclamation Division, 1701 North Congress Avenue, P.O. Box 12967, Austin, Texas, 78711-2967, Telephone: (512) 463-6900.

FOR FURTHER INFORMATION CONTACT: Mr. Jack R. Carson, Acting Director, Tulsa Field Office, Telephone: (918) 581-6430.

SUPPLEMENTARY INFORMATION:

I. Background on the Texas Program

On February 16, 1980, the Secretary of the Interior conditionally approved the Texas program. General background information on the Texas program, including the Secretary's findings, the disposition of comments, and the conditions of approval, can be found in the February 27, 1980, Federal Register (45 FR 12998). Subsequent actions concerning the Texas program and program amendments can be found at 30 CFR 943.10, 943.15, and 943.16.

II. Proposed Amendment

By letter dated May 13, 1993 (Administrative Record No. TX-551), Texas submitted a proposed amendment to its program pursuant to SMCRA. Texas submitted the proposed amendment in response to letters dated May 20, 1985; June 9, 1987; October 20, 1988; February 7, 1990; and February 21, 1990 (Administrative Record Nos. TX-358, TX-388, TX-417, TX-472, and TX-476), that OSM sent to Texas in accordance with 30 CFR 732.17(c) and in response to the required program amendments at 30 CFR 943.16(k) through (q). OSM announced receipt of the proposed amendment in the June 21, 1993, Federal Register (58 FR 33785), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on the adequacy of the amendment (Administrative Record No. TX-556). The public comment period would have closed July 21, 1993. However, by letter dated July 16, 1993, the Texas Mining and Reclamation Association requested a 30-day extension of time in which to review and provide comments on the proposed amendment (Administrative Record No. TX-563). OSM announced receipt of the extension request and reopened the comment period in the August 16, 1993, Federal Register (58 FR 43308). The extended public comment period ended August 20, 1993.

During its review of the May 13, 1993, proposed amendment, OSM identified concerns relating to several of the proposed regulations. OSM notified Texas of its concerns by letter dated July 25, 1994 (Administrative Record No. TX-578). Further Clarification of OSM's concerns were provided to Texas by letters dated November 4, 1994, November 21, 1994, and January 18, 1995 (Administrative Record Nos. TX-581, TX-589, and TX-585). Texas responded in a letter dated September 18, 1995, by submitting a revised amendment package (Administrative Record No. TX-598). OSM announced receipt of the proposed amendment in the October 25, 1995, Federal Register (60 FR 54620) and invited public comment on the adequacy of the amendment. The public comment period closed November 9, 1995.

During its review of the September 18, 1995, revised amendment, OSM identified concerns relating to several of the proposed regulations. OSM notified Texas of its concerns by letter dated June 18, 1996, (Administrative Record No. TX-614). Texas responded in a letter dated July 31, 1996, by submitting a revised amendment package (Administrative Record No. TX-621). Texas proposed revisions to its September 18, 1995, revised amendment submittal; proposed to include in its approved program new and revised regulations that were adopted in State rulemaking at Surface Mining and Reclamation Division (SMRD) 1-87, SMRD 2-87, and SMRD 2-88; and proposed editorial corrections throughout its regulations. The substantive proposals are discussed below.

A. Revisions to September 18, 1995, Revised Amendment

1. TCMR Part 709 Exemption for Coal Extraction Incidental to the Extraction of Other Minerals

a. At TCMR 709.027(f) [originally proposed as TCMR 702.11(f)], Texas proposes to revise the provisions pertaining to administrative review of its determinations on exemptions for coal extraction incidental to the extraction of other minerals by deleting paragraph (f)(2) and revising paragraph (f)(1) as follows:

(f) Appeal and review. Any adversely affected person may request appeal or review of a determination under Paragraph (e) of this Section in accordance with procedures established under Section 787.222 of this chapter.

b. At TCMR 709.033(c) [originally proposed as TCMR 702.17(c)], Texas proposes to revise the provisions pertaining to revocation of an

exemption for coal extraction incidental to the extraction of other minerals by deleting paragraph (c)(3) and revising paragraph (c)(2) as follows:

Any adversely affected person may request appeal or review of a decision whether to revoke an exemption in accordance with procedures established under Section 787.222 of this chapter.

2. TCMR 779.129 (Surface) and TCMR 783.175 (Underground) Surface Water Information

At TCMR 779.129 and 783.175, Texas proposes to require the name, location, ownership, and description of all surface water bodies in the proposed permit and adjacent areas. Texas also proposes to require information on surface-water quantity and quality sufficient to demonstrate seasonal variation and water usage.

3. TCMR 780.146 (Surface) and TCMR 784.188 (Underground) Reclamation Plan: Protection of Hydrologic Balance

a. At TCMR 780.146(a), Texas proposed to add references to Sections 816.340 and 816.341. At TCMR 784.188(a), Texas proposes to add references to sections 817.509–511, 817.516, and 817.518–23.

b. At TCMR 780.146(d)(5), Texas proposes to add references to Sections 779.128 and 779.129. At TCMR 784.188(d)(5) Texas proposes to add references to Sections 783.174 and 783.175. The following provision was added to both TCMR 780.146(d)(5) and 784.188(d)(5).

Information shall be provided on water availability and alternative water sources, including the suitability of alternative water sources for existing premining uses and approved postmining land uses.

4. TCMR 786.220 Conditions of Permits: General and Right of Entry

At TCMR 786.220(d), Texas proposes to add language that requires operators to pay all reclamation fees required by 30 CFR Subchapter R.

5. TCMR 817.514 (Underground) Hydrologic Balance: Siltation Structures

At TCMR 817.514, Texas proposes to remove the language “in Paragraph (c)(2)(ii) of this section, except as set forth.”

6. TCMR 816.347 (Surface) and TCMR 817.517 (Underground) Hydrologic Balance: Permanent and Temporary Impoundments

Texas proposes to revise TCMR 816.347(a)(5) and 817.517(a)(5) to add language requiring impoundments to have adequate freeboard so as to resist overtopping by waves and by sudden increases in storage volume.

7. TCMR 816.390 (Surface) and TCMR 817.555 (Underground) Revegetation: General Requirements

Texas proposes to remove the current language from these sections and add the following new language.

(a) The permittee shall establish on regraded areas and on all other disturbed areas except water areas and surface areas of roads that are approved as part of the postmining land use, a vegetative cover that is in accordance with the approved permit and reclamation plan and that is—

(1) Diverse, effective, and permanent;

(2) Comprised of species native to the area, or of introduced species where desirable and necessary to achieve the approved postmining land use and approved by the Commission;

(3) At least equal in extent of cover to the natural vegetation of the area; and

(4) Capable of stabilizing the soil surface from erosion.

(b) The reestablished plan species shall—

(1) Be compatible with the approved postmining land use;

(2) Have the same seasonal characteristics of growth as the original vegetation;

(3) Be capable of self-regeneration and plant succession;

(4) Be compatible with the plant and animal species of the area; and

(5) Meet the requirements of applicable State and Federal seed, poisonous and noxious plant, and introduced species laws or regulations.

(c) The Commission may grant exception to the requirements of Paragraphs (b)(2) and (b)(3) of this Section when the species are necessary to achieve a quick-growing, temporary, stabilizing cover, and measures to establish permanent vegetation are included in the approved permit and reclamation plan.

(d) When the Commission approves a cropland postmining land use, the Commission may grant exception to the requirements of Paragraphs (a)(1), (a)(3), (b)(2), and (b)(3) of this Section. The requirements of Part 823 of this Chapter apply to areas identified as prime farmland.

8. Texas is withdrawing its proposed revegetation guidelines entitled “Field Sampling Procedures for Determining Ground Cover, Productivity, and Woody-Plant Stocking Success of Reclaimed Surface Mined Land Uses; Revegetation Success Standards for Reclaimed Surface Mined Land Uses; and Normal Husbandry Practices on Unmined Land.”

B. *SMRD 1–87*. Texas proposes to include in its approved program the following regulations as added or revised in State rulemaking SMRD 1–87.

1. TCMR 701.008 Definitions

The definitions for “cropland” at TCMR 701.008(25), “historically used for cropland” at TCMR 701.008(41), “prime farmland” at TCMR 701.008(67), “soil horizons” at TCMR 701.008(84), and “topsoil” at TCMR 701.008(95) were revised.

2. TCMR Part 760 Lands Unsuitable for Mining—General

a. *TCMR 760.069, Objectives*. Texas replaced the currently approve language in TCMR 760.069 with the following language.

This Subchapter establishes the procedures and standards to be followed in determining whether a proposed surface coal mining and reclamation operation can be authorized in light of the prohibitions and limitations in Section 33 of the Act for those types of operations on certain public and private lands.

b. *TCMR 760.070, Definitions*. Texas numbered its definitions TCMR 760.070 (1) through (14); added a new definition for “owner of record” or “ownership interest of record” at TCMR 760.070(5) and “publicly-owned park” at TCMR 760.070(9); and made nonsubstantive paragraph notation and wording changes to its definitions for “public building” at TCMR 760.070(6), “public park” at TCMR 760.070(7), and “significant recreational, timber, economic, or other values incompatible with surface coal mining operations” at TCMR 760.070(11).

3. TCMR Part 761 Areas Designated by Act of Congress

a. *TCMR 761.071, Areas Where Mining is Prohibited or Limited*. Texas added a new provision at TCMR 761.071(b) concerning prohibition of mining on Federal lands; added a new provision at TCMR 761.071(e)(2) concerning an exception to the prohibition of mining within 300 feet of an occupied dwelling for specific haul roads or access roads; and made nonsubstantive editorial or wording changes at redesignated TCMR 761.071(c), (d)(2), (e), (e)(1), (f), and (g).

b. *TCMR 761.072 Procedures for Determining Whether Surface Mining Operations are Limited or Prohibited*. Texas made nonsubstantive editorial and wording changes to TCMR 761.072(a), (b), (c), (d)(1), (d)(2), (d)(3), (g), and (h); made substantive revisions to TCMR 761.072(d)(4) concerning a written finding as to whether the interest of the public and affected landowners will be protected from the proposed mining operation; added a new provision at TCMR 761.072(d)(4) pertaining to mining within 100 feet of the outside right-of-way line of a road and relocation or closure of a road; made substantive revisions to TCMR 761.072(e) concerning a written waiver for conducting mining within 300 feet of an occupied dwelling; and made substantive revisions to TCMR 761.072(f) concerning the Commission’s determination that a proposed surface coal mining operation will adversely

affect any publicly owned park or any place included in the National Register of Historic Places.

4. TCMR Part 762 Criteria for Designating Areas as Unsuitable for Surface Coal Mining Operations

Texas made nonsubstantive editorial and wording changes throughout this part and substantive revisions or additions to the following provisions.

a. *TCMR 762.074, Definitions.* Texas added a definition at TCMR 762.074(4) for “renewable resource lands” and made substantive revisions to its definition at TCMR 762.072(5) for “substantial legal and financial commitments in a surface coal mining operation.”

b. *TCMR 762.076, Land Exempt From Designation as Unsuitable for Surface Coal Mining Operations.* Texas revised TCMR 762.076(a) by changing the date of exemption from August 3, 1977, to “the date of enactment of the Act.”

5. TCMR Part 764 Process for Designating Areas Unsuitable for Surface Coal Mining Operations

Texas made nonsubstantive editorial and wording changes and clarifying language changes throughout this part. Texas made substantive revisions or additions to the following provisions.

a. *TCMR 764.079, Procedures: Petitions.* Texas added a new provision at TCMR 764.079(a) pertaining to an “injury in fact” test for persons petitioning the Commission to have an area designated as unsuitable for mining.

Texas made substantive revisions at TCMR 764.079(b) pertaining to the Commission’s determination of the information that must be provided by the petitioner for designations of lands as unsuitable for surface coal mining operations and at TCMR 764.079(c) pertaining to the Commission’s determination of the information that must be provided by petitioner to terminate designations of lands as unsuitable for mining.

b. *TCMR 764.080 Procedures: Initial Processing, Recordkeeping, and Notification Requirements.* Texas revised TCMR 764.080(a)(1) by changing the time for notifying the petitioner of whether the petition is complete from 90 days to 60 days. Texas also added a definition for “complete, for a designation or termination petition.”

At TCMR 764.080(a)(4), Texas added “or that the petitioner does not meet the requirement of Section .079(a)” to its list of reasons for returning the petition to the petitioner. Texas also defined “frivolous petition.”

Texas made a substantive revision to TCMR 764.080(a)(7) concerning the

Commission’s determination not to process a petition pertaining to lands for which an administratively complete permit application had been filed and the first newspaper notice had been published.

Texas made a substantive revision to TCMR 764.080(b)(1) concerning notification of the general public of the receipt of a petition and to TCMR 764.080(b)(2) concerning provision for a hearing or a period of written comments on completeness of petitions.

At TCMR 764.080(d), Texas added a new provision that requires the Commission to maintain information at or near the area in which the petitioned land is located.

c. *TCMR 764.081 Procedures: Hearing Requirements.* At TCMR 764.081(a), Texas clarified an expanded it provisions concerning the procedures for a public hearing on petitions.

At TCMR 764.081(b)(1)(C), Texas proposes to also give notice of the date, time, and location of a hearing to “any person known by the Commission to have a property interest in the petitioned area” via regular mail. At TCMR 764.081(b)(2), Texas proposes to send notice to petitioners and intervenors by certified mail and to government agencies and property owners by regular mail.

d. *TCMR 764.082 Procedures: Decision.* At TCMR 764.082(b), Texas proposes to send the decision “by certified mail to the petitioner and intervenors and by regular mail to all other persons with an ownership interest of record and persons known to the Commission to have an interest in the property as evidenced by the hearing registration forms.”

At TCMR 764.082(c), Texas clarifies that “all relevant portions of the data base, inventory system, and public comments received during the public comment period set by the Commission shall be considered and included in the record of the administrative proceeding.”

e. *TCMR 764.084 Public Information.* At TCMR 764.084, Texas specifies that it will make information in the data base and inventory system available to the public “except that specific information relating to location of properties proposed to be nominated to, or listed in, the National Register of Historic Places need not be disclosed if the Commission determines that the disclosure of such information could create a risk of destruction or harm to such properties.”

6. TCMR 785.201 Prime Farmland

Texas revised its prime farmland plan provisions at TCMR 785.201(b)(1) concerning the requirement for a soil

survey; TCMR 785.201(b)(2) concerning the requirement for a plan for soil reconstruction, replacement, and stabilization; TCMR 785.201(b)(3) concerning a requirement for scientific data; and TCMR 785.201(b)(4) concerning a requirement for the productivity data prior to mining. Texas also revised its provision for consultation with the Secretary of Agriculture at TCMR 785.201(c) and its provision for permit issuance at TCMR 785.201(d)(2).

7. TCMR Part 823 Special Permanent Program Performance Standards—Operations on Prime Farmland

Texas proposes to revise TCMR 823.620 pertaining to prime farmland applicability and special requirements by adding new paragraphs (a)(1) and (a)(2); redesignating the introductory paragraph as (b), paragraph (a) as (b)(1), and (b) as (b)(2); and removing old paragraph (c). New paragraphs (a)(1) and (a)(2) pertain to prime farmland areas that are not subject to the requirements of Part 823.

Texas proposes to amend TCMR 823.621 pertaining to prime farmland soil removal by revising paragraphs (a)(1), (a)(2), and (b) and removing paragraph (a)(3). The substantive revision to this section concerns the requirement that other suitable soil materials have a “greater”, rather than “equal or greater,” productive capacity than the topsoil which existed prior to mining.

Texas proposes to amend TCMR 823.622 pertaining to prime farmland soil stockpiling by reorganizing the existing requirements into paragraphs (a), (b), and (c).

Texas proposes to delete TCMR 823.623 pertaining to an alternative to separate soil horizon removal and stockpiling.

At TCMR 823.624 pertaining to prime farmland soil replacement, Texas proposes to add new paragraph (a) and to redesignate existing paragraphs (a) through (f) as (b) through (g). New paragraph (a) concerns soil reconstruction specification established by the U.S. Soil Conservation Service. Editorial and nonsubstantive language changes were made to the existing paragraphs.

At TCMR 823.625, Texas proposes to expand and clarify its requirements for prime farmland revegetation and restoration of soil productivity.

8. TCMR 843.681 Notices of Violation

At TCMR 843.681(c), Texas added an exception to the requirement that the total time for abatement of a notice of violation shall not exceed 90 days from the date of issuance. New paragraph (f)

provides the circumstances that would be considered for an extension to the abatement period. New paragraph (g) provides that interim abatement measures shall be imposed when an abatement time in excess of 90 days is allowed. New paragraph (h) provides procedures for the authorized representative's determination on a request for extension of the abatement period. New paragraph (i) provides that the determination under paragraph (h) shall be in writing and contain a right of review. New paragraph (j) specifies that an extension may not exceed 90 days and allows the permittee to request further extension.

C. *SMRD 2-87*. Texas proposes to include in its approved program the following regulations as added or reviewed in State rulemaking SMRD 2-87.

1. *TCMR 701.008 Definitions*. The definitions for "coal mine waste" at TCMR 701.008(18), "coal preparation" at TCMR 701.008(19), "experimental practice" at TCMR 701.008(34), "professional specialist" at TCMR 701.008(69), "registered professional engineer" at TCMR 701.008(76), "unwarranted failure to comply" at TCMR 701.008(102), and "willful violation" at TCMR 701.008(107) were added to the definition section.

2. *TCMR 779.127 Geology Description*. Texas revised TCMR 779.127(a) by expanding and clarifying the geology information that must be included in a permit application.

3. *TCMR 780.141 Operations Plan: Blasting*. Texas added two additional requirements for permit application blasting plans: a description of ground vibration and airblast limitations at TCMR 780.141(g) and a description of the methods to be used in controlling adverse effects of blasting at TCMR 780.141(h).

4. *TCMR 780.146 (Surface) and TCMR 784.188 (Underground) Reclamation Plan: Protection of Hydrologic Balance*. Texas revised TCMR 780.146(a) and 784.188(a) by expanding and clarifying the hydrologic information that must be included in permit applications; added TCMR 780.146(d) and 784.188(d) to require a probable hydrologic consequences determination be included in permit applications; and added TCMR 780.146(e) and 784.188(e) concerning the requirement for a cumulative hydrologic impact assessment.

5. *TCMR 788.232 Transfer, Assignment or Sale of Permit Rights: Obtaining Approval*. Texas revised TCMR 788.232(c)(2) by changing the term "person seeking approval" to "applicant."

6. *TCMR 806.311 Terms and Conditions for Liability Insurance*. Texas revised TCMR 806.311(d) by adding language concerning what is required for an applicant to meet self-insurance requirements.

7. *TCMR 807.312 Procedure for Seeking Release of Performance Bond*. Texas revised TCMR 807.312 (b) and (c) concerning the Commission's inspection and revaluation of the reclamation on areas required to be released from bond.

8. *TCMR 816.357 and TCMR 817.526 Use of Explosives: General Requirements*. Texas revised TCMR 816.357(c) and 817.526(c) concerning responsibilities of the person responsible for blasting operations by adding two additional responsibilities at (c)(1) and (c)(2). Texas also added TCMR 816.357(d) and 817.526(d) concerning submittal of an anticipated blast design under specified circumstances.

9. *TCMR 816.358 and TCMR 817.527 Use of Explosives: Pre-Blasting Survey*. Texas revised TCMR 816.358(a) and 817.527(a) by adding the requirement that the operator notify residents or owners of dwellings or other structures of how to request a preblasting survey. Texas also added TCMR 816.358(d) and 817.527(d) to require that pre-blasting surveys requested before the tenth day of planned blasting be completed before the blasting.

10. *TCMR 817.500 Signs and Markers*. Texas revised TCMR 817.500(f) concerning warning signs of surface blasting incidental to underground mining activities.

11. *TCMR 817.528 Use of Explosives: Control of Adverse Effects*. Texas made substantive revisions to TCMR 817.528(a) concerning general requirements for controlling adverse effects of blasting; TCMR 817.528(b) concerning scheduled blasting; TCMR 817.528(e) concerning access control; TCMR 817.528(f) concerning airblast limits and monitoring; and TCMR 817.528(g) concerning flyrock limitations. Texas added provisions at TCMR 817.528(c) concerning unscheduled blasting; TCMR 817.528(d) concerning blasting signs, warnings, and access control; and TCMR 817.528(h) concerning ground vibration.

12. *TCMR 817.529 Use of Explosives: Seismographic Measurements*. Texas deleted this section in State rulemaking SMRD 2-87.

13. *TCMR 817.530 Use of Explosives: Records of Blasting Operations*. Texas revised and clarified the existing provisions concerning the requirement for operator's to retain a record of each blast.

14. *TCMR 843.682 Suspension or Revocation of Permits*. Texas deleted the

definitions for "willful violation" and "unwarranted failure to comply" from TCMR 843.682(a)(1) and added them to TCMR 701.008.

15. *TCMR 845.695 Procedures for Assessment of Civil Penalties*. Texas revised TCMR 845.695(b) by adding a provision at (b)(1) concerning service of proposed assessments. Tendering a proposed assessment at the address of the person to whom it was issued, even if the person refuses to accept delivery, meets the requirements of service.

D. *SMRD 2-88*. Texas proposes to include in its approved program the following regulations as added or revised in State rulemaking SMRD 2-88.

1. *TCMR 807.312 Procedure for Seeking Release of Performance Bond*. Texas included revisions to TCMR 807.312(a) concerning the filing of a request for release of performance bond or deposit.

2. *TCMR Part 846 Individual Civil Penalties*. Texas included new regulations at TCMR 846.001 concerning definitions for "knowingly", "violation, failure, or refusal", and "willfully"; TCMR 846.002 concerning when an individual civil penalty may be assessed; TCMR 846.003 concerning the criteria used in determining the amount of an individual civil penalty; TCMR 846.004 concerning procedures for service of a notice of proposed individual civil penalty assessment and the opportunity for review; and TCMR 846.005 concerning requirements for payment of a penalty.

E. Additional Proposed Changes

1. *TCMR 701.003(1)*. Texas proposes to change the definitions of "Act" to reflect recent recodification of the Texas Surface Coal Mining and Reclamation Act at Chapter 134 of the Texas Natural Resources Code.

2. *TCMR 701.003(3)*. Texas proposes to change the definition of "APTRA" to reflect recent recodification of its Administrative Procedure Act (APA) at Chapter 2001, Texas Government Code.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Texas program.

Written Comments

Written comments should be specific, pertain only to the issue proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time

indicated under **DATES** or at locations other than the Tulsa Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under Sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (54 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was

prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose a cost of \$100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 943

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 16, 1996.

Brent Wahlquist,

Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 96-21861 Filed 8-27-96; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CO35-1-6190, CO41-1-6826, CO40-1-6701, CO42-1-6836; FRL-5559-8]

Clean Air Act Approval and Promulgation of State Implementation Plans; Colorado; New Source Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve the State implementation plan (SIP) revisions submitted by the Governor of Colorado on November 12, 1993, August 25, 1994, September 29, 1994, November 17, 1994, and January 29, 1996. These submittals revised Colorado Regulation No. 3 and the Common Provisions Regulation pertaining to the State's new source review (NSR) permitting requirements. The submittals included revisions to make the State's NSR rules more compatible with its title V operating permit program, the addition of nonattainment NSR provisions for new and modified major sources of PM-10 precursors locating in the Denver PM-10 nonattainment area, a change from the dual "source" definition to the plantwide definition of "source" in the State's nonattainment NSR permitting requirements, and correction of deficiencies in the State's

construction permitting rules. EPA is proposing to approve these regulatory revisions because they provide for consistency with the Clean Air Act (Act), as amended, and the corresponding Federal regulations and guidance.

DATES: Comments must be received in writing on or before October 28, 1996.

ADDRESSES: Written comments should be addressed to: Vicki Stamper, 8P2-A, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado, 80202-2466. Copies of the State's submittals and other information relevant to this proposed action are available for inspection during normal business hours at the following locations: Air Program, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2405; and the Air Pollution Control Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado 80222-1530.

FOR FURTHER INFORMATION CONTACT: Vicki Stamper at (303) 312-6445.

SUPPLEMENTARY INFORMATION: Section 110(k) of the Act sets out provisions governing EPA's review of SIP submittals (see 57 FR 13565-13566).

I. Procedural Background

The Act requires States to observe certain procedural requirements in developing implementation plans and plan revisions for submission to EPA. [See sections 110(a)(2) and 110(l) of the Act.] EPA also must determine whether a submittal is complete and therefore warrants further EPA review and action [see section 110(k)(1) of the Act and 57 FR 13565]. The EPA's completeness criteria for SIP submittals are set out at 40 CFR part 51, appendix V.

To entertain public comment, the Colorado Air Quality Control Commission (AQCC), after providing adequate notice, held public hearings on (1) August 20, 1992 regarding changes to the definition of "source" in the Common Provisions Regulation and Regulation No. 3; (2) July 15, 1993 regarding revisions to make the State's title V and NSR programs more compatible and on the complete restructuring of Regulation No. 3; (3) February 17, 1994 regarding PM-10 precursor NSR provisions for the Denver moderate PM-10 nonattainment area; (4) August 18, 1994 regarding revisions to Regulation No. 3 addressing title V/SIP deficiencies; and (5) March 16, 1995 regarding revisions to address other deficiencies in Regulation No. 3. Following the public hearings, the AQCC adopted the respective rule revisions. The Governor of Colorado

submitted the various rule revisions with letters dated November 17, 1994, November 12, 1993, August 25, 1994, September 29, 1994, and January 29, 1996, respectively.

The SIP revisions were reviewed by EPA to determine completeness shortly after submittal, in accordance with the completeness criteria referenced above. The submittals were found to be complete, and letters dated January 19, 1995, January 28, 1994, October 20, 1994, November 25, 1994, and July 12, 1996, respectively, were forwarded to the Governor indicating the completeness of the submittals and the next steps to be taken.

II. This Action

EPA evaluated the State's submittals by comparing them to the requirements of the amended Act, the Federal construction permitting requirements in 40 CFR 51.160–166, the Federal operating permit requirements in 40 CFR part 70 (for those provisions which the State added to the construction permit program in order to implement specific provisions of its operating permit program), and EPA guidance and policy.

A. November 12, 1993, September 29, 1994, and January 29, 1996 SIP Submittals

In July of 1993, the Colorado AQCC adopted operating permit regulations as part of Regulation No. 3 in accordance with title V of the amended Act and the corresponding Federal regulations for operating permit programs in 40 CFR part 70. Concurrent with adoption of its operating permit regulations, the State also adopted revisions to its construction permit regulations in Regulation No. 3 in order to make the two permit programs work together and in order to allow for implementation of certain title V provisions. The State completely revised and restructured Regulation No. 3, so that it is now divided into four parts, as follows:

1. Part A contains all definitions and provisions that apply to both the construction permit and operating permit programs. In this part, Colorado extended the administrative permit amendment provisions and some of the operational flexibility provisions of 40 CFR part 70 to the construction permit program;

2. Part B contains provisions which apply only to the construction permit program [including the nonattainment NSR and prevention of significant deterioration (PSD) programs]. The State made revisions to allow certain aspects of the operating permit program to also apply to construction permits (e.g., combined permits and general permits)

and to allow certain operational flexibility provisions to be implemented through the operating permit program without requiring construction permits (e.g., minor modifications, SIP equivalency, and other permit changes);

3. Part C contains provisions which apply solely to the State's operating permit program; and

4. Part D contains the Statements of Basis and Purpose for each revision to Regulation No. 3.

Parts A and C of Regulation No. 3 were submitted for approval as part of the State's title V operating permit program on November 5, 1993. Parts A and B of Regulation No. 3 were submitted for approval in the SIP on November 12, 1993.

EPA reviewed Parts A and B of Regulation No. 3 for conformance with the applicable Federal requirements and identified several deficiencies in the November 1993 SIP submittal. EPA informed the State of those deficiencies in a letter dated September 19, 1994. In that letter, EPA identified deficiencies that needed to be addressed by the State before EPA would proceed to act on the November 1993 SIP submittal. EPA also recommended other revisions to provide for clarity in the State's permitting regulations.

Some of the deficiencies identified by EPA in the State's November 12, 1993 SIP submittal were also identified as deficiencies in the State's title V operating permit program which EPA required the State to address before EPA would proceed with interim approval of the State's title V program. Those deficiencies included (1) The fact that the State does not currently have a SIP-approved generic emissions trading program under which the trading described in Section IV.B. of Part A of Regulation No. 3 would be allowed, and (2) the allowing of alternative emission limits to be developed in permits when Section IV.D.1.i. of Part B of Regulation No. 3 did not adequately provide for this flexibility. The State adopted revisions intended to address these deficiencies (as well as to address other deficiencies in its title V operating permit program) on August 18, 1994 and submitted these revisions for approval in the SIP and for revision to its title V program on September 29, 1994.

EPA's review of the September 29, 1994 submittal found that the State adequately addressed these SIP/title V deficiencies by clarifying that Section IV.B. of Part A could only be implemented if the SIP included an EPA-approved trading program and by deleting Section IV.D.1.i. of Part B. Based on this September 29, 1994 title V program revision (which also

included correction of other title V program deficiencies), EPA granted interim approval of Colorado's operating permit program on January 24, 1995 (60 FR 4563).

On March 16, 1995, the AQCC adopted further revisions to Regulation No. 3 intended to address the remaining deficiencies EPA identified in the State's November 12, 1993 SIP submittal. Those revisions were submitted to EPA for approval on January 29, 1996 and include the following:

1. Changes to the definitions of "lowest achievable emission rate (LAER)" and "net emissions increase" to be consistent with the Federal definitions in 40 CFR 51.165(a)(1)(xiii) and 40 CFR 51.165(a)(1)(vi), respectively;

2. Consolidation of the State's definitions of "air pollution source," "stationary source," and "new source" so that only the term "stationary source," which is consistent with the Federal definition, is used in the provisions of Regulation No. 3. The State also retained the definition of "air pollution source" because it reflects the definition found in State statute, but it is no longer used in Regulation No. 3;

3. The addition of a requirement to the definition of "volatile organic compound (VOC)" requiring EPA approval prior to use of any test method that is not an EPA reference test method;

4. Revisions to the administrative process in Section II.D.5. of Part A of Regulation No. 3 which allows for processing individual requests to exempt additional sources from the State's Air Pollution Emission Notice (APEN) requirements (and, consequently, from construction permit requirements) to require EPA approval of any new exemptions prior to use;

5. Revisions to the definition of "surplus" in Section V.C.10. of Part A of Regulation No. 3 to be consistent with EPA's Emission Trading Policy Statement (see 51 FR 43832, 12/4/86);

6. The addition of a provision to Section V.E. of Part A of Regulation No. 3 to ensure that new source growth cannot interfere with reasonable further progress towards attainment, in order to be consistent with section 173(a)(1)(A) of the Act;

7. The addition of a reference to the State's definition of "net emission increase" in Section V.I. of Part A of Regulation No. 3 (which discusses netting);

8. The addition of a requirement to Section IV.C.1. of Part B of Regulation No. 3 requiring the opportunity for public comment on permits for sources

trying to obtain Federally enforceable limits on their potential to emit; and

9. The deletion of an exemption from nonattainment NSR requirements for sources undergoing fuel switches due to lack of adequate fuel supply (which is not allowed by EPA). EPA believes these regulatory revisions adequately address the deficiencies described above.

The State addressed some of EPA's other comments with an opinion from the State Attorney General's office dated July 3, 1995. Those comments and the State's responses are as follows:

1. EPA recommended adding definitions to Regulation No. 3 of "begin actual construction," "necessary preconstruction approvals or permits," and "construction" to be consistent with the Federal definitions. The State did not add these definitions because the State contends that its definitions of "commenced construction," "construction" in the Common Provisions Regulation, and "modification" made the addition of these definitions unnecessary. After further review of the definitions referred to by the State, EPA agrees with the State's contention; and

2. Section IV.A. of Part A of Regulation No. 3 allows for alternative operating scenarios to be included in a construction permit, and this provision is based on the title V provision in 40 CFR 70.6(a)(9). However, in order to approve this provision for construction permits, EPA wanted assurances from the State that it would require compliance with all PSD or nonattainment NSR provisions (e.g., ambient air quality analysis or net air quality benefit) for every scenario allowed under the permit. The State's July 3, 1995 letter included an interpretation that compliance with all PSD or nonattainment NSR requirements (whichever was applicable) would be ensured under the provision in Section IV.A.2. of Regulation No. 3, which requires that the permit contain conditions to ensure each scenario meets all applicable Federal and State requirements. This satisfies EPA's concern.

EPA believes the comments discussed above were adequately addressed by the State in its revisions to Regulation No. 3 adopted on March 16, 1995 and its opinion from the State Attorney General's office. In addition, the State also addressed many of EPA's recommended revisions to Regulation No. 3, which EPA believes will help to strengthen the State's construction permit regulations.

EPA had also commented on Section IV.C. of Part A of Regulation No. 3, which provides for a construction

permit (as well as a title V operating permit) to contain terms and conditions allowing for the trading of emissions decreases and increases under a permit cap, as long as certain conditions are met. This provision is based on the title V operating permit requirement in 40 CFR 70.4(b)(12)(iii), but EPA had concerns with the use of this provision in construction permitting. EPA is currently working on revisions to the Federal NSR regulations as part of the "NSR Reform" rules that would allow a source to establish a cap in its construction permit (termed a plantwide applicability limit or PAL) for NSR applicability under which emissions trading might be allowed. EPA proposed these NSR Reform rules for public comment on July 23, 1996 (see 61 FR 38250). Until the final EPA regulations are promulgated on this issue, EPA does not believe it is appropriate to approve the State's provision allowing trading under permit caps for construction permits, as EPA could be approving a rule that is inconsistent with the forthcoming Federal regulations. However, as discussed in the preamble to the July 23, 1996 rulemaking, Colorado may be able to consider the issuance of permits with emissions caps on a case by case basis under EPA's existing regulations (see 61 FR 38264).

EPA believes the State, in the submittals of September 29, 1994 and January 29, 1996, has adequately addressed all of the deficiencies EPA identified in the State's November 12, 1993 SIP submittal. Thus, these three submittals are approvable. However, as discussed above, EPA is not acting on Section IV.C. of Part A of Regulation No. 3 at this time. For further details, see the Technical Support Document (TSD) accompanying this notice.

B. August 25, 1994 SIP Submittal of Nonattainment NSR Rules for New and Modified Sources of PM-10 Precursors

1. Background of Submittal

When the Act was amended in 1990, it included, among other things, revised requirements for nonattainment areas which are set out in part D of title I of the Act. It also set out specific deadlines for submittals of SIP revisions addressing these new requirements, including the submittal of nonattainment NSR rules for which the deadlines varied depending on the type and designation of the nonattainment area. In response to those requirements, the Governor of Colorado submitted a SIP revision on January 14, 1993 to bring the State's nonattainment NSR rules up to date with the requirements of the amended Act. EPA acted on that submittal on August 18, 1994 (59 FR

42500). Specifically, EPA approved the State's nonattainment NSR rules as meeting the requirements of the amended Act for the State's ozone and carbon monoxide areas, as well as the Canon City, Pagosa Springs, and Lamar PM-10 nonattainment areas. However, EPA only partially approved the State's NSR submittal in that action for the Aspen, Telluride, and Denver moderate PM-10 nonattainment areas because the State had not submitted NSR regulations for new and modified major sources of PM-10 precursors [as is required by section 189(e) of the amended Act for those PM-10 nonattainment areas where such sources contribute significantly to PM-10 national ambient air quality standard (NAAQS) exceedances] and because, at the time of publication of the August 18, 1994 Federal Register notice, EPA had not promulgated findings that such sources of PM-10 precursors did not contribute significantly to exceedances of the PM-10 NAAQS in any of these three areas.¹ (See 59 FR 42503-42504 for further details.)

Since that August 18, 1994 Federal Register action, EPA has promulgated findings that sources of PM-10 precursors do not contribute significantly to PM-10 NAAQS exceedances in the Aspen and Telluride PM-10 nonattainment areas (see 59 FR 47092-47093, September 14, 1994, and 59 FR 47809, September 19, 1994, respectively), resulting in the State's NSR provisions being considered fully approved for these two PM-10 nonattainment areas. However, in the Denver moderate PM-10 nonattainment area, EPA has indicated that it does consider major stationary sources of PM-10 precursors (specifically oxides of nitrogen (NO_x) and sulfur dioxide (SO₂)) to contribute significantly to exceedances of the PM-10 NAAQS (see 58 FR 66331, December 20, 1993).

On February 17, 1994, the State adopted nonattainment NSR provisions for new and modified major sources of PM-10 precursors (specifically, SO₂ and NO_x) in the Denver metro PM-10 nonattainment area. These Regulation No. 3 revisions were formally submitted to EPA for approval into the SIP on August 25, 1994.

¹ Section 189(e) of the amended Act requires that the control requirements applicable to major stationary sources of PM-10 must also apply to major stationary sources of PM-10 precursors, except where the Administrator of EPA has determined that such sources do not contribute significantly to PM-10 levels which exceed the standard in the area. Any such determination that sources of PM10 precursors do not contribute significantly is generally made concurrently with EPA's promulgation of an action on a SIP submittal for a PM₁₀ nonattainment area.

2. Evaluation of Submittal

To meet the requirements of section 189(e) of the Act, States must submit rules applying all of the nonattainment NSR provisions normally applicable to sources of PM-10 to sources of PM-10 precursors, including the 100 ton per year threshold for defining major stationary sources and the current significance level thresholds in 40 CFR 51.165(a)(1)(x) for each PM-10 precursor pollutant for defining major modifications. To address these requirements, the State made the following changes to Regulation No. 3:

(a) In the definition of "major stationary source" in Section I.B.58. of Part A of Regulation No. 3, the State added provisions clarifying that, in the Denver metro PM-10 nonattainment area, any source that is major for SO₂ or NO_x (which are considered precursors to PM-10 in the Denver area) will be considered major for PM-10 and will be subject to the nonattainment NSR requirements.

(b) In the definition of "major modification" in Section I.B.35.B. of Part A of Regulation No. 3, the State adopted a provision stating that, in the Denver metro PM-10 nonattainment area, any net emissions increase that is significant for SO₂ or NO_x shall be considered significant for PM-10. The significance levels for these two PM-10 precursor pollutants in Section I.B.57. of Part A of Regulation No. 3 are set at 40 tons per year each, which is consistent with the significance levels in 40 CFR 51.165(a)(1)(x).

(c) In Section V.F.1. of Part A of Regulation No. 3 which identifies the criteria for approval of all emissions trading transactions including NSR offsets, the State added provisions explaining which interpollutant trades between PM-10 and PM-10 precursors are allowed for NSR offsets. Specifically, Section V.F.1. provides that new or modified major sources of a PM-10 precursor can obtain offsets from reductions in that same precursor or in PM-10, while new or modified major sources of PM-10 can only obtain offsets from reductions in PM-10. This is consistent with EPA's current policy regarding offsets for PM-10.

However, the State did adopt an exception to this requirement in Section V.H.9. of Part A of Regulation No. 3. Specifically, Section V.H.9. allows interpollutant offsets other than those discussed in Section V.F.1. to be approved on a case-by-case basis, provided that the applicant demonstrates, on the basis of EPA-approved methods where possible, that the emissions increases for the new or modified source will not cause or

contribute to a violation of the NAAQS. Section V.H.9. further provides that the source's permit application will not be approved by the State until written approval has been received from the EPA. Because written approval will be required from EPA before a permit will be issued which allows an interpollutant trade for offsetting (other than those trades allowed in Section V.F.1.), EPA believes that it will be able to ensure any interpollutant offsets will meet the requirements of the Act concerning NSR. Thus, this exception is acceptable to EPA.

The State's nonattainment NSR provisions are generally found in Section IV.D.2. of Part B of Regulation No. 3. As discussed in EPA's August 18, 1994 approval mentioned above, the State's nonattainment NSR provisions, which apply in all of the State's nonattainment areas, meet all of the general NSR requirements required by the Act and Federal regulations (see 59 FR 42500-42506). Thus, since the State's revised nonattainment NSR rules now subject new and modified major stationary sources of PM-10 precursors (as well as PM-10) locating in the Denver moderate PM-10 nonattainment area to the nonattainment NSR requirements as required by section 189(e) of the Act, and since the State's nonattainment NSR provisions meet all of the applicable Federal requirements, EPA considers Colorado's nonattainment NSR rules for the Denver moderate PM-10 nonattainment area to be fully approvable.

C. November 17, 1994 SIP Submittal Revising the Definition of "Source"

1. Background of Submittal

On August 7, 1980, EPA promulgated rules for review of new major sources and major modifications in nonattainment areas (45 FR 52676). Those rules defined "source" as either an entire plant or an individual piece of process equipment within the plant. This definition precluded major sources undergoing a modification at an individual piece of process equipment from considering other emission decreases within the plant in determining the net emissions increase of the modification. However, in the Federal PSD permitting regulations (which apply to major sources and major modifications located in attainment or unclassifiable areas), a plantwide definition of source was used, under which only significant net emissions increases at the entire plant were subject to permitting requirements. Thus, under the dual source definition, a greater number of modifications at a source would be subject to NSR

permitting requirements than under the plantwide definition of source used in the PSD regulations. EPA adopted this more stringent definition of source for nonattainment area NSR permitting to aid in the cleanup of the air in nonattainment areas.

However, on October 14, 1981, EPA deleted the dual source definition from the nonattainment NSR permitting requirements and replaced it with the plantwide definition to give States the option of adopting the plantwide definition of source in nonattainment areas (see 46 FR 50766). In the October 1981 Federal Register notice, EPA set forth its rationale for allowing use of the plantwide definition (46 FR 50766-50769). EPA reasoned that, since part D of the Act requires States to adopt adequate SIPs which demonstrate attainment and maintenance of the NAAQS, "deletion of the dual definition increases State flexibility without interfering with timely attainment of the ambient standards and so is consistent with part D" (46 FR 50767). EPA also added that, by bringing more plant modifications into the NSR permitting process, the dual source definition may discourage replacement of older, dirtier processes and, hence, retard not only economic growth but also progress toward clean air. Last, EPA pointed out that, under the plantwide definition, new equipment would still be subject to any applicable new source performance standard (NSPS). Thus, EPA regarded changing to the plantwide definition as presenting, at the very worst, environmental risks that were manageable because of the independent impetus to create adequate part D plans and, at best, the potential for air quality improvements driven by the marketplace. In 1984, the Supreme Court upheld EPA's action as a reasonable accommodation of the conflicting purposes of part D of the Act and, hence, well within EPA's broad discretion. *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 104 S.Ct. 2778.

Consequently, on August 20, 1992, the Colorado AQCC adopted revisions to the Common Provisions Regulation and Regulation No. 3 to change from the dual definition of "source" to the plantwide "source" definition in its nonattainment NSR permitting requirements. Specifically, the State revised the definitions of "stationary source" and "net emissions increase" in the Common Provisions Regulation to delete references to the dual source definition. In addition, the State deleted Section V.I.4. of Colorado Regulation No. 3, which explained that the dual source definition applied in nonattainment NSR permitting. These

revisions were subsequently submitted by the Governor to EPA for approval into the SIP on November 17, 1994.

The State adopted these revisions prior to the July 1993 State adoption of a completely restructured Regulation No. 3, which was discussed in Section II.A. above. Before the July 1993 State action, the State's definitions for its construction permit program were generally found in the Common Provisions Regulation and all of its construction permit requirements were in Regulation No. 3.

(Note: at that time, Regulation No. 3 was not divided into Parts A, B, C, or D).

Under the new structure of Regulation No. 3, the definitions of "stationary source" and "net emissions increase" are in Sections I.B.58. and I.B.36., respectively, in Part A of Regulation No. 3, and the deletion of Section V.I.4. is reflected in Part B of revised Regulation No. 3. These definitions of "stationary source" and "net emissions increase" (as well as other definitions pertaining to the State's construction permit program) are also still in the Common Provisions Regulation.

2. Evaluation of Submittal

In the October 14, 1981 Federal Register discussed above in which EPA deleted the dual source definition from the Federal nonattainment NSR permitting requirements, EPA ruled that a State wishing to adopt a plantwide definition generally has complete discretion to do so, and it set only one restriction on that discretion. If a State had specifically projected emission reductions from its NSR program as a result of a dual source or similar definition and had relied on those reductions in an attainment strategy that EPA later approved, then the State needed to revise its attainment strategy as necessary to accommodate reduced NSR permitting under the plantwide definition (see 46 FR 50767 and 50769).

This 1981 ruling allowing States to adopt a plantwide definition assumed that nonattainment areas already had, or shortly would have, approved part D plans in place. However, the Act was amended in 1990, creating new requirements and deadlines for submittal of attainment plans for areas which were not in attainment of the NAAQS. In light of these changes, EPA will now approve adoption of the plantwide definition into SIPs for nonattainment areas that need but lack adequate part D attainment plans approved by EPA only if the State has demonstrated that it is making, and will continue to make, reasonable efforts to adopt and submit complete plans for timely attainment in these areas.

For the majority of Colorado's nonattainment areas that are required to have part D attainment plans, the State has EPA-approved part D plans. The only areas for which the State does not yet have fully approved part D attainment plans are the Denver PM-10, Denver carbon monoxide (CO), Longmont CO, Telluride PM-10, and Steamboat Springs PM-10 nonattainment areas. The State has submitted part D plans for the Denver PM-10 and CO nonattainment areas, the Longmont CO nonattainment area, and the Steamboat Springs PM-10 nonattainment area, but EPA has not yet completed action on these submittals. For the Telluride PM-10 nonattainment area, EPA has approved the State's attainment demonstration (see 59 FR 47808, September 19, 1994), but the plan has not been fully approved because it lacked quantitative milestones to provide for maintenance of the PM-10 NAAQS through December 31, 1997 (see 59 FR 47809). The State has subsequently submitted additional controls to provide for maintenance of the PM-10 NAAQS in the Telluride PM-10 nonattainment area through 1997, but EPA has not yet completed action on that submittal. Thus, EPA believes the State has adequately demonstrated that it has made, and will continue to make, reasonable efforts to get an approved part D attainment plan in place for these areas.

Further, the State has certified that it did not, and will not, rely on any emissions reductions from the operation of the NSR program using the dual source definition in any of its nonattainment area demonstrations of attainment. EPA's examination of the State's attainment demonstrations confirmed the State's certification. Therefore, EPA believes it is appropriate to approve Colorado's switch to a plantwide definition of source in accordance with EPA's 1981 action, inasmuch as the State has demonstrated that it is making, and will continue to make, reasonable efforts to get approved part D attainment plans in place for all of its nonattainment areas.

III. Proposed Action

EPA is proposing to approve all of the revisions to Colorado's construction permitting program in Regulation No. 3 submitted on November 12, 1993, August 25, 1994, September 29, 1994, November 17, 1994, and January 29, 1996. EPA is also proposing to approve the revisions to the Common Provisions Regulation submitted on November 17, 1994. However, for the reasons discussed above, EPA is taking no

action, at this time, on Section IV.C. of Part A of Regulation No. 3.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to a SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

IV. Administrative Requirements

A. Executive Order 12866

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214-2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600, *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on small entities affected. Moreover, due to the nature of the Federal-state relationship under the Act, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256-66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule

that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action proposed does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen oxides, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: August 14, 1996.

Jack W. McGraw,

Acting Regional Administrator.

[FR Doc. 96–21910 Filed 8–27–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Parts 180 & 185

[OPP–300360B; FRL–5394–6]

RIN 2070–AB78

Pesticides; Extension of Time for Filing Objections and Requests for Hearing for Food Additive Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of extension.

SUMMARY: EPA is extending by 30 days the time period for filing objections, requests for hearings and requests for stays pertaining to a final rule revoking the food additive tolerances for certain uses of acephate, iprodione, imazalil and triadimefon. EPA is also extending the effective date of the revocation by 30 days. EPA is taking this action under the provisions of the Food, Drug and Cosmetic Act, as modified by the recently enacted Food Quality Protection Act.

DATES: The effective date of September 27, 1996 of the final rule published at 61 FR 39528, July 29, 1996 is extended to October 28, 1996. The date for objections, requests for hearings, or stays is extended from August 28, 1996 to September 27, 1996.

FOR FURTHER INFORMATION CONTACT: Jean M. Frane, Policy and Special Projects Staff (7501C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1113, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–5944. e-mail: frane.jean@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 29, 1996 (61 FR 39528)(FRL–5388–2), EPA issued an order revoking six food additive tolerances for four pesticides. EPA revoked four tolerances based on the determination that the tolerances were inconsistent with the Delaney clause in section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA), and two tolerances because they are not needed to prevent the adulteration of food. In the final rule, EPA set an effective date of September 27, 1996 for the revocations. Any person adversely affected by the July 29, 1996 Order was allowed 30 days to: (1) file written objections to the order, (2) file a written request for an evidentiary hearing on the objections, and (3) file a petition for a stay of the effective date. Under the original date, objections and requests for hearing were to be filed by August 28, 1996.

Subsequently, on August 3, 1996, the President signed the Food Quality Protection Act of 1996 (FQPA) (Pub.L. 104–170). Among other things, this new law revised the procedures for objecting to Agency decisions on tolerance regulations. FFDCA 408(g)(2)(A) now provides 60 days instead of 30 days for the filing of objections and requests for hearings. These provisions were effective immediately upon enactment.

EPA has received requests from Valent U.S.A., Bayer Corporation and Whitmire MicroGen, requesting that, in light of other provisions of the new FQPA, EPA should extend the time for filing objections and hearing requests, or should withdraw the revocations altogether. The requesters suggest that the Agency's basis for revocations under the Delaney clause of section 409 of the FFDCA has been nullified by the enactment of the FQPA, which takes pesticide tolerances out from under the provisions of section 409 entirely. EPA believes there is merit in this argument and is currently developing an appropriate regulatory order. Given that this order is not yet complete, however,

EPA believes it is reasonable to extend the time for filing objections and requests for hearing in accordance with the new timeframes in section 408(g). EPA is taking this action in its discretion and upon its own initiative.

Accordingly, by this document, EPA is extending the date by which objections and requests for hearings and stays can be filed, and also extending the effective date of the final rule revoking the food additive tolerances for certain uses of acephate, iprodione, imazalil and triadimefon, published at 61 FR 39528, July 29, 1996.

Dated: August 22, 1996.

Susan H. Wayland,

Acting Assistant Administrator for Prevention, Pesticides, and Toxic Substances.

[FR Doc. 96–21821 Filed 8–27–96; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 300

[FRL–5554–7]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent for partial deletion of the Commencement Bay Nearshore/Tideflats Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 10 announces its intent to delete portions of the Commencement Bay Nearshore/Tideflats (CB/NT) Superfund Site from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR Part 300, which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

This proposal for partial deletion pertains only to portions of Operable Unit (OU) 1—CB/NT Sediments, and Operable Unit (OU) 5—CB/NT Sources. Specifically, it pertains to the sediments contained in and upland properties draining only to the St. Paul or Blair Waterways, and to four properties which were transferred to the Puyallup Tribe of Indians under the Puyallup Land Settlement Act of 1989 (“Puyallup Land Settlement Properties”). The four Puyallup Land Settlement Properties proposed for deletion are the: Taylor

Way Property, the East-West Road Property, the Blair Waterway Property, and the portion of the Blair Backup Property that drains only to the Blair Waterway.

DATES: The EPA will accept comments concerning its proposal for partial deletion for thirty (30) days after publication of this document in the Federal Register and a newspaper of record.

ADDRESSES: Comments may be mailed to: Jeanne O'Dell, Community Relations Coordinator, U.S. EPA, Region 10 (ECO-081), 1200 Sixth Avenue, Seattle, Washington, 98101, (1-800-424-4372 or (206) 553-6919).

Information Repositories

Comprehensive information on the CB/NT site as well as information specific to this proposed partial deletion is available for review at EPA's Region 10 office in Seattle, Washington. The Administrative Record for OU Nos. 1 and 5 and the Deletion Docket for this partial deletion are maintained at the following site document/information repositories: U.S. Environmental Protection Agency, 7th floor Records Center, 1200 Sixth Avenue, Seattle, Washington 98101, (206) 553-4494.

Citizens for a Healthy Bay, 771 Broadway, Tacoma, Washington 98402, (206) 383-2429.

FOR FURTHER INFORMATION CONTACT: Ms. Allison Hiltner, Remedial Project Manager, U.S. EPA, Region 10 (ECL-116), 1200 Sixth Avenue, Seattle, Washington, 98101, (206) 553-2140.

SUPPLEMENTARY INFORMATION:

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I. Introduction

The United States Environmental Protection Agency (EPA) Region 10 announces its intent to delete a portion of the Commencement Bay Nearshore/Tideflats Superfund Site (CB/NT Site) located in Pierce County, Washington (Figure 1) from the National Priorities List (NPL), which constitutes Appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR Part 300, and requests comments on this proposal.

This partial deletion of the CB/NT site is proposed in accordance with 40 CFR § 300.425(e) and the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List 60 Fed. Reg. 55466 (Nov. 1, 1995).

This proposal for partial deletion pertains only to portions of OU 1 (CB/

NT Sediments), and OU 5 (CB/NT Sources). At the CB/NT site, sources are defined as releases of contaminants or problem chemicals from a site or facility to a problem area identified in the 1989 CB/NT Record of Decision (ROD). Once an ongoing source is identified, regulatory mechanisms and cleanup measures are implemented to control the release of contaminants to the marine environment and to ensure compliance with environmental regulations.

Specifically, this proposal pertains to the sediments contained in and upland properties draining only to the St. Paul Waterway or Blair Waterway, and to four properties which were transferred to the Puyallup Tribe of Indians under the Puyallup Land Settlement Act of 1989 ("Puyallup Land Settlement Properties"). The four Puyallup Land Settlement Properties proposed for deletion are: the Taylor Way Property, the East-West Road Property, the Blair Waterway Property, and the portion of the Blair Backup Property that drains only to the Blair Waterway.

EPA proposes to delete the above named portions of the sites because all appropriate CERCLA response activities have been completed in those areas. Environmental investigations and cleanup work at these portions of the site are consistent with the September 1989 CB/NT ROD that describes the cleanup plan for the site.

The properties that EPA proposes to delete are all encompassed within the CB/NT site but have utilized different regulatory pathways to arrive at this point:

- *St. Paul Waterway.* Cleanup of the St. Paul Waterway was required under the CB/NT Record of Decision (ROD) dated September 1989. Cleanup had actually been performed in 1988 under a state consent decree. The cleanup was approved by EPA under CERCLA pursuant to a federal consent decree in 1991. This federal decree also required long-term monitoring to ensure protectiveness of human health and the environment.
- *Blair Waterway.* Blair Waterway was not identified as a priority problem area within the CB/NT ROD. The dredging and restoration of portions of the Blair Waterway was completed pursuant to the Sitcum Waterway Consent Decree from late 1993 through early 1995. A settlement with the Port of Tacoma for injuries to natural resources in Blair Waterway and other portions of Commencement Bay was also part of the Consent Decree.
- *Puyallup Tribe Properties.* The Puyallup Tribe of Indians Land Claims Settlement Act of 1989 required transfer

of seven commercial and industrial properties, along with a portion of the bed of the Puyallup River, to the Puyallup Tribe of Indians. Six of the properties, comprising approximately 215 acres, are within the CB/NT Superfund site. Consistent with CERCLA requirements, the Puyallup Land Claims Settlement Act of 1989, and the Puyallup Land Transfer Consent Decree among the United States, the Port of Tacoma and the Puyallup Tribe of Indians, the properties have now been transferred to the United States in trust for the Puyallup Tribe. Cleanup actions have been completed, where necessary, at the four properties within the CB/NT Superfund Site that are proposed for deletion.

This partial deletion does not include the remaining portions of OU 1 and OU 5, the other OUs of the site, or the other Puyallup Land Settlement Properties. This partial deletion does not include the portion of the Blair Backup Property that drains to the Hylebos Waterway. Response activities will continue at all areas of the site not contained in the partial deletion notice.

The NPL is a list maintained by EPA of sites that EPA has determined present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund).

Sites (or portions of sites) are deleted from the NPL when one or more of the deletion criteria have been satisfied (see next section). Deletion from the NPL does not mean that further regulatory actions are necessarily precluded or that all cleanup-related activities come to an end.

For example, any site or portion of a site deleted from the NPL remains eligible for Fund-financed remedial actions under § 104 of CERCLA if conditions at the site warrant such action. Other potential authorities that may be used to compel cleanup action if conditions warrant are enforcement authorities under § 106 of CERCLA or under applicable state or tribal law.

Cleanup-related activities that may continue after a site or portion of a site is deleted include those relating to maintaining the protectiveness of the remedy. Such activities may include the following:

- Long-term monitoring to ensure that the cleanup levels that have been attained are not exceeded again in the future.
- Operation and maintenance of cleanup measures or functions (e.g., a sediment cap or a landfill leachate collection system).
- Inspection (e.g., of an asphalt cap to ensure its continued integrity).

- Institutional controls (e.g., measures such as fish advisories or deed restrictions to restrict access or exposure to remaining contamination).

Other important requirements or activities that may be ongoing even at portions of the site deleted from the NPL include the following:

- Cost recovery from liable parties (note that deletion from the NPL does not extinguish the liability under CERCLA of potentially responsible parties connected with the site or portion of the site).
- The assessment of and recovery for damages to natural resources.
- Compliance with pollution control or other environmental requirements under applicable federal, tribal, state or local law (i.e., other than CERCLA). For example, under state law, Ecology may conduct investigations or require response actions at deleted upland and in-water portions of the site.

Finally, a partial deletion of a site from the NPL does not affect or impede the ability of EPA or the applicable state or Indian tribe to conduct response activities, including source control, at areas not deleted and remaining on the NPL.

EPA will accept comments concerning its intent for partial deletion for thirty (30) days after publication of this notice in the Federal Register and a newspaper of record.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR § 300.425(e), sites may be deleted from the NPL where no further response is appropriate to protect public health or the environment. In making such a determination pursuant to Section 300.425(e), EPA considers, in consultation with the State, with regard to the St. Paul and Blair Waterways, and with the Puyallup Tribe of Indians, with regard to the Puyallup Land Settlement Properties, whether any of the following criteria have been met:

Section 300.425(e)(1)(i). Responsible parties or other persons have implemented all appropriate response actions required; or

Section 300.425(e)(1)(ii). All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

Section 300.425(e)(1)(iii). The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate.

III. Deletion Procedures

Deletion of a portion of a site from the NPL does not itself create, alter, or revoke any person's rights or

obligations. The NPL is designed primarily for informational purposes and to assist Agency management.

The following procedures were used for the proposed partial deletion of the CB/NT site:

(1) EPA has recommended the partial deletion and has prepared the relevant documents.

(2) The State of Washington, with respect to the St. Paul and Blair Waterways, and the Puyallup Tribe of Indians, with respect to the Puyallup Land Settlement Agreement Properties, have been asked to concur on EPA's final determination regarding the partial deletion.

(3) Concurrent with this national Notice of Intent for Partial Deletion, a notice has been published in a newspaper of record and has been distributed to appropriate federal, tribal, State, and local government officials, and other interested parties. These notices announce a thirty (30) day public comment period on the deletion package, which commences on the date of publication of this notice in the Federal Register and a newspaper of record.

(4) EPA has made all relevant documents available at the information repositories listed previously.

This Federal Register notice, and a concurrent notice in a newspaper of record, announce the initiation of a thirty (30) day public comment period and the availability of the Notice of Intent for Partial Deletion. The public is asked to comment on EPA's proposal to delete portions of the site as described in this notice from the NPL. All critical documents needed to evaluate EPA's decision are included in the Deletion Docket and are available for review at the information repositories.

Upon completion of the thirty (30) day public comment period, EPA will evaluate all comments received before issuing the final decision on the partial deletion. EPA will prepare a Responsiveness Summary for comments received during the public comment period and will address concerns presented in the comments. The Responsiveness Summary will be made available to the public at the information repositories listed previously. Members of the public are encouraged to contact EPA Region 10 to obtain a copy of the Responsiveness Summary.

If, after review of all public comments, EPA determines that the partial deletion from the NPL is appropriate, EPA will publish a final notice of partial deletion in the Federal Register. Deletion will occur when the final Notice of Partial Deletion is published in the Federal Register.

IV. Basis for Intended Partial Site Deletion

The following provides EPA's rationale for deletion of portions of the

CB/NT site from the NPL and EPA's finding that the criteria in 40 CFR § 300.425(e) are satisfied for this deletion.

General Site Description

The CB/NT Superfund site is located in Tacoma, Washington at the southern end of the main basin of Puget Sound. This proposal for partial deletion of the site from the NPL is with respect to: the Blair Waterway, the St. Paul Waterway, and four of the Puyallup Land Settlement Properties. The delineation of the areas proposed for partial deletion are further described below.

The CB/NT site was listed on the NPL on September 8, 1983. The entire CB/NT site encompasses an active commercial seaport and includes 10–12 square miles of shallow water, shoreline, an adjacent land, most of which is highly developed and industrialized. The upland boundaries of the site are defined according to the contours of localized drainage basins that flow into the marine waters. The marine boundary of the site is limited to shoreline, intertidal areas, bottom sediments and water of depths less than 60 feet below mean lower low water.

The deep water portion of the bay was proposed for listing on the NPL, however, was not listed on the final NPL because water quality studies indicated there was minimal contamination in the area.

Superfund response actions at the CB/NT site are managed under six operable units. The six operable units constitute a comprehensive remedial response to actual or threatened release of hazardous substances that are associated with the Tacoma Tar pits, the ASARCO smelter and the CB/NT marine environment. The six operable units are as follows:

- OU 1—CB/NT Sediments
- OU 2—ASARCO Tacoma Smelter
- OU 3—Tacoma Tar Pits
- OU 4—ASARCO Off-Property
- OU 5—CB/NT Sources
- OU 6—ASARCO Sediments

This proposal for partial deletion of the site from the NPL is with respect only to portions of two operable units: OU 1: CB/NT Sediments, and OU 5: CB/NT Sources. The cleanup of the other operable units are being addressed separately. More information can be obtained on these other cleanup activities from EPA.

Site History

The CB/NT Remedial Investigation, completed in 1985, characterized the nature and extent of sediment contamination in the site. The CB/NT Feasibility Study, completed in 1988,

described feasible alternatives for sediment remedial action at the site.

In September 1989, the Environmental Protection Agency published a ROD, or cleanup plan, that described the response actions necessary for Operable Units 1 and 5. The response actions described in the ROD are limited to eight of the nine contaminated marine sediment problem areas identified in the Remedial Investigation/Feasibility Study (RI/FS). The ninth area, the Ruston-Pt. Defiance Shoreline problem area, is being addressed in separate actions under Operable Unit 06: ASARCO sediments.

The eight contaminated marine sediment problem areas for which response actions are required under the ROD are:

Head of Hylebos Waterway
Mouth of Hylebos Waterway
Sitcum Waterway
St. Paul Waterway
Middle Waterway
Head of Thea Foss (formerly City) Waterway
Mouth of Thea Foss (formerly City) Waterway
Wheeler-Osgood Waterway

EPA recognized that cleanup of contaminated sediments could not proceed until major sources of contamination were controlled, because ongoing sources could recontaminate clean sediment. Consequently, the ROD describes a cleanup strategy that incorporates source control and sediment cleanup.

Source control activities under OU 05 are implemented by the Washington Department of Ecology under a Cooperative Agreement with EPA. Source control activities as defined in the CB/NT ROD and EPA's 1992 Source Control Strategy are for activities that pose an actual or potential threat to marine sediments by drainage to one of the eight sediment problem areas.

EPA is the lead agency for oversight of the sediment cleanup activities implemented under OU 1. Due to the considerable variation in the types and concentrations of chemical contaminants found in each sediment problem area, the ROD explains that cleanup of these areas would proceed based on progress made in source control as well as the schedule for cleanup set forth in the ROD.

Cleanup progress has been made in all areas of the site. The notice of intent to delete portions of the site are to recognize the cleanup accomplishments to date and to designate portions of the site that do not warrant further action under the federal Superfund program.

Areas For Partial Deletion

The areas of the site that are proposed for partial deletion and for which EPA

has determined that no further response action is required under the Superfund program are: St. Paul Waterway Sediments, Blair Waterway Sediments, sources draining only to the St. Paul Waterway, sources draining only to the Blair Waterway, and four of the Puyallup Land Settlement Properties. The four Puyallup Land Settlement Properties proposed for deletion are the: the Taylor Way Property, the East-West Road Property, the Blair Waterway Property, and the portion of the Blair Backup Property that drains only to the Blair Waterway.

Blair Waterway Sources and Sediments

EPA proposes that the shoreline, intertidal sediments, bottom sediments and waters of the Blair Waterway, and the areas and sources that drain only to the Blair Waterway be deleted from the NPL.

Sediment contamination at the Blair Waterway was studied under the CB/NT RI/FS. EPA concluded in the RI/FS and ROD that Blair Waterway was a low priority area of the site and did not warrant identification as a sediment problem area.

Although Blair Waterway was not identified as a priority problem area, the dredging and restoration of portions of Blair Waterway was completed by the Port of Tacoma under the Sitcum Waterway Consent Decree. Between October 1993 and December 1994, the Port of Tacoma dredged 2.4 million cubic yards of sediment from the Blair Waterway. As part of this work, the main navigation channel as well as certain adjacent areas within the waterway were dredged to an approximate depth of 45–48 feet below Mean Lower Low Water (MLLW). A settlement with the Port of Tacoma for injuries to natural resources in Blair Waterway and other portions of Commencement Bay was also part of the Sitcum Waterway Consent Decree.

Sources that drain only to the Blair Waterway are proposed for deletion from the NPL. This includes properties in the area which is bounded (relative to the waterway) by Alexander Avenue on the northeast, the new SR 509 (formerly East-West Road) on the south and Port of Tacoma Road on the southwest, and any other properties outside of the area described above that drain only to Blair Waterway. This partial deletion from the NPL does not affect pollution control requirements otherwise required under federal or applicable state or tribal law.

St. Paul Waterway Sources and Sediments

EPA proposes that the St. Paul Waterway, and upland sources that

drain only to the St. Paul Waterway be deleted from the NPL.

In September 1988, the Simpson Tacoma Kraft Company completed source control activities and implemented sediment cleanup in the St. Paul Waterway Problem Area. Sediment cleanup actions, which were undertaken as part of a December 1987 Consent Decree with Ecology under the State of Washington's Model Toxics Control Act, consisted of the placement of clean sediments on top of contaminated sediments to isolate the contaminants from marine life and to restore intertidal and shallow subtidal habitats. The Superfund Completion Report for the St. Paul Waterway was approved by EPA in January 1991 and describes the source control and sediment cleanup efforts in the St. Paul Waterway. The work was formally approved by EPA in a federal Consent Decree in 1991 (No. C91–526DT). A corresponding amendment to the state consent decree has already removed this site from the state's Hazardous Sites List.

The sediment cap is functioning in accordance with the performance standards defined in the federal Consent Decree. The project is now in the long-term monitoring phase. Monitoring requirements are defined for ten years under the federal Consent Decree. For the past 8 years, Simpson Tacoma Kraft has performed annual monitoring to ensure that the sediment cap remains effective and that healthy marine communities live on the sediment cap. This physical, chemical, and biological sampling has shown that the sediment cap is functioning as planned, and that diverse biological communities are inhabiting the area.

On a larger scale, the project provides habitat that is supporting valuable ecological functions. Shorebirds utilize the site for feeding and rearing, and tide pools observed at low tide are abundant with invertebrates. Productive shoreline habitat exists at the project site where there was essentially no productive habitat prior to construction of the project.

Long-term monitoring will continue at the site, as required under the federal Consent Decree. Should the monitoring indicate any potential problem with or failure of the remedy, the federal Consent Decree provides a process for Early Warning, Contingency Planning, Contingency Response and Expedited Response that will address the situation and will be conducted with EPA oversight and approval. After 10 years, the need for monitoring requirements will be determined by EPA, the Puyallup Tribe of Indians, the

Muckleshoot Indian Tribe and federal and state natural resource trustees consulted as part of EPA's oversight of this project. EPA will continue to evaluate site performance to ensure protectiveness of the remedy.

Puyallup Tribe of Indians Land Settlement Properties

On August 27, 1988, the Puyallup Land Settlement Agreement (Agreement) was signed. The United States, the State of Washington, the Puyallup Tribe of Indians (Tribe) and the Port of Tacoma (Port) are among the parties to the Agreement. This landmark Agreement resolved historic land claim disputes among the Puyallup Tribe and public and private landowners in the Tacoma tideflats area. Congress formally incorporated the Settlement Agreement into federal law, the Puyallup Tribe of Indians Settlement Act of 1989, 25 U.S.C. 1773.

The Settlement Agreement provided for transfer of seven commercial and industrial properties, along with a portion of the bed of the Puyallup River, to the United States to be held in trust for the Puyallup Tribe. These lands will play a key role in future Tribal economic development plans and were a significant consideration in the Settlement Agreement. Six of these properties, comprising approximately 215 acres, are within the CB/NT Superfund Site. Under the Settlement Agreement, the Port was to complete environmental investigations and any necessary cleanup prior to property transfer. The Port completed cleanups by 1994, and the six properties have been transferred to the United States in trust for the Tribe.

The four properties proposed for deletion are: the Taylor Way Property, the East-West Road Property, the Blair Waterway Property, and the portion of the Blair Backup Property that drains only to the Blair Waterway. The legal descriptions for these properties are contained the Deletion Docket.

EPA believes that two of the Settlement properties and part of a third—the Inner Hylebos Property, the Upper Hylebos Property, and the portion of the Blair Backup Property that drains to the Hylebos Waterway—should not be deleted from the NPL at this time. The Inner Hylebos Property and the Upper Hylebos Property are adjacent to and drain to the Hylebos Waterway Sediment Problem Areas for which investigations are still underway. The need for sediment cleanup on both of these properties is an outstanding issue and will be settled as part of the Hylebos Waterway sediment cleanup. The portion of the Blair Backup Property that drains to the Hylebos

Waterway is not proposed for delisting at this time because of the potential contributions of past owners and operators to the contamination in the Hylebos Waterway.

The environmental status of each property is described briefly below. EPA, Ecology, and the Puyallup Tribe reviewed and performed oversight of all environmental investigations, and approved all cleanup decisions. Environmental information on each Puyallup Land Settlement Property, including the long-term monitoring and land use obligations by the Port of Tacoma and the Puyallup Tribe, are described in the Puyallup Land Transfer Consent Decree (No. C94-5648). For all properties, the use of shallow groundwater for drinking water purposes is prohibited.

Taylor Way Property: At this 6-acre property, environmental investigations were completed in 1991 and no cleanup actions were required.

East-West Road Property: At this 2-acre property, environmental investigations were completed in 1991 and no cleanup actions were required for the soils. Although some shallow groundwater at the property is contaminated by sludges that are buried on an adjacent site, that groundwater cleanup, if necessary, will be done by third parties under state or tribal law.

Blair Waterway Property: This 43.4 acre site, including about 8 acres of marine sediments, borders Blair Waterway. The cleanup activities were completed in 1994 and included: removal of 37,000 cubic yards of previously dredged sediments that were being temporarily stored on the property, removal of about 16,450 cubic yards of slag and soil from the central portion of the site, removal of 100 cubic yards of arsenic contaminated soils and sediment lining a ditch, dredging of the marine portion of the property pursuant to the Sitcum Waterway Consent Decree, and containment of contaminated sediments in the Lincoln Avenue Ditch. A 1.7 acre wetlands mitigation project was required for filling the ditch and is located at the Outer Hylebos Property. For institutional controls at the site, the Tribe agrees to restrict future use of the site to industrial purposes under M2 or M3 of the City of Tacoma Zoning Code (or other commercial purposes if conditions are met).

Blair Backup Property: This is an 85 acre site between Taylor Way and Alexander Avenue. The cleanup activities were completed in 1994 and focused on the 17-acre former Ohio Ferro Alloys smelter area. Cleanup included removal of about 4,264 cubic

yards of charcoal briquettes and contaminated soil for disposal in a landfill in Klickitat County. Other actions included incorporation of material removed from the Blair Waterway Property into a 7 acre portion of the Blair Backup Property which was then capped with asphalt. Ten acres of contaminated soils that surround the 7-acre asphalt cap were covered with 2 feet of sand and gravel. For institutional controls, the Tribe agrees to restrict future use of the site to industrial purposes under M2 or M3 of the City of Tacoma Zoning Code (or other commercial purposes if conditions are met), and restrict any construction activities that may damage the cap or cover. The Port is performing long-term monitoring in the capped and covered area.

Permit Exemption

Under CERCLA, response actions are exempt from obtaining federal, state or local permits where such actions are conducted on-site. On-site is defined as the areal extent of contamination and all suitable areas in very close proximity to the contamination necessary for the implementation of response actions. The substantive requirements otherwise contained in a permit must be complied with for the on-site response action under CERCLA even though the actual permit document is not obtained.

The reason for the permit exemption in CERCLA is to avoid duplication with requirements under permit processes and thus expedite cleanups and reduce costs. For example, CERCLA mandates public participation in connection with cleanup decision, on- and off-site. It would be unnecessarily time-consuming for a CERCLA action to also comply with public participation requirements under a permit process. Therefore, the CERCLA action is exempt from the nonsubstantive components of federal, state and local permits.

Although not anticipated at this time, there could be a need in the future for further response actions at deleted portions of the site. More likely, it may be necessary to use a deleted portion to implement a cleanup elsewhere at the site. For example, the deleted portion may be needed as a staging area. In either case, the same rationale for the permit exemption—to avoid duplication, expedite cleanup and reduce costs—would still exist. Accordingly, the permit exemption would be applicable so long as the response action taken at the deleted portion is performed in accordance with CERCLA.

Community Involvement

Public participation activities for the investigation and cleanup of Operable Units 1 and 5 of the CB/NT site were conducted as required under CERCLA Section 113(k), 42 U.S.C. § 9613(k), and Section 117, 42 U.S.C. § 9617. Public review included the following activities:

- A public comment period was held on the CB/NT RI and FS Reports and EPA's proposed cleanup plan from February 24 to June 24, 1989.
- A public comment period was held for the St. Paul Consent Decree, including EPA's acceptance of the 1987 state cleanup of the St. Paul Waterway, from July 5, 1991, to August 4, 1991.
- A public comment period for the Sitcum Waterway Consent Decree, which included the Blair Waterway dredging work, was held from August 26, 1993 to September 24, 1994.
- A public comment period on the Puyallup Land Transfer Consent Decree, which documented the Port of Tacoma's environmental investigations and cleanup actions at the properties to be transferred from the Port to the United States in trust for the Puyallup Tribe from December 6, 1994, to January 6, 1995.

Documents pertaining to all of these actions are available to the public at

EPA Region 10 offices, and near the site at the Tacoma Public Library, and at Citizens for a Healthy Bay.

Conclusion

EPA's proposed deletion of these portions of the site is based on a determination by EPA, in consultation with the State of Washington and the Puyallup Tribe of Indians, that all appropriate actions under CERCLA have been implemented to protect human health, welfare and the environment at these portions of the site. EPA has determined that required cleanup actions have been successfully completed, or that no cleanup is required, at the St. Paul Waterway and sources draining only to the St. Paul Waterway, Blair Waterway and sources draining only to the Blair Waterway, and the following Puyallup Tribe Transfer Properties: the Taylor Way Property, the East-West Road Property, the Blair Waterway Property, and the portion of the Blair Backup Property that drains only to the Blair Waterway. There are no further CERCLA response actions planned or scheduled for these areas of the site. Long-term monitoring

will continue at St. Paul Waterway as required under the St. Paul Consent Decree. Institutional controls will remain in place at the Blair Waterway, East-West Road, and Blair Backup Properties.

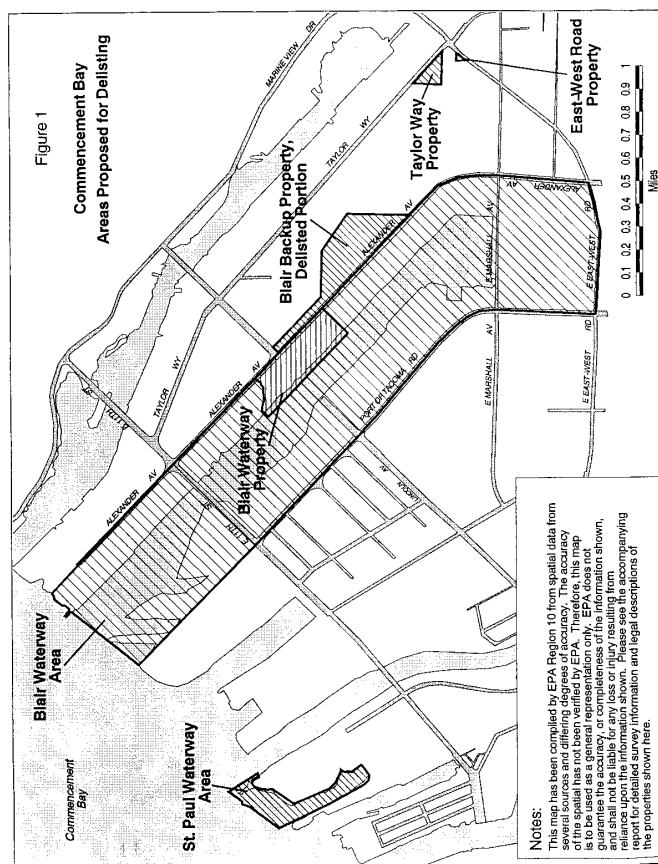
While EPA does not believe any further CERCLA response actions at these properties will be needed, if future conditions warrant such action, the proposed deletion areas of the CB/NT site remain eligible for future response actions. Furthermore, this partial deletion does not alter the status of other OUs or other portions of OUs 1 and 5 which are not proposed for deletion and remain on the NPL.

The State of Washington, through the Department of Ecology, and the Puyallup Tribe of Indians, with respect to those Puyallup Land Settlement Agreement Properties, have been asked to concur on EPA's final determination regarding the partial deletion.

Dated: August 8, 1996.

Jane S. Moore,
Acting Regional Administrator, U.S.
Environmental Protection Agency, Region 10.

BILLING CODE 6560-50-P



[FR Doc. 96-21629 Filed 8-27-96; 8:45 am]

BILLING CODE 6560-50-C

40 CFR Part 300**[FRL-5560-2]****National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List****AGENCY:** Environmental Protection Agency.**ACTION:** Notice of intent to delete the Sand Creek Industrial Site from the National Priorities List: Request for Comments.

SUMMARY: The Environmental Protection Agency (EPA), Region VIII announces its intent to delete the Sand Creek Industrial Site (Site) from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR part 300. EPA, in consultation with the Colorado Department of Health and Environment (State), has determined that all appropriate response actions have been implemented at the Site and that no further response action by responsible parties is appropriate. Moreover, EPA after consultation with the State, has determined that remedial activities conducted at the Site are protective of public health, welfare, and the environment.

DATES: Comments concerning the proposed deletion of the Sand Creek Site may be submitted to EPA on or before September 27, 1996.

ADDRESSES: Comments may be mailed to: Erna Acheson, 8EPR-SR, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2466.

Comprehensive information on this Site is available through the EPA, Region VIII public docket, which is located at EPA's Region VIII Administrative Records Center and is available for viewing from 8:00 a.m. to 4:30 p.m., Monday through Friday, excluding holidays. Requests for documents should be directed to the EPA, Region VIII Records Center.

The address for the Regional Records Center is: Administrative Records Center, U.S. Environmental Protection Agency, Region VIII, 999 18th Street, 5th Floor, Denver, Colorado 80202-2466, (303) 312-6473.

Background information from the Regional public docket is also available for viewing at the Sand Creek Industrial site information repositories located at the:

Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division, 4300 Cherry Creek Drive South, Denver, Colorado 80222, (303) 692-3300, Hours: 8:00 a.m. to 5:00 p.m., Monday through Friday
Adams County Library, 7185 Monaco Street, Commerce City, CO 80022, (303) 287-0063

FOR FURTHER INFORMATION, CONTACT:

Erna Acheson, 8EPR-SR, U.S. EPA, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2466, (303) 312-6762.

SUPPLEMENTARY INFORMATION:

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I. Introduction

The Environmental Protection Agency (EPA), Region VIII announces its intent to delete the Sand Creek Industrial Site (Site) located in Commerce City, Colorado from the National Priorities List (NPL) and requests comments on this deletion. The NPL constitutes Appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), Title 40 of the Code of Federal Regulations (40 CFR), as amended. EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as a list of those sites. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund Response Trust Fund (Fund). Pursuant to § 300.425(e)(3) of the NCP, any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that future conditions at the site warrant such action.

It is EPA's intent to delete the Sand Creek Industrial Site from the NPL. EPA will accept comments on this proposed deletion for thirty days following publication of this notice in the Federal Register.

Section II of this notice explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses how the Sand Creek Industrial site meets the deletion criteria.

Deletion of sites from the NPL does not itself create, alter, or revoke any individual's rights or obligations with regard to an individual site. The NPL is designed primarily for informational purposes and to assist EPA management.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR § 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making this determination, EPA will consider whether any of the following criteria have been met:

(i) EPA, in consultation with the State, has determined that responsible or other parties have implemented all appropriate response actions required; or

(ii) All appropriate Fund-financed responses under CERCLA have been implemented and EPA, in consultation with the State, has determined that no further cleanup by responsible parties is appropriate; or

(iii) Based on a remedial investigation, EPA, in consultation with the State, has determined that the release poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate.

For all Remedial Actions (RA) which result in hazardous substances, pollutants, or contaminants remaining at the site above levels that allow for unlimited use and unrestricted exposure, it is EPA's policy that a review of such action be conducted no less than every five years after initiation of the selected RA. As stated under "Basis for Intended Deletion," the selected remedy for the Sand Creek Industrial Site required the removal of the contaminated soils, rubble, and investigation-derived waste from the Site. There were also ground water and landfill gas components to the remedy. Site contaminants had affected the ground water aquifer. As a result of implementing this remedy, hazardous substances, pollutants, and contaminants were removed from the Site and eliminated as potential sources of contamination. The site has been remediated to allow industrial use only. Institutional Controls, groundwater monitoring, landfill gas monitoring, and operation and maintenance of the LFGES at OUs 3 & 6 are required to ensure that the remedies remain protective. In accordance with 40 CFR § 300.430(f)(4)(ii), five-year reviews are required for this Site. The first five-year review was completed on this site on September 20, 1995.

III. Deletion Procedures

EPA, Region VIII will accept and evaluate public comments before making a final decision to delete the Sand Creek Industrial Site. The following procedures were used for the intended deletion of this Site:

1. EPA, Region VIII has recommended deletion of the Sand Creek Industrial Site and has prepared the relevant documents.

2. The State of Colorado has concurred with EPA's recommendation for deletion.

3. Concurrent with this National Notice of Intent to Delete, a local notice has been published in local newspapers and has been distributed to appropriate Federal, State and local officials, and other interested parties.

4. The Region has made all relevant documents available in the Regional Office and local site information repositories.

The comments received during the notice and comment period will be evaluated before making a final decision to delete. The Region will prepare a Responsiveness Summary, which will address the comments received during the public comment period.

Subsequent to the public comment period, a deletion will occur after EPA publishes a Notice of Deletion in the Federal Register. The NPL will reflect any deletions in the next final update. Public notices and copies of the Responsiveness Summary will be made available to local residents by Region VIII.

IV. Basis for Intended Site Deletion

The following summary provides EPA's rationale for recommending deletion of the Sand Creek Industrial Superfund Site.

The Sand Creek Industrial site is located in Commerce City and Denver, Colorado. Most of the site and surrounding area is industrialized and contains trucking firms, petroleum and chemical supply and production companies, warehouses, small businesses and a few residences. Previous industrial activity and waste disposal practices at the Sand Creek site resulted in the contamination of ground water, and soil in the area. During the 1970's and early 1980's, a variety of environmental contamination was discovered and identified at the Site by the State of Colorado and EPA which included the following properties:

1. The Oriental Refinery property was the site of a fire in 1955 which resulted in the release of approximately 48,000 gallons of refined petroleum products. In 1980, the EPA discovered diesel fuel contamination in several groundwater monitoring wells.

2. The Colorado Organic Chemical Company (COC) manufactured pesticides beginning in the 1960's and intermittently through 1984. There was a serious fire at this property in 1968.

3. The L-C Corporation (LCC) property was used to store and neutralize spent acidic wastes from a herbicide chemical plant. In 1974, livestock that strayed onto the property had severe chemical burns.

4. At the 48th and Holly Landfill (Landfill) waste disposal operations were conducted between 1968 and 1975. Demolition and domestic refuse was accepted. In 1977, two

explosions of combustible gas, which killed two men and injured five others, were traced to the migration of the methane gas from the Landfill.

The Sand Creek site was added to the original National Priorities List (NPL) of 400 sites in December 1982. The primary concerns for potential harm to human health and the environment presented by these properties on the site were exposure to contaminated soils and sediments, landfill gas and debris, and potential ingestion of contaminated groundwater.

The contaminants of concern for the Sand Creek site included volatile and semi-volatile organics, pesticides, herbicides and heavy metals.

The objectives of the response actions at the Sand Creek Site were to protect human health and the environment and to restore the Site for industrial re-development. These objectives consisted of four primary goals as follows:

- To reduce the risk to industrial workers exposed to soil through ingestion or inhalation so that they would not suffer health problems;
- To ensure that a child walking or playing while trespassing onto the Site would not have health problems resulting from area soils;
- To ensure that gases generated from the Landfill would not migrate off-site and cause explosions or otherwise endanger health; and
- To reduce the contamination source area for groundwater absorption so that "potential groundwater use" would be possible.

Where appropriate, selected remedies utilized permanent solutions and alternative treatment technologies to the maximum extent practicable and satisfied the statutory preference for treatment as a principal element.

The Sand Creek site was divided into six Operable Units (OUs) or study areas to address the complexities associated with the site. These OUs and the response actions taken to address the specific problems associated with these areas are briefly described below:

Operable Unit # 1 (The Colorado Organic Chemicals Property)

Other than an estimated 1,000 cubic yards of surface soils highly contaminated with Halogenated Organic Compounds (HOCs), OU 1 remediation focused on treatment of subsurface soils contaminated with Volatile Organic Compounds (VOCs). The surface soils were treated through excavation and incineration and the subsurface soils were treated with Soil Vapor Extraction (SVE).

During 1991 and 1992, EPA removed approximately 2000 cubic yards of

debris, including four buildings, four rail cars, two concrete tanks, and 13 steel tanks. This debris was removed by a licensed hauler and disposed in permitted landfills. Between September 1993 and April 1994 EPA utilized SVE to remove over 176,000 pounds of VOC contamination from the OU1 soils, of which approximately 3,250 pounds were specified contaminants of concern for OU 1.

There were no aspects of the RA for OU 1 which failed to conform to the remedial objectives as specified in the ROD and ESD for OU 1.

Operable Unit # 2

The acid pits on the LCC property were neutralized on three occasions in the late 1970s and early 1980s. Because of these cleanup activities, in addition to low levels of contaminants of concern at the site, it was determined that no significant risk to human health or the environment existed at OU 2. Therefore, a "no further action" alternative was adopted, and no RA took place at OU 2.

OU # 3/6 (The 48th and Holly Landfill)

On August 15, 1990, EPA signed an Unilateral Administrative Order (UAO) for a removal action for OU 6 which became effective August 25, 1990 (Docket No. CERCLA-VIII-90-20). The UAO addressed risks associated with gaseous emissions from the Landfill. On December 24, 1990, EPA issued an Action Memorandum for an Enforcement-Lead Removal Action. The Action Memorandum required the installation and operation of a Landfill Gas Extraction System (LFGES), and installation and maintenance of a security fence and a vegetative cover for the Landfill. The LFGES system began operating on May 31, 1991. An EPA approved Final Removal Action Report for OU 6 (October 31, 1991) documented that the removal action was completed in accordance with the requirements of the Action Memorandum.

The selected RAs for OUs 3 and 6 were described in a single ROD since OUs 3 and 6 are both associated with the 48th and Holly Landfill. Remediation of the Landfill focused on methane gas removal, institutional controls, and monitoring.

The first requirement of the ROD was to continue operation and maintenance of the LFGES installed by the PRPs in 1991 under the August, 1990 UAO. The LFGES collects methane gas through underground pipes and destroys it in an enclosed flare system. In addition to methane gas removal, the ROD required institutional controls and monitoring of Landfill gas and groundwater. Landfill gas monitoring (for methane) began in

1991, and groundwater monitoring began in September, 1994.

An EPA approved Final Remedial Action Completion Report (RACR), dated November 22, 1994, documented that the remedial action for OUs 3/6 was completed and the on-going operation and maintenance continues in accordance with the requirements of the June 30, 1993 ROD. The RACR and all remedial actions were completed by Potentially Responsible Parties (PRPs).

There were no aspects of the RA for OUs 3/6 which failed to conform to the remedial objectives as specified in the ROD for OUs 3/6.

Operable Unit # 4

Remediation of OU 4 focused on institutional controls and monitoring of site-wide groundwater. The RA also included removal of a Light Non-Aqueous Phase Liquid (LNAPL) contamination plume.

Institutional controls for OU 4 are being implemented by the State of Colorado in conjunction with local governments. These controls will minimize exposure to contaminated groundwater in this area by preventing any use of highly contaminated groundwater and limiting general groundwater use to non-domestic purposes only.

EPA conducted quarterly groundwater monitoring and semi-annual surface water monitoring during the period of September, 1994 to June, 1995 for OU 4. Monitoring was specified as a primary objective in the April, 1994 ROD. At the time of the writing of this report, the sampling results indicate that groundwater contamination is isolated on-site and that (due to the low permeability of the subsurface soils) it is not migrating off-site. These results support the decisions documented in the ROD which identified the primary goals of OU 4 response actions as institutional controls and monitoring.

A secondary goal identified in the April, 1994 ROD was to recover a portion of an LNAPL plume located in the northwest portion of the Site. The removal was to be accomplished by utilizing Dual Vapor Extraction (DVE). The equipment used for DVE was fundamentally the same as that used for the SVE treatment of OU 1 soils. EPA operated the DVE system from October, 1994 to April, 1995. During this time, only 6000 gallons of LNAPL was recovered, far below the estimated total volume of the LNAPL. These data show that even with an active "pump and treat" system, the LNAPL contamination is very immobile. The design and results of this system can be utilized by EPA in the future if contaminants are determined to be migrating off-site and

if an active pump and treat system is deemed to be necessary to contain the contaminant migration.

An EPA approved RACR, dated September 20, 1995, documents that the remedial action for OU 4 was completed in accordance with the remedial action objectives specified in the April, 1994 ROD.

Operable Unit #5

Remediation for OU 5 focused on excavation and Low Temperature Thermal Treatment (LTTT) of surface and shallow soils (soils from ground level to a depth of five feet) contaminated with pesticides, metals, and VOCs.

A total volume of 8,254 cubic yards of soil was excavated. The excavated soil was remediated between June 28 and July 29, 1994 using LTTT. After backfilling with the treated soil, a cover crop was planted to restore the Site and to help prevent erosion.

An EPA approved RACR, dated October 28, 1994 documents that the remedial action for OU 5 was completed in accordance with the requirements of the September 8, 1993 ROD Amendment, with one exception. The target cleanup level for arsenic (12.7 mg/kg) was not achieved in a majority of post-remediation confirmatory soil samples obtained from stockpiles of 100 cubic yards of treated soil. The average post-remediation concentration of arsenic in the treated soil was 24.9 mg/kg. Because the arsenic target level was not achieved, EPA performed a post-remediation risk assessment in order to determine if the Site conditions were protective of human health and the environment. Since all other contaminants of concern were reduced below their target action levels, the maximum overall carcinogenic risk at the Site, even with the higher concentrations of arsenic, was calculated to be 2×10^{-5} . This level falls well within the EPA's acceptable risk range of 10^{-4} to 10^{-6} . Therefore, the post-remediation condition of OU 5 is considered to be protective of human health and the environment. Thus, EPA does not plan any further remedial activities at this area of the Site.

During the pre-final inspection of the Site, which occurred on August 22, 1994, EPA investigators discovered additional wastes in the area of OU 5. These wastes consisted of soils contaminated with pesticides and oil, drums containing pesticides and laboratory chemicals, and contaminated building debris and asbestos. As these wastes posed a high risk, EPA initiated a time-critical removal action to respond to the situation.

The removal response activity was carried out from October 1994 to September, 1995. This activity consisted of the removal and offsite disposal of: 188 drums containing various chemicals and pesticides, 7 compressed gas cylinders containing toxic and non-toxic gases, 2400 cubic yards of oily and pesticide contaminated soils, approximately 240 cubic yards of asbestos and oil contaminated soils, 40 cubic yards of contaminated building debris, and 30 cubic yards of RCRA contaminated drums and debris. An additional 600 gallons of Number 36 waste fuel oil was also removed and sent offsite to a recycling facility. This area of the site was regraded and reseeded following the completion of all removal and disposal activities. The Final Pollution Report (U.S. EPA, September 20, 1995) documents all removal activities performed and disposition of the wastes sent off-site.

V. Community Relations

Community interest in the Sand Creek Superfund Site has been limited. However, EPA's community relations effort was comprehensive. EPA distributed Fact Sheets to area businesses, residents, and local agencies. EPA also provided public meetings and site tours to explain the Superfund process and cleanup activities planned for the Site. In addition, EPA met with Tri-County Health Department staff, South Adams County Water and Sanitation District, the Rocky Mountain Arsenal Superfund team, Commerce City/Adams County officials, U.S. Representative Patricia Schroeder, and other interested individuals.

VI. Summary

The remedies completed at the site were mandated by the Records of Decision and based on the Remedial Design and Remedial Investigation and Feasibility Study Reports. The LTTT, SVE, and DVE were comprehensive "one-time" restoration activities and do not include operation and/or maintenance requirements. However, there are ongoing institutional controls, groundwater monitoring activities, and O & M requirements for OU 3/6 remaining at the Site. The completed remedies do result in hazardous substances remaining on site at levels which do not allow for unlimited land use and unrestricted exposure; therefore, there is a requirement for five-year reviews of the Site to ensure that remedies remain protective. The first five-year review for the Sand Creek site was completed on September 20, 1995. All completion requirements for the

Sand Creek Site have been achieved as outlined in OSWER Directive 9320.2-3A.

EPA, with the concurrence of the State of Colorado, has determined that all appropriate Fund-financed responses required by CERCLA at the Sand Creek Site have been completed. Continued maintenance of the LFGES and landfill cap/cover/fencing is required as well as continuance of the groundwater and landfill gas monitoring programs.

Dated: August 12, 1996.

Jack W. McGraw,

Acting Regional Administrator, U.S. Environmental Protection Agency, Region VIII.

[FR Doc. 96-21631 Filed 8-27-96; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 372

[OPPTS-400104D; FRL-5394-7]

RIN 2070-AC71

Addition of Facilities in Certain Industry Sectors; Toxic Chemical Release Reporting; Community Right-to-Know; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; further extension of comment period.

SUMMARY: In the Federal Register of June 27, 1996, EPA issued a proposed rule to add seven industry groups to the list of industries required to report under the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) section 313 and section 6607 of the Pollution Prevention Act of 1990 (PPA). In order to provide additional time to comment on this proposal and the additional documents available as announced in the Federal Register on August 21, 1996 (61 FR 43207), EPA is extending the comment period until September 25, 1996.

DATES: Comments must be received by September 25, 1996.

ADDRESSES: Written comments should be submitted in triplicate to: OPPT Docket Clerk, TSCA Document Receipt Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-G099, 401 M St., SW., Washington, DC 20460. Comments containing information claimed as confidential must be clearly marked as confidential business information (CBI). If CBI is claimed, three additional sanitized copies must also be submitted. Nonconfidential versions of comments on the proposed rule will be placed in the rulemaking

record and will be available for public inspection. Comments should include the docket control number for this document, OPPTS-400104D and the EPA contact for this document. Unit II. of this document contains additional information on submitting comments containing information claimed as CBI.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt.ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number OPPTS-400104D. No CBI should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit II. of this document.

FOR FURTHER INFORMATION CONTACT: Tim Crawford at 202-260-1715, e-mail: crawford.tim@epamail.epa.gov, or Brian Symmes at 202-260-9121, e-mail: symmes.brian@epamail.epa.gov, or the Emergency Planning and Community Right-to-Know Information Hotline, Environmental Protection Agency, Mail Stop 5101, 401 M St., SW., Washington, DC 20460, Toll free: 1-800-535-0202, in Virginia and Alaska: 703-412-9877 or Toll free TDD: 1-800-553-7672.

SUPPLEMENTARY INFORMATION:

I. Introduction

Current EPCRA section 313 reporting requirements apply to facilities classified in the manufacturing sector (Standard Industrial Classification codes 20-39) that have 10 or more full-time employees, and that manufacture, process, or otherwise use one or more listed section 313 chemicals above certain threshold amounts. EPA has been in the process of evaluating industry groups for potential addition under EPCRA section 313. EPA recently issued a proposed rule to add seven industry groups to the list of industries subject to EPCRA section 313 reporting requirements (61 FR 33588, June 27, 1996) (FRL-5379-3). At 61 FR 43207, August 21, 1996 (FRL-5393-4), EPA issued a Notice extending the comment period for certain additional documents to September 4, 1996. This Notice further extends the comment period for the proposal and the additional documents to September 25, 1996.

EPA believes that by extending the comment period by 30 days it can adequately satisfy the needs of those

who strongly feel that they need additional time to prepare their comments on the proposed rule as well as those who feel equally strongly that the public's right to know about toxic chemical releases and other waste information from these additional industry groups should not be delayed another year. Expanding the amount of information available to the American public about the environment in their community is a priority for EPA. The Agency remains committed to receiving and reviewing public comments and moving expeditiously to finalize this important rulemaking.

II. Rulemaking Record

A record has been established for this rulemaking under docket number "OPPTS-400104D" (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center (NCIC), located at EPA Headquarters, Rm. E-B607, 401 M St., SW., Washington, DC 20460.

Any person who submits comments claimed as CBI must mark the comments as "confidential," "CBI," or other appropriate designation. Comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR part 2. Any person submitting comments claimed to be confidential must prepare a nonconfidential public version of the comments in triplicate that EPA can put in the public file.

Electronic comments can be sent directly to EPA at:

ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

List of Subjects in 40 CFR Part 372

Environmental protection,
Community right-to-know, Reporting
and recordkeeping requirements, Toxic
chemicals.

Dated: August 23, 1996.

Susan H. Wayland,
*Acting Assistant Administrator for
Prevention, Pesticides and Toxic Substances.*

[FR Doc. 96-22012 Filed 8-23-96; 4:46 pm]

BILLING CODE 6560-50-F

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA-7190]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency
Management Agency, FEMA.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed base (1% annual chance) flood elevations and proposed base flood elevation modifications for the communities listed below. The base flood elevations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed base flood elevations for each community are available for inspection at the office of

the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street S.W., Washington, DC 20472, (202) 646-2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA or Agency) proposes to make determinations of base flood elevations and modified base flood elevations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified base flood elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act

This proposed rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Acting Associate Director, Mitigation Directorate, certifies that this proposed rule is exempt from the

requirements of the Regulatory Flexibility Act because proposed or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the National Flood Insurance Program. As a result, a regulatory flexibility analysis has not been prepared.

Regulatory Classification

This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This proposed rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

3. The tables published under the authority of § 67.4 are proposed to be amended as follows:

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
Florida	Okaloosa County (Unincorporated Areas).	Gulf of Mexico	Approximately 800 feet south of intersection of Amberjack Drive and Santa Rosa Boulevard.	*6	*10
			Approximately 1,000 feet southwest of intersection of Interstate Route 98 and Calhoun Avenue.	*9	*12
			Approximately 600 feet south of intersection of Amberjack Drive and Santa Rosa Boulevard.	None	*10

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified

Maps available for inspection at the Okaloosa County Planning and Inspection Department, 1804 Lewis Turner Boulevard, Suite 200, Fort Walton Beach, Florida.

Send comments to Mr. Dennis D. Nicholson, Chairman of the Okaloosa County Commission, 1804 Lewis Turner Boulevard, Suite 100, Fort Walton Beach, Florida 32547.

Georgia	Colquitt County (Unincorporated Areas).	Okapilco Creek	Old Berlin Road (approximately 32.5 miles above mouth).	None *280	*231 *281
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Maps available for inspection at the Colquitt County Commissioner's Office, 1220 South Main, Moultrie, Georgia.

Send comments to Mr. Franklin Sutton, Chairman of the Colquitt County Board of Commissioners, P.O. Box 517, Moultrie, Georgia 31776.

Georgia	Moultrie (City) Colquitt County.	Okapilco Creek	Approximately 37.81 miles above mouth	*263	*261
			Approximately 42.2 miles above mouth ...	*278	*280
		Channel F	Just upstream of NE 9th Street	*272	*273
			Approximately 132 feet downstream of NE 7th Street.	*272	*273
		Ochlockonee River	Approximately 0.65 mile upstream of Meigs Road bridge.	*249	None
			Approximately 1.06 miles upstream of Meigs Road bridge.	None	*250
		Channel D	Corporate limits (approximately 0.15 mile upstream of the confluence with Ochlockonee River).	None	*249
			Approximately 0.26 mile upstream of the confluence with Ochlockonee River.	None	*249

Maps available for inspection at the City of Moultrie Engineering Department, 1108 1st Street, N.E., Moultrie, Georgia.

Send comments to The Honorable William McIntosh, Mayor of the City of Moultrie, P.O. Box 250, Moultrie, Georgia 31776.

Illinois	Highland Park (City) Lake County.	Lake Michigan	Entire shoreline within the community	*584	*585
		Skokie River	At the county boundary (Lake Cook Road).	*632	*633
		Middle Fork North Branch	At Old Elm Road	*651	*650
			Approximately 1,100 feet upstream of Half Day Road.	*558	*559
		Chicato River	At Lake Cook Road (county boundary)	*650	*651

Maps available for inspection at the Municipal Building, 1707 St. John Avenue, Highland Park, Illinois.

Send comments to The Honorable Daniel Pierce, Mayor of the City of Highland Park, 1707 St. John Avenue, Highland Park, Illinois 60035.

Illinois	Huntley (Village) Kane and McHenry Counties.	South Branch Kishwaukee River.	At downstream corporate limits	None	*867
			Approximately 220 feet downstream of State Route 47	*872	*873
		Kishwaukee Creek	At South Union Road	None	*856
			At State Route 47	None	*859

Maps available for inspection at the Huntley Village Hall, 11704 Coral Street, Huntley, Illinois.

Send comments to Mr. James Dhamer, President of the Village of Huntley, 11704 Coral Street, Huntley, Illinois 60142.

Illinois	McHenry County (Unincorporated Areas).	Kishwaukee Creek	At confluence with South Branch Kishwaukee River.	None	*846
			Approximately 3,265 feet (0.62 mile) upstream of Huntley/Ackman Road.	None	*891
		South Branch Kishwaukee River.	At Seeman Road	None	*845
			At State Route 47	None	*874

Maps available for inspection at the McHenry County Government Center, 2200 North Seminary Road, Woodstock, Illinois.

Send comments to Ms. Dianne Klemm, Chairman of the McHenry County Board, 2200 North Seminary Road, Woodstock, Illinois 60098.

Kentucky	Elkhorn City (City) Pike County.	Elkhorn Creek	At the confluence with Russell Fork	*785	*786
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State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
			Approximately 700 feet upstream of Higgins Road.	None	*800

Maps available for inspection at the Elkhorn City Hall, Patty Lovelace Boulevard, Elkhorn City, Kentucky.

Send comments to The Honorable Hank Salyer, Mayor of the City of Elkhorn City, P.O. Box 681, Elkhorn City, Kentucky 41522.

Kentucky	Falmouth (City) Pendleton County.	Licking River	At confluence of South Fork Licking River/downstream corporate limits.	None	*555
			Approximately 100 feet upstream of upstream corporate limits.	None	*555
		South Fork Licking River	At confluence with Licking River	None	*555
			At the upstream corporate limits approximately 0.5 mile from U.S. Route 27.	None	*558

Maps available for inspection at the Falmouth City Hall, 212 Main Street, Falmouth, Kentucky.

Send comments to The Honorable Max Goldberg, Mayor of the City of Falmouth, 212 Main Street, Falmouth, Kentucky 41040.

Kentucky	Irvine (City) Estill County.	Kentucky River	Approximately 0.46 mile downstream of State Route 52.	None	*628
			Approximately 1.59 miles upstream of State Route 52.	None	*629
		Chamberlain Branch	At confluence with Kentucky River	None	*629
			Approximately 0.29 mile upstream of Broadway.	None	*652

Maps available for inspection at the Irvine City Hall, 142 Broadway, Irvine, Kentucky.

Send comments to The Honorable W. T. Williams, Mayor of the City of Irvine, 142 Broadway, Irvine, Kentucky 40336.

Kentucky	Liberty (City) Casey County.	Green River	Approximately 425 feet downstream of confluence of Highway 49 Tributary.	None	*794
			Approximately 0.77 mile upstream of the confluence of Convenient Tributary.	None	*808
		Convenient Tributary	At the confluence to Green River	None	*806
			Approximately 140 feet upstream of Woodrum Ridge Road.	None	*846
		Highway 49 Tributary	Approximately 450 feet downstream of Middleburg Road.	None	*794
			Approximately 1,780 feet upstream of Middleburg Road.	None	*821
		Campbells Lane Tributary	Approximately 300 feet downstream of Middleburg Road.	None	*794
			Approximately 470 feet upstream of Middleburg Road.	None	*804

Maps available for inspection at the Liberty City Hall, Courthouse Square, Liberty, Kentucky.

Send comments to The Honorable Humphrey Elliott, Mayor of the City of Liberty, Liberty City Hall, P.O. Box 127, Liberty, Kentucky 42539.

Kentucky	Pike County (Unincorporated Areas).	Johns Creek	Approximately 100 feet downstream of State Route 3227.	None	*715
			Approximately 50 feet upstream of Stinking Branch Road.	None	*839
		Long Fork	Approximately 500 feet upstream of the confluence with Shelby Creek.	None	*834
			Approximately 0.3 mile upstream of confluence of Sugarcamp Branch.	None	*959
		Elkhorn Creek	Approximately 750 feet downstream of Higgins Road.	None	*792
			Approximately 250 feet upstream of the confluence of Upper Pigeon Branch.	None	*1233
		Ashcamp Branch	At the confluence with Elkhorn Creek	*1063	*1062
			Approximately 850 feet upstream of the confluence with Elkhorn Creek.	*1063	*1062

Maps available for inspection at the Pike County Courthouse, Judge Executive's Office, 324 Main Street, Pikeville, Kentucky.

Send comments to The Honorable Donna Damron, Pike County Judge/Executive, 324 Main Street, Pikeville, Kentucky 41501.

Kentucky	Pikeville (City) Pike County.	Pikeville Pond	Approximately 800 feet upstream of the confluence with Levisa Fork.	*671	*670
			Approximately 1,750 feet upstream of Baird Avenue.	*671	*685

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified

Maps available for inspection at the Building Inspector's Office, 260 Hambley Boulevard, Pikeville, Kentucky.

Send comments to The Honorable Steven D. Combs, Mayor of the City of Pikeville, P.O. Box 1228, Pikeville, Kentucky 41502.

Michigan	Baraga (Village) Baraga County.	Voss Drain	Approximately 70 feet downstream U.S. 41.	None	*604
			At upstream corporate limit	None	*715
		North Drain	Approximately 525 feet downstream U.S. 41.	None	*604
			At upstream corporate limits	None	*816
		Diversion Drain	Approximately 250 feet downstream of U.S. 41.	None	*604
			Approximately 1,400 feet upstream of McGillan Street.	None	*763
		Center Drain	Approximately 150 feet downstream U.S. 41.	None	*604
		Tributary to Voss Drain	At upstream corporate limits	None	*787
			At confluence with Voss Drain	None	*664
			Approximately 1,800 feet upstream of confluence with Voss Drain.	None	*745
		Keweenaw Bay	Entire shoreline within the community	None	*604

Maps available for inspection at the Baraga Village Hall, 440 North Superior Avenue, Baraga, Michigan.

Send comments to Mr. William S. Yost, Baraga Village Manager, P.O. Box 290, 440 North Superior Avenue, Baraga, Michigan 49908-0290.

Michigan	Escanaba (City) Delta County.	Little Bay De Noc	Entire shoreline within community	None	*585
		Green Bay	Entire shoreline within community	*584	*585
		Portage Creek	Approximately 2,785 feet downstream of confluence with Willow Creek.	None	*589
			Approximately 75 feet downstream of confluence with Willow Creek.	None	*595
		Willow Creek	Approximately 3,300 feet downstream of 8th Avenue.	None	*596
			Approximately 100 feet upstream of New Danforth Road.	None	*627

Maps available for inspection at the City of Escanaba Protective Department, 410 Ludington Street, Escanaba, Michigan.

Send comments to Ms. Rosalind Allis, Escanaba City Manager, P.O. Box 948, 410 Ludington Street, Escanaba, Michigan 49829.

Michigan	Ford River (Township) Delta County.	Green Bay	Entire shoreline within community	*584	*585
		Ford River	Approximately 1,000 feet upstream of State Route 35.	*584	*585
			At 10.75 Road	None	*585

Maps available for inspection at the Ford River Township Building, 3845 K Road, Bark River, Michigan.

Send comments to Mr. Tom King, Ford River Township Supervisor, 3708 K Road, Bark River, Michigan 49807.

Michigan	Garden (Village) Delta County.	Big Bay De Noc/Garden Bay.	Entire shoreline within community	None	*585
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Maps available for inspection at the Garden Village Hall, Garden Avenue, Garden, Michigan.

Send comments to Mr. Stephen Minor, Garden Village President, P.O. Box 167, Garden, Michigan 49835.

Michigan	Nahma (Township) Delta County.	Big Bay De Noc	Entire shoreline within community	None	*585
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Maps available for inspection at the Township Supervisor's Home Office, 9484 EE.25 Road, Rapid River, Michigan.

Send comments to Mr. Warren Groleau, Nahma Township Supervisor, 9484 EE.25 Road, Rapid River, Michigan 49878.

Michigan	Wells (Township) Delta County.	Little Bay De Noc	Entire shoreline within community	None	*585
		Portage Creek	Approximately 75 feet downstream of confluence with Willow Creek (downstream corporate limits).	None	*595
			At confluence with Willow Creek	None	*595
		Willow Creek	At confluence with Portage Creek	None	*595
			Approximately 700 feet upstream of confluence with Portage Creek.	None	*596
		Escanaba River	From confluence with Little Bay De Noc	None	*585

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
			Approximately 500 feet upstream of U.S. Routes 2 and 41.	None	*585
Maps available for inspection at the Wells Township Building, 6436 North Eight Road, Wells, Michigan. Send comments to Mr. Bill Farley, Wells Township Supervisor, P.O. Box 188, Wells, Michigan 49894.					
Minnesota	Sibley County (Unincorporated Areas).	Minnesota River	Approximately 0.6 mile downstream of confluence of Rush River.	*742	*741
			At upstream side of Minnesota State Route 93.	*748	*747
Maps available for inspection at the Sibley County Planning and Zoning Office, 400 Court Avenue, Gaylord, Minnesota. Send comments to Mr. Gene Solmonson, Sibley County Auditor, P.O. Box 171, Gaylord, Minnesota 55334.					
New York	Brookhaven (Town) Suffolk County.	Seatuck Creek	Approximately 0.7 mile south of Long Island Railroad crossing along Seatuck Creek.	*9	*10
Maps available for inspection at the Brookhaven Town Hall, 3233 Route 112, Medford, New York. Send comments to Mr. Felix J. Grucci, Jr., Brookhaven Town Supervisor, 3233 Route 112, Medford, New York 11763.					
New York	Elmira (City) Chemung County.	Newtown Creek	Approximately 100 feet downstream of East Water Street.	*850	*849
			Approximately 680 feet upstream of confluence with Diven Creek.	*863	*861
		Interior Ponding Area	Approximately 50 feet south of the intersection of Judson Street and East Water Street.	*850	*849
			Approximately 400 feet north of the intersection of Harriet Street and East Church Street.	*853	*849
		McCann's Tributary	At its confluence with Diven Creek	*863	*861
			Approximately 325 feet upstream of its confluence with Diven Creek.	*863	*861
Maps available for inspection at the Elmira City Hall, Engineering Department, 317 East Church Street, Elmira, New York. Send comments to Mr. Samuel F. Iraci, Jr., Elmira City Manager, 317 East Church Street, Elmira, New York 14901-2792.					
New York	Riverhead (Town) Suffolk County.	Atlantic Ocean	Approximately 400 feet east of the intersection of Harding Terrace and Taft Place.	*10	*9
Maps available for inspection at the Riverhead Town Hall, 200 Howell Avenue, Riverhead, New York. Send comments to Mr. James Starks, Riverhead Town Supervisor, 200 Howell Avenue, Riverhead, New York 11901.					
New York	Southampton (Village) Suffolk County.	Seatuck Creek	North of Main Street	None	*9
Maps available for inspection at the Southampton Village Hall, 23 Main Street, Southampton, New York. Send comments to The Honorable Douglas Murtha, Mayor of the Village of Southampton, 23 Main Street, Southampton, New York 11968-4899.					
New York	Weedsport (Village) Cayuga County.	Cold Spring Brook	Approximately 500 feet upstream of Oakland Street.	*395	*394
			Approximately 70 feet downstream of CONRAIL.	*393	*392
Maps available for inspection at the Weedsport Village Office, 8892 South Street, Weedsport, New York. Send comments to The Honorable Paul F. Kloc, Mayor of the Village of Weedsport, 8892 South Street, P.O. Box 190, Weedsport, New York 13166.					
North Carolina	Bethania (Town) Forsyth County.	Muddy Creek	Approximately 25 feet upstream of the State Road 67 (Reynolda Road) bridge.	*779	*777
			Approximately 1,300 feet downstream of Bethania-Tobaccoville Road.	*792	*793

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified

Maps available for inspection at the Bethania Town Office, 5711 Enfield Road, Bethania, North Carolina.
Send comments to The Honorable Ellie Collins, Mayor of the Town of Bethania, P.O. Box 259, Bethania, North Carolina 27101.

North Carolina	Forsyth County (Unincorporated Areas).	Abbotts Creek	Approximately 0.5 mile downstream of High Point Road (State Route 1003).	*802	*807
			Approximately 1,150 feet upstream of US I-40.	*878	*879
		Bear Creek	At confluence with Muddy Creek	*780	*778
			Approximately 280 feet upstream of Bethania Road.	*780	*779
		Belews Creek	At US 158	None	*752
			At confluence of Dean Creek	*768	*767
			Approximately 300 feet upstream of Hidden Valley School Road.	None	*806
		Bill Branch	At confluence with Muddy Creek	*757	*759
			Approximately 120 feet downstream of Spicewood Drive.	*758	*759
		Blanket Bottom Creek	Approximately 500 feet upstream of confluence with the Yadkin River.	None	*684
			At Styers Ferry Road	None	*782
		Cuddybum Branch	At confluence with Abbotts Creek	*803	*807
			Approximately 850 feet upstream of confluence with Abbotts Creek.	*806	*807
		Fiddlers Creek	At confluence with South Fork Muddy Creek.	*747	*749
			Approximately 50 feet downstream of Lake Valley Road	None	*869
		Grassy Creek	Approximately 500 feet upstream of Ziglar Road.	*819	*818
			Approximately 0.8 mile upstream of Perth Road.	*964	*963
		James Branch	At confluence with Muddy Creek	*748	*745
			Approximately 1,400 feet upstream of confluence with Muddy Creek	*748	*747
		Johnson Creek	At confluence with Yadkin River	None	*707
			Approximately 1,800 feet upstream of Tanglebrook Trail.	None	*707
		Johnson Creek Tributary	At confluence with Johnson Creek	*693	*707
			Approximately 0.6 mile upstream of Tanglebrook Trail	*706	*707
		Kerners Mill Creek	Approximately 670 feet upstream of confluence with Harmon Mill Creek.	*833	*829
			At Hopkins Road	*873	*876
		Fivemile Branch	At confluence with Mill Creek	*841	*844
			Approximately 400 feet upstream of confluence with Mill Creek.	*841	*844
		Leak Creek	At confluence with South Fork Muddy Creek.	*716	*718
			Approximately 1,800 feet upstream of confluence with South Fork Muddy Creek.	*717	*718
		Little Creek	Approximately 1,800 feet downstream of Jonestown Road.	*706	*707
			Approximately 400 feet downstream of Jonestown Road.	*709	*710
		Mill Creek	Approximately 525 feet downstream of Old Rural Hall Road.	*821	*824
			At downstream side of Davis Road	*869	*870
		Mill Creek No. 3	At confluence with Muddy Creek	*789	*792
			At High Cliffs Road	*791	*792
		Muddy Creek	Approximately 60 feet upstream of Cooper Road.	*694	*693
			Approximately 1,500 feet downstream of Bethania-Tobaccoville Road.	*792	*793
		Oil Mill Branch	At confluence with Muddy Creek	*754	*753
			Approximately 900 feet upstream of confluence with Muddy Creek.	*754	*753
		Reynolds Creek	At confluence with Tomahawk Creek	*732	*731
			Approximately 1.1 miles upstream of Styers-Ferry Road.	None	*782

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
		Salem Creek	At confluence with Muddy Creek Approximately 1,850 feet downstream of WWTP Road.	*694 *711	*695 *712
		Sawmill Branch	At confluence with South Fork Muddy Creek. Approximately 800 feet upstream of con- fluence with South Fork Muddy Creek.	*782 *785	*783 *786
		Silas Creek	At confluence with Muddy Creek Approximately 0.5 mile upstream of I-40	*710 *722	*708 *723
		Soakas Creek	At confluence with South Fork Muddy Creek. Approximately 1,200 feet above con- fluence with South Fork Muddy Creek.	*729 *729	*728 *728
		South Fork Muddy Creek	Approximately 100 feet downstream of county boundary. Approximately 700 feet downstream of Piedmont Memorial Drive.	*691 *818	*690 *819
		Swaim Creek	At confluence with South Fork Muddy Creek. Approximately 1.2 miles upstream of State Road 1003.	*817 *866	*818 *867
		Tomahawk Branch	At confluence with Tomahawk Creek Approximately 70 feet upstream of con- fluence with Tomahawk Creek.	*772 *772	*770 *771
		Tomahawk Creek	At confluence with Muddy Creek Approximately 75 feet upstream of Robinhood Road.	*732 *788	*729 *787
		Vernon Branch	At confluence with South Fork Muddy Creek. Approximately 190 feet upstream of Foxmeadow Lane.	*759 *767	*761 *766
		Yadkin River	Approximately 1,300 feet downstream of Idols Dam. Approximately 500 feet upstream of Inter- state Route 40.	None None	*700 *710

Maps available for inspection at the City/County Planning Board Office, 101 North Main Street, Winston-Salem, North Carolina.

Send comments to Mr. Graham Pervier, Forsyth County Manager, Hall of Justice, Room 700, Winston-Salem, North Carolina 27101.

North Carolina	Kernersville (Town) Forsyth County.	Kerners Mill Creek	At Hopkins Road	*873	*876
			Approximately 500 feet downstream of Dogwood Lane.	*887	*886

Maps available for inspection at the Kernersville Town Hall, Planning Department, 134 East Mountain Street, Kernersville, North Carolina.

Send comments to The Honorable Thomas W. Prince, Mayor of the Town of Kernersville, P.O. Box 728, Kernersville, North Carolina 27285.

North Carolina	Winston-Salem (City). Forsyth County	Berry Branch	At confluence with Salem Creek	*772	*769
			Approximately 1,920 feet upstream of confluence with Salem Creek.	*772	*771
		Brenner Lake Branch	At confluence with Mill Creek	*756	*760
			Approximately 620 feet upstream of con- fluence with Mill Creek.	*759	*760
		Brushy Fork Creek	At confluence with Salem Creek	*771	*768
			At Reynolds Park Road	*771	*770
		Buena Vista Branch	At confluence with Silas Creek	*803	*801
			Approximately 430 feet upstream of Shaffner Park Bridge.	*803	*802
		Burke Creek	Approximately 450 feet upstream of con- fluence with Salem Creek.	*723	*724
			At Limit of Detailed Study (Silas Creek Parkway).	*787	*785
		Cloverleaf Branch	At confluence with Salem Creek	*759	*760
			Approximately 30 feet downstream of Hobson Street.	*761	*760
		Dunagun Branch	At confluence with Kerners Mill Creek	*798	*800
			Approximately 1,760 feet upstream of confluence with Kerners Mill Creek.	*799	*800
			Fiddlers Creek At confluence with South Fork Muddy Creek.	*747	*749

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
			Approximately 250 feet upstream of Oak Grove Road.	*843	*844
		Fiddlers Creek	At confluence with Fiddlers Creek	*815	*817
		Tributary	Approximately 140 feet upstream of confluence with Fiddlers Creek.	*816	*817
		Grassy Creek	At confluence with Mill Creek	*789	*790
			Just downstream of NC 66	*841	*839
		Kerners Mill Creek	At confluence with Salem Creek	*798	*800
			Approximately 850 feet upstream of confluence with Harmon Mill Creek.	*835	*829
		Leak Fork Creek	At confluence with Mill Creek	*783	*786
			Approximately 500 feet upstream of Patterson Avenue.	None	*875
		Little Creek	Approximately 1,800 feet downstream of Jonestown Road.	*706	*707
			At Limit of Detailed Study (approximately 200 feet downstream of Westview Drive).	*852	*853
		Lowery Mill	At confluence with Salem Creek	*798	*801
		Creek	Approximately 1,750 feet upstream of Old Greensboro Road.	*800	*801
		Fivemile Branch	Approximately 400 feet upstream of confluence with Mill Creek.	*841	*844
			Approximately 825 feet upstream of confluence with Mill Creek.	*843	*844
		Milhaven Creek	At confluence with Muddy Creek	*740	*739
			Approximately 300 feet upstream of confluence with Muddy Creek.	*740	*739
		Mill Creek	At confluence with Muddy Creek	*749	*747
			Approximately 150 feet upstream of Phelps Drive.	*856	*855
		Mill Creek	At confluence with Mill Creek	*803	*806
		Tributary	Approximately 900 feet upstream of confluence with Mill Creek.	*805	*806
		Monarcas Creek	Approximately 1,800 feet upstream of confluence with Mill Creek.	*782	*781
			Approximately 100 feet upstream of Linn Station Road.	*859	*860
		Muddy Creek	Approximately 0.7 mile downstream of US 421.	*725	*719
			Approximately 250 feet upstream of Reynolda Road.	*779	*777
		Muddy Creek	At confluence with Muddy Creek	*737	*736
		Tributary	Approximately 1,520 feet upstream of confluence with Muddy Creek.	*737	*736
		Peters Creek	At confluence with Salem Creek	*745	*747
			Approximately 250 feet upstream of Link Road.	*746	*747
		Petree Creek	At confluence with Mill Creek	*750	*754
			Approximately 60 feet downstream of Petree Road.	*753	*754
		Reynolda	At confluence with Mill Creek	None	*773
		Commons Bypass	Approximately 200 feet upstream of Reynolda Road.	None	*776
		Robbindale	At confluence with Fiddlers Creek	*811	*813
		Branch	Approximately 200 feet upstream of confluence with Fiddlers Creek.	*812	*813
		St. Delight Branch	At confluence with Kerners Mill Creek	*798	*801
			Approximately 290 feet upstream of Fire Road.	*800	*801
		Salem Creek	At Clemmons Road	*708	*707
			At confluence with Kerners Mill Creek	*778	*800
		Silas Creek	At confluence with Muddy Creek	*710	*708
			Approximately 1,400 feet upstream of Oldtown Club Road.	*882	*883
		Stadium Branch	At confluence with Salem Creek	*770	*766
			At Diggs Boulevard	*770	*766
		Terry Road Branch	At confluence with Salem Lake	*798	*801
			Approximately 80 feet downstream of Fire Road.	*800	*801

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified

Maps available for inspection at the City/County Planning Board Office, 101 North Main Street, Winston-Salem, North Carolina.

Send comments to Mr. Bryce A. Stuart, Winston-Salem City Manager, P.O. Box 2511, Winston-Salem, North Carolina 27102.

Ohio	West Milton (Village) Miami County.	Jones Run	Approximately 250 feet downstream of State Highway 48.	None	*905
		Hatfield Ditch	Approximately 1,000 feet upstream of State Highway 48.	None	*916
			Approximately 200 feet downstream of State Route 48.	None	*896
			Approximately 0.49 mile upstream of State Route 48.	None	*930

Maps available for inspection at the West Milton Village Hall, 701 South Miami Street, West Milton, Ohio.

Send comments to The Honorable Howard DeHart, Mayor of the Village of West Milton, 701 South Miami Street, West Milton, Ohio 45383.

Pennsylvania	East Cocalico (Township). Landcaster County	Stony Run	Approximately 265 feet upstream of confluence with Cocalico Creek.	*370	*369
			Approximately 0.6 mile upstream of Denver Road.	*426	*423

Maps available for inspection at the East Cocalico Township Hall, 100 Hill Road, Denver, Pennsylvania.

Send comments to Mr. Larry Gensemer, Chairman of the East Cocalico Township Board of Supervisors, 100 Hill Road, Denver, Pennsylvania 17517.

Pennsylvania	Stroudsburg (Borough) Monroe County.	McMichaels Creek	At upstream corporate limits	None	*425
			Approximately 158 feet upstream of confluence of Brodhead Creek.	*395	*394

Maps available for inspection at the Stroudsburg Borough Municipal Building, 700 Sarah Street, Stroudsburg, Pennsylvania.

Send comments to Ms. Pamela Caskie, Stroudsburg Borough Manager, 700 Sarah Street, Stroudsburg, Pennsylvania 18360.

West Virginia	Putnam County (Unincorporated Areas).	Pocatalico River	Approximately 450 feet upstream of the confluence of Heizer Creek.	None	*583
			At the upstream county boundary	None	*601

Maps available for inspection at the Office of Putnam County Planning and Infrastructure, Putnam County Courthouse, 3389 Winfield Road, Winfield, West Virginia.

Send comments to Mr. Franklin D. Bannister, President of the Putnam County Commission, 3389 Winfield Road, Winfield, West Virginia 25213.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Dated: August 15, 1996.

Richard W. Krimm,

Acting Associate Director for Mitigation.

[FR Doc. 96-21965 Filed 8-27-96; 8:45 am]

BILLING CODE 6718-04-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 96-171; RM-8846]

Radio Broadcasting Services; Indian Springs, NV, Mountain Pass, CA, Kingman, AZ, St. George, UT

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Claire B. Benezra, permittee of Station KPXC, Indian Springs, NV, requesting the substitution of Channel 257C for Channel 257A at Indian Springs, and the modification of Station KPXC's construction permit to specify operation on the higher class channel. The allotment of Channel 257C to Indian Springs could provide the community with a wide coverage area channel and enable Station KPXC to expand its service area. In addition, Station KPXC, operating as a Class C station, could provide a first aural reception service to approximately 1,549 persons. To accommodate the allotment of Channel 257C, petitioner also requests the substitution of Channel 259B for Channel 258B at Mountain Pass, CA, and the modification of Station KHYZ's

license accordingly, the substitution of Channel 261C2 for Channel 260C2 at Kingman, AZ, and the modification of Station KGMN's license accordingly, and the substitution of Channel 260C for Channel 259C at St. George, UT, and the modification of Station KSGI's license accordingly.

DATES: Comments must be filed on or before October 7, 1996, and reply comments on or before October 22, 1996.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Jerrold Miller, Esq., Miller and Miller, P.O. Box 33003, Washington, DC 20033 (Counsel to petitioner).

FOR FURTHER INFORMATION CONTACT:

Leslie K. Shapiro, Mass Media Bureau,
(202) 418-2180.

SUPPLEMENTARY INFORMATION: Channel 257C can be allotted to Indian Springs, NV, with a site restriction of 13.2 miles (21.2 kms) southwest, at coordinates 36-25-18 NL; 115-48-35 WL, to accommodate petitioner's desired transmitter site. Channel 261C2 can be allotted to Kingman, AZ, at Station KGMN's licensed transmitter site, at coordinates 35-06-37; 113-52-55. Channel 260C can be allotted to St. George, UT, at Station KSGI's licensed transmitter site, at coordinates 36-50-49; 113-29-28. Channel 259B can be allotted to Mountain Pass, CA, at Station KHYZ's licensed transmitter site, at coordinates 35-29-27; 115-33-27.

This is a synopsis of the Commission's *Notice of Proposed Rule Making and Order to Show Cause*, MM Docket No. 96-171, adopted August 9, 1996, and released August 16, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules
Division, Mass Media Bureau.

[FR Doc. 96-21865 Filed 8-27-96; 8:45 am]

BILLING CODE 6712-01-F

47 CFR Part 73

[MM Docket No. 96-170; RM-8844]

Radio Broadcasting Services; Franklin, LA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition by Annette G. Thompson proposing the allotment of Channel 295C3 at Franklin, Louisiana, as the community's second local FM service. Channel 295C3 can be allotted to Franklin in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 295C3 at Franklin are 29-47-42 and 91-30-12.

DATES: Comments must be filed on or before October 7, 1996, and reply comments on or before October 22, 1996.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Vincent J. Curtis, Jr., Fletcher, Heald & Hildreth, P.L.C., 1300 N. 17th Street, 11th Floor, Rosslyn, Virginia 22209 (Counsel for petitioner).

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418-2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making*, MM Docket No. 96-170, adopted August 9, 1996, and released August 16, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, ITS, Inc., (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules
Division, Mass Media Bureau.

[FR Doc. 96-21869 Filed 8-27-96; 8:45 am]

BILLING CODE 6712-01-F

47 CFR Part 73

[MM Docket No. 90-318; RM-7311, RM-7516]

Radio Broadcasting Services; Chillicothe, Forest, Lima, New Washington, Peebles and Reynoldsburg, OH

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; dismissal and denial of.

SUMMARY: The Commission, at the request of Good News Broadcasting, dismisses its request to allot Channel 227A to New Washington, Ohio, as the community's first local aural transmission service. See 55 FR 26708, June 29, 1990. The Commission also denies the proposal of Pearl Broadcasting, Inc. to reallocate Channel 227B from Chillicothe, Ohio, to Reynoldsburg, Ohio, and modify Station WKKJ(FM)'s license to specify Reynoldsburg as its community of license, allot Channel 226A to both Forest and Peebles, Ohio, as each community's first local aural transmission service, and substitute Channel 257A for Channel 226A at Lima, Ohio, and modify Station WYRX's license to specify the alternate Class A channel to accommodate the Reynoldsburg and Peebles allotments. With this action, this proceeding is terminated.

FOR FURTHER INFORMATION CONTACT:

Leslie K. Shapiro, Mass Media Bureau,
(202) 418-2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MM Docket No. 90-318, adopted August 9, 1996, and released August 20, 1996. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.
John A. Karousos,
*Chief, Allocations Branch, Policy and Rules
Division, Mass Media Bureau.*
[FR Doc. 96-21866 Filed 8-27-96; 8:45 am]
BILLING CODE 6712-01-F

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric
Administration****50 CFR Part 648****[I.D. 081596G]****Mid-Atlantic Fishery Management
Council; Public Hearings**

AGENCY: National Marine Fisheries
Service (NMFS), National Oceanic and
Atmospheric Administration (NOAA),
Commerce.

ACTION: Public hearings.

SUMMARY: The Mid-Atlantic Fishery
Management Council (Council), together
with the Atlantic States Marine
Fisheries Commission, will hold public
hearings to address a proposed
regulatory amendment/addendum to the
Scup Fishery Management Plan, which
addresses management and allocation of
the coastwide commercial quota.

DATES: The hearings will begin at 7 p.m.
and are scheduled as follows:

1. September 10, 1996, Providence, RI
2. September 10, 1996, Cape May
Courthouse, NJ
3. September 11, 1996, Buzzards Bay,
MA
4. September 12, 1996, E. Setauket,
NY

ADDRESSES: The hearings will be held at
the following locations:

1. Providence—Providence Marriott, 1
Orms Street, Providence, RI
2. Cape May Courthouse—Cape May
Agricultural Extension Office,
Dennisville Road, Cape May
Courthouse, NJ

3. Buzzards Bay—Massachusetts
Maritime Academy, Academy Drive,
Buzzards Bay, MA

4. E. Setauket—New York
Environmental Conservation Office, 205
Belle Meade Road, E. Setauket, NY

FOR FURTHER INFORMATION CONTACT:
David R. Keifer (302) 674-2331.

SUPPLEMENTARY INFORMATION:

The hearings are physically accessible
to people with disabilities. Requests for
sign language interpretation or other
auxiliary aids should be directed to
David Keifer at the Council at least 5
days prior to the hearing dates.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 21, 1996.

Donald J. Leedy,

*Acting Director, Office of Fisheries
Conservation and Management, National
Marine Fisheries Service.*

[FR Doc. 96-21873 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-22-F

Notices

Federal Register

Vol. 61, No. 168

Wednesday, August 28, 1996

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

August 23, 1996.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, D.C. 20503 and to Department Clearance Officer, USDA, OCIO, Mail Stop 7602, Washington, D.C. 20250-7630. Copies of the submission(s) may be obtained by calling (202) 720-6204 or (202) 720-6746.

• Food and Consumer Service

Title: Operating Guidelines, Forms and Waivers.

Summary: Approval standards promulgated by these Food Stamp regulations include system performance characteristics and cost effectiveness during operation. As a result, State agencies are required to report information on these standards during operation and as part of the approval process.

Need and Use of the Information: This information is needed for approval purposes per the Food Stamp Act, to determine whether activity or automation effort is eligible to receive Federal funding and explain how the program is conducted in individual states. This information is required to comply with the legislative mandate.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 53.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Quarterly.

Total Burden Hours: 4,731.

• Food and Consumer Service

Title: Report of the Child and Adult Care Food Program.

Summary: The Child and Adult Care Food Program is mandated by Section 17 of the National School Lunch Act as amended. State agencies must submit a report of program activity in order to receive Federal reimbursement for meals served to eligible participants.

Need and Use of the Information: The information collected on Form FCS-44 is used for management of the program. It is the only means by which FCS can obtain current information necessary to make payments to State agency letters of credit, and to plan for future levels of program funding. If this data were not collected, FCS would be unable to monitor the proper use of program funds.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 53.

Frequency of Responses: Reporting: Monthly; Quarterly; Semi-annually.

Total Burden Hours: 5,724.

• Farm Service Agency

Title: Request for Statement of Debts and Collateral.

Summary: The Consolidated Farm and Rural Development Act authorizes the Secretary of Agriculture to make direct loans to eligible farmers and ranchers for farm operating and emergency loans for operating purposes.

Need and Use of the Information: Information collection is necessary to obtain details regarding chatte debt for direct operating loans and for emergency loans for operating purposes. Without this information, USDA would not have verification on lien position when securing the loan and would not have exact balances on the debts in question.

Description of Respondents: Business or other for-profit; Federal Government.

Number of Respondents: 15,000.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 11,250.

• Foreign Agricultural Service

Title: Application for Import Licenses for Certain Dairy Products—1997 and thereafter.

Summary: These forms will be used in applying for import licenses for

certain dairy products subject to tariff-rate quotas and issued in accordance with the final rule governing the administration of the import licensing system.

Need and Use of the Information: The information is needed to assure that the intent of the legislature is being correctly administered.

Description of Respondents: Business or other for-profit; Individuals or households.

Number of Respondents: 500.

Frequency of Responses: Recordkeeping; Reporting: Monthly; Annually.

Total Burden Hours: 375.

Emergency processing of this submission has been requested by September 6, 1996.

• Economic Research Service

Title: Cotton Ginning Charges and Related Information.

Summary: The information collected provides specific estimates of charges paid by farmers for ginning and wrapping cotton, data on harvesting practices, and charges for major marketing services.

Need and Use of the Information: The information is used to compute cotton cost of production estimates, is used in commodity situation and outlook projections, and provides data on trends in harvesting.

Description of Respondents: Business or other for-profit.

Number of Respondents: 1170.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 195.

Donald Hulcher,

Deputy Departmental Clearance Officer.

[FR Doc. 96-21971 Filed 8-27-96; 8:45 am]

BILLING CODE 3410-01-M

Agricultural Marketing Service

[DA-96-06]

Announcement of Implementation of the Northeast Interstate Dairy Compact

AGENCY: Agricultural Marketing Service.

ACTION: Notice.

SUMMARY: This notice announces that the Secretary of Agriculture has authorized the implementation of the Northeast Interstate Dairy Compact. The Secretary has determined that a compelling public interest exists in the Compact region and has authorized the

Compact States of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont to implement the Northeast Interstate Dairy Compact, effective August 8, 1996.

EFFECTIVE DATE: August 8, 1996.

FOR FURTHER INFORMATION CONTACT:

Richard M. McKee, Director, USDA/AMS/Dairy Division, Room 2968, South Building, P.O. Box 96456, Washington, DC 20090-6456 (202) 720-4392.

SUPPLEMENTARY INFORMATION: Section 147 of the 1996 Federal Agriculture Improvement and Reform (FAIR) Act (Pub. L. 104-127) establishes Congressional consent for the Northeast Interstate Dairy Compact (the Compact) entered into by the States of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont subject to several conditions. The FAIR Act provides that "Based upon a finding by the Secretary of a compelling public interest in the Compact region, the Secretary may grant the States that have ratified the Northeast Interstate Dairy Compact, as of the date of enactment of this title, the authority to implement the Northeast Interstate Dairy Compact." The Secretary issued the following on August 8, 1996:

Finding and Authorization of Secretary Dan Glickman on the Northeast Interstate Dairy Compact

Whereas the State legislatures in Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont have approved the Northeast Interstate Dairy Compact, the governor of each Compact State has signed a resolution supporting the Compact, the Congress has consented to the Compact in the Federal Agriculture Improvement and Reform (FAIR) Act of 1996, and approximately ninety-five percent of the comments the Department of Agriculture received regarding the Compact supported its implementation, I hereby find that a compelling public interest in the Compact region exists and authorize the Compact States to implement the Northeast Interstate Dairy Compact. This finding and authorization shall be effective immediately and shall be published in the Federal Register.

On August 9, 1996, Secretary Glickman issued the following press statement concerning the Northeast Interstate Dairy Compact:

The State legislatures in Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont have approved the Northeast Interstate Dairy Compact, the governor of each Compact State has signed a resolution supporting the Compact, and the Congress has consented to the Compact in the Federal Agriculture Improvement and Reform (FAIR) Act of 1996. In addition, approximately 95 percent of the comments the Department of Agriculture received regarding the Compact supported its

implementation. For these reasons, I have found that a compelling public interest in the Compact region exists and have authorized the Compact States to implement the Northeast Interstate Dairy Compact. This finding and authorization became effective today and will be published in the Federal Register.

While it is unclear what specific actions the Compact Commission will take to implement the Compact, I am concerned about the potential effects of the Compact in several respects. I intend, therefore, to monitor closely its implementation. I also encourage Congress to exercise its oversight function and monitor the implementation of the Compact. If my expectations are not met, or if conditions otherwise warrant, I will revoke this authorization to implement the Compact.

I expect that the Compact Commission will implement the Compact in a way that does not burden other regions of the country, consistent with the provisions of the FAIR Act and the Compact. I would be greatly concerned if the Commission restricts in any way the ability of producers to ship milk into the Compact region. I will monitor whether the Compact has any adverse effects on the income of dairy producers outside the Compact region as well as the extent to which the Commission utilizes its authority to impose production controls to minimize the effect of the Compact on other dairy producing regions. I also expect the Commission to ensure that its actions are flexible and responsive to changing supply, demand and price conditions in milk markets.

Perhaps most significantly, I am deeply concerned about and will closely monitor the effect of the Compact on consumers, especially low-income families, within the Compact region. I expect that the Commission will pay close attention to and monitor the effects of its decisions on consumers before and after it takes any action. I also expect the Commission and the Compact States to provide assistance to offset any increased burden on low-income families in the Compact region. I am also concerned about the effect of the Compact on the Department of Agriculture's nutrition programs, and I expect the Commission to exercise its authority to reimburse participants in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and to fulfill its obligation to reimburse the Commodity Credit Corporation, as provided in the Compact and in the FAIR Act.

The Compact is a transitional milk marketing system for the region and will expire when a new nationwide Federal milk marketing order structure is implemented. I believe the approach outlined in this statement offers the best opportunity to strengthen the dairy industry in the Compact region during the transition to the reformed milk marketing order structure required by the FAIR Act.

Dated: August 22, 1996.

Shirley R. Watkins,

Acting Assistant Secretary, Marketing and Regulatory Programs.

[FR Doc. 96-21957 Filed 8-27-96; 8:45 am]

BILLING CODE 3410-02-P

Forest Service

Southwest Washington Provincial Advisory Committee Meeting Notice

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Southwest Washington Provincial Advisory Committee will meet on September 11, 1996, at the Skamania County Annex in Stevenson, Washington. The purpose of the meeting is to continue work on subcommittee tasks from previous meetings. The meeting will begin at 1 p.m. and continue until 4:30 p.m. The meeting will resume at 6:30 p.m. and conclude at 8:30 p.m.

Agenda items to be covered include: (1) Subcommittee recommendations on Advisory Committee vision and work priorities, (2) Advisory Committee Monitoring Opportunities, (3) Update on Advisory Committee Charter Renewals, (4) Forest Plan Allocation assumptions and their relationship to timber harvest levels, (5) Subcommittee update on socioeconomic health measures. (6) Public Open Forum.

All Southwest Washington Provincial Advisory Committee meetings are open to the public. Interested citizens are encouraged to attend. This open forum provides opportunity for the public to bring issues, concerns, and discussion topics to the Advisory Committee. The open forum is scheduled as part of agenda item (6) for this meeting. Interested speakers will need to register prior to the open forum period. The committee welcomes the public's written comments on committee business at any time.

FOR FURTHER INFORMATION CONTACT:

Direct questions regarding this meeting to Sue Lampe, Public Affairs, at (360) 750-5091, or write Forest Headquarters Office, Gifford Pinchot National Forest, PO Box 8944, Vancouver, WA 98668-8944.

Dated: August 20, 1996.

Ted C. Stubblefield,

Forest Supervisor.

[FR Doc. 96-21923 Filed 8-27-96; 8:45 am]

BILLING CODE 3410-11-M

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Meeting

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of meeting.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) has scheduled its regular business meetings to take place in Washington, D.C. on Monday, Tuesday, and Wednesday, September 9–11, 1996 at the times and location noted below.

DATES: The schedule of events is as follows:

Monday, September 9, 1996

9:00 AM–Noon Technical Programs Committee

Tuesday, September 10, 1996

2:00 PM–4:00 PM Technical Programs Committee

4:00 PM–5:00 PM Planning and Budget Committee

Wednesday, September 11, 1996

9:00 AM–11:00 AM Ad Hoc Committee on Bylaws and Statutory Review

11:00 AM–Noon Executive Committee

1:30 PM–3:30 PM Board Meeting

ADDRESSES: The meetings will be held at: Embassy Suites Hotel, 1250 22nd Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: For further information regarding the meetings, please contact Lawrence W. Roffee, Executive Director, (202) 272–5434 ext. 14 (voice) and (202) 272–5449 (TTY).

SUPPLEMENTARY INFORMATION: At the Board meeting, the Access Board will consider the following agenda items:

- Approval of the Minutes of the May 15 and July 10, 1996 Board Meetings.
- ADAAG Review Advisory Committee Report.
- Executive Committee Report.
- Technical Programs Committee Report.
- Planning and Budget Committee Report.
- Status Report by Standard Setting Agencies on Implementing Regulations for Access to Federal Facilities.
- Schedule for Completing State and Local Government Facilities Guidelines and Federal Facilities Guidelines.

All meetings are accessible to persons with disabilities. Sign language interpreters and an assistive listening system are available at all meetings.

Lawrence W. Roffee,

Executive Director.

[FR Doc. 96–21970 Filed 8–27–96; 8:45 am]

BILLING CODE 8150–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Institute of Museum Services

Agency Information Collection Activities; Comment Request

AGENCY: Institute of Museum Services, NFAH.

ACTION: Notice.

SUMMARY: This notice announces that the agency requests comment on a information collection prior to submitting it to the Office of Management and Budget for review. The collection is entitled Financial Status Report Form.

DATES: Comments must be submitted on or before October 28, 1996.

ADDRESSES: Submit written comments to: Rebecca Danvers, Program Director, Institute of Museum Services, 1100 Pennsylvania Ave., NW, Washington, D.C. 20506. Comments may also be submitted by e-mail to Iminfo@ims.fed.us.

FOR FURTHER INFORMATION CONTACT: Submit requests for more information, including copies of the proposed collection of information and supporting documentation, to IMS Program Office, Institute of Museum Services, Room 609, 1100 Pennsylvania Ave., NW, Washington, DC 20506.

SUPPLEMENTARY INFORMATION:

I. Information Collection Request

IMS is seeking comments on the following Information Collection Request.

Title: Financial Status Report OMB No. 3137–0025, Expiration date 9/30/96.

Affected Entities: Parties affected by this information collection are museums that have received grants from the Institute of Museum Services.

Abstract: This form is an abbreviated version of the OMB SF 269 (Financial Status Report). It is needed for use of museums unfamiliar with federal government requirements. Only the information required by IMS is requested on this form.

Burden Statement: For this collection, the estimated average burden hours is 1 and the frequency of response is once. The number of respondents is 900.

II. Request for Comments

IMS solicits comments to:

- (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

- (ii) Evaluate the accuracy of the agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- (iii) Enhance the quality, utility, and clarity of the information to be collected; and

- (iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated or electronic collection, or other technological collections techniques or other forms of information technology, e.g., permitting electronic submission of responses.

III. Public Inspection

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as Confidential Business Information, (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by IMS without prior notice. All comments, written and printed versions of electronic comments, not including any information claimed as CBI, are available for inspection from 8:00 a.m. to 4:30 p.m. Monday through Friday, excluding legal holidays, in Rm. 510, Institute of Museum Services, 1100 Pennsylvania Ave., NW, Washington, DC.

List of Subjects

Financial Disclosure Reporting, Grant Monitoring, Museums.

Dated: August 21, 1996.

Mamie Bittner,

Director of Public and Legislative Affairs, Institute of Museum Services.

[FR Doc. 96–21901 Filed 8–27–96; 8:45 am]

BILLING CODE 7036–01–M

Sunshine Act Meeting

AGENCY: Institute of Museum Services.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the agenda of a forthcoming meeting of the National Museum Services Board. This notice also describes the functions of the Board. Notice of this meeting is required under the Government through the Sunshine Act (Public Law 94–409) and regulations of the Institute of Museum Services, 45 CFR 1180.84.

TIME/DATE: 10:30 am–1:00 pm—
Thursday September 26, 1996.

STATUS: Open.

ADDRESS: Old Post Office Building,
Room 527, 1100 Pennsylvania Avenue,
N.W., Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT: Isa
Bauerlein, Special Assistant to the
Director, Institute of Museum Services,
1100 Pennsylvania Avenue, N.W., Room
510, Washington, D.C. 20506—(202)
606–8536.

SUPPLEMENTARY INFORMATION: The
National Museum Services Board is
established under the Museum Services
Act, Title II of the Arts, Humanities, and
Cultural Affairs Act of 1976, Public Law
94–462. The Board has responsibility for
the general policies with respect to the
powers, duties and authorities vested in
the Institute under the Museum Services
Act.

The meeting of Thursday, September
26 will be open to the public.

If you need special accommodations
due to a disability, please contact:
Institute of Museum Services, 1100
Pennsylvania Avenue, N.W.,
Washington, D.C. 20506—(202) 606–
8536—TDD (202) 606–8636 at least
seven (7) days prior to the meeting date.

AGENDA

- I. Chairman's Welcome and Approval of
Minutes
- II. Director's Report
- III. Appropriations Report
- IV. Legislative/Public Affairs Report
- V. IMS Programs Report

Dated: August 19, 1996.

Linda Bell,

*Director of Policy, Planning and Budget,
National Foundation on the Arts and the
Humanities, Institute of Museum Services.*

[FR Doc. 96–22065 Filed 8–26–96; 11:48 am]

BILLING CODE 7036–01–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–834–805]

Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Beryllium Metal and High Beryllium Alloys from Kazakstan

AGENCY: Import Administration,
International Trade Administration,
Department of Commerce.

EFFECTIVE DATE: August 28, 1996.

FOR FURTHER INFORMATION CONTACT:
Dorothy Tomaszewski or Ellen
Grebach, Office of Antidumping
Investigations, Import Administration,
International Trade Administration,
U.S. Department of Commerce, 14th

Street and Constitution Avenue, N.W.,
Washington, D.C. 20230; telephone:
(202) 482–0631 or (202) 482–3773,
respectively.

The Applicable Statute

Unless otherwise indicated, all
citations to the Tariff Act of 1930 (“the
Act”) are references to the provisions
effective January 1, 1995, the effective
date of the amendments made to the Act
by the Uruguay Rounds Agreements
Act.

Preliminary Determination

We preliminarily determine that
beryllium metal and high beryllium
alloys (“beryllium”) from Kazakstan are
being, or are likely to be, sold in the
United States at less than fair value
(“LTFV”), as provided in section 733 of
the Act. The estimated margins are
shown in the “Suspension of
Liquidation” section of this notice.

Case History

Since the initiation of this
investigation on April 3, 1996 (61 FR
15770, April 9, 1996), the following
events have occurred:

On April 26, 1996, a cable was sent
to the U.S. embassy in Kazakstan
requesting the identification of
Kazakstan producers and exporters of
beryllium exported to the United States.
On May 3, 1996, a letter of appearance
was filed on behalf of the Kazak Joint-
Stock Company of Atomic Energy and
Industry (“KATEP”) and the Joint-Stock
Company of Ulba Metallurgical Plant
(“Ulba”). The Department of Commerce
(“the Department”) received a response
from the U.S. Embassy on May 8, 1996,
identifying the same companies named
in the May 3, 1996, letter of appearance.
The record indicates that during the POI
these companies were the only
companies licensed to export beryllium
from Kazakstan and that Ulba is the
only beryllium producer in Kazakstan.
The companies did not request that
separate, exporter-specific dumping
margins be calculated.

On May 15, 1996, the Department sent
its antidumping questionnaire to the
Embassy of Kazakstan, with a request
that it be transmitted to all companies
that produce beryllium for export to the
United States and to all companies that
were engaged in selling beryllium to the
United States during the period of
investigation. A copy of the
questionnaire was also sent to Ulba and
KATEP. The Department received
responses to the questionnaire from
Ulba and KATEP during June and July.

On April 29, 1996, the United States
International Trade Commission (“ITC”) notified the Department of its
affirmative preliminary determination.

On June 18, 1996, the Department
provided interested parties with the
opportunity to submit published,
publicly-available information for the
Department to consider when valuing
the factor inputs. Petitioner, Brush
Wellman Inc., and respondents
submitted information on July 23 and
July 30, 1996. Additional comments
from petitioner and respondents were
received on August 6, 1996.

Postponement of Final Determination

Pursuant to section 735(a)(2)(A) of the
Act, on August 14, 1996, respondents
requested that, in the event of an
affirmative preliminary determination
in this investigation, the Department
postpone its final determination until
135 days after the date of publication of
the determination in the Federal
Register. Pursuant to 19 CFR 353.20(b),
because (1) our preliminary
determination is affirmative, (2) the
respondents account for a significant
proportion of exports of the subject
merchandise, and (3) no compelling
reasons for denial exist, we are granting
respondents' request and postponing the
final determination.

Scope of Investigation

The scope of this investigation is
beryllium metal and high beryllium
alloys with a beryllium content equal to
or greater than 30 percent by weight,
whether in ingot, billet, powder, block,
lump, chunk, blank, or other
semifinished form. These are
intermediate or semifinished products
that require further machining, casting
and/or fabricating into sheet, extrusions,
forgings or other shapes in order to meet
the specifications of the end user.
Beryllium and high beryllium alloys
within the scope of this investigation
are classifiable under the Harmonized
Tariff Schedule of the United States
(“HTSUS”) 8112.11.6000, 8112.11.3000,
7601.20.9075, and 7601.20.9090.
Although the HTSUS subheading is
provided for convenience and customs
purposes, our written description of the
scope of this investigation is dispositive.

Period of Investigation

The period of investigation (“POI”) is
July 1, 1995, through December 31,
1995.

Separate Rates

Respondents made no claim for
receiving a separate rate; therefore, the
Department did not address this issue.

Fair Value Comparisons

To determine whether sales of
beryllium from Kazakstan to the United
States by Ulba were made at less than
fair value, we compared the Export

Price ("EP") to the NV, as specified in the "Export Price" and "Normal Value" sections of this notice.

Export Price

We calculated EP in accordance with section 772(a) of the Act, because the subject merchandise was sold directly to the first unaffiliated purchaser in the United States prior to importation. Although respondents, Ulba and KATEP, reported that they have a U.S. subsidiary, Beryllium Metals International Ltd. ("BMI"), calculation of constructed export price ("CEP") under section 772(b) is not otherwise warranted for purposes of the preliminary determination based on the facts of this investigation. It has been the Department's longstanding and well-recognized practice that a transaction will be considered an export price sale, despite the involvement of an affiliate in the United States where: (1) the merchandise in question was shipped directly from the manufacturer to the unrelated buyer, without being introduced into the physical inventory of the related selling agent; (2) this was the customary commercial channel for sales of this merchandise between the parties involved; and (3) the related selling agent in the United States acted only as a processor of documentation and a communication link with the unrelated buyer. *See, e.g., Final Determination of Sales at Less Than Fair Value: Large Newspaper Printing Presses and Components Thereof, Whether Assembled or Unassembled, From Germany* (61 FR 38166, 38175, July 23, 1996). The facts in the present case indicate that the merchandise is not taken into the physical inventory of the U.S. subsidiary. Because there has only been one sale, we conclude that there is no "customary commercial channel." Therefore, we are disregarding this criterion for purposes of this preliminary determination. Finally, because of the limits on BMI's authority to finalize sales, it appears that BMI is acting solely as a processor of documentation and communications link. Therefore we conclude that the sale in question is properly characterized as an EP sale. However, the issue of whether the reported U.S. sale should be treated as CEP will be further examined at verification.

We calculated EP based on packed, CIF U.S. port prices to unaffiliated purchasers in the United States, as appropriate. We made deductions from the starting price, where appropriate, for foreign inland freight, international freight, and foreign brokerage and handling. Additionally, for three reported sales observations, respondents

noted that following the shipment of the subject merchandise, the price was adjusted downward from the originally invoiced unit price. For purposes of the preliminary determination, we are treating this change in price as a post-sale price discount to gross unit price.

Normal Value

A. Nonmarket Economy Country Status

The Department has treated Kazakhstan as a nonmarket economy country ("NME") in all past antidumping investigations (*see, e.g., Final Determinations of Sales at Less Than Fair Value: Ferrosilicon from Kazakhstan and Ukraine; and Postponement of Final Determination; Ferrosilicon from the Russian Federation* 58 FR 13050 (March 9, 1993)). Because neither respondents nor petitioner have challenged such treatment, we will continue to treat Kazakhstan as a NME in this investigation, in accordance with section 771(18)(C) of the Act.

When the Department is investigating imports from a NME, section 773(c)(1) of the Act directs us to base normal value ("NV") on the NME producer's factors of production, valued in a comparable market economy that is a significant producer of comparable merchandise.

B. Surrogate Country Selection

Section 773(c)(4) of the Act requires the Department to value the NME producer's factors of production, to the extent possible, in one or more market economy countries that: (1) are at a level of economic development comparable to that of the NME and (2) are significant producers of comparable merchandise. The Department has determined that Peru, Ecuador, Algeria, Colombia, and Tunisia are countries comparable to Kazakhstan in terms of overall economic development (*see* June 10, 1996, *Memorandum from David Mueller, Director, Office of Policy, to Gary Taverman, Division I Director, Office of Antidumping Investigations*).¹

¹ Respondents propose that the analysis of comparable levels of economic development should be based on per-capita purchasing power parity ("PPP"). However, it is important to note that it is the Department's longstanding practice in selecting surrogate countries to rely on market-exchange-rate-based, per-capita income as an indicator of economic development (*see, e.g., Final Determination of Sales at Less Than Fair Value: Antidumping Duty Investigation of Bicycles from the People's Republic of China*, 61 FR 19026, April 30, 1996; *Final Determination of Sales at Less Than Fair Value: Antidumping Duty Investigation of Steel Pipe from Romania*, 61 FR 24274, May 14, 1996). While arguments for relying on PPP per capita income have been considered (*see, e.g., Final Determination of Sales at Less Than Fair Value: Antidumping Duty Investigation of Manganese Metal from the People's Republic of China*, November 6, 1995, 60 FR 56048), the Department

Because none of these five countries satisfies the second statutory requirement for the selected surrogate country to be a significant producer of comparable merchandise, respondents proposed India as the appropriate surrogate country in this investigation. According to respondents, India and Kazakhstan are at a similar level of economic development based on per-capita PPP; India is "likely to be" a producer of beryllium metal; and, India is a significant producer of titanium and zirconium, which respondents deem comparable to beryllium metal in terms of physical characteristics and end use.

Petitioner proposed Brazil as the appropriate surrogate country in which to value the factors of production. Petitioner notes that Brazil and Kazakhstan both experienced negative gross domestic product growth and both countries produce beryl ore, the primary input, used in the production of beryllium.

Based on information on the record of this investigation, the only producers of beryllium (excluding waste and scrap) are the United States, Kazakhstan, and the People's Republic of China. Further, the staff of the U.S. Geological Survey and the Department's Metals Division have stated that it is not possible to identify any merchandise truly comparable to beryllium in terms of similar production process or production inputs. Even though petitioner's surrogate country choice, Brazil, is a significant producer of beryl ore, an input in producing beryllium, information on the record indicates that this ore cannot be considered to be merchandise comparable to beryllium. Moreover, Brazil's 1993 per-capita annual income was \$2930 versus \$1560 for Kazakhstan. Although the record contains market reports which make passing reference to production of beryllium metal in respondents' surrogate country choice, India, the Department has been unable to confirm such production. *See* August 21, 1996, *Memorandum to File; and Preliminary Determination of Beryllium Metal and High Beryllium Alloys from Kazakhstan, Calculation Memorandum*, August 21, 1996 ("Calculation Memorandum").

Absent information on a market economy country which produces beryllium and is at a level of economic development comparable to that of Kazakhstan, the Department selected Peru as the primary surrogate country based on its comparable level of economic development for purposes of this investigation. Peru and Kazakhstan

continues to rely primarily on exchange-rate-based per capita income for surrogate country selection in this investigation.

share approximately the same per-capita annual income.

Accordingly, where possible, we have calculated NV using Peruvian prices based on POI data to value Ulba's factors of production. The sources of individual surrogate factor prices are discussed under the "Normal Value" section, below.

C. Factors of Production

In accordance with section 773(c) of the Act, we calculated NV based on factors of production reported by Ulba (the sole Kazakhstan producer of beryllium). To calculate NV, the reported unit factor quantities were multiplied by publicly available Peru values, where possible. Because respondents ceased production of subject merchandise at the end of 1989, reported unit factor quantities are based on 1989 records. According to the staff of the U.S. Geological Survey, no known changes to the technology of producing the subject merchandise have taken place in Kazakhstan (see August 21, 1996, *Memorandum to File*). Therefore, in this investigation, the use of reported factor quantities based on 1989 records is appropriate.

Where Peru values were not available for certain of the factors, we used values from other countries. The selection of the surrogate values applied in this determination was based on the quality and contemporaneity of the data. As appropriate, we adjusted input prices to make them delivered prices. For those values not contemporaneous with the POI, we adjusted for inflation using wholesale price indices or, in the case of labor rates, consumer price indices, published in the International Monetary Fund's *International Financial Statistics*. (For further discussion, see *Calculation Memorandum*.)

Petitioner has suggested that the Department should base surrogate country selection and factor valuation on data from the year of production of the beryllium that was actually sold during the POI. We do not agree with petitioner's position. It has been the Department's practice to value factors of production in the time period contemporaneous to the date of sale of the subject merchandise (i.e., the POI) to reflect the value of that merchandise during the POI. (See, for example, *Final Determination: Antidumping Duty Investigation of Pure and Alloy Magnesium from the Russian Federation*, 61 FR 16440 (March 30, 1995); and *Final Determination: Antidumping Duty Investigation of Pure Magnesium from Ukraine*, 61 FR 16432 (March 30, 1995).) The fact that the subject merchandise sold during the POI was not produced in the POI does not

affect the choice of time period for valuing the factors. Therefore, all factor values from the surrogate country are based on POI data.

To value beryllium concentrate, the primary material input, we used the 1995 world market price provided by the U.S. Geological Survey. For all other reported direct material inputs and packing materials (the specific identities of which are business proprietary), we used 1994 *UN Trade Statistics* data—the latest available information—for Peru, except for one material input, where we used data from Colombia. Three of the reported material inputs were determined not to be direct material inputs in the production of subject merchandise and, therefore, have been treated as part of the factory overhead cost. (For further discussion, see *Calculation Memorandum*.)

To value direct skilled, direct unskilled, and packing labor, we used the 1994 wage rate—the latest available information—for the manufacturing sector in Peru published in the International Labor Organization's 1995 *Yearbook of Labour Statistics*. Because we cannot determine if the labor values from this source were for skilled or unskilled workers, we, in accordance with the Department's practice in past NME cases, applied a single earnings rate to all reported labor factors (see *Preliminary Determination of Sales at Less Than Fair Value: Polyvinyl Alcohol from the PRC*, (60 FR 52647, October 10, 1995) and *Preliminary Determination of Sales at Less Than Fair Value: Steel Pipe from Romania*, 60 FR 61532 (November 30, 1995)). Further, because this earnings rate is exclusive of benefits, we increased the amount reported to include employer-paid benefits based on information reflected in publicly available information in Price Waterhouse's 1994 publication, *Doing Business in Peru*.

To value electricity, we used 1995 electricity rates for industrial users in Peru, published quarterly by the Latin American Energy Organization ("OLADE"). We based the value of coal on 1994 *UN Trade Statistics* data—the latest available information—for Peru.

We were unable to find Peru data for either factory overhead or selling, general and administrative ("SG&A") expenses. Further, we considered these components of normal value to be most appropriately based on a market economy company that actually produces Beryllium. Accordingly, we based our calculation of factory overhead and SG&A expenses on petitioner's experience as reported in the petition.

With respect to profit, we were also unable to find surrogate data from Peru.

Therefore, we calculated surrogate profit using actual 1994—the latest available information—profit reported in the income statement of a metal producer in Brazil (see *Calculation Memorandum*).²

Absent any data for rail freight in Peru, we are using rail and truck freight data from Brazil (see *Calculation Memorandum*).

Kazakhstan-Wide Rate

The U.S. Embassy identified what we believe to be a complete list of producers and exporters of beryllium from Kazakhstan. We compared the respondents' sales data with U.S. import statistics for time periods including the POI and found no indication of unreported sales. Accordingly, the Kazakhstan-wide rate is based on the weighted-average margin calculated in this proceeding.

Verification

As provided in section 782(i) of the Act, we will verify all information used in making our final determination.

Suspension of Liquidation

In accordance with section 733(d) of the Act, we are directing the Customs Service to suspend liquidation of all entries of beryllium originating from Kazakhstan, that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the Federal Register. The Customs Service will require a cash deposit or posting of a bond equal to the estimated dumping margins by which the normal value exceeds the export price, as shown below. These suspension of liquidation instructions will remain in effect until further notice.

The weighted-average dumping margin is as follows:

Manufacturer/Producer/Exporter	Weighted-average margin (percent)
Ulba Metallurgical Plant/KATEP	70.80
Kazakhstan-Wide Rate ³	70.80

²The Kazakhstan-wide rate applies to all entries of subject merchandise originating from Kazakhstan except for entries from the exporter that is identified individually above.

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final

²We note that metal is the most similar product to beryllium for which we have publicly available information on profit.

determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than November 20, 1996, and rebuttal briefs, no later than November 27, 1996. A list of authorities used and a summary of arguments made in the briefs should accompany these briefs. Such summary should be limited to five pages total, including footnotes. We will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. At this time, the hearing is scheduled for Thursday, December 4, 1996, the time and place to be determined, at the U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room B-099, within ten days of the publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs. If this investigation proceeds normally, we will make our final determination no later than 135 days after the publication of this notice in the Federal Register.

This determination is published pursuant to section 733(f) of the Act.

Dated: August 21, 1996.

Robert S. LaRussa,
Assistant Secretary for Import
Administration.

[FR Doc. 96-21969 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-DS-P

[C-559-001]

Certain Refrigeration Compressors from the Republic of Singapore: Final Results of Countervailing Duty Administrative Review

AGENCY: International Trade Administration/Import Administration/Department of Commerce.

ACTION: Notice of final results of countervailing duty administrative review.

SUMMARY: On June 10, 1996, the Department of Commerce published the preliminary results of its administrative review of the agreement suspending the countervailing duty investigation on certain refrigeration compressors from the Republic of Singapore.

In our preliminary results of review, we preliminarily determined that the signatories to the suspension agreement complied with the terms of the suspension agreement during the period of review. We gave interested parties an opportunity to comment on our preliminary results, but we received no comments. We have not changed the margin from that presented in our preliminary results of review.

We have now completed this review, the eleventh review of this Agreement, and determine that the Government of the Republic of Singapore (GOS), Matsushita Refrigeration Industries (Singapore) Pte. Ltd. (MARIS) and Asia Matsushita Electric (Singapore) Pte. Ltd. (AMS), the signatories to the suspension agreement, have complied with the terms of the suspension agreement during the period April 1, 1993 through March 31, 1994.

EFFECTIVE DATE: August 28, 1996.

FOR FURTHER INFORMATION CONTACT: Rick Johnson or Jean Kemp, Office of AD/CVD Enforcement, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230; telephone: (202) 482-3793.

Applicable Statutes and Regulations

Unless otherwise stated, all citations to the statute and to the Department's regulations are references to the provisions as they existed on December 31, 1994.

SUPPLEMENTARY INFORMATION:

Background

On June 10, 1996, the Department of Commerce (the Department) published in the Federal Register (61 FR 29348-50) the preliminary results of its administrative review of the agreement suspending the countervailing duty investigation on certain refrigeration compressors from the Republic of Singapore (48 FR 51167; November 7, 1983). We received no comments from interested parties on our preliminary results. We have now completed this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Tariff Act).

Scope of the Review

Imports covered by this review are shipments of hermetic refrigeration

compressors rated not over one-quarter horsepower from Singapore. This merchandise is currently classified under *Harmonized Tariff Schedule* (HTS) item number 8414.30.40. The HTS item number is provided for convenience and Customs purposes. The written description remains dispositive.

The review period is April 1, 1993 through March 31, 1994, and includes three programs. (For the preliminary results of review notice, we received information on three additional programs: the Operational Headquarters Program, the Technical Assistance Fees/Royalty Payments Program, and the Investment Allowance Program. However, the Department found these programs to be non-countervailable in the tenth administrative review of this Agreement. See *Certain Refrigeration Compressors from Singapore; Final Results of Countervailing Duty Administrative Review*, 60 FR 10315, 10317-8 (March 13, 1996). Therefore, we did not consider these programs for the purposes of the final results of this review). The review covers one producer and one exporter of the subject merchandise, MARIS and AMS, respectively. These two companies, along with the GOS, are the signatories to the suspension agreement.

Under the terms of the suspension agreement, the GOS agrees to offset completely the amount of the net bounty or grant determined by the Department in this proceeding to exist with respect to the subject merchandise. The offset entails the collection by the GOS of an export charge applicable to the subject merchandise exported on or after the effective date of the agreement. See *Certain Refrigeration Compressors from the Republic of Singapore: Suspension of Countervailing Duty Investigation*, 48 FR 51167, 51170 (November 7, 1983).

Final Results of Review

We determine that the signatories to the suspension agreement have complied with the terms of the suspension agreement, including the payment of the provisional export charge for the review period. From April 1, 1993, through March 31, 1994, a rate of 5.52 percent was in effect.

We determine the total bounty or grant to be 2.22 percent of the f.o.b. value of the merchandise for the April 1, 1993 through March 31, 1994 review period. Following the methodology outlined in section B.4 of the agreement, the Department determines that, for the period of review, a negative adjustment may be made to the provisional export charge rate in effect. The adjustment will equal the difference between the

provisional rate in effect during the review period and the rate determined in this review, plus interest. This rate, established in the notice of the final results of the eighth administrative review of the suspension agreement (*See Certain Refrigeration Compressors from the Republic of Singapore; Final Results of Countervailing Duty Administrative Review*, 57 FR 46540 (October 9, 1992)) is 5.52 percent. For this period the GOS may refund or credit, in accordance with section B.4.c of the agreement, the difference to the companies, plus interest, calculated in accordance with section 778(b) of the Tariff Act.

The Department intends to notify the GOS that the provisional export charge rate on all exports of the subject merchandise to the United States with Outward Declarations filed on or after the date of publication of the final results of this administrative review shall be 2.22 percent of the f.o.b. value of the merchandise.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 355.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and section 355.22 of the Department's regulations (19 CFR 355.22(1994)).

Dated: August 22, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96-21967 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-DS-P

[C- 301-003, C-301-601]

Roses and Other Fresh Cut Flowers and Miniature Carnations From Colombia

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Amended final results of reviews pursuant to court remand: Asociación Colombiana de Exportadores de Flores and its members ("ASOCOLFLORES") and the Government of Colombia ("GOC") v. The United States: USA-96-04-01072.

SUMMARY: On March 8, 1996, the Department of Commerce ("the

Department") published the final results of its administrative reviews of the countervailing duty suspension agreements on certain roses and other fresh cut flowers and miniature carnations from Colombia. The reviews covered over 800 Colombian producers/exporters of roses, over 100 Colombian producers/exporters of miniature carnations and the GOC for the period covering January 1, 1993 through December 31, 1993. In order to remove inadvertently-included language, we are amending the final results.

EFFECTIVE DATE: August 28, 1996.

FOR FURTHER INFORMATION CONTACT: N. Gerard Zapiain at (202) 482-1090 or Jean Kemp at (202) 482-4037 at Antidumping/Countervailing Enforcement, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230.

Background

On June 14, 1996, the Court of International Trade ("CIT") issued an order remanding to the Department the final results of the Department's reviews of the countervailing duty ("CVD") suspension agreements on miniature carnations and roses and other cut flowers (See 61 Fed. Reg. 9429 (March 8, 1996)). The reviews covered the period January 1, 1993 through December 31, 1993. In its order, the Court granted the defendant's consent motion and ordered: (1) that the Department correct inadvertently-included language in the final results of the administrative reviews; (2) that the remand results be filed with the Court on or before 30 days from the date of the order; and (3) that the administrative record be filed with the Court, if necessary, on or before 70 days from the date of the order. In the final results of the reviews covering the 1993 period, the Department stated that the GOC and Colombian producers/exporters of the subject merchandise were to complete "repayment and/or refinancing for any outstanding peso- and dollar-denominated loans to meet the new short- and long-term benchmarks [within] 90 days" of the publication of the final results in the Federal Register (61 Fed. Reg. at 9434). The Department found in its 1993 final results that all peso-denominated loans given under the programs covered by the suspension agreements had been issued in compliance with the suspension agreements, in accordance with pre-existing benchmarks set by the Department. There is no requirement in the suspension agreements for respondents to refinance loans that the Department has found, in previous review periods, to be in compliance

with the benchmarks in effect at the time of issuance of the loans. Therefore, the Department requested a remand to correct the 1993 final results of the reviews for the limited purpose of removing the requirement to refinance loans that were issued at rates in compliance with Department-set benchmarks.

On July 15, 1996, the Department reconsidered the final results of the reviews in light of the Court's order and determined that it contained improper language. The Department concluded that it cannot compel respondents to comply with conditions not required in the suspension agreements. On July 26, 1996, the CIT affirmed the Department's redetermination. We rescind the requirement that producers/exporters of subject merchandise refinance peso-denominated loans granted in accordance with pre-existing benchmarks.

These amended final results of the reviews are published in accordance with section 751 of the Tariff Act of 1930 as amended and 19 CFR 353.28(c).

Dated: August 22, 1996.

Robert S. LaRussa,

Acting Assistant Secretary for Import Administration.

[FR Doc. 96-21968 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-DS-P

Export Trade Certificate of Review

ACTION: Notice of application.

SUMMARY: The Office of Export Trading Company Affairs ("OETCA"), International Trade Administration, Department of Commerce, has received an application for an Export Trade Certificate of Review. This notice summarizes the conduct for which certification is sought and requests comments relevant to whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: W. Dawn Busby, Director, Office of Export Trading Company Affairs, International Trade Administration, (202) 482-5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001-21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. A Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private, treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Act

and 15 CFR 325.6(a) require the Secretary to publish a notice in the Federal Register identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. An original and five (5) copies should be submitted no later than 20 days after the date of this notice to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, Room 1800H, Washington, D.C. 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). Comments should refer to this application as "Export Trade Certificate of Review, application number 96-00005." A summary of the application follows.

Summary of the Application

Applicant: Spirit Index Ltd., 342 White Horse Pike, Clementon, New Jersey 08021-4345.

Contact: Thomas P. Kaczur, Vice President.

Telephone: (800) 581-1002.

Application No.: 96-00005.

Date Deemed Submitted: August 21, 1996.

Members (in addition to applicant): None.

Spirit Index Ltd. seeks a Certificate to cover the following specific Export Trade, Export Markets, and Export Trade Activities and Methods of Operations.

Export Trade

1. Products. All products.
2. Services. All services.
3. Technology rights. Technology rights, including, but not limited to, patents, trademarks, copyrights and trade secrets that relate to Products and Services.

4. Export Trade Facilitation Services (as they relate to the export of products, services and technology rights). Export Trade Facilitation Services include professional services in the areas of government relations and assistance with state and federal programs; foreign trade and business protocol; consulting; market research and analysis; collection of information on trade opportunities; marketing; negotiations; joint ventures; shipping, export management; export licensing; advertising; documentation and services related to compliance with customs requirements; insurance and financing; bonding; warehousing; export trade promotion; trade show exhibitions; organizational

development; management and labor strategies; transfer of technology; transportation; and facilitating the formation of shippers' associations.

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands).

Export Trade Activities and Methods of Operation

Spirit Index Ltd. may:

1. Provide and/or arrange for the provision of Export Trade Facilitation Services through corporate planning activities, organizational structure, management and managerial structure, or labor utilization;
2. Engage in promotion and marketing activities and collect information on trade opportunities in the Export Market and distribute such information;
3. Enter into exclusive and/or non-exclusive agreements with distributors, foreign buyers, and/or sales representatives in Export Markets;
4. Enter into exclusive or non-exclusive licensing, and/or sales agreements with Suppliers, Export Intermediaries, or persons for the transfer of title to property; Products, Services, know-how and/or Technology Rights;
5. Enter into exclusive or non-exclusive pricing and/or consignment agreements for the sale and shipment of goods and services;
6. Allocate the sales, export orders and/or divide Export Markets, among Suppliers, Export Intermediaries, or persons for the sale, licensing and/or transfer of title to property, Products, Services, know-how and/or Technology Rights;
7. Enter into exclusive or non-exclusive agreements for the pooling of tangible property, resources, tying of goods and services, price setting, distributionship, transportation services, shipping, handling and/or services in the Export Markets;
8. Enter into agreements to invest in overseas warehousing, production and/or manufacturing facilities for minor product or packaging modification activities; and
9. Enter into agreements to consolidate purchasing, warehousing operations, production and/or manufacturing facilities.

Definitions

1. "Export Intermediary" means a person who acts as a distributor, sales representative, sales or marketing agent, or broker, or who performs similar functions, including providing or arranging for the provision of Export Trade Facilitation Services.
2. "Supplier" means a person who produces, provides, or sells a Product and/or Service.

Dated: August 23, 1996.

W. Dawn Busby,

Director, Office of Export Trading Company Affairs.

[FR Doc. 96-21925 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-DR-I

National Institute of Standards and Technology

Public Meeting on U.S. Technical Participation in 10th Quadrennial Conference of the International Organization of Legal Metrology (OIML)

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Announcement of pre-conference meeting prior to OIML 10th Quadrennial International Conference.

SUMMARY: The National Institute of Standards and Technology (NIST) will hold a public meeting to discuss U.S. technical participation in the 10th Quadrennial Conference of the International Organization of Legal Metrology (OIML). The principal focus will be on 29 OIML Recommendations on legal measuring instruments that will be presented for ratification by the Conference. These Recommendations and OIML-member nations' technical comments on them will be reviewed with interested parties who will be given an opportunity to present their views on the Recommendations and other relevant issues of the Conference.

The public meeting is open to all interested parties. Participants with an expressed interest in particular topics may obtain copies of the Conference technical agenda, including copies of the Recommendations to be ratified. A written summary of oral presentations by interested parties should be arranged and scheduled beforehand. Written comments are welcome at any time.

DATES: Pre-conference meeting at NIST: 20 September 1996 from 10a.m. to 12 noon; Tenth OIML International Conference in Vancouver, British Columbia: 4-8 November 1996.

LOCATION: Pre-conference meeting: National Institute of Standards and Technology (NIST North), Conference Room 145, 820 West Diamond Avenue, Gaithersburg, Maryland; International Conference: Pan Pacific Hotel, Vancouver, British Columbia, Canada.

FOR FURTHER INFORMATION CONTACT: Samuel E. Chappell, Chief, Standards Management, Office of Standards Services, National Institute of Standards and Technology, Gaithersburg, Maryland 20899; telephone: 301/975-4023, fax: 301/9266-559, e-mail: Samuel.Chappell@nist.gov.

SUPPLEMENTARY INFORMATION: The International Organization of Legal Metrology (OIML) is an intergovernmental (treaty) organization in which the United States and 53 other nations participate. Its principal purpose is to harmonize national laws and regulations pertaining to testing and verifying the performance of legal measuring instruments used for equity in commerce, for public and worker health and safety, and for monitoring and protection of the environment. The harmonized results are to promote international trade of measuring instruments and products affected by measurement.

Twenty-nine Recommendations will be presented for ratification by the Conference in these categories: (1) Those already approved by the International Committee of Legal Metrology (CIML) between 1993 and 1995, and (2) those that are expected to be submitted directly to the Conference for approval. These Recommendations and the OIML-member nations holding the responsible secretariat for their development are as follows:

Category 1:

- R14 Polarizmetric saccharimeters (France)
- R31 Diaphragm gas meters (Netherlands)
- R50 Continuous totalizing automatic weighing instruments (UK)
- R 51 Automatic catchweighing instruments (UK)
- R 61 Automatic gravimetric filling instruments (UK)
- R 63 Petroleum measurement tables (USA)
- R 102 Annex: Test procedures for sound calibrators Germany)
- R 106 Annex: Test procedures for automatic rail-weighbridges (UK)
- R 107 Annex: Test procedures for discontinuous totalizing automatic weighing instruments (UK)
- R 110 Pressure balances (Bulgaria and Czech Republic)
- R 111 Weights of classes E₁, E₂, F₁, F₂, M₁, M₂, M₃, (USA)
- R 112 High performance liquid chromatographs for measurement of pesticides and other toxic substances (USA)
- R 113 Portable gas chromatographs for field measurements of hazardous chemical pollutants (USA)
- R 114 Clinical electrical thermometers for continuous measurement (Germany)
- R 115 Clinical electrical thermometers with maximum device (Germany)
- R 116 Inductively coupled plasma atomic emission spectrometers for measurement of metal pollutants in water (USA)

- R 117 Measuring assemblies for liquids other than water (Germany)
- R 118 Testing procedures and test report format for pattern evaluation of fuel dispensers for motor vehicles (Germany)
- R 119 Pipe provers for testing measuring systems for liquids other than water (Japan)
- R 120 Standard capacity measures for testing measuring systems for liquids other than water (Germany/France)
- R 121 The scale of relative humidity of air certified against saturated salt solutions (People's Republic of China)
- R 122 Equipment for speech audiometers (Germany)
- R 123 Portable and transportable X-ray fluorescence spectrometers for field measurement of hazardous elemental pollutants (USA)

Category 2:

- Revision of R 49: Water meters (UK)
- Revision of R 54: pH-scale for aqueous solutions (Russia)
- Revision of R 58: Sound level meters including development of Annex: Test report format for the evaluation of sound level meters (Germany)
- Revision of R 79: Information on labels of prepackaged products (USA)
- Revision of R 88: Integrating-averaging sound level meters including development of Annex: Test report format for the evaluation of integrating-averaging sound level meters (Germany)
- Refractometers for measuring the sugar content of grape must (France)

Dated: August 21, 1996.

Samuel Kramer,
Associate Director.

[FR Doc. 96-21863 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-13-M

[Docket No. 960308063-6214-02]

RIN 0693-XX15]

Withdrawal of Voluntary Product Standard PS 73-89 Glass Bottles for Carbonated Soft Drinks

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Announcement of withdrawal of Voluntary Product Standard PS 73-89 Glass Bottles for Carbonated Soft Drinks.

SUMMARY: The National Institute of Standards and Technology (NIST) announces the withdrawal of Voluntary Product Standard PS 73-89 Glass Bottles for Carbonated Soft Drinks. This action is taken in accordance with 10.13 of the Department of Commerce (Department) Procedures for the

Development of Voluntary Product Standards (15 CFR Part 10) and terminates the authority to refer to the standard as a Voluntary Product Standard developed under the Department procedures.

EFFECTIVE DATE: October 28, 1996.

FOR FURTHER INFORMATION CONTACT:

Barbara M. Meigs, Standards Management Program, Office of Standards Services, National Institute of Standards and Technology, Building 820, Room 164, Gaithersburg, Maryland 20899, Tel.: 301-975-4025, Fax: 301-926-1559.

SUPPLEMENTARY INFORMATION: NIST announced in the Federal Register (61 FR 14555) on April 2, 1996, that it intended to withdraw Voluntary Product Standard PS 73-89 due to lack of a proponent organization or government agency to cover costs for administrative and technical support services provided by the Department, a requirement for Department sponsorship under section 10(b)(6) of the Procedures for the Development of Voluntary Product Standards (15 CFR Part 10). NIST received no oral or written objections to the withdrawal of PS 73-89 in response to the announcement and therefore determined that the standard be withdrawn.

Authority: 15 U.S.C. 272.

Dated: August 21, 1996.

Samuel Kramer,
Associate Director.

[FR Doc. 96-21864 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-13-M

National Oceanic and Atmospheric Administration

Evaluation of State Coastal Management Programs and National Estuarine Research Reserves

AGENCY: Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), DOC.

ACTION: Notice of availability of evaluation final findings.

SUMMARY: Notice is hereby given of the availability of the final evaluation findings for the Guam and Wisconsin Coastal Management Programs, Hudson River (New York), Weeks Bay (Alabama), Tijuana River (California), North Inlet/Winyah Bay (South Carolina), Narragansett Bay (Rhode Island) and North Carolina National Estuarine Research Reserves (NERRs). Sections 312 and 315 of the Coastal Zone Management Act of 1972 (CZMA),

as amended, require a continuing review of the performance of coastal states with respect to approved coastal management programs and the operation and management of NERRs.

The State of Wisconsin and the Territory of Guam were found to be adhering to and implementing and enforcing their Federally approved coastal management programs, addressing the national coastal management objectives identified in CZMA Section 303(a)(A)–(K), and adhering to the programmatic terms of their financial assistance awards.

Hudson River, Tijuana River, North Inlet/Winyah Bay, Narragansett Bay and North Carolina NERRs were found to be adhering to programmatic requirements of the NERR system. Weeks Bay was found to be not fully adhering to the NERR System goals, the Federally approved NERR management plan, and to the terms of its financial assistance awards.

Copies of these final evaluation findings may be obtained upon written request from: Vickie Allin, Chief, Policy Coordination Division, Office of Ocean and Coastal Resource Management, NOS/NOAA, 1305 East-West Highway, 11th Floor, Silver Spring, Maryland 20910 (301) 713–3087x126.

(Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration)

Dated: August 21, 1996.

W. Stanley Wilson,

Assistant Administrator for Ocean Services and Coastal Zone Management.

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[Docket No. 95106161159–6230–04; I.D. 0820961]

RIN 0648–ZA16

The Fishing Capacity Reduction Initiative (FCRI); Final Program Notice and Announcement of Availability of Federal Assistance

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final program notice.

SUMMARY: NMFS issues this notice to respond to comments on the proposed FCRI, describe the final program requirements, and announce the availability of Federal assistance. The Department of Commerce (Commerce) has made \$25 million available for a grant program for fishermen who hold Northeast multispecies limited access groundfish fishery permits, and who scrap or make their vessels permanently

ineligible to participate in any fishery and surrender all associated Federal fish harvesting permits. The FCRI's objectives are to provide grants to eligible fishermen adversely impacted by the groundfish fishery disaster, and to aid the long-term viability of the groundfish fishery resource through the reduction of active harvesting capacity at the lowest cost.

DATES: Applications must be postmarked by October 28, 1996.

ADDRESSES: Application forms may be obtained from, and completed applications sent to, the Northeast Financial Services Branch, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930–2298.

FOR FURTHER INFORMATION CONTACT: Leo Erwin, NMFS, (508) 281–9203.

SUPPLEMENTARY INFORMATION:

I. Background

As a result of the August 2, 1995, declaration of a fishery resource disaster by the Secretary of Commerce (Secretary), \$25 million in emergency disaster assistance has been made available to NOAA for the FCRI. The authority for this program is contained in section 308(d) of the Interjurisdictional Fisheries Act (IFA) of 1986 (16 U.S.C. 4107(d)), as amended.

The IFA requires that before providing financial assistance under a fishing capacity reduction program, the Secretary determine that adequate conservation and management measures are in place in that fishery. On May 15, 1996, the Secretary approved Amendment 7 to the Northeast Multispecies Groundfish Management Plan, which implements several major measures designed to rebuild overfished groundfish resources. The Secretary hereby determines, therefore, that the measures contained in Amendment 7 are adequate conservation and management measures for purposes of implementing a fishing capacity reduction program.

On June 4, 1996, NMFS published a Federal Register notice (61 FR 28177) announcing the proposed FCRI and requesting comments on a number of issues including eligibility, scoring methods, vessel reuse, scrapping, and program mission. The background for this program is provided in the June 4, 1996, notice and is not repeated here.

II. Comments and Responses

Fifteen comments were received from the following entities: U.S. Coast Guard Station, Portland, ME; Atlantic Trawlers Fishing, Inc.; Associated Fisheries of Maine, The Groundfish Group; Athearn Marine Agency, Inc.; Endangered Seas

Campaign, World Wildlife Fund International; Atlantic Salmon of Maine; Chairman, Board of Supervisors, Cochise County, AZ; Environmental Defense Fund; Conservation Law Foundation; New England Fishery Management Council; and five individuals. Similar comments have been combined.

Comment 1: Two commenters suggested NMFS should not proceed with the \$25 million program until the agency had established appropriate means to evaluate whether the Fishing Capacity Reduction Demonstration Program (FCRDP) achieved its objective and was able to ensure that a larger program would not cause substantial damage to other fisheries.

Response 1: The objectives of the FCRDP were to demonstrate that such a program could be successfully designed and implemented, and that the fishing industry was interested in participating in the program. Under the \$2 million FCRDP, NMFS successfully removed 11 vessels and 26 permits from the fishery, and received bids from fishermen worth over \$52 million. Clearly the objectives of the program were met. With respect to harming other fisheries, NMFS relies on sound conservation and management plans to protect fishery resources. Many New England fisheries are under limited entry schemes, which means that anyone wishing to enter one of those fisheries must purchase an existing permitted vessel. A fisherman participating in the FCRI may only enter the groundfish fishery if he purchases a vessel that is already permitted for that fishery. However, the FCRI does not restrict a participant's privilege to fish. Participants are free to purchase a permitted groundfish vessel, or fish with a different vessel in an open access fishery. Finally, under the FCRDP, NMFS removed 15 limited access permits from other fisheries and anticipates that the larger program will provide substantial spillover benefits to the non-groundfish fisheries because vessel owners are required to surrender all Federal fishing permits.

Comment 2: Several commenters believed that the program's design to remove active fishing capacity has no long-term utility and should be changed to remove potential fishing capacity.

Response 2: NMFS believes that focusing the program on reducing active fishing capacity is an appropriate design to aid in the long-term viability of the groundfish fishery resource. The program gauges active fishing capacity in terms of a vessel's performance, as measured by its groundfish revenues. In this manner, the program should target those vessels associated with higher

landings. Potential or latent fishing capacity is difficult to measure, particularly since the skill of individual vessel captains plays a key role. However, NMFS recognizes that latent fishing capacity is a concern and may address it in future programs.

Comment 3: Several comments reflected the view that using revenues as a measure of capacity does not necessarily mean that the boats with the most capacity will be removed.

Response 3: NMFS believes using revenues as a measure of capacity is simple and provides a cost-effective standard. Measuring fishing capacity can involve many complicated variables and NMFS remains convinced that the program objective of removing active fishing capacity at the least cost is best achieved by using revenues as a measure of capacity.

Comment 4: A number of comments discussed the various scoring proposals. Comments were fairly evenly divided in support of Scoring Alternatives I and III. No comments supported Alternative II.

Response 4: NMFS outlined three alternative scoring proposals in the proposed program notice and, based on the comments received, sees no compelling reason to change the scoring method used in the demonstration program. NMFS believes Alternative I, which was used in the demonstration program, is the most effective way to remove active groundfish capacity at the least cost.

Comment 5: One commenter wanted NMFS to prohibit eligibility of corporations owned by Fishery Management Council members.

Response 5: NMFS agrees and has incorporated this prohibition into the final program.

Comment 6: A fisherman commented that he would like to see a clear statement that recipients of FCRI financial assistance are not giving up their rights to fish.

Response 6: NMFS agrees that the FCRI is not intended to eliminate a participant's privilege to fish, and has incorporated this comment into the final program.

Comment 7: NMFS received the most comments on the issues associated with vessel reuse, mandatory scrapping, and the transfer of fishing vessels abroad. Some commenters supported a continuation of the mandatory scrapping requirement; some wanted foreign transfers prohibited because of vessel tracking and enforcement concerns, while others wanted NMFS to allow vessels to be reused for any activity.

Response 7: At the time of implementation of the pilot program, mandatory scrapping or sinking were

the only ways for NMFS to ensure that fishing vessels did not reenter another fishery. Subsequently, Congress amended the IFA to provide NMFS with statutory authority to ensure that vessels do not reenter any fishery after receiving a FCRI grant. The IFA now allows for vessel reuse and specifically identifies vessel transfers to nonprofit organizations for purposes of research, education, and training. The IFA also authorizes the Secretary to allow other appropriate non-fishing uses. As described in the proposed program notice, NMFS proposed allowing vessels to also be reused for humanitarian, safety, or law enforcement purposes, and requested comments on allowing foreign transfers to public and private entities. Based on the comments, NMFS will allow vessel transfers to a U.S. public entity, a U.S. nonprofit organization, and foreign national governments for research (including fisheries research), education, training, humanitarian, safety, or law enforcement purposes. Transfers to foreign private entities will not be allowed due to tracking and enforcement problems.

Comment 8: One fishing group strongly opposed releasing any information on applicants until after the selection process is over.

Response 8: NMFS intends to provide legal notice of the names of vessels and their owners for which a successful investigation has been completed. During program implementation, all scores and bids will be treated as proprietary information and will only be disclosed to Federal officials who are responsible for the FCRI or otherwise when required by court order or other applicable law, such as the Freedom of Information Act (FOIA). The amount of the bids of successful applicants will be released after completion of the program, and not prior to selection. The FOIA prohibits NMFS from releasing commercial or financial information that is privileged or confidential.

Comment 9: One commenter argued that in view of the Nation's financial status and cuts in various programs such as Medicare, Social Security, and education programs, the Federal government should not be spending \$25 million on a vessel and permit buy out.

Response 9: The FCRI is an integral part of the Administration's response to the groundfish disaster in New England. The FCRI is specifically aimed at providing economic assistance to people, in this case fishermen and their families, who have been harmed as a result of the fishery disaster. The funds being used for the FCRI are statutorily restricted to provide financial assistance

to fishermen adversely impacted by fishing resource disasters and cannot be used for other purposes.

Comment 10: One commenter worried that the FCRI would dislocate highly skilled fishermen with no provisions for retraining.

Response 10: As stated earlier in this notice, the FCRI is intended to provide fishermen with an alternative to remaining in the fishery. The program is not intended to force people into unemployment. The FCRI is a voluntary program. Fishermen choose to submit bids and relinquish their permits and vessels. Presumably, the fishermen who participate in the program have thought through the pros and cons of offering their vessels and permits.

Comment 11: One commenter was concerned that no environmental impact statement on the FCRI had been prepared.

Response 11: NMFS has prepared an Environmental Assessment (EA) of the FCRI. An EA is required for compliance with the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4371 *et seq.*, which is a condition for the grant. The purpose of an EA is to determine whether significant impacts on the quality of the human environment could result from the proposed action. The environmental analysis in this EA provides the basis for this determination and must evaluate the intensity or severity of the impact of an action and the significance of an action with respect to society as a whole, the affected region and interests, and the locality. If the action is determined not to be significant, the EA and resulting finding of no significant impact would be the final environmental documents required by NEPA. An Environmental Impact Statement (EIS) must be prepared only if the proposed action may cause a significant impact to the quality of the human environment. With respect to the FCRI, the EA prepared by NMFS found that the proposed action would not have a significant impact on the quality of the human environment. Therefore, no EIS was prepared.

Comment 12: One commenter suggested NMFS should match landings slips with tax records as a way to validate groundfish landings because some boats may have slipped by last time.

Response 12: NMFS will continue to use every means available to validate landings and, as in the pilot program, landings that cannot be verified will not be allowed.

Comment 13: One commenter expressed concern that fishing vessels should be "fishable" at the time of grant award closing.

Response 13: NMFS agrees with this comment and has incorporated a relevant provision into the final program.

Comment 14: One commenter stated that the pilot program allowed fishermen to receive more than the fair market value of their vessel, which then allowed for the fisherman to purchase a better vessel and continue fishing.

Response 14: The FCRI does not use a fair market value test or vessel survey because the fair market value of the vessel would not capture the full value of the fisherman's bid. The bid includes the vessel's worth and the value of the associated permits. Each fisherman's bid is scored in relation to the groundfish revenues associated with the vessel being offered. All bids receive a score and are ranked against all other bids. Successful applicants are not prevented from purchasing another fishing vessel just as they can today. However, the net effect is that, because there is a moratorium on new vessels entering the fishery, there would be one less vessel and permit in the fishery.

III. Definitions

Eligible multispecies limited access permit means those limited access permits defined in the regulations implementing the Northeast Multispecies Fishery Management Plan, as amended by Amendment 7, 50 CFR 651.4(b). To be eligible, a permit must be free of all permit sanctions or Notice of Permit Sanction, at the time of application and at grant award closing. Owners of permits who have been issued a permit sanction or a Notice of Permit Sanction are not eligible for consideration because compensation of fishermen who violate fishery regulations would contravene the program's objective to aid the long-term viability of the fishery resource.

Fisherman means any natural or legal person who (1) owns a fishing vessel with an eligible multispecies limited access permit, (2) has less than \$2,000,000 in net revenues from commercial fishing annually, and (3) is a U.S. citizen or permanent resident alien.

Qualifying period means the calendar years of 1991, 1992, 1993 and 1994.

Regulated groundfish species means those species that are regulated under the Northeast Multispecies Fishery Management Plan and are limited to cod, haddock, pollock, yellowtail flounder, winter flounder, gray sole, American plaice, windowpane flounder, white hake, and redfish.

U.S. citizen means a U.S. citizen for the purpose of documenting vessels in the U.S. coastwise trade. Coastwise trade documentation requires: (1) All

sole proprietors to be U.S. citizens, (2) 75 percent of all partners (and 100 percent of all general partners) in a partnership to be U.S. citizens, and (3) 75 percent of all owners of a corporation (as well as its chief executive officer and the minority of its directors necessary to constitute a quorum) to be U.S. citizens. 46 CFR 67, Subpart C.

IV. FCRI Program Overview

The objectives of the FCRI are to provide grants to eligible fishermen adversely impacted by the groundfish fishery disaster, and to aid the long-term viability of the fishery resource through the reduction of active fishing capacity at the lowest cost. All fishing vessels with an eligible valid multispecies limited access permit may apply. The FCRI allows the applicant to establish a price for offered vessels and permits that will be scored in a competitive manner. Although the FCRI is designed to remove vessels and permits from the groundfish fishery, successful applicants do not forfeit their privilege to fish.

A successful applicant with an undocumented vessel will be required to scrap the vessel. Sinking will also be allowed, so long as it is conducted in compliance with all applicable Federal, state, and local environmental laws and regulations. A successful applicant with a documented vessel will be required to scrap or sink the vessel or transfer it to a U.S. public entity, a U.S. nonprofit organization, or a foreign national government for research (including fisheries research), education, training, humanitarian, safety, or law enforcement purposes. If a vessel is transferred to an eligible entity, NMFS will require that the title include a provision that the vessel be scrapped by that entity once it has served the purpose for which it was transferred. Before any vessel may be transferred, NMFS will require that the vessel's Coast Guard document has a permanent restriction prohibiting that vessel from holding a fishery endorsement. NMFS reserves the right to approve all vessel transfers.

Vessel Transfers

Recognizing that limited Federal funding is available for this program, the fishermen may leverage these monies with non-Federal resources. NMFS will allow vessels to be either donated or sold to a U.S. public entity, a U.S. nonprofit organization, or a foreign national government. The ability to sell their vessels should allow fishermen to submit lower bids, and consequently exit the fishery at a lower cost to the government. Because the fishermen will have been partially

compensated by the government through the purchase of their permits, acquiring entities may be able to purchase the vessels at below market value, allowing these entities to obtain vessels that otherwise would have been beyond their limited budgets. In engaging in these transfers, fishermen have the opportunity to receive the best value for the loss of their vessels and permits. Vessel transfers will benefit all parties and enhance the government's ability to remove the greatest capacity at the least cost.

Regardless of the manner in which a vessel is disposed of or transferred, all Federal fishing permits associated with that vessel must be surrendered at the time of grant award closing.

V. How to Apply

A. Eligible Applications

Applications for FCRI grants will only be considered from eligible fishermen, as defined in this notice, who are owners of eligible vessels, which meet the conditions stated below. Federal Government agencies or employees, including full-time, part-time, and intermittent personnel, and Fishery Management Council members (or corporations owned by them) and employees are not eligible to submit an application.

For a vessel to be eligible for the FCRI, it must meet the following conditions:

1. Have an eligible multispecies limited access fishing permit. Vessel owners will be required to surrender such permits along with ALL other Federal fishing permits issued to that vessel if awarded financial assistance under the FCRI. Although pending or assessed civil penalties for state or Federal fisheries violations do not disqualify a vessel owner from application, all outstanding and/or pending investigations, charges, and penalties must be resolved within a reasonable period of time prior to grant award closing. The Secretary retains discretion to determine the applicant's integrity and responsibility to receive Federal assistance funds and to comply with the terms and conditions of the FCRI award, and may deny funding or impose special award conditions pursuant to any pending or outstanding state or Federal fishery violation.

2. Be active and functioning. Successful applicants will be required to show proof that their vessel made at least two (2) fishing trips (of any duration for any species) during the 60 days prior to the date for the submission of applications for FCRI assistance and that the vessel is capable of fishing for groundfish in Federal waters under its

own power at the time of application and grant award closing.

3. Have derived 65 percent or more of its gross annual revenues from the sale of regulated groundfish species in each of the 3 years during the qualifying period. This means that in 1991, 1992, 1993, and 1994, successful applicants must be able to prove that 65 percent or more of the gross revenues (for the vessel involved) in each of the 3 years chosen during the qualifying period was from the sale of regulated groundfish species.

B. Submission of Applications

Applicants are limited to one bid per vessel under the FCRI. If the amount of a bid is predicated upon a transfer for money to a third party, but that transfer is not approved, applicants may not submit a new bid.

Vessel owners will be given 60 days from the date of filing for public

inspection at the Office of the Federal Register of this final FCRI notice to submit a FCRI application form. Proof of eligibility need not be submitted with the application. Applicants will be required to submit one signed original application. No facsimile applications will be accepted. NMFS will provide applicants with proof of receipt. The anticipated time required to process applications is 120 days from the date of this notice.

All multispecies limited access fishing permit holders will be mailed a copy of the FCRI application form along with a copy of this Federal Register notice. FCRI application forms are also available at the NMFS Regional Office (See ADDRESSES).

VI. Application Review and Scoring

All timely submitted and completed applications will be assigned a score calculated by the following method:

$$\text{SCORE} = \frac{\text{Bid}}{(\text{average annual revenues from sale of regulated groundfish species in highest 3 years})}$$

Determining a bid amount is extremely important, since this will be a key factor in the success of an applicant. If the bid is too high in relation to the vessel's overall performance, the bid may not be competitive. In the pilot program, successful applicants submitted bids that resulted in scores between 0.494 and 0.725. Applicants will need to carefully consider all costs involved with receiving financial assistance under the FCRI; these costs include satisfying vessel liens, vessel scrapping or vessel transfer costs, and tax liabilities. Applicants will also need to consider whether they are willing to accept a bid that was predicated upon a transfer agreement that may not subsequently be approved. Applicants may wish to consider selling vessel gear and equipment separately as a way of reducing the amount of a bid. Vessel owners may retain any removable gear and equipment for private disposition, as long as it was not purchased under another Federal grant. In that situation, the equipment must be disposed of in accordance with the original grant terms.

VII. Ranking of Applications

Applications will be ranked, starting with the lowest score. The Assistant Administrator for Fisheries, NOAA, will determine which applications are eligible for further consideration based on the ranking of the applications. NMFS may initially find eligible more

applications than it can fund but will investigate all such applications in order of their ranking. NMFS reserves the right to reject any or all applications if it is determined by NMFS that such action is in the best interests of the program or if revisions to the program are warranted in the future. NMFS may also solicit additional applications. If additional applications are solicited, all applications submitted previously and not determined to be eligible will be considered rejected. NMFS will notify eligible applicants in writing. However, eligible applicants are not guaranteed funding by simply having a competitive bid; they will be subject to a thorough investigation as described in section VII.

VIII. Investigation of Applications

A representative from the NMFS Financial Services Division will contact eligible applicants with competitive bids regarding the following:

1. Ensuring that applicants meet all eligibility requirements and can document all claims made in their applications.
2. Determining what debts exist against the vessel offered in the application, including any outstanding civil penalties or fines.
3. Determining how applicants will satisfy all vessel liens before scrapping or transferring the vessels. Eligible applicants will have to provide written evidence of vessel lienors' willingness to satisfy vessel liens for specific amounts.

Step A. Identify Bid

The bid is the dollar amount submitted by the applicant in the application.

Step B. Calculate Vessel Performance

Vessel performance will be determined by averaging the annual revenues from the sale of regulated groundfish species harvested by that vessel for the highest 3 years during the qualifying period. Applicants may only use revenues from those years in which 65 percent or more of gross revenues were derived from the sale of regulated groundfish species.

Step C. Determine Vessel Score

A vessel score will be calculated using the following formula:

4. Ensuring availability of documentation required to support eligible applications, including the following:

a. Multispecies limited access fishing permit. The applicant may provide a copy of the permit to NMFS, but the actual permit must be surrendered at the time of grant award closing.

b. Proof of landings of regulated species. NMFS will require proof that 65 percent or more of a vessel's gross revenues came from the sale of regulated groundfish species in 3 years during the qualifying period. Landing slips or sales tickets may be used to verify claimed revenues.

c. Proof of gross revenues for highest 3 years. Vessel owners must be able to prove the annual gross revenues from the sale of fish for the vessel involved for the 3 years used on the application. Documentation to support income may include, but is not limited to, individual or corporate tax returns, or fish sale receipts accompanied by vessel settlement reports. NMFS may require sworn affidavits from the reporting party regarding the accuracy of the information contained in supporting documentation. Sales that cannot be substantiated *will not be included* in the calculation of either gross revenues or revenues from regulated groundfish species.

d. Documentation of active and functioning fishing vessel. NMFS will require documentation that the vessel made at least two fishing trips (of any

duration for any species) within 60 days prior to October 28, 1996. NMFS will also ascertain that the vessel is capable of fishing for groundfish in Federal waters under its own power at the time of grant award closing.

NMFS will provide legal notice of names of vessels and their owners for which an investigation has been successfully completed, and in order to facilitate vessel transfers, may provide copies of the published legal notices to interested eligible entities. Publication of the legal notice does not obligate NOAA to make an award. NOAA may also establish a World Wide Web Internet site prior to termination of the application period in order to facilitate communication between potential participants in vessel transfer agreements.

Proprietary information submitted by applicants will only be disclosed to Federal officials who are responsible for the FCRI or otherwise when required by court order or other applicable law, such as the Freedom of Information Act (FOIA). The FOIA prohibits NMFS from releasing commercial or financial information that is privileged or confidential.

IX. Establishment of Award Terms

Representatives from the NMFS Financial Services Division will establish the programmatic terms of each financial assistance award for eligible applications validated during the investigation process. These terms will be binding on the applicants and will control the applicant's post award rights and obligations. Terms of the award will address such matters as how the outstanding liens on the vessels will be satisfied and how the vessel covered in the application will be scrapped or transferred to an eligible entity for an eligible use. NMFS reserves the right to approve all transfers. If a bid is submitted that relies upon an unapproved transfer, and that transfer is subsequently disapproved, an applicant cannot submit another bid. NOAA also reserves the right to terminate financial assistance as a result of any enforcement actions that NMFS regards as indicating a lack of grantee integrity and responsibility to receive Federal assistance funds and comply with the terms and conditions of the FCRI award.

X. Grant Award Procedures

After NMFS Financial Services Division and the NOAA Grants Management Division have reviewed and approved the terms of eligible and validated applications, then applicants will be notified in writing of the award and a grant award closing date will be set. Applicants may be required to have

an attorney present at the grant award closing. To the extent necessary, attorneys will be required to pay grant funds to vessel lienors in return for lien releases. Should vessel liens exceed the amount of the FCRI award, attorneys must obtain funds from applicants and exchange them for lien releases. If a vessel is going to be scrapped, 75 percent of the award will be available at the grant award closing. The remaining 25 percent will be available only when applicants have made arrangements for vessel scrapping and other prescraping dispositions acceptable to NMFS. If these arrangements have been made by the time of grant award closing, 100 percent of the award may be available at that time. Vessel scrapping must occur promptly. If a vessel is going to be transferred to an eligible entity, the transfer must also occur at the grant award closing and 75 percent of the award will be available at that time. The remaining 25 percent will be available when the applicant shows proof that the transferred vessel has a permanent restriction on its certificate of documentation prohibiting that vessel from participating in the fisheries of the U.S. If these arrangements have been made by the grant award closing, 100 percent of the award may be available at that time. NMFS reserves the right to terminate financial assistance negotiations with an applicant, if in the opinion of NMFS there are material adverse changes in an applicant's ability to meet the terms and conditions of a FCRI award agreement, including any outstanding and/or pending investigation, charge, or penalty relating to a violation of state or Federal fisheries laws. As a precaution against insured vessel losses, NOAA reserves the right to reduce financial assistance awards by the amount recovered by the applicant through insurance claims.

XI. Administrative Requirements

A. Primary Applicant Certification

Applicants whose applications are recommended for funding will be required to submit a completed Standard Form 424B, "Assurances—Non-Construction Programs" and Form CD-511, "Certification Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying," and the following explanations are hereby provided:

1. Nonprocurement debarment and suspension. Prospective participants (as defined at 15 CFR 26.105) are subject to 15 CFR part 26, "Nonprocurement Debarment and Suspension" and the related section of the certification form prescribed above applies.

2. Drug-free workplace. Grantees (as defined at 15 CFR 26.605) are subject to 15 CFR part 26, subpart F, "Governmentwide Requirements for Drug-Free Workplace (Grants)" and the related section of the certification form prescribed above applies.

3. Anti-lobbying. Persons (as defined at 15 CFR 28.105) are subject to the lobbying provisions of 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," and the lobbying section of the certification form prescribed above applies to applications/bids for grants, cooperative agreements, and contracts for more than \$100,000, and loans and loan guarantees for more than \$150,000, or the single family maximum mortgage limit for affected programs, whichever is greater.

4. Anti-lobbying disclosure. Any applicant who has paid or will pay for lobbying using any funds must submit an SF-LLL, "Disclosure of Lobbying Activities," as required under 15 CFR part 28, Appendix B.

5. Lower tier certifications.

Applicants shall require applicants/bidders for subgrants, contracts, subcontracts, or other lower tier covered transactions at any tier under the award to submit, if applicable, a completed Form CD-512, "Certifications Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions and Lobbying," and disclosure form SF-LLL, "Disclosure of Lobbying Activities." Form CD-512 is intended for the use of recipients and should not be transmitted to Commerce. SF-LLL submitted by any tier recipient or subrecipient should be submitted to the Department in accordance with the instructions contained in the award document.

B. Other Requirements

1. Federal policies and procedures. FCRI grant recipients and subrecipients are subject to all Federal laws and Federal and Department policies, regulations, and procedures applicable to Federal financial assistance awards. Federal assistance funds cannot be used to pay a Federal debt.

2. Name check review. Applicants are subject to a name check review process. Name checks are intended to reveal if any key individuals associated with the recipient have been convicted of, or are presently facing, criminal charges such as fraud, theft, perjury, or other matters that significantly reflect on the recipient's management, honesty, or financial integrity.

3. A false statement on the application is grounds for denial or termination of funds and grounds for possible

punishment by a fine or imprisonment (18 U.S.C. 1001).

4. Financial management certification/preaward accounting survey. Applicants, at the discretion of the NOAA Grants Officer, may be required to have their financial management systems certified by an independent public accountant as being in compliance with Federal standards specified in the applicable Office of Management and Budget (OMB) Circulars prior to execution of the award. Any first-time applicant for Federal grant funds may be subject to a pre-award accounting survey by the Department prior to execution of the award.

5. Past performance. Unsatisfactory performance under prior Federal awards may result in an application not being considered for funding.

6. Delinquent Federal debts. No award of Federal funds shall be made to an applicant or to its subrecipients who have an outstanding delinquent Federal debt or fine until either:

- a. The delinquent account is paid in full,
- b. A negotiated repayment schedule is established and at least one payment is received, or
- c. Other arrangements satisfactory to the Department are made.

7. Buy American-made equipment or products. Applicants are hereby notified that they are encouraged, to the extent feasible, to purchase American-made equipment and products with funding under this program.

8. Pre-award activities. If applicants incur any costs prior to an award being made, they do so solely at their own risk of not being reimbursed by the Government. Notwithstanding any verbal or written assurance that may have been received, there is no obligation on the part of the Department to cover pre-award costs.

Catalogue of Federal Domestic Assistance

The FCRI is listed in the "Catalogue of Federal Domestic Assistance" under No. 11.452, unallied Industry Projects.

Classification

This action has been determined to be not significant for purposes of E.O. 12866. Applications under this program are subject to E.O. 12372, "Intergovernmental Review of Federal Programs." This notice contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA). The collection of this information has been approved by OMB under control number 0648-0289. Public reporting burden for preparation of the grant application is estimated to

be 1 hour per response including the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. An additional 15-hour reporting burden is estimated for those applicants who are accepted by NMFS including time for documenting the income claims on their applications, how outstanding liens on their vessels will be satisfied, and how the vessels will be scrapped. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to NMFS (See ADDRESSES).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to, a penalty for failure to comply with a collection of information, subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

The Assistant General Counsel for Legislation and Regulation of the Department certified to the Chief Counsel for Advocacy of the Small Business Administration that this notice would not have a significant economic impact on a substantial number of small entities. As of August 20, 1996, 1,664 fishermen held multispecies limited access permits, representing the entire universe of fishermen potentially eligible to participate in the FCRI. The FCRI is expected to result in the elimination of approximately 80 vessels, along with their associated permits.

There is no doubt that the FCRI will have a significant economic impact, as defined under the Regulatory Flexibility Act (RFA), on those fishermen who participate in this program. The FCRI, however, will not affect a "substantial number" of small entities, defined as more than 20 percent of the business entities which are potentially eligible for participation in the program. Indeed, assuming 80 fishermen are ultimately bought out, these fishermen would represent only 4.8 percent of the small entities potentially affected by the FCRI. Therefore, the impacts of the notice are not significant within the meaning of the RFA. They are not likely to lead to a reduction in the annual gross revenues by more than 5 percent or an increase in total costs of production by more than 5 percent, nor would this action result in any greater compliance costs.

Dated: August 22, 1996.
Charles Karnella,
*Acting Assistant Administrator for Fisheries,
National Marine Fisheries Service.*
[FR Doc. 96-21875 Filed 8-23-96; 1:01 pm]
BILLING CODE 3510-22-P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11:00 a.m., Friday, September 6, 1996.

PLACE: 1155 21st St., N.W., Washington, D.C. 9th Fl. Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202-418-5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 96-22072 Filed 8-26-96; 12:45 pm]

BILLING CODE 6351-01-M

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11:00 a.m., Friday, September 13, 1996.

PLACE: 1155 21st St., N.W., Washington, D.C. 9th Fl. Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202-418-5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 96-22073 Filed 8-26-96; 12:45 pm]

BILLING CODE 6351-01-M

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11:00 a.m., Friday, September 20, 1996.

PLACE: 1155 21st St., N.W., Washington, D.C. 9th Fl. Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202-418-5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 96-22074 Filed 8-26-96; 12:45 pm]

BILLING CODE 6351-01-M

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

TIME AND DATE: 11:00 a.m., Friday, September 27, 1996.

PLACE: 1155 21st St., N.W., Washington, D.C. 9th Fl. Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202-418-5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 96-22075 Filed 8-26-96; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF EDUCATION

Advisory Committee on Student Financial Assistance; Meeting

AGENCY: Advisory Committee on Student Financial Assistance, Education.

ACTION: Notice of upcoming meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting sponsored by the Advisory Committee on Student Financial Assistance. This notice also describes the functions of the Committee. This document is intended to notify the general public.

DATES AND TIMES: Wednesday, September 18, 1996, beginning at 9:30 a.m. and ending at approximately 5:00 p.m. and Thursday, September 19, 1996, beginning at 8:30 a.m. and ending at approximately 2:00 p.m.

ADDRESSES: Washington State University, Lewis Alumni Centre, the Regents Room, Wilson Road and Quad Services Road, in Pullman, Washington 99164.

FOR FURTHER INFORMATION CONTACT: Dr. Brian K. Fitzgerald, Staff Director, Advisory Committee on Student Financial Assistance, 1280 Maryland Avenue, S.W., Suite 601, Washington, D.C. 20202-7582 (202) 708-7439.

SUPPLEMENTARY INFORMATION: The Advisory Committee on Student Financial Assistance is established under Section 491 of the Higher Education Act of 1965 as amended by Public Law 100-50 (20 U.S.C. 1098). The Advisory Committee is established to provide advice and counsel to the Congress and the Secretary of Education on student financial aid matters including providing technical expertise with regard to systems of need analysis and application forms, making recommendations that will result in the maintenance of access to postsecondary education for low- and middle-income students, conducting a study of institutional lending in the Stafford

Student Loan Program and an in-depth study of student loan simplification.

The Advisory Committee fulfills its charge by conducting objective, nonpartisan, and independent analyses of important student aid issues. As a result of passage of the Omnibus Budget Reconciliation Act (OBRA) of 1993, Congress assigned the Advisory Committee the major task of evaluating the Ford Federal Direct Loan Program (FDLP) and the Federal Family Education Loan Program (FFELP). The Committee will report to the Secretary and Congress on not less than an annual basis on the operation of both programs and submit a final report by January 1, 1997.

The Advisory Committee will meet in Pullman, Washington on September 18, 1996, from 9:30 a.m. to approximately 5:00 p.m. and on September 19, from 8:30 a.m. to approximately 2:00 p.m.

The proposed agenda will consist of discussion sessions on the Advisory Committee's activities pertaining to the upcoming reauthorization of the Higher Education Act and all Title IV programs including the delivery system, and other legislative proposals. In addition, the Committee will discuss activities planned for fiscal year 1997. Space is limited and you are encouraged to register early if you plan to attend. To register, please fax your name, title, affiliation, complete address (including Internet and E-Mail—if available), telephone number, and fax number to the Advisory Committee staff office at (202) 401-3467. If you are unable to fax, please mail your registration information or contact the Advisory Committee staff office at (202) 708-7439. Also, you may register through Internet at ADV-COMSFA@ED.gov or Tracy-Deanna-Jones@ED.gov. The registration deadline is Monday, September 9, 1996.

Records are kept of all Committee proceedings, and are available for public inspection at the Office of the Advisory Committee on Student Financial Assistance, 1280 Maryland Avenue, S.W., Suite 601, Washington, D.C. from the hours of 9:00 a.m. to 5:30 p.m., weekdays, except Federal holidays.

Dated: August 22, 1996.

Dr. Brian K. Fitzgerald,

Staff Director, Advisory Committee on Student Financial Assistance.

[FR Doc. 96-21918 Filed 8-27-96; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER96-2251-000]

Atmos Energy Services, Inc.; Notice of Issuance of Order

August 22, 1996.

Atmos Energy Services, Inc. (Atmos Energy) submitted for filing a rate schedule under which Atmos Energy will engage in wholesale electric power and energy transactions as a marketer. Atmos Energy also requested waiver of various Commission regulations. In particular, Atmos Energy requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Atmos Energy.

On August 21, 1996, pursuant to delegated authority, the Director, Division of Applications, Office of Electric Power Regulation, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest, the blanket approval of issuances of securities or assumptions of liability by Atmos Energy should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Atmos Energy is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Atmos Energy's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is September 20, 1996.

Copies of the full text of the order are available from the Commission's Public

Reference Branch, 888 First Street, N.E.
Washington, D.C. 20426.
Linwood A. Watson, Jr.,
Acting Secretary.
[FR Doc. 96-21894 Filed 8-27-96; 8:45 am]
BILLING CODE 6717-01-M

Notice of Declaration of Intention

August 22, 1996.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. Type of Application: Declaration of Intention.

b. Docket No.: DI96-11-000.

c. Date Filed: 7/19/96.

d. Applicant: U.S. Forest Service (Ketchikan, AK).

e. Name of Project: Swan Lake-Lake Tyee Intertie.

f. Location: Between Swan Lake hydroelectric project switchyard (P-3015) and the Lake Tyee hydroelectric project switchyard (P-2911), Ketchikan and Stikine areas, AK.

g. Filed Pursuant to: Section 23(b) of the Federal Power Act, 16 U.S.C. 817(b).

h. Applicant Contact: Bill Angelus, EIS Coordinator, Ketchikan Ranger District, Tongass National Forest, 3031 Tongass Avenue, Ketchikan, AK 99901, (907) 225-2148.

i. FERC Contact: Diane M. Murray, (202) 219-2682.

j. Comment Date: September 27, 1996.

k. Description of Project: The proposed transmission line would consist of: (1) A 138 kV electric transmission line that would intertie the electrical systems of Ketchikan Public Utilities.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) Would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. Purpose of Project: The proposed transmission line would allow the City of Ketchikan to meet its energy needs by accessing surplus energy at the Lake Tyee project.

m. This notice also consists of the following standard paragraphs: B, C1, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters and title

“COMMENTS”, “RECOMMENDATIONS FOR TERMS AND CONDITIONS”, “PROTEST”, or “MOTION TO INTERVENE”, as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 96-21895 Filed 8-27-96; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-00196; FRL-5394-3]

National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of open meeting and chemicals to be addressed.

SUMMARY: The third meeting of the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL) will be held on September 17-19, 1996, in Washington, DC. At this meeting, the committee continue deliberations on various aspects of the acute toxicology and development of Acute Exposure Guideline Levels (AEGLs) for the following chemicals: ammonia, methyl mercaptan, hydrogen fluoride, and cyanogen chloride. In addition, as time permits, the committee intends to address the development of AEGLs for the following chemicals: hydrogen cyanide, 1,2-dichloroethylene, arsine, dimethyldichlorosilane, and nitric acid.

DATES: The second meeting of the NAC/AEGL will be held from 10 a.m. to 5 p.m. on Tuesday, September 17; from 8:45 a.m. to 4:45 p.m. on September 18; and from 9 a.m. to noon on September 19, 1996.

ADDRESSES: The meeting will be held at the Green Room on the third floor of the Ariel Rios Building, 1200 Pennsylvania Avenue NW., Washington DC.

FOR FURTHER INFORMATION CONTACT: Paul Tobin, Office of Prevention, Pesticides and Toxic Substances (7406), 401 M St., SW., Washington, DC 20460, (202) 260-1736, e-mail: tobin.paul@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The meeting of the NAC/AEGL will be open to the public. Oral statements will be limited to ten minutes. Since space is limited, those wishing to attend as observers should contact the NAC/AEGL Designated Federal Officer (DFO). Inquiries regarding the submission of written statements or chemical specific information should also be directed to the DFO.

Chemicals to be addressed at this meeting of the NAC/AEGL include ammonia, methyl mercaptan, hydrogen fluoride, cyanogen chloride, hydrogen cyanide, 1,2-dichloroethylene, arsine, dimethyldichlorosilane, and nitric acid. For available information, questions, or to submit information on these chemicals, contact Dr. Paul S. Tobin, DFO (see FOR FURTHER INFORMATION CONTACT).

List of Subjects

Environmental protection.

Dated: August 23, 1996.

William H. Sanders III,
*Director, Office Pollution Prevention and
Toxics.*

[FR Doc. 96-21953 Filed 8-27-96; 8:45 am]

BILLING CODE 6560-50-F

[FRL-5601-3]

**Benchmark Dose Peer Consultation
Workshop**

AGENCY: U.S. Environmental Protection
Agency.

ACTION: Notice of meeting.

SUMMARY: The EPA's Risk Assessment Forum is organizing a workshop on the use of the Benchmark Dose approach in cancer and noncancer risk assessments. A panel consisting of experts will discuss general principles related to the application of the Benchmark Dose approach as discussed in the EPA draft report Benchmark Dose Technical Guidance Document (EPA/600/P-96/002A). This draft guidance document is currently under development, but is being made available at this stage for a peer consultation workshop. Several experts in the areas of toxicology, statistics, and mathematical modeling have been asked to review the document and provide input at this early stage of development on several issues for which there is ongoing discussion within the Agency. The workshop will be open to members of the public as observers.

DATES: The meeting will begin on Tuesday, September 10, 1996, at 8:00 a.m. and end on Wednesday, September 11, 1996, at 3:00 p.m.

ADDRESSES: The meeting will be held at the Holiday Inn Bethesda, 8120 Wisconsin Avenue, Eastern Research Group, Inc., an EPA contractor, is providing logistical support for the workshop. To attend the workshop as an observer, contact Eastern Research Group, Inc., Tel: (617) 674-7474 by September 2, 1996. Space is limited so please register early.

FOR FURTHER INFORMATION CONTACT: For further information concerning the workshop, please contact Dr. Carole Kimmel, U.S. EPA, Office of Research and Development, 401 M Street, S.W., Washington, D.C., Telephone (202) 260-7331. To obtain a copy of the document, contact ORD Publications, Technology Transfer and Support Division, National Risk Management Laboratory, Cincinnati, OH; telephone 513-569-7562; fax: 513-569-7566. The document should be available on or about August 20, 1996.

SUPPLEMENTARY INFORMATION: The US EPA conducts risk assessments for an array of non-cancer health effects as well as for cancer. Historically, dose-response analysis has been done very differently, but with the recent publication of EPA's Proposed Guidance for Carcinogen Risk Assessment (61 FR 17960-18011), the dichotomy between quantitative approaches for cancer and noncancer risks will begin to breakdown. The EPA is exploring the use of the Benchmark Dose approach as a way of modeling effects data in the observable range and determining the point of departure that can be used as the basis for linear low-dose extrapolation, calculation of a margin of exposure (MOE), or application of uncertainty factors for calculating oral reference doses (RfDs), inhalation reference concentrations (RfCs), or other exposure estimates for human health risk assessment.

Issues to be discussed at the workshop include: the appropriate selection of studies and responses for benchmark dose analysis, use of biological significance or limit of detection for selection of the benchmark response, model selection and fitting, use of the lower confidence limit, and the default decision approach proposed in the document.

Dated: August 16, 1996.

Joseph Alexander,
*Acting Assistant Administrator for Research
and Development.*

[FR Doc. 96-21943 Filed 8-27-96; 8:45 am]

BILLING CODE 6560-50-M

[FRL-5602-2]

**Revised Hours for Public Access to the
Headquarters Library and INFOTERRA**

AGENCY: U.S. Environmental Protection
Agency.

SUMMARY: Notice is hereby given that beginning September 3, 1996, the Headquarters Library and INFOTERRA will be open to the public from 8:00 a.m. to 5 p.m. This constitutes an expansion in hours.

FOR FURTHER INFORMATION CONTACT:

Irvin Weiss, Library Manager at 202-260-9388 or Emma McNamara, INFOTERRA Manager at 202-260-1522.

Dated: August 23, 1996.

Irvin Weiss,
Library Manager.

[FR Doc. 96-21947 Filed 8-27-96; 8:45 am]

BILLING CODE 6560-50-M

[OPP-00445; FRL-5390-7]

**Testing Guidelines; Notice of
Availability**

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA has established a unified library for Test Guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS), and is announcing the availability of final testing guidelines for the following two series: Series 830-Product Properties Test Guidelines and Series 860-Residue Chemistry Test Guidelines. Guidelines in these series were peer reviewed on September 27, 1995, by the Scientific Advisory Panel (SAP) and have been revised in response to SAP and public comments. This notice also describes the unified library of OPPTS Test Guidelines. The Agency issues Federal Register notices periodically as new test guidelines are added to the OPPTS unified library.

ADDRESSES: The guidelines are available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial (202) 512-1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), internet: http:// fedbbs.access.gpo.gov, or call (202) 512-1532 for disks or paper copies. The guidelines are also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher (gopher.epa.gov) under the heading "Environmental Test Methods and Guidelines."

FOR FURTHER INFORMATION CONTACT: For general information: By mail:

Toxic Substances Control Act (TSCA) information: Contact the TSCA Hotline at: TAIS/7408, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone number: (202) 554-1404; fax (202) 554-5603, e-mail: tsca-hotline@epamail.epa.gov.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) information: Contact the Communications Branch (7506C), Field Operations Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Telephone number: (703) 305-5017; fax is (703) 305-5558.

For technical questions on series 830: Robert Boethling, (202) 260-3912, e-mail: boethling.robert@epamail.epa.gov or Francis Griffith, (703) 305-5826, e-mail: griffith.francis@epamail.epa.gov.

For technical questions on series 860: Randolph Perfetti, (703) 305-5381, e-

mail: perfetti.randolph@epamail.epa.gov or Richard Loranger, (703) 305-6912, e-mail: loranger.richard@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. EPA's Process for Developing a Unified Library of Test Guidelines

EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS) has been engaged in a multi-year project to harmonize and/or update test guidelines among the Office of Pesticide Programs (OPP), the Office of Pollution Prevention and Toxics (OPPT), and the Organization for Economic Cooperation and Development (OECD). The goals of the project include the formulation of harmonized OPP and OPPT guidelines for those in common between the two programs, the harmonization of OPPT and/or OPP guidelines with those of the OECD, as well as the updating of any guidelines unique to OPP or OPPT programs.

Testing guidelines that are changed substantively in the harmonization process or through other updating/amending activities, or which are new (e.g., for a previously unaddressed testing endpoint) will be made available for public comment by notice in the Federal Register. Additionally, EPA submits substantively revised and new test guidelines to peer review by expert scientific panels. Guidelines which are reformatted but not changed in any substantive way are not made available for public comment or submitted to peer review.

All final guidelines will be made available through the GPO Electronic Bulletin Board and the Internet on the EPA Public Access Gopher as a unified library of OPPTS Test Guidelines for use by either EPA program office. Printed versions of the unified library of OPPTS test guidelines will also be available to the public through the GPO. For purposes of this Federal Register notice, "publication" of the unified library of guidelines generally describes the availability of these final guidelines through the GPO and Internet. Because harmonization and updating is an ongoing task that will periodically result in modified guidelines, some guidelines being made available via GPO and Internet will be revised in the future. These efforts will ensure that industry is provided with testing guidelines that are current.

The test guidelines appearing in the unified library will be given numerical designations that are different from the designations provided at 40 CFR parts 158, 795, 796, 797, 798, and 799. OPPTS test guidelines will be published in 10 disciplinary series as follows:

Series 810—Product Performance Test Guidelines

Series 830—Product Properties Test Guidelines

Series 835—Fate, Transport and Transformation Test Guidelines

Series 840—Spray Drift Test Guidelines

Series 850—Ecological Effects Test Guidelines

Series 860—Residue Chemistry Test Guidelines

Series 870—Health Effects Test Guidelines

Series 875—Occupational and Residential Exposure Test Guidelines

Series 880—Biochemicals Test Guidelines

Series 885—Microbial Pesticide Test Guidelines

The Agency issues Federal Register notices periodically announcing any new test guidelines added to the OPPTS unified library. As each set of guidelines is published, it will be accompanied by a Master List which cross references the new OPPTS guideline numbers to the original OPP and OPPT numbers.

II. OPP and OPPT Procedures

Currently, OPP makes its test guidelines available through the National Technical Information Service (NTIS) as a series of twelve subdivisions. Explicit test requirements for pesticide registration are set out in 40 CFR part 158 which refers to specific guidelines by guideline number. EPA recommends that the test guidelines available through GPO and Internet be consulted instead of those test guidelines that were published through NTIS. Once final guidelines are available through GPO and Internet earlier guidelines will be removed from NTIS. Studies initiated 45 days or more after final publication should be performed in accordance with the revised guidelines. As test guidelines are published, the Agency will inform industry and the general public by means of Pesticide Registration (PR) Notices as well as Federal Register Notices. In addition, Data Call In letters to pesticide registrants will carry a dual numbering system for test guidelines until all test guidelines have been published. Part 158, which is currently being revised, will also carry a dual numbering system for test guidelines when it is proposed and finalized in the Federal Register.

In contrast, OPPT has been publishing its test guidelines in the Code of Federal Regulations (CFR) in 40 CFR parts 795 through 798 and are referenced on a

chemical-specific basis in its TSCA section 4 test rules in 40 CFR part 799. Although OPPT is currently evaluating whether to continue to publish its test guidelines in the CFR, OPPT test guidelines and modifications to those test guidelines that have been incorporated by an existing test rule will be retained in the CFR until OPPT announces that it will no longer publish its test guidelines in the CFR. Therefore, to the extent that a manufacturer or processor became subject to a test rule prior to the adoption of a harmonized test guideline, that test rule still requires compliance with the test guideline that was referenced by the test rule and published in the CFR. However, if the manufacturer or processor subject to the test rule is interested in seeking a modification to the requirement to comply with the test guideline that appears in the CFR, and which is incorporated by reference in that test rule, EPA encourages that manufacturer or processor to consult the modification procedures outlined in 40 CFR part 790. EPA has removed, and will continue to remove from the CFR those test guidelines that are no longer incorporated by reference in an existing and applicable test rule.

III. Peer Review of Test Guidelines

The Agency has updated and harmonized test guidelines for Product Properties (830 series) and Residue Chemistry (series 860) and submitted the revisions to these series to peer review by the FIFRA Scientific Advisory Panel (SAP) on September 27, 1995. EPA also made these revised guidelines available to the public for comment through the EPA docket. Guidelines in these series have been revised in response to peer review and public comment. In the 830 series, a comprehensive background guideline (OPPTS 830.1000) was added to provide general guidance on test methods and data reporting and an overview of the use of this series of test guidelines for pesticides. Additional standard test methods as suggested by SAP and public comment were added to individual test guidelines. For the 860 series, the Agency responded to SAP comments by revising the appropriate guidelines. The table "Raw Agricultural and Processed Commodities and Livestock Feeds Derived from Field Crops" in OPPTS guideline 860.1000 was also revised as a result of workshops held during the revision process. These workshops involved experts from academia, government, and the pesticide and livestock production industries, thus ensuring that the table is the end product of extensive peer

involvement. Additional comments received from the public were mainly editorial in nature and the guidelines were revised as appropriate. Copies of the Agency's comment/response documentation are available through the Public Response and Program Resources Branch and also on the EPA Public Access Gopher. See "ADDRESSES" at the beginning of this notice for the mailing address, telephone number, or public access gopher address.

The Agency has also updated and harmonized test guidelines for Health Effects (series 870). These guidelines were made available for public comment in June 1996 (61 FR 31522,

June 20, 1996) (FRL-5367-7) and will be peer reviewed in October 1996. Harmonized draft test guidelines for OPPTS in Ecological Effects (series 850) and OPPT guidelines in Fate, Transport and Transformation (series 835) were peer reviewed at a SAP meeting on May 29-30, 1996 (61 FR 16486, April 15, 1996) (FRL-5363-1). Final testing guidelines for the following three series: Occupational and Residential Exposure (series 875), Biochemicals (series 880), and Microbial Pesticides (series 885) were made available in March 1996 (61 FR 8279, March 4, 1996) (FRL-4990-3).

EPA is also announcing that later in 1996, it intends to make available

through GPO and the Internet the Spray Drift test guidelines (series 840) without any substantive changes. In addition, the revised test guidelines for Fate, Transport, and Transformation for application to pesticides (series 835) and Product Performance (series 810) will be made available for public comment during 1996.

IV. Notice of Availability of Final Test Guidelines

This notice announces the availability of final test guidelines in the 830 and 860 series. The following is the list of guidelines being made available at this time.

Series 830—Product Properties Test Guidelines

OPPTS Number	Name	Existing Numbers			EPA Pub. no.
		OTS	OPP	OECD	712-C-
830.1000	Background for product properties test guidelines Group A—Product Identity, Composition, and Analysis Test Guidelines.	none	none	none	96-310
830.1550	Product identity and composition	none	158.155	none	96-006
830.1600	Description of materials used to produce the product	none	158.160	none	96-007
830.1620	Description of production process	none	158.162	none	96-008
830.1650	Description of formulation process	none	158.165	none	96-009
830.1670	Discussion of formation of impurities	none	158.167	none	96-010
830.1700	Preliminary analysis	none	158.170	none	96-011
830.1750	Certified limits	none	158.175	none	96-012
830.1800	Enforcement analytical method	none	158.180	none	96-013
830.1900	Submittal of samples	none	64-1	none	96-015
	Group B—Physical/Chemical Properties Test Guidelines.				
830.6302	Color	none	63-2	none	96-019
830.6303	Physical state	none	63-3	none	96-020
830.6304	Odor	none	63-4	none	96-021
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	none	63-13	none	96-022
830.6314	Oxidation/reduction: chemical incompatibility	none	63-14	none	96-023
830.6315	Flammability	none	63-15	none	96-024
830.6316	Explosibility	none	63-16	none	96-025
830.6317	Storage stability	none	63-17	none	96-026
830.6319	Miscibility	none	63-19	none	96-027
830.6320	Corrosion characteristics	none	63-20	none	96-028
830.6321	Dielectric breakdown voltage	none	63-21	none	96-029
830.7000	pH	796.1450	63-12	none	96-030
830.7050	UV/Visible absorption	796.1050	none	101	96-031
830.7100	Viscosity	none	63-18	114	96-032
830.7200	Melting point/melting range	796.1300	63-5	102	96-033
830.7220	Boiling point/boiling range	796.1220	63-6	103	96-034
830.7300	Density/relative density/bulk density	796.1150	63-7	109	96-035
830.7370	Dissociation constants in water	796.1370	63-10	112	96-036
830.7520	Particle size, fiber length, and diameter distribution	796.1520	none	110	96-037
830.7550	Partition coefficient (<i>n</i> -octanol/water), shake flask method	796.1550	63-11	107	96-038
830.7560	Partition coefficient (<i>n</i> -octanol/water), generator column method	796.1720	63-11	none	96-039
830.7570	Partition coefficient (<i>n</i> -octanol/water), estimation by liquid chromatography	796.1570	63-11	117	96-040
830.7840	Water solubility: Column elution method; shake flask method	796.1840	63-8	105	96-041
830.7860	Water solubility, generator column method	796.1860	63-8	none	96-042
830.7950	Vapor pressure	796.1950	63-9	104	96-043

Series 860—Residue Chemistry Test Guidelines

OPPTS Number	Name	Existing Numbers			EPA Pub. no.
		OTS	OPP	OECD	712-C-
860.1000	Background	none	170-1	none	95-169
860.1100	Chemical identity	none	171-2	none	95-170
860.1200	Directions for use	none	171-3	none	95-171
860.1300	Nature of the residue—plants, livestock	none	171-4a,b	none	95-172
860.1340	Residue analytical method	none	171-4c,d	none	95-174
860.1360	Multiresidue method	none	171-4m	none	95-176
860.1380	Storage stability data	none	171-4e	none	95-177
860.1400	Water, fish, and irrigated crops	none	171-4f,g,h,165-5	none	95-178
860.1460	Food handling	none	171-4i	none	95-181
860.1480	Meat/milk/poultry/eggs	none	171-4j	none	95-182
860.1500	Crop field trials	none	171-4k	none	95-183
860.1520	Processed food/feed	none	171-4l	none	95-184
860.1550	Proposed tolerances	none	171-6	none	95-186
860.1560	Reasonable grounds in support of the petition	none	171-7	none	95-187
860.1650	Submittal of analytical reference standards	none	171-13	none	95-016
860.1850	Confined accumulation in rotational crops	none	165-1	none	95-188
860.1900	Field accumulation in rotational crops	none	165-2	none	95-189

List of Subjects

Environmental protection, Test guidelines.

Dated: August 21, 1996.

Lynn R. Goldman,
Assistant Administrator for Prevention,
Pesticides and Toxic Substances.

[FR Doc. 96-21822 Filed 8-27-96; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

Public Safety Wireless Advisory Committee; Steering Committee Meeting

AGENCIES: The National Telecommunications and Information Administration (NTIA), Larry Irving, Assistant Secretary for Communications and Information, and the Federal Communications Commission (FCC), Reed E. Hundt, Chairman.

ACTION: Notice of the next meeting of the Steering Committee.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, this notice advises interested persons of the next meeting of the Steering Committee of the Public Safety Wireless Advisory Committee. The NTIA and the FCC established a Public Safety Wireless Advisory Committee, Subcommittees,

and Steering Committee to prepare a final report to advise the NTIA and the FCC on operational, technical and spectrum requirements of Federal, state and local Public Safety entities through the year 2010. All interested parties are invited to attend and to participate in the Steering Committee meeting.

DATES: September 16, 1996 (Monday).

ADDRESSES: Department of Commerce, Herbert Hoover Building—Auditorium 14th and Constitution Avenue, N.W. Washington, D.C. 20230.

FOR INFORMATION CONTACT: Deborah Behlin at 202-418-0650 (phone), 202-418-2643 (fax), or dbehlin@fcc.gov (email). Information is also available from the Internet at the Public Safety Wireless Advisory Committee homepage (<http://pswac.ntia.doc.gov>).

SUPPLEMENTARY INFORMATION: The Steering Committee of the Public Safety Wireless Advisory Committee will hold its next meeting as follows:

September 16, 1996: The Steering Committee will meet starting at 2:00 p.m.

The tentative agenda for the Steering Committee meeting is as follows:

1. Welcoming Remarks
2. Approval of Agenda
3. Administrative Matters
4. Discussion of Final Report
5. Other Business
6. Closing Remarks

It is expected that this will be the final meeting of the Public Safety Wireless Advisory Committee.

The Co-Designated Federal Officials of the Public Safety Wireless Advisory Committee are William Donald Speights, NTIA, and John J. Borkowski, FCC. For public inspection, a file designated WTB-1 is maintained in the Private Wireless Division of the Wireless Telecommunications Bureau, Federal Communications Commission, Room 8010, 2025 M Street, N.W., Washington, D.C. 20554.

Federal Communications Commission.

Robert H. McNamara,

Chief, Private Wireless Division, Wireless Telecommunications Bureau.

[FR Doc. 96-22002 Filed 8-27-96; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 11, 1996.

A. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Jack Brandenburger*, Flower Mound, Texas; to acquire 14.31 percent; William H. Ellis, Flower Mound, Texas, to acquire 14.31 percent; Charles R. Fellers, Argyle, Texas, to acquire 14.31 percent; Johnny Glyn Gilliam, Graham, Texas, to acquire 7.95 percent; David D. Hickerson, Copper Canyon, Texas, to acquire 14.31 percent; and Frank R. Scheer, Flower Mound, Texas, to acquire 14.31 percent of the voting shares of First Bryson Bancorporation, Inc., Bryson, Texas, and thereby indirectly acquire Bryson Bancshares, Inc., Bryson, Texas, and The First State Bank of Bryson, Bryson, Texas.

Board of Governors of the Federal Reserve System, August 22, 1996.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 96-21911 Filed 8-27-96; 8:45 am]

BILLING CODE 6210-01-F

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of

a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 20, 1996.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Robertson Holding Company, L.P.*, Speedwell, Tennessee; to become a bank holding company by acquiring 52.68 percent of the voting shares of Commercial BancGroup, Inc., Harrogate, Tennessee, and thereby indirectly acquire Commercial Bank, Harrogate, Tennessee.

Board of Governors of the Federal Reserve System, August 22, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

[FR Doc. 96-21912 Filed 8-27-96; 8:45 am]

BILLING CODE 6210-01-F

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies

owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 23, 1996.

A. Federal Reserve Bank of Cleveland (R. Chris Moore, Senior Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *First Financial Bancorp*, Hamilton, Ohio; to merge with Farmers State Bancorp, Liberty, Indiana, and thereby indirectly acquire Farmers State Bank, Liberty, Indiana.

B. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. *Mid-Peninsula Bancorp*, Palo Alto, California; to merge with Cupertino National Bancorp, Cupertino, California, and thereby indirectly acquire Cupertino National Bank & Trust, Cupertino, California.

Board of Governors of the Federal Reserve System, August 23, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

[FR Doc. 96-21949 Filed 8-27-96; 8:45 am]

BILLING CODE 6210-01-F

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act, including whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. 1843). Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 12, 1996.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Bankers Bancorp of Oklahoma, Inc.*, Oklahoma City, Oklahoma; to engage *de novo* in a joint venture through its subsidiary, Bankers Bank Systems, Oklahoma City, Oklahoma, in data processing activities, pursuant to § 225.25(b)(7) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, August 23, 1996.

Jennifer J. Johnson

Deputy Secretary of the Board

[FR Doc. 96-21948 Filed 8-27-96; 8:45 am]

BILLING CODE 6210-01-F

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System

TIME AND DATE: 11:00 a.m., Tuesday, September 3, 1996.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: August 26, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96-22052 Filed 8-26-96; 10:59 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Vaccine Advisory Committee (NVAC), Subcommittee on Vaccine Safety, Subcommittee on Immunization Coverage, Subcommittee on Future Vaccines, and the Advisory Commission on Childhood Vaccines (ACCV), Subcommittee on Vaccine Safety: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease

Control and Prevention (CDC) announces the following Federal advisory committee meetings.

Name: National Vaccine Advisory Committee (NVAC).

Times and Dates: 9 a.m.-1:30 p.m., September 9, 1996. 8:30 a.m.-12:30 p.m., September 10, 1996.

Place: Hubert H. Humphrey Building, Room 702A, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each day either between 8 and 8:30 a.m. or 12:30 and 1 p.m. so they can be escorted to the meeting. Entrance to the meeting at other times during the day cannot be assured.

Purpose: The Committee shall advise and make recommendations to the Director of the National Vaccine Program on matters related to the Program responsibilities.

Matters to be Discussed: The Committee will receive reports on the status of NVAC nominees to replace members whose terms have ended, status of new exofficio members from the Department of Agriculture and the Health Care Financing Administration, and a discussion regarding the addition of liaison representatives to the Committee; the recruitment status for the Director, National Vaccine Program Office (NVPO); update alternatives for adverse event surveillance and funding options; update immunization registry; confidentiality issues; NVAC endorsement of the immunization information system confidentiality paper; update philosophical exemption to immunization; the Measles Vaccine Timing Study—Discussion of Edmonston-Zagreb (EZ) Vaccine Study; Institutes of Medicine risk communication safety forum; an update on the Subcommittee on Immunization Coverage Draft Papers, Thirteen Points of Leverage to Increase Coverage and Access to Immunization; an update on the Subcommittee on Future Vaccines, vaccine research partnership, and a status report on Sabin case studies; an update on the Subcommittee on Vaccine Safety; update on Adult Immunization Work Group; report on children's vaccine initiative; update on the National Vaccine Injury Compensation Program, a report from the Task Force on Safer Vaccines, a review of adverse events litigation and compensation in adults; and an update on Acellular Pertussis.

Agenda items are subject to change as priorities dictate.

Name: NVAC Subcommittee on Vaccine Safety and the ACCV, Subcommittee on Vaccine Safety.

Time and Date: 1:30 p.m.-5 p.m., September 9, 1996.

Place: Hubert H. Humphrey Building, Room 425A, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This joint ACCV/NVAC subcommittee will review issues relevant to

vaccine safety and adverse reactions to vaccines.

Matters to be Discussed: The Subcommittee will discuss the inclusion of influenza and pneumococcal vaccines in the National Vaccine Injury Compensation Program summation, direction and closure; focus of safety subcommittees; and a review of report and recommendations from the Task Force on Safer Childhood Vaccines.

Name: NVAC Subcommittee on Immunization Coverage.

Time and Date: 1:30 p.m.–5 p.m., September 9, 1996.

Place: Hubert H. Humphrey Building, Room 423A, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This subcommittee will identify and propose solutions that provide a multifaceted and holistic approach to reducing barriers that result in low immunization coverage for children.

Matters to be Discussed: The Subcommittee will discuss the forum on assessment and related immunization issues; the outline for the Subcommittee's report; and the assessment of immunization coverage.

Name: NVAC Subcommittee on Future Vaccines.

Time and Date: 1:30 p.m.–5 p.m., September 9, 1996.

Place: Hubert H. Humphrey Building, Room 405A, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This subcommittee will develop policy options and guide the National Vaccine Program activities which will lead to development, licensure, and best use of new and existing vaccines in the simplest possible immunization schedules.

Matters to be Discussed: The Subcommittee will discuss updates on vaccine procurement strategies, the United States Agency for International Development vaccine research agenda, and a discussion of case studies in vaccine development.

Contact Person for More Information: Felecia D. Pearson, Committee Management Specialist, NVPO, CDC, 1600 Clifton Road, NE, M/S D50, Atlanta, Georgia 30333, telephone 404/639-7250.

This notice is being published less than 15 days prior to the meeting due to the inability to transmit the document electronically.

Dated: August 22, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-21924 Filed 8-27-96; 8:45 am]

BILLING CODE 4163-18-M

Health Resources and Services Administration

Advisory Council; Notice of Establishment

Pursuant to the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. Appendix 2), the Secretary, Department of Health and Human Services announces the establishment of the following advisory council.

Designation: Advisory Committee to the Administrator, HRSA.

Purpose: Advises the Secretary of HHS and the Administrator of HRSA on policy matters pertinent to HRSA mission responsibilities in the conduct and support of health care delivery, health workforce, and related programs.

The committee may make recommendations concerning program development, resource allocation, and HRSA administrative practices and policies, and other specific matters which affect the operation of the Agency.

Structure: The Committee shall consist of the Secretary or designee as Chair and 16 members. Eleven members shall be authorities who are knowledgeable in the fields of health care delivery and finance, the health workforce and training of the workforce, public health, and the special needs of disadvantaged populations. Five members shall be representatives of the general public.

Dated: August 22, 1996.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 96-21919 Filed 8-27-96; 8:45 am]

BILLING CODE 4160-15-P

National Institutes of Health

Notice of Meeting of the National Advisory Council for Human Genome Research

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Council for Human Genome Research, National Center for Human Genome Research, September 16-17, 1996, Holiday Inn, Washington/Chevy Chase, Palladian West/Center, 5522 Wisconsin Avenue, Chevy Chase, Maryland.

This meeting will be open to the public on Monday, September 16, from 8:30 to 1:00 p.m. to discuss administrative details or other issues relating to committee activities. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, the meeting will be closed to the public on September 16 from 1:00 p.m. to recess and on September 17 from 8:30 a.m. to adjournment, for the

review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Elke Jordan, Deputy Director, National Center for Human Genome Research, National Institutes of Health, Building 31, Room 4B09, Bethesda, Maryland 20892, (301) 496-0844, will furnish the meeting agenda, rosters of Committee members and consultants, and substantive program information upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Jane Ades, (301) 594-1229, two weeks in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.172, Human Genome Research)

Dated: August 21, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-21897 Filed 8-27-96; 8:45 am]

BILLING CODE 4140-01-M

National Cancer Institute; Notice of Meetings of the National Cancer Advisory Board and its Subcommittee

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Cancer Advisory Board, National Cancer Institute, and its Subcommittees on September 10-11, 1996. Except as noted below, the meetings of the Board and its Subcommittees will be open to the public to discuss issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available.

A portion of the Board meeting will be closed to the public in accordance with the provisions set forth in secs. 552b(c)(4), 552b(c)(6), and 552(c)(9)(B), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications and for discussion of issues pertaining to programmatic areas and/or NCI personnel, and discussion of subcommittee recommendations regarding NCI staff support to the Board and operating procedures. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning the individuals associated

with the applications or programs, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy and premature disclosure of recommendations which would inhibit the final outcome and subsequent implementation of recommendations.

The Committee Management Office, National Cancer Institute, National Institutes of Health, Executive Plaza North, Room 630E, 9000 Rockville Pike, Bethesda, Maryland 20892 (301/496-5708), will provide summaries of the meetings and rosters of the Board members, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Carole Frank, Committee Management Specialist, at 301/496-5708 in advance of the meeting.

Name of Committee: National Cancer Advisory Board.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, NIH, Executive Plaza North, Room 600A, 6130 Executive Blvd., Bethesda, MD 20892-7405; (301) 496-5147.

Dates of Meeting: September 10-11, 1996.

Place of Meeting: Conference Room 10, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Open: September 10-8 am to approximately 12:15 pm.

Agenda: Director's Report on the National Cancer Institute; NCI Strategic Planning and Evaluation Structure; NCAB: 25th Anniversary Initiatives; New Business; Scientific Presentations; and Report on the Activities of the President's Cancer Panel.

Closed: September 10-2:30 pm to approximately 4:30 pm.

Agenda: For review and discussion of individual grant, applications, and extramural/intramural programmatic, and personnel policies.

Open: September 11-8:30 am to 11 am.

Agenda: Scientific Presentations; Subcommittee Reports; Report on the NCAB Retreat; Peer Review Initiatives; Continuing New Business.

Closed: September 11-11 am to 4:30 pm.

Agenda: Review and evaluation of NCAB staff support, structure and function.

Name of Committee: Subcommittee on Clinical Investigations.

Contact Person: Dr. Robert Wittes, Executive Secretary, National Cancer Institute, NIH, Building 31, Room 3A44, Bethesda, MD 20892; (301) 496-4291.

Date of Meeting: September 10, 1996.

Place of Meeting: Conference Room 7, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Open: 12:30 pm to 1:30 pm.

Agenda: To discuss the By Pass Budget and translational research as well as the possibilities for allocating NCI dollars to defray clinical costs.

Name of Committee: Subcommittee on Planning and Budget.

Contact Person: Ms. Cherie Nichols, Executive Secretary, National Cancer

Institute, NIH, Building 31, Room 11A19, Bethesda, MD 20892; (301) 496-5515.

Date of Meeting: September 10, 1996.

Place of Meeting: Conference Room 9, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Open: 12:30 pm to 1:30 pm.

Agenda: To discuss the NCI budget and various planning issues.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: August 22, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96-21898 Filed 8-27-96; 8:45 am]

BILLING CODE 4140-01-M

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Pub.L. 92-463, notice is hereby given of a meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council to be held in September 1996.

A portion of the meeting will be open and include discussion of the Center's policy issues and current administrative, legislative, and program developments.

The meeting will include the review, discussion, and evaluation of individual grant applications, contract proposals, and discussion of information about the Center's procurement plans. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(3), (4), and (6) and 5 U.S.C. App. 2, § 10(d).

A summary of the meeting and roster of council members may be obtained from: Ms. Joann M. Exline, National Advisory Council, CSAT, Rockwall II Building, Suite 619, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-8923.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Center for Substance Abuse Treatment National Advisory Council

Meeting Dates: September 18, 1996, 9:00 a.m.—5:00 p.m. September 19, 1996, 9:00 a.m.—2:15 p.m.

Place: Holiday Inn, 5520 Wisconsin Avenue, Chase Room, Chevy Chase, Maryland 20856

Type: CLOSED: September 18, 9:00 a.m.—11:00 a.m. OPEN: September 18, 11:15 a.m.—5:00 p.m. September 19, 9:00 a.m.—2:15 p.m.

Contact: Marjorie M. Cashion, Executive Secretary, Telephone: (301) 443-8923, and FAX: (301) 480-6077.

Dated: August 22, 1996.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 96-21921 Filed 8-27-96; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner; Federally Assisted Low-Income Housing Drug Elimination Announcement of Funding Awards Fiscal Year 1995

[Docket No. FR-3858-N-02]

AGENCY: Office of the Assistant Secretary for Housing - Federal Housing Commissioner, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding awards made by the Department for the Federally Assisted Low-Income Drug Elimination Grant Program. This announcement contains the names and addresses of the Federally Assisted Low-Income Housing Drug Elimination Program grantees and the amount of the awards.

FOR FURTHER INFORMATION CONTACT: Michael Diggs, Office of Multifamily Housing Asset Management and Disposition, Department of Housing and Urban Development, room 6176, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708-0558 (this is not a toll-free number). A telecommunications device for hearing- and speech-impaired individuals (TTY) is available at 1-800-877-8339 (Federal Information Relay Service).

SUPPLEMENTARY INFORMATION: These grants are authorized under Chapter 2, Subtitle C, Title V of the Anti-Drug Abuse Act of 1988 (42 U.S.C. 11901 *et seq.*), as amended by Section 581 of the Cranston-Gonzales National Affordable Housing Act (NAHA) of 1990 (42 U.S.C. 8011). Section 581 of NAHA expanded the Drug Elimination Program to include Federally assisted low-income housing. The Departments of Veterans Affairs and Housing and Urban Development, and Independent

Agencies Appropriations Act of 1995 (Pub. L. 103-327; approved September 28, 1994) appropriated funds for Federally Assisted Low-income housing.

Fiscal Year 1995 funds were announced in a Federal Register Notice of Funding Availability (NOFA) published on February 17, 1995 (60 FR 9544). The NOFA announced the availability of \$17,415 million for Federally Assisted Low-income housing. The purpose of the Drug Elimination program is to provide funding for carrying out drug elimination activities in accordance with the criteria of eligible activities as outlined in the NOFA. Applications are awarded funding if they meet the eligibility criteria indicated in the NOFA.

In accordance with section 102 (a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101-235, approved December 15, 1989), the Department is hereby publishing the names and addresses of the grantees that received funding under the NOFA, and the amount of funds awarded to each. The total amount awarded during this period was \$17,415 million to 165 grantees. This information is provided in Appendix A to this document.

The Assisted Housing Drug Elimination Program is listed in the Catalog of Federal Domestic Assistance as number 14-854.

Dated: August 21, 1996.

Stephanie A. Smith,
General Deputy Assistant Secretary for
Housing-Federal Housing Commissioner.

FISCAL YEAR 1995 DRUG ELIMINATION GRANTEEES

MINNEAPOLIS OFFICE

RECIPIENT NAME: RIDGECREST LDHA
PROJECT NUMBER/NAME: 048-44014
RIDGECREST VILLAGE
APARTMENTS
PROJECT ADDRESS: 1069 RIDGECREST
DRIVE, FLINT, MICHIGAN 48505
PROPERTY CONTACT: MELANIE
DEVARY (517) 351-6840
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: FINDLAY
APARTMENTS LIMITED
PROJECT NUMBER/NAME: 046-35175
FINDLAY APARTMENTS
PROJECT ADDRESS: 1534 RACE + ELM
& FINDLAY STREETS, CINCINNATI,
OHIO 45202
PROPERTY CONTACT: THOMAS A.
DENHART (513) 241-6328
AMOUNT OF GRANT: \$122,800
RECIPIENT NAME: PLEASANT
APARTMENTS LIMITED
PROJECT NUMBER/NAME: 046-35268
PLEASANT APARTMENTS

PROJECT ADDRESS:
PLEASANT+ELM+SCATTERED
SITES, CINCINNATI, OHIO 45202
PROPERTY CONTACT: THOMAS A.
DENHART (513) 241-6328
AMOUNT OF GRANT: \$124,580
RECIPIENT NAME: WALNUT
APARTMENTS, LTD.
PROJECT NUMBER/NAME: 046-35259
WALNUT
PROJECT ADDRESS: 1341-55
WALNUT/29-35 E 14TH,
CINCINNATI, OHIO 45202
PROPERTY CONTACT: THOMAS A.
DENHART (513) 241-6328
AMOUNT OF GRANT: \$49,225
RECIPIENT NAME: ALMS HILL
APARTMENTS
PROJECT NUMBER/NAME: 046-44122
ALMS HILL
PROJECT ADDRESS: 2525 VICTORY
PARKWAY, CINCINNATI, OHIO
45206
PROPERTY CONTACT: WILLIAM
STRITE(513) 861-1584/JOHN M.
ORHEK(614) 848-4330
AMOUNT OF GRANT: \$73,570
RECIPIENT NAME: NORTHCREST
GARDENS APTS. JOINT VENTURE
PROJECT NUMBER/NAME: 046-44015
NORTHCREST GARDENS
PROJECT ADDRESS: 5000
NORTHCREST, DAYTON, OHIO
45402
PROPERTY CONTACT: E. CLARK
WHITE, (619) 431-9100, EXT. 3372
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: BROADWALK
LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 042-35378
BOARDWALK APARTMENTS
PROJECT ADDRESS: 543 E 105TH ST +
SITES, CLEVELAND, OHIO 44108
PROPERTY CONTACT: LISA
STRICKLAND, (216) 681-4501
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: KENMORE
GARDENS LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 042-44014
KENMORE GARDENS
PROJECT ADDRESS: 1389 ANSEL RD.,
CLEVELAND, OHIO 44106
PROPERTY CONTACT: MORTON Q.
LEVIN (216) 771-2175
AMOUNT OF GRANT: \$35,000
RECIPIENT NAME: LIMA I, LTD.
PROJECT NUMBER/NAME: 043-35295
LIMA ESTATES I
PROJECT ADDRESS: 510 EAST NORTH
STREET, LIMA, OHIO 45801
PROPERTY CONTACT: PATRICK
RAWLINGS/JUDY ALLEN (614) 538-
1333
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: WASHINGTON
COURTS LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 071-35593
WASHINGTON COURTS APTS.
PROJECT ADDRESS: 5416-30 W
WASHINGTON, CHICAGO, ILLINOIS
60644

PROPERTY CONTACT: MARSHA
HARPER (312) 287-4131
AMOUNT OF GRANT: \$98,300
RECIPIENT NAME: LA VERGNE
COURTS LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 071-35597
LA VERGNE COURTS APTS.
PROJECT ADDRESS: 1950 E 71ST
STREET, CHICAGO, ILLINOIS 60644
PROPERTY CONTACT: LYNN
RAILSBACK (312) 287-4131
AMOUNT OF GRANT: \$98,300
RECIPIENT NAME: LANCASTER
VILLAGE COOPERATIVE
PROJECT NUMBER/NAME: 044-44005
LANCASTER VILLAGE
COOPERATIVE
PROJECT ADDRESS: 633 PALMER
DRIVE, PONTIAC, MICHIGAN 48057
PROPERTY CONTACT: LEONA
PATTERSON (810) 373-4780
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: LAFAYETTE
TERRACE ASSOCIATES
PROJECT NUMBER/NAME: 071-35487
LAFAYETTE TERRACE
PROJECT ADDRESS: 75TH
LAFAYETTE, CHICAGO, ILLINOIS
60644
PROPERTY CONTACT: ROWE
CHOCKLEY (412) 795-4755
AMOUNT OF GRANT: \$121,727
RECIPIENT NAME: MADISON
TERRACE ASSOCIATES
PROJECT NUMBER/NAME: 071-35441
MADISON TERRACE APTS.
PROJECT ADDRESS: 3153 WEST
MADISON STREET, CHICAGO,
ILLINOIS 60612
PROPERTY CONTACT: EARL WILEY
(312) 826-6611
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: WHITMORE
LIMITED PARTNERSHIP
PROJECT NUMBER/NAME:
IL06HDE0060195 WHITMORE
APARTMENTS
412-25 & 505-11 S CENTRAL
CHICAGO, ILLINOIS 60644
PROPERTY CONTACT: M. COLEMAN
(312) 379-4412
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: ENGLEWOOD
APT., LTD
PROJECT NUMBER/NAME: 071-44114
ENGLEWOOD GARDENS
PROJECT ADDRESS: 7000-7058
SOUTH EGGLESTO, CHICAGO,
ILLINOIS 60621
PROPERTY CONTACT: ROWE
SHOCKLEY (412) 795-4755
AMOUNT OF GRANT: \$65,759
RECIPIENT NAME: SWIFTON
COMMONS ASSOCIATES
PROJECT NUMBER/NAME: 071-44101
BRADFORD COURTS APTS.
PROJECT ADDRESS: 930 COLLEGE
BLVD., ADDISON, ILLINOIS 60101
PROPERTY CONTACT: KATHERINA
FRASHESKI (708) 495-3225

AMOUNT OF GRANT: \$124,940
RECIPIENT NAME: ADA THROOP ASSOCIATES LTD
PROJECT NUMBER/NAME: 071-44125
ADA-TROOP APARTMENTS
PROJECT ADDRESS: 6848-58 S THROOP, CHICAGO, ILLINOIS 60636
PROPERTY CONTACT: ROWE CHOCKLEY (412) 795-4755
AMOUNT OF GRANT: \$50,618
RECIPIENT NAME: SHERWOOD GLEN ON THE FOX I
PROJECT NUMBER/NAME: 071-44069
FOX VIEW APTS. I
PROJECT ADDRESS: 3 OXFORD RD #14, CARPENTERVILLE, ILLINOIS 60110
PROPERTY CONTACT: DIANE PEDERSON (847) 428-7771
AMOUNT OF GRANT: \$121,729
RECIPIENT NAME: SHERWOOD GLEN ON THE FOX APARTMENTS II
PROJECT NUMBER/NAME: 071-44124
FOX VIEW APTS. II
PROJECT ADDRESS: 3 OXFORD RD #14, CARPENTERVILLE, ILLINOIS 60110
PROPERTY CONTACT: DIANE PEDERSON (847) 428-7771
AMOUNT OF GRANT: \$121,729
RECIPIENT NAME: MAPLE RIDGE ASSOCIATES
PROJECT NUMBER/NAME: 071-94028
MAPLE RIDGE APARTMENTS
PROJECT ADDRESS: 3700 5TH STREET, ROCK ISLAND, ILLINOIS 61201
PROPERTY CONTACT: SALLY PETERS (309) 786-2639
AMOUNT OF GRANT: \$101,500
RECIPIENT NAME: UPGRADE DEVELOPMENT CORPORATION
PROJECT NUMBER/NAME: IL06H121168
PIERSON HILLS II
1720 GREAT OAK RD
PEORIA, ILLINOIS 61604
PROPERTY CONTACT: CAROL JONES (309) 676-4717
AMOUNT OF GRANT: \$27,665
RECIPIENT NAME: UPGRADE DEVELOPMENT CORPORATION
PROJECT NUMBER/NAME: 072-44004
LINCOLN TERRACE, UFR
PROJECT ADDRESS: 2825 WEST ANN APT 4I, PEORIA, ILLINOIS 61604
PROPERTY CONTACT: CAROL JONES (309) 676-4717
AMOUNT OF GRANT: \$44,163
RECIPIENT NAME: UPGRADE DEVELOPMENT CORPORATION
PROJECT NUMBER/NAME: 072-44015
PIERSON HILLS I
PROJECT ADDRESS: 1720 GREAT OAK RD., PEORIA, ILLINOIS 61605
PROPERTY CONTACT: CAROL JONES (309) 676-4717
AMOUNT OF GRANT: \$51,664
RECIPIENT NAME: LYONS VIEW DEVELOPMENT, ATTN. ALLAN GREENE

PROJECT NUMBER/NAME: 071-36653
PARKWAY GARDENS
PROJECT ADDRESS: 6415 S CALUMET AVE., CHICAGO, ILLINOIS 60637
PROPERTY CONTACT: SUELLYN CATES (312) 299-6701
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: GREYSTONE ASSOCIATES
PROJECT NUMBER/NAME: 072-35055
GREYSTONE APARTMENTS
PROJECT ADDRESS: 103 GREYSTONE DRIVE, ALORTON, ILLINOIS 62207
PROPERTY CONTACT: CAROL CHAPMAN (618) 332-6446
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: GILL PARK COOPERATIVE
PROJECT NUMBER/NAME: 071-35372
GILL PARK COOPS
PROJECT ADDRESS: 810 WEST GRACE STREET, CHICAGO, ILLINOIS 60613
PROPERTY CONTACT: HAKEEM DUROJARYE (312) 929-3325
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: HARBORSIDE HOUSING ASSO. LP
PROJECT NUMBER/NAME: 073-55007
HARBORSIDE APTS.
PROJECT ADDRESS: 3610 ALDER ST., EAST CHICAGO, INDIANA 46312
PROPERTY CONTACT: JERRY BERNSTEIN (219) 938-1600
AMOUNT OF GRANT: \$124,953
RECIPIENT NAME: ANTIOCH JOINT VENTURE
PROJECT NUMBER/NAME: 073-55120
EDEN GREEN IN FORT WAYNE
PROJECT ADDRESS: 2201 REED ST., FT. WAYNE, INDIANA 46803
PROPERTY CONTACT: AARON THOMAS (317) 842-6612
AMOUNT OF GRANT: \$106,000
RECIPIENT NAME: FEDERAL PROPERTY MANAGEMENT CORP.
PROJECT NUMBER/NAME: 073-44455
WEYERBACHER TERRACE
PROJECT ADDRESS: 2534 N CAPITAL AVE., INDIANAPOLIS, INDIANA 46208
PROPERTY CONTACT: MARILYN ELDRIDGE (513) 223-7626
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: JUNEAU AVENUE ASSOCIATES
PROJECT NUMBER/NAME: 075-94002
WINDSOR COURT APARTMENTS
PROJECT ADDRESS: 1831 WEST JUNEAU AVENUE, MILWAUKEE, WISCONSIN 53203
PROPERTY CONTACT: PATTY OWNBY (615) 525-7500
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: BANCROFT EDDY LDHA PARTNERSHIP
PROJECT NUMBER/NAME: MI28H150191
BANCROFT & EDDY APTS. 107 S. WASH. ST. SAGINAW, MICHIGAN 48607

PROPERTY CONTACT: JOHN BROCAVICH (517) 752-5233
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: LINCOLNSHIRE HOMES OF ALBION
PROJECT NUMBER/NAME: 047-44022
LINCOLNSHIRE OF ALBION
PROJECT ADDRESS: 900-1 BOYD DRIVE, ALBION, MICHIGAN 49224
PROPERTY CONTACT: JOHN KATSMAS (517) 629-4270
AMOUNT OF GRANT: \$117,528
RECIPIENT NAME: M L K LIMITED DIVIDEND HOUSING ASSO.
PROJECT NUMBER/NAME: 044-94054
MARTIN LUTHER KING APARTMENTS
PROJECT ADDRESS: 595 CHENE STREET, DETROIT, MICHIGAN 48207
PROPERTY CONTACT: NANCY HOPKINS (810) 851-9600
AMOUNT OF GRANT: \$93,905
RECIPIENT NAME: PARKVIEW ASSOCIATES
PROJECT NUMBER/NAME: 092-92011
PARKVIEW APARTMENTS
PROJECT ADDRESS: 1201 12TH AVENUE NORTH, MINNEAPOLIS, MINNESOTA 55411
PROPERTY CONTACT: DAVID ALTMAN (612) 377-4050
AMOUNT OF GRANT: \$124,965
RECIPIENT NAME: MERCER APARTMENT COMPANY
PROJECT NUMBER/NAME: 046-35242
MERCER APARTMENTS
PROJECT ADDRESS: 214 W LIBERTY STREET, CINCINNATI, OHIO 45202
PROPERTY CONTACT: W.R. HILL (513) 621-3685
AMOUNT OF GRANT: \$13,250
RECIPIENT NAME: TINA APARTMENT COMPANY
PROJECT NUMBER/NAME: 046-35297
TINA APARTMENTS
PROJECT ADDRESS: 212 W LIBERTY, CINCINNATI, OHIO 45210
PROPERTY CONTACT: W.R. HILL (513) 621-3685
AMOUNT OF GRANT: \$50,200
RECIPIENT NAME: SENATE APARTMENT COMPANY
PROJECT NUMBER/NAME: 046-35222
SENATE APARTMENTS
PROJECT ADDRESS: 216-18 W 12TH ST., CINCINNATI, OHIO 45210
PROPERTY CONTACT: W.R. HILL (513) 621-3685
AMOUNT OF GRANT: \$46,800
RECIPIENT NAME: COMMODORE APARTMENT COMPANY
PROJECT NUMBER/NAME: 046-35279
COMMODORE APARTMENTS
PROJECT ADDRESS: 3637-39 READING ROAD, CINCINNATI, OHIO 45229
PROPERTY CONTACT: W.R. HILL (513) 621-3685
AMOUNT OF GRANT: \$40,080

RECIPIENT NAME: WALNUT HILLS
REDEVELOPMENT FOUNDATION
PROJECT NUMBER/NAME: 046-35293
WALNUT HILLS, SCATTERED SITES
PROJECT ADDRESS: 2601 MELROSE
AVE., CINCINNATI, OHIO 45206
PROPERTY CONTACT: DAPHNE A.
SLONE (513) 861-6111
AMOUNT OF GRANT: \$125,000

LITTLE ROCK OFFICE

RECIPIENT NAME: CORONADO
COURTS LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 123-94011
CORONADO COURTS
PROJECT ADDRESS: 1830 BONITA
AVE., DOUGLAS, ARIZONA 85607
PROPERTY CONTACT: BEVERLY
HOGAN (520) 366-4637
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: FRIENDSHIP
VILLAGE, INC.
PROJECT NUMBER/NAME: 121-44075
FRIENDSHIP VILLAGE APTS. II
PROJECT ADDRESS: 40 FRIENDSHIP,
SAN FRANCISCO, CALIFORNIA
94115
PROPERTY CONTACT: WALTER
SCOTT (415) 467-9701
AMOUNT OF GRANT: \$123,800

RECIPIENT NAME: BANNEKER
HOMES INC.
PROJECT NUMBER/NAME: 121-55036
BANNEKER HOMES
PROJECT ADDRESS: 725 FULTON,
SAN FRANCISCO, CALIFORNIA
94102
PROPERTY CONTACT: AL REYNOLDS
(415) 693-9263
AMOUNT OF GRANT: \$107,760

RECIPIENT NAME: JEFFERSON
APARTMENT CO.
PROJECT NUMBER/NAME: 082-35005
SOUTHEAST APARTMENTS
PROJECT ADDRESS: 38TH &
KENTUCKY ST., PINE BLUFF,
ARKANSAS 71601
PROPERTY CONTACT: DONNA
SEXTON (501) 782-7268
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: JEFFERSON
MANOR LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 082-44018
JEFFERSON MANOR
PROJECT ADDRESS: 2600 JOHN
ASHLEY DRIVE, NORTH LITTLE
ROCK, ARKANSAS 72114
PROPERTY CONTACT: DONNA
SEXTON (501) 782-7268
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: ALLIED GARDENS
LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 082-44019
ALLIED GARDENS ESTATES
PROJECT ADDRESS: 5400 JOHNSON,
FORT SMITH, ARKANSAS 72901
PROPERTY CONTACT: DONNA
SEXTON (501) 782-7268
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: HILLSBORO
TOWNHOUSE LTD. PARTNERSHIP
PROJECT NUMBER/NAME: 082-35017
HILLSBORO TOWNHOUSE
PROJECT ADDRESS: 1600 E
HILLSBORO, EL DORADO,
ARKANSAS 72902
PROPERTY CONTACT: DONNA
SEXTON (501) 782-7268
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: APOLLO TERRACE
LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 082-35032
APOLLO TERRACE
PROJECT ADDRESS: 4200 GILLIAM
PARK, LITTLE ROCK, ARKANSAS
72206
PROPERTY CONTACT: GEORGE MAYS
(501) 375-6369
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: WILSHIRE-
SHORTER LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 082-35002
SHORTER COLLEGE GARDENS
PROJECT ADDRESS: 800 N BEECH
STREET, LITTLE ROCK, ARKANSAS
72206
PROPERTY CONTACT: GEORGE MAYS
(501) 375-6369
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: TERRACE GREEN
LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 082-35029
TERRACE GREEN
PROJECT ADDRESS: 8223 SCOTT
HAMILTON, LITTLE ROCK,
ARKANSAS 72209
PROPERTY CONTACT: DONNA
SEXTON (501) 782-7268
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: BOSTON
FINANCIAL C/O MR. MILES
HAPGOOD
PROJECT NUMBER/NAME: 101-94006
WINDSOR COURT
PROJECT ADDRESS: 1550 JOLIET
STREET, AURORA, COLORADO
80010
PROPERTY CONTACT: RON RAE
(303) 360-9916
AMOUNT OF GRANT: \$117,900

RECIPIENT NAME: DOUGLAS
HOUSING CORPORATION
PROJECT NUMBER/NAME: 123-35132
CASAS DE ESPERANZA
PROJECT ADDRESS: 1135-1159 3RD &
BONITA, DOUGLAS, ARIZONA
85607
PROPERTY CONTACT: BEVERLY
HOGAN (520) 366-4637
AMOUNT OF GRANT: \$125,000

RECIPIENT NAME: C & L
PARTNERSHIP
PROJECT NUMBER/NAME:
ND990024017 C & L MANOR
20 EAST 6TH ST
GRAFTON, NORTH DAKOTA 58237
PROPERTY CONTACT: GLEN
GILLESHAMMER (701) 352-3070

AMOUNT OF GRANT: \$109,200
RECIPIENT NAME: ROSALIE G.
WALLACE
PROJECT NUMBER/NAME: 064-44037
WESLEY CHAPEL APARTMENTS
PROJECT ADDRESS: 1008 AVENUE L,
BATON ROUGE, LOUISIANA 70807
PROPERTY CONTACT: ROSALIE G.
WALLACE (504) 775-6638
AMOUNT OF GRANT: \$123,920
RECIPIENT NAME: FAIRWOOD
MANOR DEVELOPMENT COMPANY
PROJECT NUMBER/NAME: 064-44017
FAIRWOOD MANOR APARTMENTS
PROJECT ADDRESS: 1011 WEST 18TH
STR, LAKE CHARLES, LOUISIANA
70601
PROPERTY CONTACT: SHERIL L.
WINGO (305) 566-2955
AMOUNT OF GRANT: \$76,911
RECIPIENT NAME: GORDON PLAZA
APARTMENTS
PROJECT NUMBER/NAME: 064-35178
GORDON PLAZA APARTMENTS
PROJECT ADDRESS: 3251 ST.
FERDINAND STREET, NEW
ORLEANS, LOUISIANA 70126
PROPERTY CONTACT: WILBERT
THOMAS, SR. (504) 945-0731
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: MARIANNA LTD.
PROJECT NUMBER/NAME: 171-35170
THE MARIANNA
PROJECT ADDRESS: 3204 W 4TH,
KENNEWIC, WASHINGTON 99336
PROPERTY CONTACT: DOUG
REPMAN (206) 334-5018
AMOUNT OF GRANT: \$73,247
RECIPIENT NAME: MANNY L. NEVES
PROJECT NUMBER/NAME:
WA190041005 CEDAR VILLAGE
6230 S. 129TH ST
SEATTLE, WASHINGTON 98178
PROPERTY CONTACT: MANY L.
NEVIS (206) 881-7253
AMOUNT OF GRANT: \$117,100
RECIPIENT NAME: HUNT BUILDING
CORPORATION
PROJECT NUMBER/NAME:
TX59E000003 MASON MANOR
APARTMENTS
1137 GUNTER
AUSTIN, TEXAS 78721
PROPERTY CONTACT: DALE
GARDNER (915) 545-2631
AMOUNT OF GRANT: \$117,492
RECIPIENT NAME: BONILLA & SMITH
PROJECT NUMBER/NAME: 115-35024
NORTHSIDE MANOR APARTMENTS
PROJECT ADDRESS: 1401 N
ALEMEDA, CORPUS CRISTI, TEXAS
78411
PROPERTY CONTACT: JOHN CONDIT
(210) 733-1908
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: FAIRWAY
VILLAGE LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 115-44006
FAIRWAY VILLAGE APARTMENTS

PROJECT ADDRESS: 6118 FAIRWAY DRIVE, AUSTIN, TEXAS 78741
 PROPERTY CONTACT: SHERRY PUGH (512) 474-4242
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: ARISTOCRAT APARTMENTS/NCHP
 PROJECT NUMBER/NAME: 114-44031
 ARISTOCRAT APARTMENTS
 PROJECT ADDRESS: 4400 W. AIRPORT BLV., HOUSTON, TEXAS 77045
 PROPERTY CONTACT: CHARLES WILKINS, JR. (202) 347-6247
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: PARKER SQUARE APTS-C/O NHP PMI INC.
 PROJECT NUMBER/NAME: 114-44024
 PARKER SQUARE APARTMENTS
 PROJECT ADDRESS: 10300 SHADY LANE, HOUSTON, TEXAS 77016
 PROPERTY CONTACT: CHARLES WILKINS, JR. (202) 347-6247
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: CENTENNIAL PARK ARMS, A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 125-44015
 CENTENNIAL PARK ARMS I
 PROJECT ADDRESS: 2627 DONNA ST., NORTH LAS VEGAS, NEVADA 89030
 PROPERTY CONTACT: TOM PIERCE (702) 873-3071
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: DOMICILE PROPERTY MGT. INVESTMENTS
 PROJECT NUMBER/NAME: TX24K023002 PEAR ORCHARD
 4365 SOUTH 4TH STREET
 BEAUMONT, TEXAS 77705
 PROPERTY CONTACT: SHARON GUIDRY (409) 892-6604
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: SAMBELT DEVELOPMENT COMPANY
 PROJECT NUMBER/NAME: 126-35017
 FREMONT MANOR APARTMENTS
 PROJECT ADDRESS: 233 N FREMONT ST., PORTLAND, OREGON 97227
 PROPERTY CONTACT: MARLYS LAZER (503) 242-3614
 AMOUNT OF GRANT: \$94,093
 RECIPIENT NAME: PIEDMONT PLAZA ASSOCIATES
 PROJECT NUMBER/NAME: 126-44116
 PIEDMONT PLAZA APARTMENTS
 PROJECT ADDRESS: 5700 MICHIGAN ST., PORTLAND, OREGON 97227
 PROPERTY CONTACT: BILL WOOD (503) 595-2244
 AMOUNT OF GRANT: \$88,000
 RECIPIENT NAME: ECUMENICAL ASSOC. FOR HOUSING-CONTRA COS
 PROJECT NUMBER/NAME: 121-55017
 CRESCENT PARK
 PROJECT ADDRESS: 5000 HARTNETT AVE., RICHMOND, CALIFORNIA 94804
 PROPERTY CONTACT: PEGGY FRANKLIN (415) 258-1818

AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: NORMANDY APARTMENT, LTD
 PROJECT NUMBER/NAME: 118-55012
 NORMANDY APARTMENTS
 PROJECT ADDRESS: 6221 E 38 ST., TULSA, OKLAHOMA 74135
 PROPERTY CONTACT: A.C. CUNNINGHAM (405) 236-8332
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: CONCORD VILLAGE, INC.
 PROJECT NUMBER/NAME: 123-55002,4,5,6,7 CONCORD VILL. COOP
 PROJECT ADDRESS: 631 E LEXINGTON PL., TEMPE, ARIZONA 85281
 PROPERTY CONTACT: GEORGIA TABOR CONRAD (602) 946-4271
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: HOUSING AUTHORITY OF THE CITY OF LAS CRUCES
 PROJECT NUMBER/NAME: NM020002004 HOUSING AUTHORITY APTS.
 926 S. SAN PEDRO
 LAS CRUCES, NEW MEXICO 88001
 PROPERTY CONTACT: DAVE ROBERTS (505) 526-5541
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: CRESCENT MANOR ASSO, A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 136-44281
 VILLAGE EAST APTS.
 PROJECT ADDRESS: 2501 EAST LAFAYETTE ST., STOCKTON, CALIFORNIA 95205
 PROPERTY CONTACT: GAIL MADSEN (916) 448-1172
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: ROBERT LAIRD
 PROJECT NUMBER/NAME: 136-55010
 FLORIN MEADOWS I & II
 PROJECT ADDRESS: 7301 29TH ST., SACRAMENTO, CALIFORNIA 95822
 PROPERTY CONTACT: JOHN BERKLEY (916) 444-9300
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: HOWARD E. BOARD
 PROJECT NUMBER/NAME: 136-35631/
 35652 COUNTRYWOOD VILL.& EAST
 PROJECT ADDRESS: 5500 MACK ROAD, SACRAMENTO, CALIFORNIA 95823
 PROPERTY CONTACT: RICHARD FISHER (415) 571-2250
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: JACKIE ROBINSON APARTMENTS, INC.
 PROJECT NUMBER/NAME: 121-44023
 JACKIE ROBINSON GARDEN APTS.
 PROJECT ADDRESS: 1340 HUDSON AVE., SAN FRANCISCO, CALIFORNIA 94124
 PROPERTY CONTACT: JOHN STEWART (415) 391-5321

AMOUNT OF GRANT: \$85,078
 RECIPIENT NAME: FRIENDSHIP VILLAGE, INC.
 PROJECT NUMBER/NAME: 121-44032
 FRIENDSHIP VILLAGE APTS. I
 PROJECT ADDRESS: 40 FRIENDSHIP, SAN FRANCISCO, CALIFORNIA 94115
 PROPERTY CONTACT: WALTER SCOTT (415) 467-9701
 AMOUNT OF GRANT: \$123,800
KNOXVILLE OFFICE
 RECIPIENT NAME: KNOXVILLE'S COMMUNITY DEVELOPMENT CORPORATION
 PROJECT NUMBER/NAME: TN378023002 COLLEGE HILLS APTS.
 2121 RIDGEBROOK LANE
 KNOXVILLE, TENNESSEE 37921
 PROPERTY CONTACT: GAIL GILLISPIE (423) 594-8650/521-8770
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: HOBSON GROVE ASSOCIATES, LIMITED
 PROJECT NUMBER/NAME: 083-44060
 HOBSON GROVE APARTMENTS
 PROJECT ADDRESS: 901 JACKSON ST., BOWLING GREEN, KENTUCKY 42101
 PROPERTY CONTACT: MARILYN DOWNEY (502) 781-4511
 AMOUNT OF GRANT: \$79,827
 RECIPIENT NAME: HAVERSHAM APARTMENTS, LTD
 PROJECT NUMBER/NAME: 062-44062
 SUMMIT RIDGE APARTMENTS
 PROJECT ADDRESS: 149 HAVERSHAM DRIVE, BIRMINGHAM, ALABAMA 35215
 PROPERTY CONTACT: JOANN FRAZIER (205) 854-5331
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: NEW BREEZY POINT APARTMENTS ASSOCIATES
 PROJECT NUMBER/NAME: 081-44017
 NEW BREEZY POINT APTS.
 PROJECT ADDRESS: 2801 RAJA ROAD, MEMPHIS, TENNESSEE 38127
 PROPERTY CONTACT: IRENE HALE (901) 358-1328
 AMOUNT OF GRANT: \$109,265
 RECIPIENT NAME: BONHOMIE APTS. LTD C/O J. EDWARD TURNER
 PROJECT NUMBER/NAME: 065-35214
 BONHOMIE APARTMENTS
 PROJECT ADDRESS: 1810 COUNTRY CLUB RD., HATTIESBURG, MISSISSIPPI 39401
 PROPERTY CONTACT: PEGGY FLUKER (601) 544-9733
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: FOX RIDGE APARTMENTS, LIMITED
 PROJECT NUMBER/NAME: 061-35307
 FOXRIDGE APARTMENTS
 PROJECT ADDRESS: E-5 PACKINGHOUSE ROAD, STATESBORO, GEORGIA 30458

PROPERTY CONTACT: MARTHA BROWN (912) 764-6797
 AMOUNT OF GRANT: \$117,620
 RECIPIENT NAME: MONTBLANC GARDENS
 PROJECT NUMBER/NAME: RQ46R000015 MONTBLANC GARDENS
 BO SUSA BAJA
 YAUCO, PUERTO RICO 00698
 PROPERTY CONTACT: EBEOIN MOGICE (809) 722-1741
 AMOUNT OF GRANT: \$124,500
 RECIPIENT NAME: HOMES OF OAKRIDGE AND DES MOINES AREA COUNCIL OF CHURCHES
 PROJECT NUMBER/NAME: 074-35003 DMACC HOMES OF OAKRIDGE
 PROJECT ADDRESS: 1236 OAKRIDGE DRIVE, DES MOINES, IOWA 50314
 PROPERTY CONTACT: MARGARET TOOMEY (515) 244-7702 X143
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: HILL TOP VILLAGE ASSOCIATES
 PROJECT NUMBER/NAME: 063-35019 HILLTOP VILLAGE
 PROJECT ADDRESS: 1646 W 45TH ST., JACKSONVILLE, FLORIDA 32208
 PROPERTY CONTACT: KATHY REVELL (904) 764-7796
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: GRIER PARK, A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 053-35449 GRIER PARK
 PROJECT ADDRESS: 3424 OAK ARBOR LANE, CHARLOTTE, NORTH CAROLINA 28205
 PROPERTY CONTACT: DAWN CHAPMAN (704) 334-8026
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: LINCOLN REDEVELOPMENT CORP LIMITED
 PROJECT NUMBER/NAME: 084-44027 LINCOLN GARDENS
 PROJECT ADDRESS: 1700 E 22ND ST., KANSAS CITY, MISSOURI 64108
 PROPERTY CONTACT: DEBBIE JOHNSON (816) 842-1266
 AMOUNT OF GRANT: \$122,922
 RECIPIENT NAME: BFTG LAKESHORE II APARTMENT ASSOCIATES
 PROJECT NUMBER/NAME: 054-55014 LAKESHORE II APARTMENTS
 PROJECT ADDRESS: RT. 13, LAKESIDE ROAD, GREENVILLE, SOUTH CAROLINA 29611
 PROPERTY CONTACT: JEAN FARMER (802) 277-6687
 AMOUNT OF GRANT: \$124,932
 RECIPIENT NAME: TOMMIE ROSE GARDENS APTS. JOINT VENTURE
 PROJECT NUMBER/NAME: 103-35065 TOMMIE ROSE GARDENS APTS.
 PROJECT ADDRESS: 2400 N 34TH AVE., OMAHA, NEBRASKA 68111
 PROPERTY CONTACT: ROMONA BOONE (402) 451-7300

AMOUNT OF GRANT: \$100,602
 RECIPIENT NAME: PARKER SQUARE LIMITED
 PROJECT NUMBER/NAME: 084-44107 PARKER SQUARE
 PROJECT ADDRESS: 1051 BASIE ST., KANSAS CITY, MISSOURI 64106
 PROPERTY CONTACT: BOLAJI SIFFRE (816) 421-5457
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: BOULEVARD ASSOCIATES
 PROJECT NUMBER/NAME: 084-35277 BOULEVARD VILLAGE
 PROJECT ADDRESS: 3218 HARDESTY DRIVE, KANSAS CITY, MISSOURI 64128
 PROPERTY CONTACT: JAMES FULLER (816) 861-1200
 AMOUNT OF GRANT: \$100,550
 RECIPIENT NAME: PLAZA PARK LTD. PTR.
 PROJECT NUMBER/NAME: 102-92005 VALLEY VIEW DBA PLAZA PARK
 PROJECT ADDRESS: 2940 RALPH BUNCHE DRIVE, LEAVENWORTH, KANSAS 66048
 PROPERTY CONTACT: F. PATRICK DOUGHERTY (913) 651-2967
 AMOUNT OF GRANT: \$82,505
 RECIPIENT NAME: STRAWBERRY CREEK ASSOCIATES LIMITED
 PROJECT NUMBER/NAME: 063-35073 OAKWOOD VILLA
 PROJECT ADDRESS: 8201 KONA AVENUE, JACKSONVILLE, FLORIDA 32211
 PROPERTY CONTACT: PAMELA LAPORTE (904) 725-7566
 AMOUNT OF GRANT: \$116,803
 RECIPIENT NAME: FIRST FARMINGTON APTS., A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 053-44084 FIRST FARMINGTON APTS
 PROJECT ADDRESS: 226 BRENTWOOD ST., HIGH POINT, NORTH CAROLINA 27260
 PROPERTY CONTACT: KAREN HILL (910) 883-4528
 AMOUNT OF GRANT: \$115,782
 RECIPIENT NAME: CORNELIUS VILLAGE, A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: NC19R000061 CORNELIUS VILLAGE
 19315 MERIDAN STREET
 CORNELIUS, NORTH CAROLINA 28301
 PROPERTY CONTACT: KRIS FINCHER (704) 892-3912
 AMOUNT OF GRANT: \$124,070
 RECIPIENT NAME: CENTURY PACIFIC HOUSING PARTNERSHIP IX
 PROJECT NUMBER/NAME: 102-44032 WINDRIDGE
 PROJECT ADDRESS: 2502 WILDWOOD LANE, WICHITA, KANSAS 67217
 PROPERTY CONTACT: JULIE ANDERSON (316) 942-4286

AMOUNT OF GRANT: \$116,634
 RECIPIENT NAME: NEWGATE, A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 053-44257 NEWGATE GARDENS
 PROJECT ADDRESS: 605D GRANBY ST., HIGH POINT, NORTH CAROLINA 27260
 PROPERTY CONTACT: SANDRA DUBOSE (910) 886-5528
 AMOUNT OF GRANT: \$120,882
 RECIPIENT NAME: GATEWOOD MANOR LIMITED
 PROJECT NUMBER/NAME: 053-35404 ROCHELLE MANOR
 PROJECT ADDRESS: 1238 LOLLY LANE, DURHAM, NORTH CAROLINA 27702
 PROPERTY CONTACT: INGRID HARMON (919) 598-1396
 AMOUNT OF GRANT: \$124,358
 RECIPIENT NAME: STONECROFTS ASSOCIATES, LTD
 PROJECT NUMBER/NAME: 053-35309 STONECROFT VILLAGE APTS
 PROJECT ADDRESS: 1001 FAREWELL ST+RAGAN ST+SCATTERED SITES, GASTONIA, NORTH CAROLINA 28052
 PROPERTY CONTACT: ANNETTE FAULKNER (704) 861-0793
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: DOVE MEADOWS
 PROJECT NUMBER/NAME: 053-35479 DOVE MEADOWS
 PROJECT ADDRESS: 240 SOUTHERN BLVD., DURHAM, NORTH CAROLINA 28401
 PROPERTY CONTACT: MIKE VANDERGRIFT (910) 762-4442
 AMOUNT OF GRANT: \$68,620
 RECIPIENT NAME: CREEK ROAD LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 053-44059 CHEEK ROAD APARTMENTS
 PROJECT ADDRESS: 1835 CHEEK ROAD, DURHAM, NORTH CAROLINA 27702
 PROPERTY CONTACT: MADGE GUPTON (919) 682-2701
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: WESTVIEW VALLEY, A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 053-35179 WESTVIEW VALLEY
 PROJECT ADDRESS: 436 GUILFORD COLLEGE ROAD, GREENSBORO, NORTH CAROLINA 27510
 PROPERTY CONTACT: KIM MELVIN (910) 299-9778
 AMOUNT OF GRANT: \$119,109
 RECIPIENT NAME: STANLEY SQUARE, A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 053-35367 STANLEY SQUARE APTS
 PROJECT ADDRESS: 814 NORTH BUCK OAK ST., STANLEY, NORTH CAROLINA 28164
 PROPERTY CONTACT: RHONDA GREENE (704) 263-1000/DANA ROBERTSON (704) 263-2577

AMOUNT OF GRANT: \$124,400
 RECIPIENT NAME: HOLLY RIDGE, A LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 053-35322 HOLLY RIDGE
 PROJECT ADDRESS: 406 BLDG 6 SINCLAIR STREET, LUMBERTON, NORTH CAROLINA 28358
 PROPERTY CONTACT: DELORIS MCCOY (910) 738-5430
 AMOUNT OF GRANT: \$77,903
 RECIPIENT NAME: COMMERCIAL INVESTMENT GREEN PARK, INC.
 PROJECT NUMBER/NAME: 102-44012 GREEN PARK APARTMENTS
 PROJECT ADDRESS: 1439 N CALHOUN, JUNCTION CITY, KANSAS 66441
 PROPERTY CONTACT: BARBARA GILL (816) 842-1266
 AMOUNT OF GRANT: \$97,400
 RECIPIENT NAME: EASTWIND APARTMENTS
 PROJECT NUMBER/NAME: FL290015001 EASTWIND APARTMENTS
 240 SOMBRERO RD MARATHON, FLORIDA 33050
 PROPERTY CONTACT: NOELIA CARBONELL (305) 296-5621
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: ARLINGTON APARTMENTS, INC.
 PROJECT NUMBER/NAME: 067-35043 BRIARSTONE APARTMENTS
 PROJECT ADDRESS: 3034 LIPSCOMB STREET, MELBOURNE, FLORIDA 32901
 PROPERTY CONTACT: JUDY PARKER (407) 876-2427
 AMOUNT OF GRANT: \$42,200
 RECIPIENT NAME: WESTWICK II LIMITED
 PROJECT NUMBER/NAME: 065-44004 WESTWICK I & II
 PROJECT ADDRESS: 348 FLAG CHAPEL RD., JACKSON, MISSISSIPPI 39209
 PROPERTY CONTACT: DORIS MURRAY (601) 922-8247
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: JONES WALKER PALM GARDENS JOINT VENTURE
 PROJECT NUMBER/NAME: 066-35038 JAMES WALKER PALM GARDENS
 PROJECT ADDRESS: 2909 BLOUNT ST., FT. MYERS, FLORIDA 33901
 PROPERTY CONTACT: LINDA STEELE (813) 334-7305
 AMOUNT OF GRANT: \$102,736
 RECIPIENT NAME: ROYAL ARMS APARTMENTS
 PROJECT NUMBER/NAME: TN40H112007 ROYAL ARMS APARTMENTS
 1580 NORTH ROYAL ST JACKSON, TENNESSEE 38301
 PROPERTY CONTACT: CHRISTINE REED (615) 297-8281

AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: NATIONAL HOUSING PARTNERSHIP
 PROJECT NUMBER/NAME: 061-44169 GREATER MOUNT CALVARY APTS.
 PROJECT ADDRESS: 259 RICHARDSON ST., ATLANTA, GEORGIA 30312
 PROPERTY CONTACT: ANITA HALE (404) 524-0286
 AMOUNT OF GRANT: \$96,138
 RECIPIENT NAME: HURBELL II, LIMITED PARTNERSHIP, ALP
 PROJECT NUMBER/NAME: 054-44049 ANDERSON GARDENS
 PROJECT ADDRESS: 110 HOWARD LANE, ANDERSON, SOUTH CAROLINA 29621
 PROPERTY CONTACT: ANTONIO ALLEN (803) 226-2475
 AMOUNT OF GRANT: \$125,000
BUFFALO OFFICE
 RECIPIENT NAME: NORTHGATE HOUSING LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 026-55001/55002 NORTHGATE/GREENFIELD APTS.
 PROJECT ADDRESS: 275 NORTHGATE ROAD, BURLINGTON, VERMONT 05401
 PROPERTY CONTACT: SUSI TAYLOR (802) 658-2744
 AMOUNT OF GRANT: \$124,278
 RECIPIENT NAME: PROVIDENCE BUILDING SANITARY EDUCATION ASSN
 PROJECT NUMBER/NAME: 016-55003 WIGGIN VILLAGE
 PROJECT ADDRESS: 207 CRANSTON ST., PROVIDENCE, RHODE ISLAND
 PROPERTY CONTACT: JACQUELYN MCDONALD (508) 996-0449
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: BERMUDA RUN LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 051-35267 BERMUDA RUN APTS PHASE I
 PROJECT ADDRESS: 2700-2720 MARTINGALE RD/15101-15105 LORIMER RD., COLONIAL HEIGHTS, VIRGINIA 23834
 PROPERTY CONTACT: SARAH SALESBEE (804) 520-4277
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: CAROL A. MASON, BERMUDA RUN II LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 051-35316 BERMUDA RUN APTS PHASE II
 PROJECT ADDRESS: 2609 (2600-2608) MANGOWOOD DR., COLONIAL HEIGHTS, VIRGINIA 23834
 PROPERTY CONTACT: SARAH SALESBEE (804) 520-4277
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: GREENWILLOW ASSOCIATES LIMITED PARTNERSHIP
 PROJECT NUMBER/NAME: 052-44153 GREENWILLOW MANOR APTS.

PROJECT ADDRESS: 900-920 PENNSYLVANIA AVE., BALTIMORE, MARYLAND 21201
 PROPERTY CONTACT: EDGEWOOD MGT (301) 654-9110/LARRY DAVIS (410) 728-6100
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: ELLIOT BERNOLD, PRES, EDGEWOOD MANAGEMENT CORPORATION
 PROJECT NUMBER/NAME: 052-44197 WOODLAND STREET APTS.
 PROJECT ADDRESS: 1300-1510 EVEN PENNSYLVANIA AVE/1501-1513&1/2 ARGYLE AVE., BALTIMORE, MARYLAND 21201
 PROPERTY CONTACT: EDGEWOOD MGT (301) 654-9110/LARRY DAVIS (410) 728-6100
 AMOUNT OF GRANT: \$125,000
 RECIPIENT NAME: NATIONAL HOUSING PARTNERSHIP
 PROJECT NUMBER/NAME: 034-44171 SHERMAN HILLS APARTMENTS
 PROJECT ADDRESS: 300 PARKVIEW CIRCLE, WILKES-BARRE, PENNSYLVANIA 18702
 PROPERTY CONTACT: DARLENE LAUMEYER (717) 823-5124
 AMOUNT OF GRANT: \$49,175
 RECIPIENT NAME: HOUSING AND NEIGHBORHOOD DEVELOPMENT SERVICES
 PROJECT NUMBER/NAME: 033-35020 FIRST ERIE BETTER HOUSING EAST
 PROJECT ADDRESS: 16TH & HOLLAND STS., ERIE, PENNSYLVANIA 16503
 PROPERTY CONTACT: CHARLES SCALISE/JENNIFER MARTIN (814) 459-1047
 AMOUNT OF GRANT: \$29,944
 RECIPIENT NAME: HOUSING AND NEIGHBORHOOD DEVELOPMENT SERVICES
 PROJECT NUMBER/NAME: 033-44098 FIRST ERIE BETTER HOUSING WEST
 PROJECT ADDRESS: 16TH & HOLLAND STS., ERIE, PENNSYLVANIA 16503
 PROPERTY CONTACT: CHARLES SCALISE/JENNIFER MARTIN (814) 459-1047
 AMOUNT OF GRANT: \$29,944
 RECIPIENT NAME: HOUSING AND NEIGHBORHOOD DEVELOPMENT SERVICES
 PROJECT NUMBER/NAME: 033-35008 FIRST ERIE BETTER HOUSING OLD
 PROJECT ADDRESS: 16TH & HOLLAND STS., ERIE, PENNSYLVANIA 16503
 PROPERTY CONTACT: CHARLES SCALISE/JENNIFER MARTIN (814) 459-1047
 AMOUNT OF GRANT: \$17,967
 RECIPIENT NAME: CAPITOL GREEN HOUSING CORPORATION

PROJECT NUMBER/NAME:
DE26H004002 CAPITOL GREEN
APTS.
479 RIVER ROAD
DOVER, DELAWARE 19901
PROPERTY CONTACT: WANDA L.
RHODES (302) 629-8751/629-8580
AMOUNT OF GRANT: \$20,595
RECIPIENT NAME: HEWES MEWS
ASSOCIATES
PROJECT NUMBER/NAME: 012-57124
HEWES MEWS
PROJECT ADDRESS: 393 S 3 ST.,
BROOKLYN, NEW YORK 11106-4928
PROPERTY CONTACT: ARMONDO
GUZMAN (718) 983-0610
AMOUNT OF GRANT: \$124,980
RECIPIENT NAME: JACKSON
TERRACE ASSOCIATES
PROJECT NUMBER/NAME: 012-35088
JACKSON TERRACE
PROJECT ADDRESS: 100 TERRACE
AV., HEMPSTEAD, NEW YORK
11550
PROPERTY CONTACT: COSTEN
HARGETT (516) 292-0404
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: 236-1
ASSOCIATES
PROJECT NUMBER/NAME: 012-
07SLA, 909SLA, 10SLA, 11SLA
355 SOUTH 2ND STREET
BROOKLYN, NEW YORK 11211
PROPERTY CONTACT: HUNTER
CUSHING (718) 274-5000
AMOUNT OF GRANT: \$124,9500
RECIPIENT NAME: DEVELOPMENT
ASSOCIATES (BUFF)
PROJECT NUMBER/NAME: 01202SLA
269 SOUTH SECOND STREET
(BUFF)
269 SOUTH 1ST STREET
BROOKLYN, NEW YORK 11106-4928
PROPERTY CONTACT: HUNTER
CUSHING (718) 274-5000
AMOUNT OF GRANT: \$122,247
RECIPIENT NAME: LAMBERT HOUSES
REDEVELOPMENT COMPANY
PROJECT NUMBER/NAME: 012-55250
LAMBERT HOUSE EAST
PROJECT ADDRESS: 1046-50
E180&1075-7 E179, BRONX, NEW
YORK 10460
PROPERTY CONTACT: ROBERT
PINCUS (212) 243-9090 X2040
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: LAMBERT HOUSES
REDEVELOPMENT COMPANY
PROJECT NUMBER/NAME: 012-55125
LAMBERT HOUSE NORTH
PROJECT ADDRESS: 2123 BOSTON
RD-1016BXPBS, BRONX, NEW
YORK 10460
PROPERTY CONTACT: ROBERT
PINCUS (212) 243-9090 X2040
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: LAMBERT HOUSES
REDEVELOPMENT COMPANY
PROJECT NUMBER/NAME: 012-55240
LAMBERT HOUSE SOUTH

PROJECT ADDRESS: 997-99 E179&986-
96 E 180, BRONX, NEW YORK 10460
PROPERTY CONTACT: ROBERT
PINCUS (212) 243-9090 X2040
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: FOX HILLS
ASSOCIATES
PROJECT NUMBER/NAME: 012-55001
FOX HILLS APARTMENTS
PROJECT ADDRESS: 320/350
VANDERBILT AVE., STATEN
ISLAND, NEW YORK 10304
PROPERTY CONTACT: INGRID
CUNNINGHAM (718) 273-7311
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: LEVITT-SOBOL
PARTNERSHIP
PROJECT NUMBER/NAME:
NJ39H085065 BRIGANTINE HOMES
1062 BRIGANTINE BLVD
ATLANTIC CITY, NEW JERSEY 08401
PROPERTY CONTACT: DENNIS
BASSFORD (609) 344-7069
AMOUNT OF GRANT: \$107,300
RECIPIENT NAME: NIA ASSOCIATES
PROJECT NUMBER/NAME:
NJ39H085129 NIA APARTMENTS
130 PAMPHYLIA AVE/BLDG 18
BRIDGETON, NEW JERSEY 08302
PROPERTY CONTACT: ROSE HARPER
(609) 451-0116
AMOUNT OF GRANT: \$123,800
RECIPIENT NAME: LEVITT-SOBOL
PARTNERSHIP
PROJECT NUMBER/NAME: 035-35001
TOWNHOUSE TERRACE EAST II
PROJECT ADDRESS: 925 CASPIAN
AVENUE, ATLANTIC CITY, NEW
JERSEY 08401
PROPERTY CONTACT: EDDY
STODDARD (609) 347-7174
AMOUNT OF GRANT: \$97,100
RECIPIENT NAME: LEVITT-SOBOL
PARTNERSHIP
PROJECT NUMBER/NAME: 035-44004
ATLANTIC VILLAS
PROJECT ADDRESS: 818K NORTH
MARYLAND AVE., ATLANTIC CITY,
NEW JERSEY 08401
PROPERTY CONTACT: DENISE
HUBBARD (609) 347-9210
AMOUNT OF GRANT: \$124,365
RECIPIENT NAME: LEVITT-SOBOL
PARTNERSHIP
PROJECT NUMBER/NAME: 035-55010
TOWNHOUSE TERRACE WEST
PROJECT ADDRESS: 732A NORTH
MARYLAND AVE., ATLANTIC CITY,
NEW JERSEY 08401
PROPERTY CONTACT: EDDY
STODDARD (609) 347-7174
AMOUNT OF GRANT: \$124,000
RECIPIENT NAME: HIGH PARK
GARDENS COOPERATIVE CORP.
PROJECT NUMBER/NAME: 031-55009
HIGH PARK GARDENS I
PROJECT ADDRESS: 108 SPRUCE
STREET, NEWARK, NEW JERSEY
07108

PROPERTY CONTACT: BLONNIE
WATSON (201) 623-3155
AMOUNT OF GRANT: \$120,535
RECIPIENT NAME: HIGH PARK
GARDENS COOPERATIVE CORP.
PROJECT NUMBER/NAME: 031-55010
HIGH PARK GARDENS II
PROJECT ADDRESS: 108 SPRUCE
STREET, NEWARK, NEW JERSEY
07108
PROPERTY CONTACT: BLONNIE
WATSON (201) 623-3155
AMOUNT OF GRANT: \$120,535
RECIPIENT NAME: BRICK TOWERS
ASSOCIATES, L.P.
PROJECT NUMBER/NAME: 031-94002
BRICK TOWERS
PROJECT ADDRESS: 685 HIGH ST/83
MILFORD, NEWARK, NEW JERSEY
07104
PROPERTY CONTACT: MEIR HERTZ
(908) 905-8588
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: MADISON PARK
HOUSING CORPORATION
PROJECT NUMBER/NAME: 023-35245
MADISON PARK VILLAGE
PROJECT ADDRESS: 122 DEWITT DR +
SHAWMUT AVE., ROXBURY,
MASSACHUSETTS 02120
PROPERTY CONTACT: DIANNA J.
KELLY (617) 449-7887/(617) 445-
8338
AMOUNT OF GRANT: \$124,980
RECIPIENT NAME: WAYNE APTS.
PROJECT LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 023-12007
WAYNE APARTMENTS
PROJECT ADDRESS: 30-58 FRANKLIN
HILL AVE+SCATTERED SITES,
ROXBURY, MASSACHUSETTS
02119
PROPERTY CONTACT: LYNN
WHIPPLE (617) 445-8117
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: HARBOR POINT
APARTMENTS COMPANY
PROJECT NUMBER/NAME: 023-36602
HARBOR POINT APARTMENTS
PROJECT ADDRESS: ONE NORTH
POINT DRIVE, DORCHESTER,
MASSACHUSETTS 02125
PROPERTY CONTACT: ETTA
JOHNSON (617) 288-5701
AMOUNT OF GRANT: \$124,920
RECIPIENT NAME: URBAN EDGE
HOUSING CORPORATION
PROJECT NUMBER/NAME: 023-55168
JAMAICA PLAIN APARTMENTS
PROJECT ADDRESS: 620 CENTRE
STREET, ROXBURY,
MASSACHUSETTS 02119
PROPERTY CONTACT: LEROY
STODDARD (617) 288-5701
AMOUNT OF GRANT: \$125,000
RECIPIENT NAME: EASTGATE
APARTMENTS ASSOCIATES
PROJECT NUMBER/NAME:
MA06H058107 BAY MEADOW
APTS.

100 BAY MEADOW ROAD
SPRINGFIELD, MASSACHUSETTS
01109
PROPERTY CONTACT: PAULA HATCH
(413) 733-3316
AMOUNT OF GRANT: \$92,259
RECIPIENT NAME: VILLA NUEVA
VISTA ASSOCIATES
PROJECT NUMBER/NAME: 023-35253
VILLA NUEVA VISTA/
CUMBERLAND VILLAGE
PROJECT ADDRESS: 36 CUMBERLAND
STREET, SPRINGFIELD,
MASSACHUSETTS 01107
PROPERTY CONTACT: SHARON
STARINOVICH (413) 737-7748
AMOUNT OF GRANT: \$112,137
RECIPIENT NAME: CHESTNUT PARK
ASSOCIATES
PROJECT NUMBER/NAME: 023-126N
CHESTNUT STREET APARTMENTS
68 HARRISON AVENUE
SPRINGFIELD, MASSACHUSETTS
01103
PROPERTY CONTACT: STEVEN
DONATO (413) 731-0900
AMOUNT OF GRANT: \$118,514
RECIPIENT NAME: COBBET HILL
ASSOCIATES
PROJECT NUMBER/NAME:
MA06K023001 COBBET HILL
APARTMENTS
498 ESSEX ST/SUITE 125
LYNN, MASSACHUSETTS 01902
PROPERTY CONTACT: ALISON
LEVINS (617) 581-2180
AMOUNT OF GRANT: \$72,219
RECIPIENT NAME: JARVIS HEIGHTS
APARTMENTS ASSOCIATES
PROJECT NUMBER/NAME: 023-045NI
JARVIS HEIGHTS APARTMENTS
GERARD WAY
HOLYOKE, MASSACHUSETTS 01040
PROPERTY CONTACT: ANN BEREZIN
(413) 539-9500
AMOUNT OF GRANT: \$47,000
RECIPIENT NAME: RIVERPLACE
APARTMENTS LTD. PARTNERSHIP
PROJECT NUMBER/NAME:
MA06K005005 RIVERPLACE
APARTMENTS
69 SUFFOLK ST
HOLYOKE, MASSACHUSETTS 01040
PROPERTY CONTACT: ANN BEREZIN
(413) 539-9500
AMOUNT OF GRANT: \$47,000
RECIPIENT NAME: SARGEANT WEST
APARTMENTS
PROJECT NUMBER/NAME: 023-44199
SARGEANT WEST APARTMENTS
PROJECT ADDRESS: 151 WEST ST.,
HOLYOKE, MASSACHUSETTS
01040
PROPERTY CONTACT: ANN BEREZIN
(413) 539-9500
AMOUNT OF GRANT: \$47,000
RECIPIENT NAME: SHORELINE
LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 014-01NI
SHORELINE I

200 NIAGARA STREET
BUFFALO, NEW YORK 14201
PROPERTY CONTACT: PEARL JONES
(716) 852-2027
AMOUNT OF GRANT: \$121,080
RECIPIENT NAME: WATERFRONT
LIMITED PARTNERSHIP
PROJECT NUMBER/NAME: 014-02NI
SHORELINE II
200 NIAGARA STREET
BUFFALO, NEW YORK 14201
PROPERTY CONTACT: PEARL JONES
(716) 852-2027
AMOUNT OF GRANT: \$121,080
RECIPIENT NAME: ONODAGA
HILLTOP HOMES C/O M.B. GROUP
PROJECT NUMBER/NAME:
NY06A004001 ROLLING GREEN
ESTATES
2005 EAST FAYETTE ST
SYRACUSE, NEW YORK 13224
PROPERTY CONTACT: DARNELL
MOODY (315) 475-5027
AMOUNT OF GRANT: \$5,000
[FR Doc. 96-21899 Filed 8-27-96; 8:45 am]
BILLING CODE 4210-27-P

[Docket No. FR-4052-N-03]

**Office of the Assistant Secretary for
Housing—Federal Housing
Commissioner; Notice of Amended
Allocation for Pittsburgh HUD Office
Under the Fiscal Year 1996 Notice of
Funding Availability (NOFA) for
Supportive Housing for the Elderly**

AGENCY: Office of the Assistant
Secretary for Housing—Federal Housing
Commissioner, HUD.

ACTION: Notice of amended allocation of
funds for the Pittsburgh HUD Office for
Fiscal Year (FY) 1996.

SUMMARY: This notice announces
amended allocation amounts for the
Pittsburgh HUD Office under the Fiscal
Year (FY) 1996 notice of funding
availability (NOFA) for the Section 202
Program of Supportive Housing for the
Elderly. This NOFA was published on
July 8, 1996.

DATES: This notice does not change the
deadline date for receipt of applications,
as originally announced in the NOFA
published on July 8, 1996 (61 FR
35866), and as extended by a notice
published on August 9, 1996 (61 FR
41647). The deadline for receipt of
applications is 4:00 p.m. local time on
September 6, 1996.

ADDRESSES: This notice does not change
the information regarding where to
submit applications that was originally
announced in the NOFA published on
July 8, 1996 (61 FR 35866). Applications
must be delivered to the Director of the
Multifamily Housing Division in the
HUD Office for your jurisdiction. A

listing of HUD Offices, their addresses,
and telephone numbers was attached as
appendix A to the July 8, 1996 NOFA.

FOR FURTHER INFORMATION CONTACT: The
HUD Office for your jurisdiction, as
listed in appendix A to the July 8, 1996
NOFA (61 FR 35866).

SUPPLEMENTARY INFORMATION: On July 8,
1996 (61 FR 35866), HUD published a
notice announcing the availability of
Fiscal Year (FY) 1996 funding for the
Section 202 Program of Supportive
Housing for the Elderly. On August 9,
1996 (61 FR 41647), HUD published a
notice extending the application due
date to September 6, 1996.

As a result of a HUD administrative
error, it has become necessary to fund
the Alverno project in Millvale,
Pennsylvania from the Fiscal Year 1996
allocation to the Pittsburgh,
Pennsylvania HUD Office. Therefore,
the FY 1996 allocation for the Pittsburgh
HUD Office for metropolitan capital
advances for Supportive Housing for the
Elderly is reduced from \$6,927,904 to
\$3,346,804, and the number of units is
reduced from 103 units to 50 units. This
notice does not change the allocation for
nonmetropolitan capital advances for
the Pittsburgh HUD Office. Therefore,
the total capital advance allocation for
the Pittsburgh HUD Office is \$4,807,686
for 72 units.

This notice does not change any of the
other allocation amounts provided in
the July 8, 1996 NOFA for Supportive
Housing for the Elderly (61 FR 35866).

Dated: August 23, 1996.

Stephanie A. Smith,
*General Deputy Assistant Secretary for
Housing—Federal Housing Commissioner*
[FR Doc. 96-22060 Filed 8-26-96; 11:52 am]
BILLING CODE 4210-27-P

DEPARTMENT OF THE INTERIOR

**Western Water Policy Review Advisory
Commission Meeting**

AGENCY: Department of the Interior.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the Federal
Advisory Committee Act, notice is
hereby given that the Western Water
Policy Review Advisory Commission
(Commission), established by the
Secretary of the Interior under the
Reclamation Projects Authorization and
Adjustment Act of 1992, will hold a
public audio teleconference meeting.
This meeting will exclusively address
the selection of Mr. Donald Glaser to
serve as the Commission's Executive
Director.

Due to the specific nature of the
agenda, time for public presentations is

not scheduled. Members of the public may submit written comments to the address listed below.

DATES: Teleconference meeting will be Thursday, September 12, 1996, from 3:00 p.m. to 3:30 p.m. Eastern Daylight Time.

ADDRESSES: Written statements may be provided to the following address: Western Water Policy Review Office, D-5001; P.O. Box 25007; Denver, CO 80225-0007.

FOR FURTHER INFORMATION CONTACT:

Members of the public wishing to listen to this teleconference should contact the Commission Office by telephone, 303-236-6211, or fax, 303-236-4286, by no later than September 10, 1996.

Participants will be asked to provide a telephone number where they will be contacted by the conference call operator prior to the beginning of the meeting.

Dated: August 21, 1996.

Larry Schulz,
Administrative Officer.

[FR Doc. 96-21876 Filed 8-27-96; 8:45 am]

BILLING CODE 4310-94-M

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, et seq.):

Applicant: Dennis G. Bailey, Pelham, NH, PRT-818420.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygarcus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Jimmie Rosenbruch, Santa Clara, UT, PRT-818660.

The applicant requests a permit to import a sport-hunted cheetah (*Acinonyx jubatus*) from Namibia for the purpose of enhancement of the survival of the species.

Applicant: Jerome Bofferding, Maple Grove, MN, PRT-818684.

The applicant requests a permit to import a sport-hunted cheetah (*Acinonyx jubatus*) from Namibia for the purpose of enhancement of the survival of the species.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management

Authority, 4401 North Fairfax Drive, Room 430, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 430, Arlington, Virginia 22203. Phone: (703/358-2104); FAX: (703/358-2281).

Dated: August 23, 1996.

Mary Ellen Amtower,
Acting Chief Branch of Permits, Office of Management Authority.

[FR Doc. 96-21974 Filed 8-27-96; 8:45 am]

BILLING CODE 4310-55-U

Species Being Considered for Amendments to the Appendices to the Convention on International Trade in Endangered Species of Wild Fauna and Flora; Request for Information

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) regulates international trade in certain animal and plant species, which are listed in the appendices of this treaty. The United States, as a Party to CITES, may propose amendments to the appendices for consideration by the other Parties.

This notice invites comments and information from the public on species that have been suggested as candidates for U.S. proposals to amend Appendix I or II at the tenth regular meeting of the Conference of the Parties (COP10, June 9-20, 1997, Harare, Zimbabwe) and which the U.S. Fish and Wildlife Service (Service) believes deserve further review. For reasons explained below, the Service has opted against consideration of other recommendations by the public for species listings and will reconsider these only under circumstances presented by new scientific data or studies.

A separate, concurrent Federal Register notice presents COP10 provisional agenda topics, and announces draft resolutions or other documents that the United States is considering for submission for consideration by the Parties at COP10.

DATES: The Service will consider all comments received by October 11, 1996, on species proposals described in this notice. A public meeting on these proposals, and on proposed resolutions and agenda items for COP10, will be held from 2:00 to 4:00 p.m. on October 3, 1996, Room 200, Arlington Square Building, 4401 North Fairfax Drive, Arlington, Virginia (see separate Federal Register notice).

ADDRESSES: Please send correspondence concerning this notice to Chief, Office of Scientific Authority; 4401 North Fairfax Drive, Room 750; Arlington, Virginia 22203. Fax number 703-358-2276. Comments and other information received will be available for public inspection by appointment, from 8 a.m. to 4 p.m. Monday through Friday, at the above address.

FOR FURTHER INFORMATION CONTACT: Dr. Marshall A. Howe, Office of Scientific Authority, at the above address, telephone 703-358-1708.

SUPPLEMENTARY INFORMATION: CITES regulates import, export, re-export, and introduction from the sea of certain animal and plant species. Species for which trade is controlled are included in one of three appendices. Appendix I includes species threatened with extinction that are or may be affected by international trade. Appendix II includes species that, although not necessarily now threatened with extinction, may become so unless the trade is strictly controlled. It also lists species that must be subject to regulation in order that trade in other currently or potentially threatened species may be brought under effective control (e.g., because of difficulty in distinguishing specimens of currently or potentially threatened species from those of other species). Appendix III includes species that any Party country identifies as being subject to regulation within its jurisdiction for purposes of preventing or restricting exploitation, and for which it needs the cooperation of other Parties to control trade.

In a March 1, 1996, Federal Register notice (61 FR 8019), the Service requested public recommendations or draft proposals to amend Appendix I or II that the Service might consider proposing on behalf of the United States at COP10. That notice described the provisions of CITES for listing species in the appendices and set forth information requirements for proposals, based on new listing criteria adopted by the Parties at COP9. The present notice announces the recommendations and proposals on taxa received, explains why the Service does not intend to consider certain recommendations or proposals, and describes those that will

receive further consideration, prior to a decision as to whether to submit any of these proposals to the CITES Secretariat by the January 10, 1997, deadline. A separate but concurrent Federal Register notice addresses the COP10 provisional agenda, and proposed resolutions and agenda items being considered by the United States for COP10; that notice also announces the public meeting on all these topics to be held in early October 1996 (see **DATES** above).

The Service received recommendations or proposals on taxa from the following: Defenders of Wildlife (DOW), Environmental Investigation Agency (EIA), Humane Society of the United States (HSUS), International Wildlife Coalition (IWC), North American Falconers Association (NAFA), National Trappers Association (NTA), New York Turtle and Tortoise Society (NYTTS), Ocean Wildlife Campaign (OWC), a consortium of the National Audubon Society, National Coalition for Marine Conservation, National Resources Defense Council, New England Aquarium, Wildlife Conservation Society, and World Wildlife Fund-US, Oregon Natural Resources Council (ONRC), Safari Club International (SCI), World Wildlife Fund-US (WWF), two members of the Northeast Pacific Region of the IUCN Shark Specialist Group, and several unaffiliated individuals, by the comment deadline of April 30, 1996. These proponents recommended amending (adding to, deleting from, or transferring between) the appendices for 29 different taxa (species or genera). In addition, DOW, EIA, IWC, and NYTTS requested a review of the status of Appendix II parrots (Psittaciformes) and proposed the uplisting of any of those species qualifying for Appendix I. WWF proposed consideration of certain Southeast Asia unlisted songbird species, based on a trade analysis. DOW and OWC, respectively, proposed consideration of shark species in general and shark species of the family Carcharhinidae, specifically. In addition, the Service is considering (1) delisting four species of freshwater mussels presently in Appendix II, and (2) cosponsoring with Germany a proposal for including most or all populations of urial sheep (*Ovis vignei*) in Appendix I, depending on the results of further review by the Service.

All proposals and recommendations received have been reviewed in the context of the new CITES listing criteria adopted by the Parties at COP9 (Resolution Conf. 9.24). This resolution, available from the Service on request at the above address, presents detailed

biological and trade criteria for listing and delisting, and for transferring listed species between appendices. Emphasis is placed on the principle that scientific uncertainty should not be used as a reason for failing to act in the best interest of the conservation of species affected or potentially affected by international trade. The following sections present the Service's decisions on which proposals it does not plan to submit, and which ones remain under consideration and for which additional information and comment is sought.

Proposals That the Service Does Not Plan to Submit

DOW and IWC raised concerns about whether a mechanism was in place to transfer the South African population of the southern white rhinoceros (*Ceratotherium simum simum*) to Appendix I, if there existed any significant conservation problems resulting from its annotated downlisting at COP9. Absent such a mechanism, they recommended that the United States prepare a proposal to transfer the population back to Appendix I, if no other Party were preparing such a proposal.

The transfer of the South African population to Appendix II at COP9 was annotated to restrict trade to live animals "to appropriate destinations" and sport-hunted trophies only. It was agreed by the Parties at COP9 that the downlisting would be reviewed at COP10 to determine if the new listing status was having a detrimental impact on the population. In response to the recommendation from DOW and IWC, the Service contacted the Secretariat and was informed that no "automatic" uplisting mechanism was in place and that the record of the discussion at COP9 did not connote an assumption that an uplisting proposal should be prepared, such as has been done by the depositary government (Switzerland) in the case of populations of Appendix I species transferred to Appendix II subject to quota provisions. The depositary government agreed with the Secretariat's interpretation and indicated it had no plans to prepare such a proposal.

The Service has received no information to suggest that the downlisting at COP9 has resulted in any threats to the South African white rhinoceros population. Furthermore, the Service understands that South Africa is preparing a report on its implementation of the downlisting and that this report will be provided to the Service and submitted to the Parties for their consideration at COP10. This issue is included in the provisional agenda for

COP10 (see item XIV.7 in the Service's concurrent Federal Register notice).

In the unlikely event that a conservation problem arises as a consequence of the downlisting, the Service believes that any substantive concerns can be addressed by South Africa and/or collectively by other Parties, or if appropriate, through the postal-vote process of CITES. Therefore the Service does not intend to pursue this recommendation further.

The NTA recommended that the Service propose removal of the bobcat (*Lynx rufus*), Canadian lynx (*L. canadensis*), and river otter (*Lontra canadensis*) from Appendix II. Each of these species (except the Mexican race of the bobcat *Lynx rufus escuinapae*, which was listed in 1975) was included in Appendix II in 1977 with the listing of the entire cat family, Felidae, and the otter subfamily, Lutrinae. In 1983, the United States and Canada stated their position (recorded in the plenary minutes of COP4) that these three species (excepting the Mexican bobcat) were listed under provisions of CITES Article II(2)(b), i.e., only because of the need to control trade in similar-appearing cat or otter species that are listed because of their population status and vulnerability to trade [Article II(1) or II(2)(a)]. The Service believes that the traded parts of these species, including various portions of the pelts, are sufficiently similar in appearance to those of other species listed under provisions of Article II(2)(a) and Article II(1) to justify continuation of the current listing in Appendix II under provisions of Article II(2)(b).

SCI recommended that the United States submit a proposal clarifying that the listing of the urial sheep (*Ovis vignei*) in Appendix I applies only to one race of the species, *O. v. vignei*. The Service has long considered the taxonomic intent of the original listing to apply only to *O. v. vignei* (with other races unlisted). It is expected that the review of the population status of the entire species currently being conducted by a working group of the CITES Animals Committee, in consultation with the IUCN Caprinae Specialist Group, will clarify the listing(s) appropriate for each race. Germany has offered to submit a proposal based on this analysis and the United States has indicated that it will consider cosponsoring such a proposal. Therefore the Service will not consider advancing the proposal suggested by SCI.

NAFA recommended that the Service propose removal of the North American population of the red-tailed hawk (*Buteo jamaicensis*) and American kestrel (*Falco sparverius*) from

Appendix II. These species were listed on Appendix II in 1979 as part of a listing of most of the order Falconiformes (including almost all hawks, eagles, and falcons). North American populations of the red-tailed hawk and kestrel appear to be healthy and are certainly not threatened by trade. However, delisting of the American kestrel may introduce a trade enforcement problem, because of its similarity of appearance to several other species of kestrels listed in Appendix I. Delisting of either species would also create similarity-of-appearance problems with other populations of the same or related species, which would continue to be listed in Appendix II. For these reasons, the Service does not support this recommendation.

EIA and IWC, supported by DOW and NYTTS, recommended that the Service propose transferring the blue-crowned conure (*Aratinga acuticaudata neoxena*) from Appendix II to Appendix I. DOW further recommended transfer of other species of parrots from Appendix II to I, if appropriate. Regarding the conure, its population consists of 50–60 individuals endemic to the island of Margarita in Venezuela, it is a very poorly marked subspecies, and it is not known at present to be affected by international trade. The Service intends to consult with Venezuelan authorities with respect to the conservation and taxonomic status of this subspecies. Regarding other parrots, the Service believes there are likely species (other than those proposed below) that would qualify for transfer from Appendix II to I. However, the Service presently has no supporting information and no additional information has been submitted.

HSUS, supported by DOW, EIA, IWC, and NYTTS submitted a proposal to list the common snapping turtle (*Chelydra serpentina*) in Appendix II. Common snapping turtles, native to the Americas from Canada to Ecuador, are harvested in large numbers both for food and for the pet trade. Although certain local or regional (e.g., Ontario) populations may have been depleted by overharvest, this species continues to be generally common and widely distributed. Much of the market is domestic. Although international trade involving the United States may be increasing, the Service believes the species does not qualify for listing in Appendix II, given the general abundance of the species throughout most of its range and considering its apparently higher reproductive potential than many other turtle species.

DOW also recommended that the Service should support efforts to bring additional protection to declining

species of corals. The Service acknowledges the many difficulties involved in assuring sustainability of trade in CITES-listed corals. Although not presently considering proposing the listing of additional coral taxa, the Service, in consultation with the National Marine Fisheries Service (NMFS) and TRAFFIC-USA, is participating in the “significant trade” analysis presently being conducted under the auspices of the CITES Animals Committee. The Service plans to propose a resolution at COP10 establishing guidelines for more effective documentation of corals involved in international trade. The Service has also produced coral identification keys and is exploring the possibility of sponsoring coral workshops in cooperation with the NMFS and the Department of State.

The above-listed proposals will be reconsidered for COP10 only if new scientific data warrant. Any change in the Service’s position on these species will be announced in a future Federal Register notice.

Proposals for Which the Service Seeks Additional Information

To determine whether they should be proposed by the United States as amendments to the appendices, the Service solicits additional information or comment on the following proposals or recommendations. Respondents to this notice are encouraged to present their comments in the specific context of the new listing criteria (Resolution Conf. 9.24), indicating where possible the applicability (or lack thereof) of specific elements of the resolution annexes to the recommendation or proposal being addressed.

1. Urial (*Ovis vignei*)

The urial of the central Asian steppes, a species of sheep popular among sport trophy hunters, has been listed on CITES Appendix I since 1975. Due to uncertainty about the taxonomic relationships among populations of this and related sheep species, confusion exists among the Parties as to the precise taxonomic entity intended for protection by the original listing. The history of this situation is described in detail in a January 27, 1994, Federal Register notice (59 FR 3833). In conducting its own analysis, the Service concluded that the original listing applied only to certain populations in India and Pakistan and that other populations are presently unlisted. Import of specimens of *Ovis vignei* into the United States has been guided by this interpretation of the CITES listing.

A working group of the CITES Animals and Nomenclature Committees,

in consultation with the IUCN Caprinae Specialist Group, has been studying this problem and is attempting a fresh assessment of the status of *Ovis vignei* populations (based on the taxon described in the nomenclatural reference for mammals now adopted by the Parties: “Mammal Species of the World,” 2nd Edition, by Wilson and Reeder). On the basis of this assessment, Germany will prepare a listing proposal clarifying the appropriate appendix for each of the populations. Based on information presently available to the working group, it is likely that all populations of the urial will be proposed by Germany for listing in Appendix I. The Service has participated in the working group and is considering the possibility of cosponsoring the proposal prepared by Germany. The Service solicits information bearing on the status of these sheep populations and the merits of cosponsoring the German proposal.

2. Gyrfalcon (*Falco rusticolus*)

NAFA recommended that the Service propose transferring the gyrfalcon from Appendix I to Appendix II and is preparing a proposal in support of this recommendation. The gyrfalcon is circumpolar in distribution, including arctic and subarctic regions of Alaska, Canada, Iceland and Greenland. It was listed in Appendix I by the Parties in 1975 due to concern over threats to raptors in general and because of extraordinarily high prices commanded by the species in trade. Being the largest species of falcon and having a largely white color morph, the gyrfalcon has long been popular among falconers. Although the North American population was transferred to Appendix II in 1981, the Parties adopted a proposal from Denmark at COP5 in 1985 to transfer it back to Appendix I because of concern over illegal trade.

The Service is not aware of any evidence that the North American gyrfalcon population has ever been threatened due to habitat loss, nest-robbing, or trade. Service records indicate that a total of 126 gyrfalcons were legally imported into or exported from the United States from 1990 through June 1996, and there were no seizures of illegally traded specimens during that period. European range States have expressed concern in the past about enforcement problems that could arise if the North American population were downlisted. However, husbandry techniques have been developed for breeding the species in captivity (all but four of the 126 birds mentioned above were captive-bred); and the prices asked now are far lower

than in the past, at least in part because of the availability of captive-bred birds. Therefore, the Service will consider a transfer of the North American population of the gyrfalcon to Appendix II if a substantive proposal is received. In such a case, the Service will consult with Canada and other range States before making a final decision. The Service solicits any information and comment bearing on this downlisting recommendation.

3. Amazon Parrots (*Amazona viridigenalis*, *A. oratrix* and *A. finschi*)

EIA, WWF, IWC, NYTTS, and DOW recommended that the Service propose the green-cheeked (red-crowned) parrot (*Amazona viridigenalis*), a Mexican endemic, for transfer from Appendix II to Appendix I. EIA, IWC, NYTTS, AND, DOW also proposed the same action for the yellow-headed amazon (*A. oratrix*), endemic to Mexico and Belize. In addition, WWF has also recommended the lilac-crowned parrot (*A. finschi*), another Mexican endemic, for transfer from II to I. The first two of these species have experienced severe population declines. The status of the third species is not as clear. Except for limited statutory exemptions, imports into the United States of the first two species have been banned since October 1992 under the Wild Bird Conservation Act. Imports of *A. finschi* have been banned since October 1993. Mexican law prohibits export from Mexico of all native, wild-caught parrots. Between 1990 and 1994, 337 *viridigenalis*, 542 *oratrix*, and 149 *finschi* were confiscated by wildlife law enforcement agents at the U.S.-Mexico border.

Amazona viridigenalis is endemic to riparian forests and deciduous woodlands of Tamaulipas and San Luis Potosi in northeast Mexico. Feral populations have been established in several locations, including Texas. Recent population estimates of only 3,000 to 6,500 birds in the wild represent a severe decline from populations several decades ago. Habitat loss, control as an agricultural pest, and extensive exploitation for the pet trade have all contributed to the decline. Although protected from capture and trade in Mexico since 1982, the level of illegal trade suggested by confiscations is highly significant relative to the estimated population of the species. *Amazona oratrix*, though more widely distributed than the previous species, is restricted to the Atlantic and Pacific lowlands of Mexico and Belize and has also suffered massive population declines (particularly in Mexico) because of habitat loss and the pet trade.

It has long been one of the most popular parrots in international trade.

The level of known, illegal international trade relative to the population status of *A. viridigenalis* and *A. oratrix* indicates that trade is a significant contributor to the precarious status of their populations. The Service believes that Appendix I trade controls would further discourage illegal trade, because of the more stringent permitting requirements and because of the rigorous criteria that captive-breeding facilities for Appendix I species must meet. Both species qualify for transfer to Appendix I under the new listing criteria. More information is needed on the status of *A. finschi* in the wild to clarify whether an Appendix I listing is warranted. The Service is reviewing this situation with Mexico. The Service also understands that Mexican authorities support the listing of *A. viridigenalis* and *A. oratrix* and may prepare listing proposals themselves. In the event this takes place, the Service will consider offering to cosponsor the proposals. The Service solicits any additional information on population status and trade of all three amazon parrots.

4. Straw-headed Bulbul (*Pycnonotus zeylanicus*)

WWF proposed that "southeast Asian songbirds" involved extensively in the pet trade be considered for CITES protection, but did not provide a draft proposal. The Service examined the information contained in the TRAFFIC Southeast Asia report, "Sold for a Song," provided by WWF. Although an extensive trade clearly exists for many Southeast Asian passerines, the Service has not reviewed information on the status of most of these species in the wild. Because such information, in addition to information on trade levels, is desirable in most Appendix II listing proposals, the Service proposes to defer consideration of most of these species until a future time.

However, the Service believes that sufficient information may be available to warrant listing in Appendix II of one species identified in the report, the straw-headed bulbul (*Pycnonotus zeylanicus*). This species has declined or been extirpated from all but the remotest parts of its range in Indonesia by a combination of excessive trapping and habitat destruction. *Birds To Watch 2: The World List of Threatened Birds* states the population has declined over 50 percent in the past 20 years and lists its status as vulnerable. Although the species remains widespread and common in Peninsular Malaysia, it is a popular cagebird and birds are being imported into Indonesia from Malaysia

through Singapore, despite legal protection in Malaysia. Since the species' remaining range in Peninsular Malaysia is smaller than its former range in Sumatra, Kalimantan and Java, trade in this species may cause further population declines unless regulated. The Netherlands is also considering submitting an Appendix II proposal for this species. Cosponsorship will be discussed with the Netherlands if they choose to proceed with a proposal. The Service seeks additional comments and information on proposing the straw-headed bulbul for Appendix II.

5. North American Softshell Turtles (*Apalone* spp.)

HSUS, supported by DOW, EIA, IWC, and NYTTS, prepared a proposal to include the softshell turtle genus *Apalone* in Appendix II. This genus consists of three species of freshwater turtles inhabiting both riverine and stillwater habitats: *A. spinifera*, ranging across most of the United States and northern Mexico, except for the very far West; *A. mutica*, inhabiting the Missouri, Ohio, and Mississippi River drainages south to the Gulf of Mexico and extending to western Florida and central Texas, with an isolated population in New Mexico; and *A. ferox*, ranging through southern South Carolina, Georgia, Florida, and the coastal plain of Alabama. Egg-laying potential of these species appears to be higher than for many species of turtles, with maximum clutch size ranging from 24 in *A. ferox* to 39 in *A. spinifera*, and number of clutches per year ranging from 1–2 in *A. mutica* to 6 in *A. ferox*. Information on population sizes and trends is very limited, but anecdotal evidence suggests declines in some populations of *A. spinifera* and *A. mutica* that have been studied. All species are vulnerable to damming of rivers and to loss of preferred habitats in general. *A. ferox* appears to be more vulnerable to pesticides than other species of turtles. All species are taken for human consumption and some animals enter the pet trade.

Information on volume of catch for commercial trade appears to be available only for Florida, where *A. ferox*, the largest of the three species, seems to be heavily targeted for a trade destined domestically for New York, San Francisco, and Boston in particular. In addition to food, much of the use of these animals appears to be of the ribs and shells as medicinal products in Asian communities. An analysis of trade conducted during the period from July 1, 1990 to June 30, 1991 showed 27,494 sold in Florida or to dealers in other States. There appear to be no

comparable data for other States or for any species outside of Florida. Based on Service export records identified to genus only, the volume of international trade in the genus is expanding significantly. The number of live exports was reported as 5,517 in 1992, 13,524 in 1993, and 34,467 in 1994. There was no clear trade pattern for meat or parts.

Although the Service is concerned about the increasing volume of international export of *Apalone* spp. and possible expansion of foreign markets, the proposal does not make a convincing case for a likely impact on populations. However, the Service recognizes the importance of leaving the option for an Appendix II proposal open if new information can be brought to bear. In this regard, the Service solicits additional information on populations of any *Apalone* species and more specific information on both domestic and international trends in trade, including the geographic origins of animals in trade. Mexico is also being consulted on the two species in the genus whose ranges include Mexico.

6. Map Turtles (*Graptemys* spp.)

HSUS, supported by DOW, EIA, IWC, and NYTTS, prepared a proposal to include the twelve species of map turtles, genus *Graptemys*, in Appendix II and requested the Service to consider proposing it at COP10. This genus includes the following species: *Graptemys geographica*, *barbouri*, *pulchra*, *ernsti*, *gibbonsi*, *caglei*, *pseudogeographica*, *ouachitensis*, *versa*, *oculifera*, *flavimaculata*, and *nigrinoda*. While most species are confined to portions of the southeastern United States or Texas (*G. versa*), *G. geographica* occurs throughout most of the eastern half of the United States and southeastern Canada; *G. pseudogeographica* ranges through the Missouri and Mississippi River drainages; and *G. ouachitensis* overlaps extensively with the latter but extends farther east and west. *Grapttemys flavimaculata* and *G. oculifera* are the most geographically restricted species, occurring only in limited river systems in Mississippi (and Louisiana—*G. oculifera* only). Both are listed as threatened under the Endangered Species Act (ESA). *Grapttemys nigrinoda* is classified as endangered under Mississippi State law and *G. barbouri* is considered vulnerable to extirpation in Florida. A variety of less severe State restrictions on collecting or commercial use apply to various species. All map turtles inhabit freshwater systems, but habitat preferences vary among species.

Most prefer streams or rivers with strong currents.

As with most turtle species, population data are very limited and equivocal, except for the species already considered endangered or threatened. Biologists who have studied seven of the species believe that populations have generally declined. At least four species are very popular in the pet trade, because of their bright colors: *G. barbouri*, *flavimaculata*, *pseudogeographica*, and *pulchra*. Data from Service's wildlife enforcement records suggest that international trade is substantial and may be increasing significantly. Exports of *Grapttemys* spp. totalled 8,695 in 1991, 20,378 in 1992, and 37,233 in 1993.

As with softshell turtles, the Service is concerned about the level of international trade. However, most *Grapttemys* species have more restricted distributions than *Apalone* species; and empirical evidence of population problems exists for several species, such as those listed under provisions of the ESA. The Service believes that the combination of population vulnerability and international trade may qualify at least *Grapttemys* species for inclusion in Appendix II under provisions on Article II(2)(a). Other members of the genus might be appropriately listed under provisions of Article II(2)(b), due to similarity of appearance. Some of the species are extremely difficult to distinguish from one another on the basis of physical appearance. The Service solicits additional information and comment on this proposed listing.

7. Alligator Snapping Turtle (*Macrolemys temminckii*)

HSUS, supported by DOW, EIA, IWC, and NYTTS, submitted a proposal to include the alligator snapping turtle (*Macrolemys temminckii*) in Appendix II and requested the Service to consider proposing it at COP10. The alligator snapping turtle, the largest freshwater turtle in North America, inhabits most river systems emptying into the Gulf of Mexico, including the Mississippi River as far north as Illinois. It also makes use of bodies of still water associated with river systems. Only one clutch of eggs is produced annually. Clutch size ranges from 9 to 52 eggs, with a mean of 25. From mostly anecdotal evidence, especially from turtle trappers, it is evident that the species has declined severely throughout much of its range, particularly in Georgia and Louisiana. The primary agents of population decline appear to be degradation and damming of river systems and widespread commercial harvest for its

meat, which is marketed both domestically and internationally.

This species in the past has been the source of turtle meat in a national brand of soups and continues to be harvested both for personal use and commercially for human consumption on a locally large scale. It has been reported that Louisiana, because of depleted State populations, now imports much of its alligator snapper meat from surrounding States. A major source was Arkansas until commercial harvest was prohibited there in 1993. Louisiana now lists the species as a species of special concern. In the southeastern States comprising the bulk of the species' range, it appears that only Mississippi and Louisiana continue to permit commercial harvest. It is listed as rare, threatened, or endangered in many of the States on the periphery of the range, and in Georgia. There is a smaller market for pets (mainly smaller animals), and freeze-dried hatchlings are sold internationally as curios. Service wildlife enforcement records show an increase in the export of live turtles from 290 in 1989 to 4,477 in 1994, primarily to markets in Japan, Hong Kong, and Western Europe. There are also records of a much smaller trade in skins and skulls.

The Service is concerned about the status of this species. The reported level of international, commercial trade is cause for concern in light of the depleted population status of the species overall. As with most species not protected by federal law, export records in the wildlife enforcement database represent minimum estimates, as exports may not always be recorded at the species level. The Service seeks additional information bearing on the proposed listing of the alligator snapping turtle in Appendix II.

8. Gila Monster and Beaded Lizard (*Heloderma* spp.)

HSUS, supported by DOW, EIA, IWC, and NYTTS, submitted a proposal to transfer the Gila monster (*Heloderma suspectum*) and the beaded lizard (*H. horridum*) from Appendix II to Appendix I and requested the Service to consider submitting it at COP10. These unique lizards known for their poisonous bites are endemic to xeric habitats of Mexico and the southwestern United States. The Gila monster occurs from southwestern Utah and southern Nevada and California south through Arizona, southwestern New Mexico, and into northern Mexico. The beaded lizard is patchily distributed through Mexico from Sonora to northern Chiapas, and one isolated race occurs in eastern Guatemala. While the Gila monster prefers arid and semi-arid

gravelly and sandy habitats with some shrubs, the beaded lizard is more partial to tropical dry forests and is partly arboreal. The Gila monster has a clutch size of 2 to 12 eggs and may not breed every year; the beaded lizard is known to produce 15 eggs per clutch in captivity and probably has a one-year cycle.

Populations of both species are believed to be declining due to habitat degradation and local depletion by collectors for the pet trade and roadside zoos. Because both species are very secretive, however, there are no reliable data on populations in the wild. The prices of both species in the pet trade have risen from a few dollars in the 1930's to over \$1,000 each and up to \$2,800 for a pair today, suggesting both rarity and demand. Commercial collection from the wild is largely prohibited in all range States in the United States and by Mexican law. Although specimens have been bred in captivity, concern has been expressed over the potential and likelihood of illegal laundering of wild animals into the captive-bred trade. Reported international exports from the United States, as well as worldwide trade reported to CITES (1989–1993) have been very low, with annual exports of both species from the United States being fewer than 10 (except 52 in 1992) and annual worldwide figures averaging only 12 for *H. horridum* and 5 for *suspectum*. There is evidence, however, of a significant illegal trade, both within the United States, between the United States and Mexico, and otherwise internationally. Mexican authorities are in the process of considering whether *Heloderma* qualifies for inclusion in Appendix I. The Service continues to consider this proposal and solicits comments and new information.

9. Sail-fin Lizards (*Hydrosaurus* spp., *Hypsilurus* spp., and *Physignathus lesueurii*)

Gregory Watkins-Colwell, a biologist and expert on the genus *Hydrosaurus*, submitted a proposal for the inclusion of the two species in this genus (*H. amboinensis* = *weberi* and *H. pustulatus*) in Appendix II under provisions of Article II(2)(a), and the genus *Hypsilurus* (incorporating 11 species) and the species *Physignathus lesueurii* in Appendix II under provisions of Article II(2)(b) (similarity of appearance), and asked the Service to consider submitting the proposal to COP10. These species, also commonly known as sail lizards, sail-tail dragons, and water dragons, are native to the southwestern Pacific region, including Australia. *Hydrosaurus* lizards are

endemic to the Philippines and eastern Indonesia, including western Irian Jaya. The species of *Hypsilurus* are *H. boydii*, *spinipes*, *nigrigularis*, *dilophus*, *auritus*, *binotatus*, *godeffroyi*, *geelvinkianus*, *modestus*, *papuensis*, and *schoedei*. Most *Hypsilurus* are found primarily in New Guinea, with *godeffroyi* extending to Fiji and Oceania. *Hypsilurus spinipes* and *boydii* are endemic to coastal New South Wales, Australia, and to coastal Queensland, Australia, respectively. *Physignathus lesueurii* appears to be confined to eastern Australia.

Hydrosaurus lizards occupy riparian forest habitat in the Philippines, a habitat being lost increasingly to commercial logging. It is suspected that the riparian forests are used only because primary forests have virtually disappeared from the islands. Although they appear to be somewhat adaptable to human-altered habitats, the extent to which survivorship is diminished when animals are forced into sub-optimal habitats is unknown. Virtually nothing is known about the current sizes or trends of populations. Clutch size ranges from 5 to 9 eggs, and reproduction occurs on an annual cycle.

In addition to habitat loss, collection for the pet trade, a practice facilitated by the loss of natural habitat, is perceived to be a potential threat to at least some populations. Price discounts for orders of 50 or more are known to have been offered in U.S. markets. Service wildlife enforcement records indicate imports of 2,732 *H. pustulatus* between September 1993 and February 1996. Only 20 *H. amboinensis* were reported, but it is likely that many are reported as *pustulatus* and that most of both species are not recorded in the database at all at the species or genus level at this time. The Service notes that, although specific population data are lacking, populations are undoubtedly severely reduced by habitat loss; and current levels of trade may be significant enough to warrant inclusion in Appendix II. Additional information and comments are sought.

10. Timber Rattlesnake, Eastern Diamondback Rattlesnake, and Western Diamondback Rattlesnake (*Crotalus horridus*, *C. adamanteus*, and *C. atrox*)

EIA, supported by HSUS and IWC, submitted proposals for including the timber rattlesnake (*Crotalus horridus*) and the eastern diamondback rattlesnake (*C. adamanteus*) in Appendix II and recommended that the Service consider submitting them at COP10. The timber rattlesnake occurs in 27 States, from New Hampshire and Minnesota south to Texas and Florida, having been extirpated from Maine and Rhode Island. They occupy a variety of

habitats, particularly rugged, rocky outcroppings. Southern forms ("canebrake" rattlesnakes) use a variety of lowland sites such as pine flatwoods, floodplains, and bottomland hardwoods. Eastern diamondbacks range through lowlands from North Carolina to extreme eastern Louisiana. One of its main preferred habitats is mature longleaf pine forest, more than 90 percent of which has been lost and often replaced with commercially managed pines. These snakes now survive in reduced numbers in a range of other natural and human-altered habitats. Reproductive potential is limited both by delayed sexual maturity (2–3 years in *C. adamanteus* and up to 9 years in northern populations of *horridus*) and long inter-birth intervals (2–3 years in *adamanteus* and 3–4 years in *horridus*).

Populations of timber rattlesnakes have declined greatly over much of their range to the extent that in many States only relict populations remain and large local populations are almost non-existent. They are listed as endangered in most northern States and commercial use is prohibited in most other States. Population declines have apparently not been quite as dramatic in the eastern diamondback, but substantial enough for the species to be classified as a species of special concern in South Carolina, Florida, and Alabama. Habitat degradation has been an important factor in population declines, as with most species. However, because rattlesnakes represent a potential threat to human health and life, both species have historically been killed intentionally in large numbers.

Commercial utilization of both species for the pet trade, and for meat, skins, and novelty jewelry is significant and represents cause for concern, given the limited biological resilience of these species to heightened levels of mortality. Records from Florida snake dealers indicate taking (mostly from other southeastern States) of nearly 5,000 *C. horridus* from 1992 to 1994 and nearly 43,000 *adamanteus* from 1990 to 1994. Most of these snakes enter the international skin trade for boots in particular. Service wildlife enforcement data for *C. horridus* show 753 and 450 leather pieces exported from the United States in 1992 and 1993 respectively. Comparable figures for the diamondback were 1,510 and 1,475. Numbers of novelty items were also quite high for the diamondback, but it is difficult to relate numbers of novelty items to numbers of snakes. Rattlesnake meat also shows up in the international trade, with records for 1992, 1993, and 1994 indicating 26.7, 119.8, and 2,419.7

pounds of eastern diamondback meat. The Service notes the apparently poor population status of the timber rattlesnake in particular, but also that of the eastern diamondback. Because the numbers appearing in trade statistics appear to be significant in some years and not in others, the extent to which international trade is impacting these species is unclear. International trade may be more significant for the eastern diamondback. Although no proposal was received for the western diamondback rattlesnake (*Crotalus atrox*), the Service believes that this species, which ranges from central Arkansas west to California and into Mexico, should be proposed for listing in Appendix II for reasons of similarity of appearance to the eastern diamondback, if a decision is made to propose the latter. This species is protected in Mexico. The Service solicits additional information and comments.

11. Requiem Sharks (Carcharhinidae spp.) (Western Atlantic and Gulf of Mexico Populations of Species Meeting Appendix II Criteria)

The Service had received proposals for the listing of shark species in preparation for COP8 and COP9. In preparation for COP8 the Service had received a recommendation from the National Audubon Society to propose requiem sharks (*Carcharhinidae* spp.) and hammerhead sharks (*Sphyrnidae* spp.) for listing in Appendix II or III. Before COP9 the Service received from EIA a recommendation that the whale shark (*Rhincodon typus*) and the basking shark (*Cetorhinus maximus*) be considered for CITES listing. Although neither of these species nor the above-mentioned families were ultimately proposed for listing, the United States proposed inclusion of a discussion about the impact of international trade on shark populations on the COP9 agenda. As a consequence of this discussion, Resolution Conf. 9.17 was adopted. It called for the CITES Animals Committee to review all information on the biological status of sharks and the effects of international trade and to submit a report to COP10. It also requested that the Food and Agriculture Organization of the United Nations submit information on these topics to COP11. The United States, particularly NMFS, is presently working with other CITES Parties, intergovernmental fishery management organizations, and non-governmental organizations to assist the Animals Committee in its implementation of this resolution. Evaluation of sharks overall in the

context of listing will be more feasible when this process is completed.

However, DOW, without providing specific suggestions or documentation, suggested that the Service consider proposing for listing at COP10 any species of sharks (*Chondrichthyes*) that meet the new listing criteria. OWC recommended that the Service propose listing in Appendix II populations of all shark species in the *Carcharhinidae* family that occur in the western Atlantic and Gulf of Mexico. Some of the species are highly migratory. Several of these species are regularly targeted by commercial shark longline and gillnet fisheries, and they are also taken incidental to fisheries targeting other species and by sport fishing interests. Recent increases in world-wide catches of sharks for meat, fins, and medicinal purposes have been documented.

The Fishery Management Plan for Sharks of the Atlantic Ocean (FMP) produced by NMFS placed most of these sharks in the "large coastal species" group. In preparation for development of the FMP, a peer review group composed of NMFS personnel and other experts reviewed available information and determined that the "large coastal species" group of sharks was overfished in the northwest Atlantic. As a consequence, annual quotas for commercial landings imposed for the large coastal shark species were set at levels 29 percent below the 1986–1991 average. A proposed increase in the 1995 quota was delayed indefinitely and the quota remains at 1994 levels. The initial stock rebuilding schedule has been determined to be overly optimistic. Because of their K-selected life history patterns (long-lived, slow-growing animals with a limited reproductive potential), these sharks are particularly vulnerable to over-exploitation. OWC has submitted information on the dusky shark (*Carcharhinus obscurus*) and the sandbar shark (*C. plumbeus*) and intends to submit full proposals for these species. The Service solicits additional data and comment relevant to the potential listing of these carcharhinid shark species.

12. Spiny Dogfish (Squalus acanthias)

Additionally, OWC proposed that the spiny dogfish (*Squalus acanthias*) population in western Atlantic waters be listed in Appendix II and intends to submit a full proposal for this species. The western Atlantic population ranges from Greenland to Florida. Like the sharks mentioned above, the spiny dogfish is an elasmobranch or cartilaginous fish. It shares with other elasmobranchs life history characteristics that make these species

more vulnerable to over-exploitation than many bony fishes.

Once fished intensively for liver oil, fisheries for this species declined to lower levels once vitamin A could be synthesized. Since the late 1980s, however, demand for dogfish meat has increased. Between 1987 and 1993, spiny dogfish landings appear to have increased five-fold. The vast majority of this catch is exported, mainly to Europe, where dogfish is replacing the traditional species used for "fish-and-chips." Recreational catches have also increased recently. Discards from other fisheries, especially from vessels targeting groundfish, contribute an unknown but substantial fraction to current mortality levels.

The National Marine Fisheries Service considers Atlantic coast spiny dogfish to be fully exploited. Given its particular life history characteristics, this species may not be able to sustain current levels of fishing. Mortality rates are considered to be in excess of reproductive rates. While current biomass estimates indicate spiny dogfish are abundant in the northwest Atlantic, mature females appear to be overexploited. Although all dogfish on the Atlantic coast are included for data collection purposes in the FMP, currently none of the dogfish species is managed for conservation purposes. The Service solicits information and comment relative to this recommendation.

13. Sawfishes (Pristiiformes spp.)

Sid F. Cook and Madeline Oettinger, two members of the Northeast Pacific Region of the IUCN Shark Specialist Group, submitted a proposal to include all species of the order Pristiiformes (sawfishes) in Appendix I. The order consists of only one family, Pristidae, incorporating seven species (although the taxonomy of the group is debated). These are: *Pristis pectinata* (smallmouth sawfish), inhabiting marine habitats in selected parts of the eastern Pacific Ocean, western and eastern Atlantic Ocean, Mediterranean Sea, Indo-Pacific, and Red Sea, and freshwater habitats in North, Central and South America, Africa, and India; *P. clavata* (dwarf or Queensland sawfish), inhabiting nearshore and estuarine waters of northern Australia; *P. zijsron* (green sawfish), inhabiting marine habitats of the Indo-West Pacific from South Africa to the Persian Gulf, the Indian subcontinent, Indonesia, Australia, and Viet Nam, and throughout the Indo-Australian Archipelago, and also freshwater habitats in Thailand, Malaysia, Indonesia, and Australia; *P. pristis* (common sawfish), inhabiting marine habitats in the western

Mediterranean and eastern Atlantic, possibly Africa; *P. microdon* (freshwater, Leichhardt's, great-tooth, largetooth sawfish), inhabiting marine habitats in the Indo-West Pacific and freshwater habitats in Africa, Asia, Pacific Islands, and Australia; *P. perotteti* (largetooth sawfish), inhabiting warm-temperate to tropical-marine waters in the Atlantic and eastern Pacific, possibly in the eastern Mediterranean, and freshwater habitats in Central and South America and Africa; and *Anoxypristis cuspidata* (knifetooth, pointed or narrow sawfish), inhabiting marine habitats in the Indo-West Pacific from the Red Sea and Persian Gulf to Australia and China, and brackish waters in Papua New Guinea, India, Myanmar, and Thailand. Of these species, *P. perotteti* and *P. pectinata* occur in U.S. waters.

Sawfishes are a very small group of cartilaginous fishes related to sharks, rays and chimeras (class Chondrichthyes). They share with those species several life history characteristics (e.g., slow growth, low fecundity, late sexual maturity, long life-span, long gestational period) that render them more vulnerable to reduced survivorship than many bony fishes. Other factors increasing the potential vulnerability of these species are restriction to a narrow depth range and disjunct distribution patterns. Threats to sawfishes include collection for the curio trade, habitat degradation, direct and incidental take in fisheries, destructive fishing practices (such as cyanide and dynamite fishing), and acquisition for live displays in public aquaria. Most species have exhibited either severe population declines or have an extremely localized distribution. Although data on international trade and other forms of exploitation of sawfishes are sketchy, localized effects can be seen in individual populations.

Although the proposal received was very detailed and appears to demonstrate that the family qualifies for inclusion in Appendix I, the Service seeks additional information bearing on this recommendation, especially information on biology and human-induced mortality of sawfish.

14. Freshwater Mussels

The 10-year Review Working Group of the CITES Animals Committee has repeatedly questioned the listing of six freshwater mussels in Appendix II since no trade in these species has been reported. Recognizing that as many as 20 percent of the approximately 300 species and subspecies of freshwater mussels may be threatened or

endangered, the Service has been reluctant to propose that any of these species be delisted, at least until inspection opportunities have been improved which could confirm that there was in fact no trade in these species. The United States submitted a proposal to COP9 to place all freshwater mussel species in Appendix II, except for those already in Appendix I and those more identifiable, thick-shelled, white-nacred, non-endangered species exported for pearl blanks. That proposal was withdrawn because of identification and inspection concerns.

Effective August 1, 1996, the Service's regulations on importation, exportation, and transportation of wildlife were revised to require that wildlife exports, including freshwater mussels, be made available for inspection and cleared for export prior to being exported from the United States. This provision should enable the Service to better ensure that endangered mussels are not exported, and therefore reduce the need for the application of CITES for non-endangered mussels, especially for those that do not appear to be traded.

Therefore, the Service is considering proposing to remove *Cyprogenia aberti*, *Fusconaia subrotunda*, *Lampsilis brevicula* (= *Lampsilis reeviana brevicula*), and *Lexingtonia dolabelloides* from Appendix II. However, the Service does not propose any change in the status of *Epioblasma torulosa rangiana* and *Pleurobema clava*, which are listed as endangered under the ESA. Comments and additional information are solicited.

15. Bigleaf Mahogany (*Swietenia macrophylla*)

The World Wildlife Fund (WWF), Defenders of Wildlife, and individuals have requested that the United States propose this species for inclusion in Appendix II. The United States is the largest importer of the wood of this species, which occurs from Mexico to Brazil and Bolivia. Bigleaf mahogany from the Americas was listed in Appendix III by Costa Rica in 1995, including its saw-logs, sawn wood, and veneer sheets only—i.e., no other parts or derivatives such as furniture (see the Federal Register of February 22, 1996 [61 FR 6793]). Species listed in Appendix II or Appendix III can be traded commercially, whereas trade for primarily commercial purposes is prohibited for the species included in Appendix I.

Proposals to include this species in Appendix II were separately submitted to COP9 or COP8 by three governments. At COP9, 50 of 83 Parties voted in favor of including this species and its logs, sawn wood, and veneer sheets in

Appendix II, which fell 6 votes short of the two-thirds majority needed for adoption (see the Federal Register notices of November 8, 1994 [59 FR 55617] and January 3, 1995 [60 FR 73]). At COP9 (as well as COP8), the majority of the range States were in support of including this species in Appendix II.

The United States is reviewing all pertinent information related to a proposal. In particular, the Service seeks new information to supplement the information summarized in the COP9 and COP8 proposals or otherwise available to the Parties at those meetings. Comments should be submitted in relation to the listing criteria as outlined above and delineated in Resolution Conf. 9.24 (cf. Federal Register of March 1, 1996 [61 FR 8019]). The Service also seeks details on implementation from the inclusion of this species in Appendix III, which entered into force on November 16, 1995.

16. Pacific Yew (*Taxus brevifolia*)

The Oregon Natural Resources Council has recommended that the United States propose the Pacific yew for inclusion in Appendix II. This slow-growing species occurs in a limited range in the western United States and Canada. An effective anti-cancer compound (paclitaxel or taxol) is obtained especially from its bark, as well as to an increasing but unknown extent from other species of *Taxus*. Some companies are working on methods of obtaining paclitaxel from *Taxus* needles and branches (which could avoid loss of the whole plant). Laboratory substitutes for the natural compound are either not available or not available in adequate commercial quantity, but there is some semi-synthetic production. The species is not grown commercially in large quantity for medicinal use, but there is some ornamental cultivation. There is some export of Pacific yew biomass for manufacture of paclitaxel in other countries. The Himalayan yew (*Taxus wallichiana*) was listed in Appendix II at COP9, excluding the finished pharmaceutical products (i.e., the end-product medicine).

The Service seeks information regarding: (1) The intensity and purposes of removal of the several parts of this species from the wild in various areas, the characteristics of the populations impacted by these extractions, and the trends in those populations; (2) the location, characteristics, and safety of populations that will not be available for extraction; (3) the extent to which biomass from the wild (i.e., materials

other than the end-point medicine) is exported from either country; and (4) the degree to which the medicinal trade involves other wild species, and/or non-wild sources of the compound (e.g., from cultivated Pacific yew or other species, or from laboratory synthesis).

17. *Goldenseal (Hydrastis canadensis)*

WWF has recommended that the United States propose this species for inclusion in Appendix II. This is a herbaceous species of the eastern deciduous forest of the United States and Canada (southern Ontario). Before European settlement and exploitation of this species, it was thought to be abundant only in the central part of its range (Indiana to West Virginia and Kentucky), and it is now considered uncommon to critically imperilled in at least 16 of the 28 States where it is found.

Goldenseal is a well-known medicinal in the herbal products industry, with a wholesale price in 1995 of over \$50 but less than \$100 per pound dry weight, mostly for rhizomes or roots (with 200–300 roots per pound). It has been estimated that 150,000 pounds of goldenseal root are collected annually from the wild. The species is cultivated to a limited but unknown extent. Both the internal trade and export are believed to be escalating, with the international trade (primarily to Europe) being considered well below a quarter of the market.

The Service is interested in information especially regarding: (1) The biological status and life history of this species; (2) the extent to which it is cultivated (i.e., artificially propagated without use of seeds or other parts from the wild); and (3) the extent to which it is collected for trade, and in particular, the extent to which it is exported and the forms in which it is exported.

18. *Aloe Vera (Aloe vera var. vera)*—*Wild Population*

At its meeting in June 1995, the CITES Plants Committee recognized that this taxon may be endangered rather than extinct within its native range, which is increasingly considered to be on the Arabian Peninsula (or possibly the adjacent horn of Africa). At COP9, the wild population was delisted along with the artificially propagated population. All other aloes are listed in Appendix II or Appendix I, but the cultivated specimens of *Aloe vera var. vera* (and products derived from them) are very common in international trade.

A succulent specialist has recommended that the United States submit a proposal to return this wild population to Appendix II. The United States is considering this subject, in

coordination with the North Africa representative to the Plants Committee (as agreed upon at the June 1995 meeting of the Plants Committee). Because the focus would be on protecting the plants of this taxon in its isolated native range, such a listing would not interfere with the unregulated trade in the very common artificially propagated specimens. Comments are requested on the status of this taxon in the wild.

19. *Tweedy's Bitterroot (Lewisia tweedyi or Cistanthe tweedyi)*

The recommendation to remove this species from Appendix II was initiated by the CITES Plants Committee, as part of the ongoing process of reviewing listed taxa at 10-year intervals. This herbaceous mountain species is native in the State of Washington and nearby in the Province of British Columbia (Canada). Because it was found to be sufficiently secure within its range, this species was removed from consideration for the U.S. Endangered Species Act in a 1985 Federal Register notice on many taxa (50 FR 39526). Moreover, this species is believed to be sufficiently easy to propagate and available in cultivation to supply rock-garden enthusiasts.

Since the biological status of the species is considered less vulnerable than when it was listed in 1983, and since there have been no applications to export it from the wild in the last decade (and almost none to export it from cultivation as artificially propagated specimens), removal of the species from Appendix II seems appropriate. Information is sought on the status of the species in the wild, and the likelihood and extent of international trade in wild specimens of this species.

Future Actions

The Service will consider all available information, including that presented at the public meeting (see DATES above) or received in writing during the comment period, in deciding which proposals warrant consideration by the Parties. The proposals decided upon will be submitted to the CITES Secretariat by January 10, 1997, for consideration at the June 1997 meeting of the Conference of the Parties in Harare, Zimbabwe. In February 1997, the Service will publish a Federal Register notice announcing the proposals submitted to the Secretariat. Persons having current biological or trade information about the species being considered are invited to contact the Service's Office of Scientific Authority (see ADDRESSES above).

The primary authors of this notice are Dr. Marshall A. Howe, Zoologist, and Dr. Bruce MacBryde, Botanist, Office of Scientific Authority, under the authority of the Endangered Species Act of 1973, 16 U.S.C. 1531 *et seq.*

Lists of Subjects in 50 CFR Part 23

Endangered and threatened species, Exports, Imports, Treaties.

Dated: August 22, 1996.

J.L. Gerst,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 96–21976 Filed 8–27–96; 8:45 am]

BILLING CODE 4310–55–P

Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora; Tenth Regular Meeting; Provisional Agenda; Proposed Resolutions and Agenda Items Being Considered; Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The United States, as a Party to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), may submit proposed resolutions and/or agenda items for consideration at meetings of the Conference of the Parties to CITES. The United States may also propose amendments to the CITES Appendices for consideration at meetings of the Conference of the Parties. The tenth regular meeting of the Conference of the Parties to CITES (COP10) will be held in Harare, Zimbabwe, June 9–20, 1997.

With this notice the U.S. Fish and Wildlife Service (Service): (1) Publishes the provisional agenda for COP10; (2) lists potential proposed resolutions and/or agenda items that the United States is considering submitting for discussion at COP10; (3) invites comments and information from the public on these potential proposals; (4) announces a public meeting to discuss species proposals and proposed resolutions and agenda items that it is considering submitting for discussion at COP10; and (5) provides information on how non-governmental organizations based in the United States can attend COP10 as observers. A separate, concurrent Federal Register notice invites comments and information from the public on possible candidate species for U.S. proposals to amend the CITES Appendices at COP10.

DATES: The public meeting will be held on at October 3, 1996 at 2:00 PM. The Service will consider information and comments from the public concerning

items of concern to COP10 received by October 11, 1996.

ADDRESSES: The public meeting will be held in room 200 of the U.S. Fish and Wildlife Service building at 4401 N. Fairfax Drive, Arlington, Virginia. Directions to the building can be obtained by contacting the Office of Management Authority. Comments pertaining to the provisional agenda or proposed resolutions or agenda items should be sent to the U.S. Fish and Wildlife Service, Office of Management Authority, Room 430, 4401 N. Fairfax Drive, Arlington, VA 22203. Any comments pertaining to species amendments should be sent to the Service's Office of Scientific Authority, Room 750, at the same address. Comments and materials received will be available for public inspection, by appointment, from 8 a.m. to 4 p.m., Monday through Friday, at either the Office of Management Authority or the Office of Scientific Authority.

FOR FURTHER INFORMATION CONTACT: Dr. Susan Lieberman, U.S. Fish and Wildlife Service, Office of Management Authority, telephone (703) 358-2095, fax (703) 358-2280; E-mail "Susan_Lieberman@mail.fws.gov".

SUPPLEMENTARY INFORMATION:

Background

The Convention on International Trade in Endangered Species of Wild Fauna and Flora, TIAS 8249, hereinafter referred to as CITES, is an international treaty to regulate international trade in certain animal and plant species that are threatened with extinction or could become threatened with extinction if their trade is not regulated, and species that must be subject to regulation in order that trade in other currently or potentially threatened species may be brought under effective control.

These species are listed in Appendices to CITES, copies of which are available from the Office of Management Authority or the Office of Scientific Authority at the addresses above. Currently, 132 countries, including the United States, are CITES Parties. The CITES treaty calls for biennial meetings of the Conference of the Parties (COP). Those meetings review the treaty's implementation, make provisions enabling the CITES Secretariat in Switzerland to carry out its functions, consider amendments to the list of species in Appendices I and II, consider reports presented by the Secretariat, and make recommendations for the improved effectiveness of CITES. Any country that is a Party to CITES may propose amendments to Appendices I and II, resolutions, and agenda items for consideration by the

other Parties. Only party countries may submit proposals and resolutions for consideration by the meeting of the Conference of the Parties. Accredited non-governmental organizations may participate in the meeting, including speaking during sessions, but may not vote.

This is the second in a series of Federal Register notices which, together with announced public meetings, provide an opportunity for the public to participate in the development of the United States' negotiating positions for the tenth regular meeting of the Conference of the Parties to CITES (COP10). The first Federal Register notice was published on March 1, 1996 (61 FR 8019), and requested information from the public on potential species amendments, resolutions, and agenda items for the United States to consider submitting for discussion at COP10. The Service's regulations governing this public process are found in Title 50 of the Code of Federal Regulations §§ 23.31-23.39.

Provisional Agenda for COP10

The CITES Secretariat recently provided the Service with an initial provisional agenda for COP10, which will be held in Harare, Zimbabwe, June 9-20, 1997. Zimbabwe was selected as the host of COP10 at COP9, which was held in Fort Lauderdale, Florida, in November 1994. The CITES Parties must submit any proposed additional agenda items to the Secretariat before September 30, 1996. The Secretariat will submit the provisional Rules of Procedure for COP10 to the CITES Standing Committee for approval at its next meeting in Rome, Italy, December 2-6, 1996. After the Standing Committee meeting, the Secretariat will provide the Parties with the rules of procedure, a revised provisional agenda, and a provisional working program. Listed below is the initial provisional agenda for COP10. A brief discussion follows for those agenda items that may not be self-evident to the public. Additional information on agenda items or explanations are available from the Office of Management Authority.

I. Opening ceremony by the Authorities of Zimbabwe

II. Welcoming addresses

III. Rules of Procedure

(a) Voting before credentials have been accepted.

(b) Adoption of the Rules of Procedure.

IV. Election of Chair and Vice-Chair of the meeting and of Chair of Committees I and II and of the Budget Committee

V. Adoption of the Agenda and Working Programmes

VI. Establishment of the Credentials Committee

VII. Report of the Credentials Committee

The Credentials Committee is made up of Party government representatives, and examines the credentials of each delegate from their respective Foreign Ministry, in order to determine eligibility to vote.

VIII. Admission of Observers

National non-governmental organizations can be admitted as observers if they are approved by their national government (Parties only). International non-governmental organizations are approved by the CITES Secretariat. Criteria for admission of observers are spelled out in Article XI, paragraph 7 of the Convention (see "Observers", below). Approved observers are admitted as observers unless one-third of the Parties present object.

IX. Matters Related to the Standing Committee

1. Report of the Chair.
2. Regional representation on the Standing Committee.

Currently, Mexico is the regional representative on the Standing Committee for North America. In CITES, North America includes the United States, Mexico, and Canada. Each CITES geographic region meets during the COP to select which country will be its regional representative. Based on a decision at COP9, regions with large numbers of countries have more than one representative on the Standing Committee. The CITES regions are: North America; South and Central America and the Caribbean (2 representatives); Europe (2 representatives); Asia (2 representatives); Africa (3 representatives); and Oceania. The Standing Committee also includes representatives of the previous host country (currently the United States), the next host country (currently Zimbabwe), and the Depositary Government (Switzerland).

3. Election of new regional and alternate regional members.

X. Report of the Secretariat

XI. Financing and Budgeting of the Secretariat and of Meetings of the Conference of the Parties

1. Financial report for 1994, 1995, and 1996.

2. Anticipated expenditures for 1997.
3. Budget for 1998–2000 and Medium-term Plan for 1998–2002.
4. External funding.

The Secretariat submits its financial report and budget to the meeting of the Conference of the Parties for the COP's approval. The COP may choose to modify the budget. The Secretariat's budget is from a Trust Fund made up of voluntary contributions from governments, who contribute based on a U.N. scale. External funding is for projects that are approved by the Standing Committee, and is paid for through funds from governments and non-governmental organizations; that funding is outside of the core Trust Fund budget of the Secretariat.

XII. Committee Reports and Recommendations

1. Animals Committee

- (a) Report of the Chairman.
- (b) Election of new regional and alternate regional members.

The Chairman (currently Mr. Robert Jenkins of Australia) will report on the activities of the Animals Committee since COP9. The first meeting of the Animals Committee after COP9 was held in Antigua, Guatemala in September, 1995; the second and final meeting before COP10 will be held in Pruhonice, Czech Republic September 23–27, 1996. Copies of the agenda of both Animals Committee meetings, and of the minutes of the 1995 meeting, are available from either the Office of Management Authority or the Office of Scientific Authority. Each of the CITES regions has either one or two representatives on the Animals Committee, depending on the number of countries in the region. Based on Resolution Conf. 6.1 (Annex 2), members of the Animals Committee are individuals chosen by the party countries within each CITES region. Currently, Dr. Charles Dauphine of Canada is the North American regional representative on the Animals Committee.

2. Plants Committee

- (a) Report of the Chairman.
- (b) Election of new regional and alternate regional members.

The Chairman (currently Dr. James Armstrong of Australia) will report on the activities of the Plants Committee since COP9. The first meeting of the Plants Committee after COP9 was held in Tenerife, Spain in June 1995; the second and final meeting before COP10 will be held in San Jose, Costa Rica in November, 1996. Copies of the agenda of both Plants Committee meetings are available from the Office of Scientific

Authority. Each of the CITES regions has either one or two representatives on the Plants Committee, depending on the number of countries in the region. Based on Resolution Conf. 6.1 (Annex 3), members of the Plants Committee are individuals chosen by the party countries within each CITES region. Currently, Dr. Bruce MacBryde of the U.S. Fish and Wildlife Service's Office of Scientific Authority is the North American regional representative on the Plants Committee.

3. Identification Manual Committee

4. Nomenclature Committee

- (a) Report of the Chairman.
- (b) Recommendations of the Committee.

The Nomenclature Committee is charged with reviewing nomenclature and taxonomic issues pertaining to species that are listed in the CITES Appendices. It is also responsible for preparation and adoption of checklists for the various taxa included in the CITES Appendices. The Chairman of the Nomenclature Committee is currently Dr. Steven Edwards, an employee of the International Union for the Conservation of Nature (IUCN, also called World Conservation Union). The Nomenclature Committee does not have regional representatives, and meets on an ad hoc basis.

XIII. Evolution of the Convention

Both of these items refer to efforts that have been undertaken by the CITES Party governments to improve the effectiveness of the implementation and administration of the Convention.

1. How to improve the effectiveness of the Convention

Based on a decision of the Parties at COP9 in 1994, a study on ways to improve the effectiveness of the Convention has been undertaken. That study is being managed and coordinated by the Standing Committee, which has the responsibility to conduct a review of the effectiveness of the provisions and implementation of the Convention, and to report its findings to the next meeting of the COP. An international contractor in the United Kingdom, Environmental Resources Management, has been engaged for this study by the CITES Standing Committee, and produced a questionnaire for governments to respond to. Public input from written comments received by the Service was considered in formulating the United States response to this questionnaire. This study was discussed in detail in a notice published in the Federal Register on June 14, 1996 (61 FR 30255). It is expected that the contractor will submit

its report to the Standing Committee prior to the December 2–6 meeting of the committee; the report and any follow-up recommendations will be discussed by the Standing Committee at that time, which will determine what recommendations to make to the COP. The United States looks forward to meaningful discussion in the report and at the COP that will lead to improvements in the implementation and enforcement of the Convention.

2. Relationship between CITES and UNEP

A Working Group was established by the Standing Committee at its meeting in March, 1996, in response to several concerns that were raised at that meeting regarding the United Nations Environment Programme (UNEP). UNEP provides for the administration of the CITES Secretariat, as spelled out in Article XII of the Convention; that administrative role includes the CITES Trust Fund, the CITES budget, and personnel selection issues. The first meeting of the Working Group was held in Bern, Switzerland on June 27–28, 1996, at the invitation of the Swiss CITES Management Authority. The countries that are members of the Working Group were selected by the Standing Committee. Countries attending the meeting were: Argentina (Chair); Japan; Senegal (substituting as an alternate for Namibia, whose representative was unable to attend); Switzerland; and the United States. The Working Group agreed to discuss financial and personnel issues, based on the Terms of Reference of the Working Group, which were decided upon by the Standing Committee; the Terms of Reference are available from the Office of Management Authority. Financial issues discussed included: evaluation of the 13 per cent overhead charged by UNEP, externally funded projects, management of the Trust Fund, and issues pertaining to the budget of the Secretariat. Personnel issues discussed included UNEP selection procedures, recent personnel actions pertaining to the posts of Deputy Secretary General and Enforcement Officer, and related issues. There was also discussion of the 1992 Memorandum of Understanding (MOU) between the CITES Parties and UNEP. It was agreed that while the 1992 MOU is still quite valid, the Working Group would recommend to the Standing Committee that the MOU be amended/expanded upon, with a new MOU, which should clearly spell out the various functions and services provided by UNEP. The Working Group agreed to submit its report to the Standing Committee by the middle of October. The report will be available

from the Office of Management Authority after that time. The United States is exceedingly interested in ensuring that the administration of the Secretariat is efficient and well managed. The United States supports the work of the Working Group and looks forward to developing a new MOU that will clearly articulate the various roles and responsibilities of UNEP in its administration of CITES.

XIV. Interpretation and Implementation of the Convention

It is expected that draft resolutions will be submitted by one or more Parties dealing with many of these agenda items. Resolutions can only be submitted by Parties (or the Secretariat) and must be submitted to the Secretariat by January 10, 1997. With this notice, the United States continues the process begun in the Service's notice of March 1, 1996, of receiving input from the public on possible draft resolutions the United States may submit.

1. Review of the Resolutions of the Conference of the Parties

(a) Deletion of resolutions that are out of date.

(b) Consolidation of valid resolutions.

This is the continuation of a very useful process that was begun at COP9, at the request of the Standing Committee. At COP9, the process was begun to delete resolutions that are out of date, and to consolidate resolutions that deal with the same topic. This agenda item will complete the COP9 consolidation process. This does not involve actual revisions of resolutions, but rather a consolidation to reduce the number and complexity of resolutions. The Service expects to receive copies of draft of those consolidations prepared by the Secretariat just prior to the December meeting of the Standing Committee. The Secretariat has also produced a compendium of all extant resolutions from COP1-8. That compendium, the resolutions from COP9, and information on how to retrieve them electronically, are available from the Office of Management Authority.

2. Report on National Reports Under Article VIII, Paragraph 7, of the Convention

Each Party is required by the Convention to submit an annual report containing a summary of the permits it has granted, and the types and numbers of specimens of species in the CITES Appendices that it has imported, exported, and re-exported. This agenda item will include a summary from the Secretariat of those countries that have submitted their annual reports in a timely fashion, as well as those that

have not, or have not submitted them at all.

3. Review of Alleged Infractions and Other Problems of Implementation of the Convention

The Secretariat prepares an Infractions Report for each meeting of the Conference of the Parties, which details instances where (1) species listed in the Appendices have been adversely affected by trade, (2) the Convention is not being effectively implemented, or (3) actions by Party countries undermine the effectiveness of the Convention. The Infractions Report also includes summaries of major enforcement cases. The COP9 Infractions Report highlighted those cases of the most serious infractions, in order to focus the attention of the Parties; the COP10 Infractions Report is expected to do the same.

4. National Laws for Implementation of the Convention

(a) Analysis of the national legislation of Parties.

(b) Measures taken by Parties to improve their legislation.

(c) Measures to be taken with regard to Parties without proper legislation.

(d) Technical assistance provided to Parties.

This is a continuation of an important project begun by the Parties at COP8, reported on at COP9 by the Secretariat, and discussed in detail at COP9. Resolution Conf. 8.4 (National Laws for Implementation of the Convention) relates to analysis of national legislation of the Parties for the implementation of the Convention, as required by Article VIII of the treaty. A decision of COP9 directed the Secretariat to engage in a number of activities regarding national legislation and implementation of this resolution, and to report to COP10 on measures taken by Parties whose national legislation is determined to not meet the basic requirements of the Convention. Discussions under this agenda item will include measures taken by the Parties, status of national legislation and improvements since COP9, technical assistance provided and future needs, and measures regarding Parties that have not taken the required actions. During the comment period one organization recommended that the Service urge the Parties and Standing Committee to direct the Secretariat to implement these decisions. The Service believes that this will take place and that a detailed report will be presented to the COP by the Secretariat, but will certainly discuss the issue at the next meeting of the Standing Committee.

5. Exports of Leopard Hunting Trophies and Skins

This refers to the exportation of leopard skins, including hunting trophies, under a quota system approved by the Conference of the Parties. The relevant resolutions from prior meetings of the COP are available on request from the Management Authority. The Secretariat will provide a report on the implementation of this quota system, including a country-by-country assessment. Any country wishing a new or revised quota from the COP will submit supporting documentation. Even if there is a hunting trophy quota for a given country, the importing country is still required under Article III of the Convention to make the required findings, including the finding that the import will be for purposes not detrimental to the survival of the species.

6. Trade in Specimens of Species Transferred to Appendix II Subject to Annual Export Quotas

This refers to species listed in Appendix I, which have populations that have been transferred to Appendix II pursuant to annual export quotas, which are voted upon by the Conference of the Parties. The Secretariat will provide a report on the implementation and compliance with these quotas, including country-by-country reports.

7. Trade in Live Rhinoceros From South Africa

At COP9, the Parties adopted a proposal to transfer the population of white rhinoceros in South Africa from Appendix I to II, with an annotation that only trade in live animals and sport-hunted trophies would be allowed. This agenda item will allow South Africa to report on its implementation of this annotated listing. The United States expects that trade in sport-hunted trophies of white rhinoceros from South Africa will also be discussed under this agenda item, and the Service intends to communicate that understanding to the Secretariat. For further information on proposals for COP10 concerning live rhinoceros, see this subject heading in the concurrent Federal Register notice on proposals to amend Appendix I or II.

8. Trade in Tiger Specimens

This refers to the conservation of tigers (*Panthera tigris*) and illegal trade in their parts and products, principally for the medicinal market, and will also include a discussion of efforts that have been taken by the Parties to control poaching of tigers, and to more effectively enforce the Convention's prohibitions on trade in tiger parts and

products. The problem was discussed at COP9, and a resolution (Conf. 9.13) was adopted at COP9, which presented several recommendations to tiger range and consumer States, and directed the Standing Committee to continue its efforts on this critical issue. The tiger issue has been discussed at the last several Standing Committee meetings, will be discussed at the December 2-6, 1996 Standing Committee meeting (SC31), and is expected to be an issue of particular concern to the Parties and a subject of discussion at COP10. One organization commented recommending that the United States ensure that the Standing Committee and COP fully review this issue; the Service believes that this will take place. Range and consumer countries have been asked to submit papers to the next meeting of the Standing Committee as well. Since COP9, the Service has been actively involved in an educational outreach program with consumer communities in the United States, and submitted a paper on these efforts to the March 1996 meeting of the Standing Committee. In addition, through appropriations under the Rhinoceros and Tiger Conservation Act, the Service is considering support for several projects that will benefit the conservation of tigers in the wild. The Service is also working with the National Fish and Wildlife Foundation in providing input into its grant making efforts through its Save the Tiger Fund.

9. Biological and Trade Status of Sharks

At COP9, Resolution Conf. 9.17, concerning the conservation of sharks, was adopted based on an agenda item submitted by the United States. The resolution calls for the CITES Animals Committee to review all information concerning the biological status of sharks and the effects of international trade on them in order to submit a report to the Parties at COP10. It also requests that the Food and Agriculture Organization of the United Nations submit information on these topics to the COP11. The United States, particularly the National Marine Fisheries Service (NMFS), is working with other CITES Parties, intergovernmental fishery management organizations and non-governmental organizations to assist in implementation of the resolution. Draft discussion papers on this topic will be discussed at the 13th Meeting of the Animals Committee in Pruhonice, Czech Republic, in September 1996. It is likely that a draft resolution concerning follow-up of Conf. 9.17 will be considered at that meeting.

10. Trade in Plant Specimens

This agenda item provides consideration for particular subjects in the regulation of trade in plant specimens that emerge as needing particular attention by the Parties.

(a) Implementation of the Convention for timber species.

This will include a discussion of the reports of the Timber Species Working Group. COP9 called upon the Standing Committee to establish a Timber Species Working Group to evaluate in detail issues pertaining to the implementation of CITES for listed species of trees that are subject to the international timber trade. The United States is a member of the Working Group, and was represented at the first meeting by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture, the U.S. Forest Service, and the Fish and Wildlife Service. The report of the first meeting of the Working Group is available from the Management Authority. The last meeting before COP10 will be held in Panama City, Panama October 7-11, 1996.

(b) Other Issues.

The Plants Committee will meet in Costa Rica from November 11-15, 1996, and other issues that need particular attention may arise from that meeting, which could be submitted for COP10 either by Parties or in certain cases by the Secretariat on behalf of the Committee. The Service would welcome comments regarding particular regulatory problems or conservation concerns to bring to that November meeting.

11. Significant Trade in Appendix II Species

This refers to the trade in those Appendix II species identified as subject to significant levels of trade, for which insufficient biological information may exist to warrant trade at current levels.

(a) Animals.

The Parties adopted Resolution Conf. 8.9 at COP8 in Kyoto, Japan in 1992, which represented a landmark decision to take positive measures to encourage the implementation of Article IV of the Convention. That Article refers to the required findings that exports are not detrimental to the survival of a species, and other scientific findings, for Appendix II species. Implementation of this resolution has been successful for a large number of countries and species, although much more work needs to be done in terms of field assessments and development of management plans for heavily traded species. The Animals and Standing Committees have been very active in implementation of this

resolution. The Secretariat has worked closely with many countries under the umbrella of this resolution; the United States has implemented several decisions of the Standing Committee regarding these issues as well.

(b) Plants.

The Plants Committee is making some progress in reviewing trade in some trading categories or scientific categories of species within the higher tax on listings of plants included in Appendix II. Summaries are given in the reports of the recent meetings of the Committee. An informal working group of the Committee was charged with preparing a draft resolution for plants by adapting Resolution Conf. 8.9; this draft should be available for discussion at the Committee's November 1996 meeting.

12. Non-Commercial Samples of Skins

At previous meetings of the COP, some countries have raised concerns that when a business person wishes to take samples of skins or products from one country to another, but does not intend to sell the samples themselves, the process for obtaining a series of CITES permits for the same samples is complex and burdensome. The United States believes that this agenda item will include discussion of ways to facilitate such movement of samples, without creating loopholes for illegal trade. The United States supports the discussion of measures that, while consistent with the terms of CITES, would ease documentary requirements for exports and re-exports when no sale will take place in any of the importing countries.

13. Universal Tagging System for the Identification of Crocodilian Skins

This refers to work by the Animals Committee to institute a system of universal marking for all crocodilian skins in trade, as a response to serious problems of illegal trade in crocodilian skins, parts, and products. The Parties adopted Resolution Conf. 9.22 at COP9, which clarified the requirements that all crocodilian skins in trade must be tagged. The Secretariat, in consultation with the Animals Committee, is responsible for monitoring the implementation of this resolution and will be submitting a report to the Parties for their consideration at COP10. We also expect discussion of some possible technical revisions to the resolution, including a description of the parts tag.

14. Transport of Live Specimens

Issues pertaining to the transport of live specimens, particularly live animals, have been discussed at every COP. Resolution Conf. 9.23 recommends that all live animals be shipped in

accordance with the International Air Transport Association (IATA) Live Animals Regulations, for air transport, or the CITES Guidelines for other transport. It is also recommended that all permits for live animals be conditioned upon compliance with these requirements. At COP9, these issues were transferred to the Animals Committee. Currently, the Chair of the Animals Committee Working Group on this issue is Dr. Susan Lieberman of the Service's Office of Management Authority. This discussion will include a report on implementation of relevant resolutions pertaining to transport of live animals, particularly Conf. 9.23, as well as a report on discussions and recommendations of the Animals Committee.

15. Captive Breeding

At COP9, the Parties directed the Secretariat, working with the Animals Committee, to prepare a new resolution consolidating the various extant resolutions dealing with determination whether a specimen is bred-in-captivity, and dealing with captive breeding for commercial purposes of Appendix I animals. The Animals Committee, at its upcoming September meeting in the Czech Republic, will discuss these issues. The Secretariat is expected to prepare a draft resolution on these topics. The Service is actively involved in these discussions.

(a) Implementation of Article VII, paragraphs 4 and 5.

This issue will include discussion of when it is appropriate to utilize the exemptions in either of these two paragraphs, for individual animals of Appendix I species that are bred in captivity. The key issues are how to determine whether specimens qualify as bred-in-captivity, and how to facilitate their trade when appropriate, while at the same time not increasing opportunities for illegal trade or the fraudulent representation of wild-caught specimens as captive-bred.

(b) Proposals to register the first commercial captive-breeding operation for an Appendix I animal species.

Under Conf. 8.15, Parties must submit proposals for inclusion of operations breeding Appendix I species in captivity for commercial purposes. The Secretariat maintains a register of those facilities. Proposals are submitted to the Secretariat, which circulates them to the Parties. When a Party objects to inclusion of a facility in the Secretariat's register, and the objection cannot be resolved by the interested Parties, the proposal is discussed and voted upon by the COP (if the proponent country so wishes). This agenda item will include discussion of those proposals.

16. Standard Nomenclature

This agenda item includes a discussion of nomenclature issues related to listed taxa, and possible adoption of checklists that allow for uniformity among the Parties.

17. Conservation of Edible-Nest Swiftlets of the Genus *Collocalia*

At COP9, in response to a proposal that was submitted by the government of Italy for inclusion of the genus *Collocalia* in Appendix II, Resolution Conf. 9.15 was adopted. The resolution called for a workshop to evaluate the conservation status of these species, and trade in their nests. The Secretariat notified the Parties in Notification Number 927 (dated July 30, 1996) that this workshop will take place November 4-7, 1996, in Indonesia.

18. Trade in African Elephant Ivory

(a) Revision of resolution Conf. 9.16.

(b) Revision of resolution Conf. 7.9.

(c) Stockpiles of ivory.

This agenda item will be greatly influenced by any proposals to transfer populations of African elephants submitted by the deadline of January 10, 1997. The Service also notes that there will be a meeting of African elephant range states in Dakar, Senegal in November, 1996, organized by IUCN at the request of the African representatives on the Standing Committee, at which time the range states will discuss all of these issues. The Service has agreed to provide partial funding for that meeting. The Service is hopeful that consensus can be reached on a number of these issues by the range states themselves.

Resolution Conf. 7.9 was adopted by COP7 after the transfer of all African elephant populations to Appendix I. Conf. 7.9 establishes a Panel of Experts to evaluate any proposals to transfer a population back to Appendix II, and includes a number of criteria for the Panel to evaluate. Based on discussions at COP9 and at subsequent meetings of the Standing Committee, there will be discussion at COP10 to amend Conf. 7.9 to expand the Terms of Reference of the Panel of Experts to allow for discussion of trade in non-ivory products, trade with specific identified importing countries, and other issues. The Service believes that much of Conf. 7.9 has been made redundant or unnecessary by the adoption of new listing criteria (Conf. 9.24) at COP9, although the Service recognizes that the enforcement control issues in Conf. 7.9 remain highly relevant.

19. Proposals Concerning Export Quotas for Specimens of Appendix I Species

Under provisions of resolution Conf. 8.10 (Rev.) export quotas were established for leopards (*Panthera pardus*) and any changes to these quotas are to be approved by the Parties. Such changes may be submitted for consideration at COP10. In addition, proposals to establish quotas on other species may be submitted for consideration by the Parties under provisions of Conf. 9.21. Furthermore, the Animals Committee may submit a document or draft resolution to discuss the management responsibilities of a Party permitting the sport hunting of Appendix I species. During the comment period one organization recommended that the Service seek a formal review of implementation of Resolution Conf. 9.21. Pending the outcome of discussions at the Animals Committee meeting, the Service will consider this recommendation.

20. Implementation of the Convention in Small Island Developing States

This issue pertains to a decision at COP9 directing the Standing Committee to reach out to small island developing countries, particularly in Oceania, to facilitate their accession to CITES, including missions to those countries. There was discussion at COP9 of efforts to facilitate regional Management and Scientific Authorities. A report was presented by the Secretariat at the March 1996 meeting of the Standing Committee.

21. Criteria for Granting Export Permits in Accordance with Article V, Paragraph 2

Article V, paragraph 2 contains the provisions for issuance of export permits for species in Appendix III. Export permits are required only from those countries that have included the species in Appendix III; all other exports require the issuance of Certificates of Origin. Resolution Conf. 9.25 addressed issues pertaining to inclusion of species in Appendix III.

22. Problem of Hybrids

The Animals Committee discussed at its September 1995 meeting issues pertaining to implementation of the Convention for hybrids; these issues have been discussed at previous meetings of the COP for plants. The Animals Committee will discuss these issues further at its September 1996 meeting. Resolution Conf. 2.13 makes clear recommendations to the Parties pertaining to how hybrids are to be treated under the Convention. Some countries have concerns pertaining to

hybrids between Appendix I species and unlisted species. The discussion at COP10 will be guided by recommendations arising out of the upcoming Animals Committee meeting. There are several significant enforcement concerns regarding trade in live animals that are claimed to be hybrids.

23. Marking of CITES Specimens

The Animals Committee will discuss issues pertaining to marking of CITES specimens, which later will be discussed at COP10, including: marking of products from registered facilities that breed Appendix I animals for commercial purposes; marking of products from ranching operations; and marking of live animals in trade, including the use of transponders.

24. Exports of Vicuña Cloth

At COP9, certain populations of the vicuña (*Vicugna vicugna*) in Chile and Peru were transferred from Appendix I to II, with an annotation allowing export only of cloth products, wool sheared from live animals, and the Peruvian stockpile of 3249 kg extant in November, 1994. Although the Service has received and is now reviewing a petition to reclassify the species to threatened status under the Endangered Species Act, the vicuña is currently listed as endangered, which means its products cannot be imported into the United States. This agenda item will probably discuss the trade in the Peruvian stockpile, as well as other issues pertaining to implementation of the COP9 downlisting of these vicuña populations.

25. Frequent Cross-Border Movements of Privately Owned Animals

This issue pertains to non-commercial imports/exports of live animals that comprise travelling exhibitions or personal pets. The United States is aware that the governments of Switzerland, Germany, and Australia are engaged in dialogue on this issue, in order to develop a practical solution to some implementation problems that have arisen. The discussion will be limited to cases where live animals are exported (or re-exported) temporarily, for non-commercial purposes, by their owner, with the intent of returning to the country from which they were exported (or re-exported).

XV. Consideration of Proposals for Amendment of Appendices I and II

Proposals for amendment of Appendices I and II can only be submitted by Parties, and must be submitted to the Secretariat by January 10, 1997. A separate, concurrent Federal

Register notice invites comments and information from the public on possible candidate species for U.S. proposals to amend CITES Appendices I and II at COP10.

1. Proposals Submitted Pursuant to Resolution on Ranching

The Parties will consider proposals to transfer species from Appendix I to Appendix II under the provisions of Conf. 3.15, 5.16, 6.22 and Conf. 8.22. Any such proposals should have been submitted to the Secretariat 330 days prior to the meeting of the COP.

2. Proposals Resulting from Reviews by the Animals and Plants Committees

Resolution Conf. 3.20 established a process (known as the 10-year review) for the periodic review of species included in Appendices I and II. Conf. 6.1 reassigned this responsibility for the periodic review of species included in the appendices to the Animals Committee. Proposals for the transfer of species between, or removal from, the appendices may be considered under this agenda item.

3. Proposals Concerning Export Quotas for Specimens of Appendix I Species

Resolution Conf. 9.24, the new listing criteria resolution, contains provisions for transferring species from Appendix I to II with export quotas approved by the Parties. Proposals, if submitted under the provisions of these resolutions, will be considered at COP10.

4. Other Proposals

Any Party may submit proposals for the addition or deletion of species to/from an appendix or transfer between appendices. These proposals will be considered by the Parties at COP10. The United States has identified those proposals on species that it is considering submitting for consideration of the Parties in a separate Federal Register notice. These proposals must be submitted to the CITES Secretariat 150 days prior to the meeting of the COP, and any proposals submitted by other countries will be identified in a Federal Register notice after the submission date. All such proposals will be considered at the COP unless withdrawn by the submitting Party or Parties.

XVI. Conclusion of the meeting

1. Determination of the Time and Venue of the Next Regular Meeting of the Conference of the Parties

If more than one country offers to host the next meeting of the Conference of the Parties (COP11), to take place

probably in late 1999 or early 2000, a vote will be taken. If a vote is necessary, the country that receives the most votes (through a secret ballot) will be the host of COP11.

2. Closing Remarks

Proposed Resolutions and/or Agenda Items that the Service Might Submit for Consideration at COP10

In its Federal Register notice published on March 1, 1996 (61 FR 8019), the Service requested suggestions from the public on resolutions and/or agenda items for the United States to consider submitting for discussion at COP10. Suggested resolutions and/or agenda items were received from the following organizations or individuals: Animal Welfare Institute, Center for International Environmental Law, Defenders of Wildlife, Environmental Investigation Agency, Georgia Department of Natural Resources, Humane Society of the United States, International Wildlife Coalition, New York Turtle and Tortoise Society, World Wildlife Fund, and Delia and Mark Owens.

The Service considered all of those suggestions in compiling the following list of possible resolutions and/or agenda items that the Service might submit for consideration of the Parties at COP10 (comments referred to below were in response to this March 1, 1996 Federal Register notice). The Service welcomes comments and information regarding these resolutions that it may submit, as well as on those resolutions it is not currently planning to submit.

1. Trade in Appendix I Specimens

On April 24, 1996, the CITES Secretariat raised concerns (Notification 913) regarding the inconsistent treatment of Appendix I specimens. Article III of the treaty contains the provisions for issuance of export and import permits for Appendix I specimens, while Article VII (paragraphs 4 and 5) provides exceptions for specimens bred-in-captivity for commercial and non-commercial purposes, respectively. The CITES Secretariat is drafting a comprehensive resolution which will address both the issues raised in paragraphs 12 and 13 of this notice (general bred-in-captivity determinations and breeding of Appendix-I species in captivity for commercial purposes) and implementation of Article III for captive-born specimens that do not qualify as captive-bred under Conf. 2.12 (Rev.). The Service has provided a draft resolution to the Secretariat, which clarifies this issue, but will defer a

decision on whether to propose a separate resolution based on continuing dialogue with the Secretariat and other Parties and comments received from the public.

2. Personal Effects

Resolutions Conf. 4.12 (Rev.) (Control of Tourist Souvenir Specimens) and Conf. 6.8 (Implementation of the Convention with Regard to Personal and Household Effects) make recommendations to the Parties on how to implement the exemption in Article VII of the treaty for certain personal effects. Travellers experience some problems because the United States recognizes the personal effects exemption under Article VII, paragraph 3 of the treaty, while other countries either do not recognize it or implement it differently. This also causes problems for implementation of CITES at ports of entry. The personal effects exemption only applies if the country of export does not require a permit, and port inspectors of importing countries do not have a quick way of determining which countries require permits for personal items. The Service is considering submitting a draft resolution, and is considering practical, yet enforceable, provisions to be included in such a resolution. The government of Australia has been working on such a document and the United States may co-sponsor it, thus precluding the need to submit a separate resolution.

3. Circuses

Resolution Conf. 8.16 (Travelling Live-Animal Exhibitions) makes recommendations to the Parties on the implementation of Article VII, paragraph 7, of the treaty. There are a few technical issues in that resolution, such as the requirement of a separate certificate for each specimen, that the Service would like to review. The Service also recognizes that circuses would like to include captive-born, late maturing species (e.g., Asian elephants) that do not yet qualify as captive-bred under Conf. 2.12 (Rev.) under these provisions. The Service is considering drafting a discussion paper or resolution for consideration at COP10 on these issues, depending on the outcome of discussions with other countries and comments received.

4. Standardization of Permits

Resolution Conf. 9.3 recommends that all Parties use standard formatting and information when issuing CITES documents. The Service has found that some CITES Parties are interpreting some sections of the resolution differently which creates problems in implementing the Convention. The

Service proposes to reorganize the document and clarify specific provisions, such as redefining the source code "F". Clarification is also needed on the standard information required to be on a Certificate of Origin for Appendix III specimens. The Service is discussing these recommendations with the Secretariat, and it is possible that the Secretariat will include them in their recommendations to the Parties, thus possibly precluding the need for a separate U.S. draft resolution. In addition, during the comment period one organization recommended that the Service clarify the relationship of CITES' permitting provisions with those of other conventions relating to marine species, as regards paragraphs 4 and 5 of Article XIV. The Service submitted a document and draft resolution on this issue to COP9 (Doc.9.40), but many Parties did not see the necessity for a separate resolution on the issue. The Service is not considering a separate draft resolution at this time, but may incorporate a discussion of general certificate requirements into this potential revision of Conf. 9.3.

5. Trade in Live Animals and Plants That Have a High Probability of Becoming Naturalized/Feral Pests

The intentional or accidental introduction of non-indigenous species into terrestrial, aquatic and marine environments may pose significant threats to native species and their ecosystems. They may out-compete indigenous species or may introduce and transmit parasites and disease. Many species that are included in CITES Appendices II and III are either pests in their country of origin, or have a high potential of becoming naturalized pests in countries of import. The Convention on Biological Diversity has begun to examine the introduction of exotic species, particularly in the marine environment. A scientific conference on this topic was just held in Norway, attended by representatives of the Service and other agencies. The Service recognizes that there are many cases where commercial export of live specimens may not be detrimental to the populations of the species in its country of origin, but if introduced unintentionally into the wild in the country of import serious ecological harm could ensue. The Service recognizes that the consideration of ecological impacts in importing countries is not a CITES requirement in the strict sense. However, some of the IUCN Specialist Groups have recently focussed on this critical conservation issue, and during the comment period five organizations recommended that

the Service submit a draft resolution to COP10 on this issue. The Service is considering submitting a discussion paper on this subject at COP10.

6. Pre-Convention

Article VII, paragraph 2 of the Convention provides an exemption from Articles III, IV and V for specimens that were acquired before the provisions of the Convention applied. The Service has become aware, through discussions with many countries and with the Secretariat, that confusion exists as to the implementation of Resolution Conf. 5.11 (Definition of the Term "Pre-Convention Specimen"). Currently, in order to determine the date of reference for a pre-Convention specimen, a Party must factor in the date it acceded to the Convention. The result is that the same specimen will be considered pre-Convention by one country, but subject to the provisions of the Convention under Articles III, IV, or V by another. This confusion and potential inconsistencies create opportunities for the laundering of specimens. This has led to further confusion as the number of Parties has increased, and the number of possible accession dates has proliferated. The Service is considering submitting a draft resolution whereby the pre-Convention date would be the date the species was first included in the CITES Appendices, regardless of the date of accession of the Party concerned.

7. Significant Mortality/Transport of Live Animals

This issue was also discussed under Agenda item 14, above. Dr. Susan Lieberman of the Service's Office of Management Authority is currently Chair of the Animals Committee Working Group on the Transport of Live Animals. At its upcoming meeting, the Animals Committee will be discussing the implementation of the treaty's requirements for humane transport of live animals, along with Resolution Conf. 9.23 (Transport of Live Specimens). Based on decisions of the Working Group and recommendations to the Animals Committee at the last meeting of the Committee, the Chair of the Animals Committee requested the submission of a resolution dealing with these issues. That draft resolution will be discussed at the September meeting of the Animals Committee; it deals with means to assist the Parties in implementing the treaty's requirements for the transport of live animals, by working towards a reduction in mortality and morbidity during transport and preparation for shipment. The draft resolution deals with a process whereby the Animals

Committee, in cooperation with the Parties, the Secretariat, and experts, would review trade and transport in species that are traded in large volumes as live animals, and make recommendations to the Parties for remedial measures, when necessary. This would be similar to the process implemented through Resolution Conf. 8.9. The Service's submission for COP10 on this issue is pending further discussions by the Animals Committee. During the comment period five organizations recommended that the Service submit a draft resolution to COP10 on this issue, and submitted draft text as well.

8. Trade With Parties That Have Not Identified a Scientific Authority

Articles III and IV of the CITES treaty require specific advice to be issued by the Scientific Authority before certain permits can be issued by the Management Authority. Properly made findings are essential to ensuring that the trade in specimens of listed species are not detrimental to the survival of the species. In order for other Parties to have assurance that these findings are being made and to consult with Parties on specific findings, it is essential that the Scientific Authorities have been designated and are known to all Parties. If this treaty obligation is not fulfilled by a Party, there is no way to assure other Parties that CITES permits issued by that Party are valid. Therefore, the United States is considering submitting a resolution that would recommend against allowing any wildlife trade with any Party that has not notified the Secretariat of the name and address of its Scientific Authority(s).

9. Coral Reporting and Identification

CITES Notification to the Parties No.788 dated March 10, 1994 lays out the guidelines for reporting of information in the annual report. The Service is considering submitting a resolution to expand the required description and quantity for coral to include live coral reported in units or pieces. In addition, the Service is experiencing difficulties in identification to species of readily recognizable coral gravel and live rock. Both commodities are protected by CITES, but identification to species is almost impossible, even by trained scientists. The Service is considering recommending that coral gravel and live rock be allowed to be classified at the Order level for permit issuance due to identification and enforcement problems.

10. Regulation of CITES Shipments Traveling on a Customs Carnet

CITES shipments for exhibition or show that are not intended for permanent destination into a country often travel on a customs carnet to alleviate customs duties. Customs laws treat import and subsequent re-export of these types of shipments differently from other CITES shipments. Shipments often enter a country on a customs carnet without the knowledge of the Management Authority, and are subsequently re-exported without the required CITES documentation. These shipments encounter problems when they are re-exported back to their originating country without any CITES re-export documents. The Service would like to propose a resolution that encourages Management Authorities to work more closely with CITES enforcement officers and customs officers to ensure that shipments traveling on a customs carnet meet all the applicable CITES requirements.

11. Crocodile Tagging

Resolution Conf. 9.22 established a universal system for the identification of crocodilian skins. The Secretariat, in consultation with the Animals Committee, is responsible for monitoring the implementation of this resolution. The United States, after consultation with the Animals Committee and the Secretariat, is considering submitting a resolution to clarify some points in the resolution, including a description of the parts tag. One organization (a State Natural Resources Department) recommended a similar tagging system for snake skins. The Service is not considering proposing such a resolution at this time, but welcomes comments as to the feasibility of and necessity for such a requirement.

12. Bred in Captivity

CITES Resolution Conf. 2.12 (Rev.) provides criteria for certifying specimens as bred in captivity for the exemptions provided for in Article VII, paragraphs 4 and 5. Whereas the CITES Secretariat has been directed to develop a new resolution that would replace Conf. 2.12 (Rev.) by consolidating it with Conf. 8.15 and Conf. 8.22 (also dealing with animals bred in captivity), the Service is considering submission of a revised resolution that would retain the basic elements of Conf. 2.12 (Rev.) but add clarifying definitions and examples. However, the Service will defer a decision on whether to propose such a resolution until further discussion of this topic by the Animals Committee at its September meeting.

13. Breeding Appendix-I Species in Captivity for Commercial Purposes

Operations breeding Appendix-I species in captivity for commercial purposes must be registered with the CITES Secretariat according to the procedures established in Resolution Conf. 8.15. Once an operation is registered for a given Appendix-I species, specimens of that species produced at that operation (including parts and derivatives thereof) may be deemed to be specimens of an Appendix-II species and are subject to the permitting requirements of Article IV. While the CITES Secretariat has been directed to prepare a new resolution consolidating extant resolutions dealing with animal specimens bred in captivity, including Appendix-I species bred for commercial purposes, the Service is considering proposing a revised version of Conf. 8.15 in which inconsistencies in the present resolution would be corrected and a few information requirements deleted. Before proceeding with such a proposed resolution, the Service will wait until after discussion of this topic by the Animals Committee at its September meeting to determine if such a resolution may be needed.

14. Illegal Trade in Whale Meat

In support of the prohibition by the International Whaling Commission (IWC) of commercial whaling for various whale species, all species of the great whales are listed in Appendix I of CITES. Since 1980, a number of illegal shipments of whale meat have been stopped or seized by several government authorities. A resolution was adopted by the Parties at COP9, which calls for further cooperation between CITES and the IWC in order to stop illegal international trade in whale products. Analogous resolutions were adopted by the IWC in 1995 and 1996. The United States may submit a resolution at COP10 urging continued cooperation between CITES and the IWC with regard to halting the illegal trade in whale products. During the comment period one organization recommended that the Service raise this issue at both the next meeting of the Standing Committee and the COP. It is on the agenda of both the COP and the Standing Committee, was the focus of a recent Notification to the Parties, and certainly will receive significant attention.

Resolutions That the Service May Not Submit for Consideration at COP10

There were a number of recommendations submitted to the Service as suggested resolutions or agenda items for consideration at COP10

that the Service is either not considering submitting at this time, or the Service will address in ways other than through a draft resolution. Some of these are excellent suggestions, which are precluded by higher priorities. The Service notes that the agenda for COP10 is already extremely full, and that many issues will be addressed in either the Animals or Plants Committees, or may be addressed in other ways at COP10. The Service welcomes information on these issues, including an assessment of whether they should be given a higher priority by the Service than other issues. There are some issues that the Service may consider submitting documents on, depending on the outcome of discussions in the Animals, Plants, and Standing Committees.

1. Appendix I tourist items at airports: The Service received comments from six organizations recommending a resolution dealing with the sale of Appendix I products in airports and duty-free zones. The suggested resolution would deal with this important enforcement problem, whereby many international airports continue to sell tourist souvenirs of Appendix I specimens, in spite of the fact that they cannot be legally exported or imported by the traveller. The Service agrees that Parties should be more vigilant, and such sales are a conservation concern. However, the Service believes at this time this issue can be addressed directly by the Secretariat through its ongoing educational efforts.

2. Bear parts trade: The Service received comments from six organizations recommending submission of a draft resolution regarding illegal trade in parts and products of Appendix I bear species. The Service agrees that this is a very high priority issue. At the request of the United States, this issue is on the agenda of both the Animals Committee and the Standing Committee. The Service may submit a discussion paper to the Animals Committee, and based on the outcome of discussions in both Committees will assess whether or not a discussion paper should be submitted to COP10. More appropriately, the Secretariat may be asked by either Committee to prepare a discussion paper for COP10.

3. Enforcement: Five organizations submitted comments recommending that the United States submit a resolution on enforcement. The Service agrees with all of the recommendations to the Parties suggested by these organizations, but believes that they are adequately covered by other resolutions, including Resolution Conf. 9.8, as well

as by efforts of the Secretariat. One organization raised valid concerns about the unfortunate delay in selection of the Secretariat Enforcement Officer. The Service has expressed these concerns through the Standing Committee, as well as in other fora. One organization submitted a draft resolution recommending coordination between Customs and other enforcement agencies, development of national legislation, training, and other measures designed to enforce the Convention. The Service agrees that enforcement by Parties and international cooperation in enforcement are the highest priorities necessary to increase the effectiveness of the Convention, but does not believe that a new resolution is necessary at this time. The Service welcomes comments and information on this issue, and may develop such a resolution for submission to COP10.

4. Criteria for Sustainability: Two organizations recommended that the United States develop criteria for assessing the sustainability of international commercial trade in wild fauna and flora. The Service considers this to be an excellent idea, but current time availability and personnel and other resources available to the Service preclude the implementation of such a project. The Service does note that it recently published a final rule which established criteria for evaluation of sustainable use management plans for wild birds subject to international trade, which has direct bearing on this issue. The Service agrees that such practical criteria could assist Parties in making their required non-detriment findings under Article IV, and would be very useful for the Parties, and welcomes any comments or suggestions on this concept.

5. Relationship between CITES, the General Agreement on Tariffs and Trade (GATT), and the World Trade Organization (WTO): One organization submitted comments recommending that the United States submit a resolution establishing the primacy of CITES over the GATT and WTO rules. The Service believes that this is already the case, and therefore a draft resolution is unnecessary. The Service welcomes comments on this issue however.

Announcement of Public Meeting

In order to discuss with the public species proposals and proposed resolutions and/or agenda items that it is considering submitting for discussion at COP10, the Service announces that it will hold a public meeting on October 3, 1996, from 2:00 to 4:00 P.M. in room 200 of the U.S. Fish and Wildlife Service building in Arlington, Virginia,

at 4401 N. Fairfax Drive. Persons wishing directions to the public meeting or additional information should contact the Office of Management Authority in writing (see ADDRESSES, above) or at (703) 358-2095.

Request for Information and Comments

The Service invites comments and information from the public on the COP10 possible agenda items discussed above, and COP10 potential proposed resolutions and/or agenda items discussed above. Information and comments should be submitted to the Service no later than October 11, 1996 to be ensured of consideration.

Observers

Article XI, paragraph 7 of the Convention states:

Any body or agency technically qualified in protection, conservation or management of wild fauna and flora, in the following categories, which has informed the Secretariat of its desire to be represented at meetings of the Conference by observers, shall be admitted unless at least one-third of the Parties present object:

(a) International agencies or bodies, either governmental or non-governmental, and national governmental agencies and bodies; and

(b) National non-governmental agencies or bodies which have been approved for these purposes by the State in which they are located.

Once admitted, these observers shall have the right to participate but not to vote.

Persons wishing to be observers representing U.S. national non-governmental organizations must receive prior approval of the Service. International organizations (which must have offices in more than one country) may request approval directly from the Secretariat. After granting of that approval, a national non-governmental organization is eligible to register with the CITES Secretariat and must register with the Secretariat prior to the COP in order to participate in the COP as an observer. Individuals that are not affiliated with an organization may not register as observers. Requests for such approval should include evidence of technical qualification in protection, conservation or management of wild fauna and/or flora, on the part of both the organization and the individual representative(s). Organizations previously approved by the Service must submit a request but do not need to provide as detailed information concerning their qualifications as those seeking approval for the first time. Organizations seeking approval for the first time should detail their experience

in the protection, conservation, or management of wild fauna and/or flora, as well as their purposes for wishing to participate in the COP as an observer. Such requests should be sent to the Office of Management Authority (OMA; see **ADDRESSES**, above) or submitted to OMA electronically via E-mail to: Mark__Albert@mail.fws.gov. Upon approval by OMA, an organization will receive instructions for registration with the CITES Secretariat in Switzerland, including relevant travel and hotel information. Any organization requesting approval for observer status at COP10 will be added to the Service's CITES Mailing List if it is not already included, and will receive copies of all future Federal Register notices and other information pertaining to COP10. A list of organizations approved for observer status at COP10 will be available from OMA just prior to the start of COP10.

Future Actions

COP10 is scheduled for June 9–20, 1997, in Harare, Zimbabwe. Any proposals to amend Appendix I or II at COP10 and any proposed resolutions for discussion at COP10 must be submitted by the United States to the CITES Secretariat at least 150 days prior to the meeting (January 10, 1997). Therefore, as part of the consultation process with countries within which the proposed species occur, the Service plans to send any such proposals for species not endemic to the United States to those countries for comment by mid-October 1996 and to the Secretariat by January 10, 1997.

The Service plans to publish a Federal Register notice in February 1997 to announce the Service's decisions on species proposals and proposed resolutions that are submitted by the United States to the CITES Secretariat. Through a series of additional notices in advance of COP10, the Service will inform the public about preliminary and final negotiating positions on resolutions and amendments to the Appendices proposed by other Parties for consideration at COP10. The Service will also publish an announcement of a public meeting to be held in April 1997 to receive public input on its proposed negotiating positions for COP10.

Author: This notice was prepared by Dr. Susan Lieberman, Office of Management Authority, under the authority of the U.S. Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

List of Subjects in 50 CFR Part 23

Endangered and threatened species, Exports, Imports, Treaties.

Dated: August 22, 1996.

Jay L. Gerst,
Acting Director.

[FR Doc. 96–21975 Filed 8–27–96; 8:45 am]

BILLING CODE 4310–55–P

Bureau of Land Management

[WY–920–06–1330–01; WYW139796, WYW139797, WYW139798, WYW139799, WYW139800, WYW139801, WYW139802, WYW128038]

Cheyenne, Wyoming; Notice of Sodium Lease Offerings by Sealed Bid

AGENCY: Bureau of Land Management, Interior, Wyoming.

SUMMARY: Notice is hereby given that certain sodium resources in the lands hereinafter described, located in Sweetwater County, Wyoming, will be offered for competitive lease by sealed bid in accordance with the provisions of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 181 *et seq.*) as amended.

DATES: The lease sale will be held at 2:00 p.m., on Thursday, September 26, 1996. Sealed bids must be submitted before 1:00 p.m., on Thursday, September 26, 1996.

ADDRESSES: The lease sale will be held in the first floor conference room (Room 107) of the Wyoming State Office, 5353 Yellowstone Road, P.O. Box 1828, Cheyenne, Wyoming 82003. Sealed bids must be submitted to the Cashier, Wyoming State Office, at the address given above.

FOR FURTHER INFORMATION CONTACT: Mavis Love, Land Law Examiner, at 307–775–6258.

SUPPLEMENTARY INFORMATION: These offerings are being made as a result of expressions of interest filed in the Wyoming State Office. The tracts will be leased to the qualified bidder of the highest cash amount provided that the high bid meets the fair market value determinations of the tracts. The minimum bid is \$200.00 per acre. No bid less than \$200.00 per acre will be considered. The minimum bid is not intended to represent fair market value. The fair market value will be determined by the Authorized Officer after the sale.

The resource to be offered consists of all the sodium in the following described lands located in Sweetwater County, Wyoming. Minalable reserves are defined as beds that are maximum of 2000 feet deep, are a minimum of 8 feet thick, and have a minimum quality greater than 85 percent trona and less than 2 percent halite.

Tract A (WYW139796)

T. 17 N., R. 109 W., 6th P.M., Wyoming

Sec. 20: All;

Sec. 28: All.

Containing 1,280 acres.

Tract A contains an estimated 37.1 million tons in Bed 14, 25.3 million tons in Bed 12, 8.4 million tons in Bed 2, and 1.6 million tons in Bed 1 for a rounded total of 72.5 million tons of minable trona in the tract.

Tract B (WYW139797)

T. 17 N., R. 109 W., 6th P.M., Wyoming

Sec. 22: All;

Sec. 26: All.

Containing 1,280 acres.

Tract B contains as estimated 25.4 million tons in Bed 17, 12.9 million tons in Bed 14, .6 million tons in Bed 12, 6.2 million tons in Bed 9, and 12.9 million tons in Bed 2 for a rounded total of 67.0 million tons of minable trona in the tract.

Tract C (WYW139798)

T. 17 N., R. 109 W., 6th P.M., Wyoming

Sec. 14: All;

Sec. 24: Lots 1 thru 16.

Containing 1,193.60 acres.

Tract C contains as estimated 35.8 million tons in Bed 17, 4.3 million tons in Bed 14, 3.4 million tons in Bed 12, 7.0 million tons in Bed 9, and 5.4 million tons in Bed 2 for a rounded total of 55.9 million tons of minable trona in the tract.

Tract D (WYW139799)

T. 17 N., R. 108 W., 6th P.M., Wyoming

Sec. 6: Lots 8 thru 14, S2NE, SENW, E2SW, SE;

Sec. 8: All;

Sec. 18: Lots 5 thru 8, E2W2, E2;

T. 17 N., R. 109 W., 6th P.M., Wyoming
Sec. 12: Lots 1, 4 thru 6, 8 thru 10, SW, SWSE.

Containing 2,312.01 acres.

Tract D contains as estimated 50.0 million tons in Bed 17, 17.1 million tons in Bed 14, and 11.5 million tons in Bed 5 for a rounded total of 78.6 million tons of minable trona in the tract.

Tract E (WYW139800)

T. 17 N., R. 108 W., 6th P.M., Wyoming

Sec. 30: Lots 5 thru 8, E2W2, E2.

Containing 638.80 acres.

Tract E contains an estimated 20.8 million tons in Bed 17, .9 million tons in Bed 9, 16.4 million tons in Bed 5, and 13.8 million tons in Bed 3 for a rounded total of 51.9 million tons of minable trona in the tract.

Tract F (WYW139801)

T. 17 N., R. 108 W., 6th P.M., Wyoming

Sec. 20: All;

Sec. 28: All;

Sec. 34: All.

Containing 1,920 acres.

Tract F contains an estimated 45.8 million tons in Bed 17, .5 million tons

in Bed 14, 2.9 million tons in Bed 2, and 9.4 million tons in Bed 1 for a rounded total of 58.7 million tons of minable trona in the tract.

Tract G (WYW139802)

T. 15 N., R. 108 W., 6th P.M., Wyoming
Sec. 6: Lots 1 thru 7, S2NE, SENW, E2SW, SE;

Sec. 8: All.

Containing 1,269.52 acres.

Tract G contains an estimated 1.4 million tons in Bed 17, 4.9 million tons in Bed 9, 31.3 million tons in Bed 4, and 51.7 million tons in Bed 2 for a rounded total of 89.2 million tons of minable trona in the tract.

Tract H (WYW128038)

T. 17 N., R. 110 W., 6th P.M., Wyoming

Sec. 10: All;

Sec. 12: All.

Containing 1,280 acres.

Tract H contains an estimated 2.6 million tons in Bed 17, .6 million tons in Bed 14, and 30.8 million tons in Bed 12 for a rounded total of 34.0 million tons of minable trona in the tract. The lands included in Tract H were previously offered as Parcel 3 at the sodium sale held May 1, 1996; however, the one bid received for the parcel did not meet fair market value as determined by the Authorized Officer.

The leases issued as a result of this offering will provide for payment of annual rentals for each acre, or fraction thereof, as follows: 25 cents for the first calendar year or fraction thereof; 50 cents for the second, third, fourth and fifth calendar years, respectively; and, one dollar for the sixth and each and very calendar year thereafter during the continuance of the leases. The rental paid for any year shall be credited against the first royalties as they accrue under the lease during the year for which the rental was paid. The production royalty rate shall be 8 percent of the quantity or gross value of the output of sodium compounds and related products at the point of shipment to market.

The Bureau of Land Management reserves the right to withdraw any or all of the parcels at any time prior to the sale.

Bidding instructions for the offered tracts are included in the Detailed Statement of Lease Sale. Copies of the statement and of the proposed sodium leases are available at the Wyoming State Office. Case file documents are also available at that office for public inspection.

Dennis R. Stenger,

Acting Deputy State Director, Minerals and Lands.

[FR Doc. 96-21503 Filed 8-27-96; 8:45 am]

BILLING CODE 4310-22-M

Minerals Management Service

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of availability of the proposed final 5-Year Outer Continental Shelf (OCS) Oil and Gas Leading Program for 1997-2002.

The MMS has issued a Proposed Final OCS Oil and Gas Program for 1997-2002. This is the last of three program proposals required to be prepared before approval of a new 5-year OCS program in accordance with section 18 of the OCS Lands Act, as amended. In addition to the requirements of section 18, the President's and Secretary's policy objectives of consensus-based decisionmaking, science-based decisionmaking, and the use of natural gas as an environmentally preferred fuel have been considered in developing the Proposed Final Program.

Sixty days after issuance of the Proposed Final Program, the new program may be approved to succeed the current one, which covers the period July 1992 through June 1997. The 5-year OCS program provides a means for the Federal Government, affected States and localities, industry, and other interested parties to plan, consult, and coordinate on OCS activities.

A final Environmental Impact Statement (EIS) prepared in accordance with section 102(2)(C) of the National Environmental Policy Act is being issued along with the Proposed Final Program.

Proposed Final Program and final EIS information and documents can be obtained from the following: Regional Director, MS-5000, Gulf of Mexico Region, Minerals Management Service, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123-2394, telephone (504) 736-2947 or 1-800-200-GULF; Regional Director, MS-7000, Pacific Region, Minerals Management Service, 770 Paseo Camarillo, Camarillo, California 93010, telephone (805) 389-7533; and Regional Director, MS-8000, Alaska Region, Minerals Management Service, University Plaza Building, Suite 300, 949 East 36th Avenue, Anchorage, Alaska 99508, telephone (907) 271-6070.

Proposed Final Program information and documents also can be obtained from: Chief, Branch of Program Development and Planning, MS-4430, Minerals Management Service, Room 2328, 381 Elden Street, Herndon, Virginia 22070-4817, telephone (703) 787-1215.

Final EIS information and documents also can be obtained from: Chief, Environmental Projects Coordination Branch, MS-4320, Minerals

Management Service, 831 Elden Street, Herndon Virginia 22070-4817, telephone (703) 787-1674.

For information on the development of the Proposed Final Program for 1997-2002, telephone Carol Hartgen or Tim Redding, Branch of Program Development and Planning, at (703) 787-1215.

Dated: August 22, 1996.

Cynthia Quarterman,

Director, Minerals Management Service.

[FR Doc. 96-21984 Filed 8-27-96; 8:45 am]

BILLING CODE 4310-MR-M

National Park Service

Cape Cod National Seashore Advisory Commission; Establishment

AGENCY: National Park Service, Department of the Interior.

ACTION: Establishment.

SUMMARY: The National Park Service (NPS) is giving notice of its intent to establish the Cape Cod National Seashore Advisory Commission in accordance with the Federal Advisory Committee Act (PL 92-463, 86 Stat. 770, 5 U.S.C. Appx., section 10).

The Commission was originally established by Section 8 of PL 87-126, August 7, 1961. It was reestablished by PL 99-349, Amendment 24, July 2, 1986, and extended to May 31, 1996, by PL 99-420, September 25, 1986. Because the need for the Commission is expected to continue indefinitely, the National Park Service is administratively re-establishing the Commission in the same form as it has existed under its expired statutory authority. In this way the Commission may continue its work without interruption.

The purpose of the Commission is to consult with the Secretary of the Interior, or the Secretary's designee, with respect to matters relating to the development of the Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

Composition: The Commission is to consist of 10 members as follows:

(1) Six members appointed from recommendations made by each of the boards of selectmen of the towns of Truro, Wellfleet, Eastham, Orleans, Chatham, and Provincetown, Commonwealth of Massachusetts;

(2) One member to be appointed from recommendations of the county commissioners of Barnstable County, Commonwealth of Massachusetts;

(3) Two members to be appointed from recommendations of the Governor

of the Commonwealth of Massachusetts; and

(4) One member to be appointed at the discretion of the Secretary.

Copies of the Commission's charter will be filed with the appropriate committees of Congress and with the Library of Congress in accordance with section 9(c) of the Federal Advisory Committee Act (FACA), 5 U.S.C. appx.

NPS invites any interested person to comment on the proposal to establish this Commission.

Records of Meetings: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. Appx. 1988, the NPS will keep a record of all Commission meetings.

Administrative Support: To the extent authorized by law, the NPS will fund the costs of the Commission and provide administrative support and technical assistance for the activities of the Commission.

Certification: I hereby certify that the administrative establishment of the Cape Cod National Seashore Advisory Commission is necessary and in the public interest in connection with the performance of duties imposed on the Department of the Interior by the Act of August 25, 1916, 16 U.S.C. 1 et seq., and other statutes relating to the administration of the National Park System.

Dated: June 20, 1996.

Bruce Babbitt,

Secretary of the Interior

[FR Doc. 96-21913 Filed 8-27-96; 8:45 am]

BILLING CODE 4310-70-P

Bureau of Reclamation

Bay-Delta Advisory Council Meeting

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of meeting.

SUMMARY: The Bay-Delta Advisory Council (BDAC) will meet to discuss several issues including: the process and schedule to refine the alternative components in Phase II of the program; status reports on the program components; and status reports outlining activities and concerns from the BDAC Work Groups and CALFED technical groups. This meeting is open to the public. Interested persons may make oral statements to the BDAC or may file written statements for consideration.

DATES: The Bay-Delta Advisory Council meeting will be held from 10 a.m. to 5 p.m. on Friday, September 20, 1996.

ADDRESSES: The Bay-Delta Advisory Council will meet at the Sacramento

Convention Center, 1400 J Street, Room 308, Sacramento, CA.

CONTACT PERSON FOR MORE INFORMATION: Sharon Gross, CALFED Bay-Delta Program, at (916) 657-2666. If reasonable accommodation is needed due to a disability, please contact the Equal Employment Opportunity Office at (916) 653-6952 or TDD (916) 653-6934 at least one week prior to the meeting.

SUPPLEMENTARY INFORMATION: The San Francisco Bay/Sacramento-San Joaquin Delta Estuary (Bay-Delta system) is a critically important part of California's natural environment and economy. In recognition of the serious problems facing the region and the complex resource management decisions that must be made, the state of California and the Federal government are working together to stabilize, protect, restore, and enhance the Bay-Delta system. The State and Federal agencies with management and regulatory responsibilities in the Bay-Delta system are working together as CALFED to provide policy direction and oversight for the process.

One area of Bay-Delta management includes the establishment of a joint State-Federal process to develop long-term solutions to problems in the Bay-Delta system related to fish and wildlife, water supply reliability, natural disasters, and water quality. The intent is to develop a comprehensive and balanced plan which addresses all of the resource problems. This effort, the CALFED Bay-Delta Program (Program), is being carried out under the policy direction of CALFED. The CALFED Bay-Delta Program is exploring and developing a long-term solution for a cooperative planning process that will determine the most appropriate strategy and actions necessary to improve water quality, restore health to the Bay-Delta ecosystem, provide for a variety of beneficial uses, and minimize Bay-Delta system vulnerability. A group of citizen advisors representing California's agricultural, environmental, urban, business, fishing, and other interests who have a stake in finding long-term solutions for the problems affecting the Bay-Delta system has been chartered under the Federal Advisory Committee Act (FACA) as the Bay-Delta Advisory Council (BDAC) to advise CALFED on the program mission, problems to be addressed, and objectives for the CALFED Bay-Delta Program. BDAC provides a forum to help ensure public participation, and will review reports and other materials prepared by CALFED staff.

Minutes of the meeting will be maintained by the CALFED Bay-Delta

Program, Suite 1155, 1416 Ninth Street, Sacramento, CA 95814, and will be available for public inspection during regular business hours, Monday through Friday, within 30 days following the meeting.

Dated: August 21, 1996.

Roger Patterson,

Regional Director, Mid-Pacific Region.

[FR Doc. 96-21972 Filed 8-27-96; 8:45 am]

BILLING CODE 4310-94-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-380]

Certain Agricultural Tractors Under 50 Power Take-Off Horsepower

Notice is hereby given that the prehearing conference in this matter will commence at 8:30 a.m. on August 29, 1996, in Courtroom A (Room 100), U.S. International Trade Commission Building, 500 E St. S.W., Washington, D.C., and the hearing will commence immediately thereafter.

The Secretary shall publish this notice in the Federal Register.

Issued: August 20, 1996.

Paul J. Luckern,

Administrative Law Judge.

[FR Doc. 96-21956 Filed 8-27-96; 8:45 am]

BILLING CODE 7020-02-P

[Investigation No. 731-TA-751 (Preliminary)]

Open-End Spun Rayon Singles Yarn From Austria

AGENCY: United States International Trade Commission.

ACTION: Institution of antidumping investigation and scheduling of a preliminary phase antidumping investigation.

SUMMARY: The Commission hereby gives notice of the institution of an investigation and commencement of preliminary phase antidumping investigation No. 731-TA-751 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. § 1673b(a)) (the Act) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from Austria of open-end spun rayon singles yarn, provided for in subheading 5510.11.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold

in the United States at less than fair value. Unless the Department of Commerce extends the time for initiation pursuant to section 732(c)(1)(B) of the Act (19 U.S.C. § 1673a(c)(1)(B)), the Commission must reach a preliminary determination in antidumping investigations in 45 days, or in this case by October 4, 1996. The Commission's views are due at the Department of Commerce within five business days thereafter, or by October 11.

For further information concerning the conduct of this investigation and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207), as amended in 61 FR 37818 (July 22, 1996).
EFFECTIVE DATE: August 20, 1996.

FOR FURTHER INFORMATION CONTACT: Tim Timberlake (202-205-3188), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<http://www.usitc.gov> or <ftp://ftp.usitc.gov>).

SUPPLEMENTARY INFORMATION

Background.—This investigation is being instituted in response to a petition filed on August 20, 1996, by the Ad-Hoc Committee of Open-End Spun Rayon Yarn Producers, Gastonia, North Carolina. The Committee includes Burlington Madison Yarn Company, Greensboro, NC; Carolina Mills, Inc., Maiden, NC; National Spinning Company, Washington, NC; and Uniblend Spinners, Inc., Union, SC.

Participation in the investigation and public service list.—Persons (other than petitioners) wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the Federal Register. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping investigations. The Secretary will prepare a public service list containing

the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this investigation available to authorized applicants representing interested who are parties to the investigation under the APO issued in the investigation, provided that the application is made not later than seven days after the publication of this notice in the Federal Register. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Operations has scheduled a conference in connection with this investigation for 9:30 a.m. on September 10, 1996, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Tim Timberlake (202-205-3188) not later than September 6 to arrange for their appearance. Parties in support of the imposition of antidumping duties in this investigation and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before September 13, 1996, a written brief containing information and arguments pertinent to the subject matter of the investigation. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

Issued: August 22, 1996.

By order of the Commission.

Donna R. Koehnke,
Secretary.

[FR Doc. 96-21973 Filed 8-27-96; 8:45 am]

BILLING CODE 7020-02-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Committee on Rules of Practice and Procedure

AGENCY: Judicial Conference of the United States, Committee on Rules of Practice and Procedure.

ACTION: Notice of Request for Comment on the Preliminary Draft of Proposed Amendments to the Federal Rules of Appellate, Civil, and Criminal Procedure, and the Official Bankruptcy Forms.

SUMMARY: The Advisory Committees on Rules of Appellate, Bankruptcy, Civil, and Criminal Procedure have proposed amendments to the following rules and forms:

Appellate Rules and Forms—5.5.1, and Form 4
Bankruptcy Forms—1, 3, 6, 8, 9, 10, 14, 17, 18, and new Forms 20A and 20B
Civil Rules—23
Criminal Rules—5.1, 26.2, 31, 33, 35, and 43

Public hearings will be held on the amendments to:

Appellate Rules in Denver, Colorado on November 15, 1996;

Civil Rules in Philadelphia, Pennsylvania on November 22, 1996, Dallas, Texas on December 16, 1996, and San Francisco, California on January 17, 1997; and

Criminal Rules in Oakland, California on December 13, 1997.

The Judicial Conference Committee on Rules of Practice and Procedure submits these rules for public comment. All comments and suggestions with respect to them must be placed in the hands of the Secretary as soon as convenient and, in any event, no later than February 15, 1997.

Anyone interested in testifying should write to Mr. Peter G. McCabe, Secretary, Committee on Rules of Practice and Procedure, Administrative Office of the United States Courts, Washington, DC 20544, at least 30 days before the hearing.

FOR FURTHER INFORMATION CONTACT: John K. Rabiej, Chief, Rules Committee

Support Office, Administrative Office of the United States Courts, Washington, D.C. 20544, telephone (202) 273-1820.

Dated: August 22, 1996.

John K. Rabiej,

Chief, Rules Committee Support Office.

[FR Doc. 96-21977 Filed 8-27-96; 8:45 am]

BILLING CODE 221001-M

Meeting of the Judicial Conference Advisory Committee on Rules of Bankruptcy Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Bankruptcy Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Bankruptcy Procedure will hold a two-day meeting. The meeting will be open to public observation but not participation and will be held each day from 8:30 a.m. to 5:00 p.m.

DATES: September 26-27, 1996.

ADDRESSES: Park Hyatt San Francisco, 333 Battery Street, San Francisco, California.

FOR FURTHER INFORMATION CONTACT:

John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, D.C. 20544, telephone (202) 273-1820.

Dated: August 23, 1996.

John K. Rabiej,

Chief, Rules Committee Support Office.

[FR Doc. 96-21978 Filed 8-27-96; 8:45 am]

BILLING CODE 2210-01-M

Meeting of the Judicial Conference Advisory Committee on Rules of Criminal Procedure

AGENCY: Judicial Conference of the United States; Advisory Committee on Rules of Criminal Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Criminal Procedure will hold a two-day meeting. The meeting will be open to public observation but not participation and will be held the first day from 8:30 a.m. to 5:00 p.m. and the second day from 8:30 a.m. to 12 Noon.

DATES: October 7-8, 1996.

ADDRESSES: Salishan Lodge, 7760 Highway 101 North, Gleneden Beach, Oregon.

FOR FURTHER INFORMATION CONTACT:

John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, D.C. 20544, telephone (202) 273-1820.

Dated: August 23, 1996.

John K. Rabiej,

Chief, Rules Committee Support Office.

[FR Doc. 96-21979 Filed 8-27-96; 8:45 am]

BILLING CODE 2210-01-M

Meeting of the Judicial Conference Advisory Committee on Rules of Civil Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Civil Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Civil Procedure will hold a two-day meeting. The meeting will be open to public observation but not participation and will be held each day from 8:30 a.m. to 5:00 p.m.

DATES: October 17-18, 1996.

ADDRESSES: Thurgood Marshall Federal Judiciary Building, Judicial Conference Center, One Columbus Circle, N.E., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, D.C. 20544, telephone (202) 273-1820.

Dated: August 23, 1996.

John K. Rabiej,

Chief, Rules Committee Support Office.

[FR Doc. 96-21980 Filed 8-27-96; 8:45 am]

BILLING CODE 2210-01-M

Meeting of the Judicial Conference Committee on Rules of Practice

AGENCY: Judicial Conference of the United States, Committee on Rules of Practice and Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Committee on Rules of Practice and Procedure will hold a three-day meeting. The meeting will be open to public observation but not participation on will commence the first day at 6:30 p.m. and the second and third days at 8:30 a.m.

DATES: January 8-10, 1997.

ADDRESSES: Westward Look Resort, 245 East Ina Road, Tucson, Arizona.

FOR FURTHER INFORMATION CONTACT:

John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, D.C. 20544, telephone (202) 273-1820.

Dated: August 23, 1996.

John K. Rabiej,

Chief, Rules Committee Support Office.

[FR Doc. 96-21981 Filed 8-27-96; 8:45 am]

BILLING CODE 2210-01-M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA")

In accordance with Departmental policy, 28 C.F.R. § 50.7, notice is hereby given that a proposed consent decree in *United States v. Scott A. Musselman*, Civil No. 1:96cv254, was lodged on August 19, 1996 with the United States District Court for the Western District of Michigan. The decree pertains to the Peerless Plating Superfund Site in Muskegon, Michigan.

The Consent Decree requires Mr. Musselman to pay to the Hazardous Substances Superfund the sum of \$157,836, plus interest accruing from the date of entry of the Decree, at the rate provided in Section 107(a) of CERCLA, 42 U.S.C. § 9607(a). Such payment may be made in three installments over the next one and a half years.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, Washington, D.C., 20430, and should refer to *United States v. Scott A. Musselman* (W.D. Mich.) and DOJ Ref. No. 90-11-3-65C.

The proposed Consent Decree may be examined at the Office of the United States Attorney, West District of Michigan, 330 Ionia N.W., Fifth Floor, Grand Rapids, Michigan 49503; the Region 5 office of U.S. EPA, 77 West Jackson Blvd., Chicago Illinois (60604-3590); and at the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. (20005), 202-624-0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, N.W., 4th Floor, Washington, D.C. 20005. In requesting a copy please enclose a check in the amount of \$4.50 (25 cents per page reproduction costs) payable to "Consent Decree Library."

Walker B. Smith,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96-21906 Filed 8-27-96; 8:45 am]

BILLING CODE 4410-01-M

Antitrust Division**Notice Pursuant to the National Cooperative Research and Production Act of 1993 Advanced Lead-Acid Battery Consortium**

Notice is hereby given that, on August 13, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* ("the Act"), the Advanced Lead-Acid Battery Consortium ("ALABC"), a discrete program of the International Lead Zinc Research Organization, Inc. ("ILZRO"), filed a written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing the addition of one member to the ALABC. The notification was filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the ALABC advised that Electric Utility Research Consortia, Electric Power Research Institute, Palo Alto, CA has made a written commitment effective August 5, 1996 to become a member of the ALABC.

No other changes have been made in either the membership or planned activity of the ALABC. Membership in the ALABC remains open and the ALABC intends to file additional written notification disclosing any future changes in membership.

On June 15, 1992, the ALABC filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to section 6(b) of the Act on July 29, 1992, 57 FR 33522. The last notification was filed with the Department on July 17, 1996.

Constance K. Robinson,
Director of Operations, Antitrust Division.
[FR Doc. 96-21902 Filed 8-27-96; 8:45 am]
BILLING CODE 4410-01-M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Biotechnology Research and Development Corporation ("BRDC")

Notice is hereby given that, on August 6, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Biotechnology Research and Development Corporation ("BRDC") filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in the membership. The notifications were filed for the purpose of extending the

Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Specifically, American Cyanamid Company, Princeton, NJ; and Pig Improvement Company, Inc., Franklin, KY have withdrawn from participation. Hewlett Packard Company, Palo Alto, CA, plans to withdraw effective May 14, 1997. Dalgely plc, Cambridge, ENGLAND; Bernard Technologies, Inc., Chicago, IL; and Alexion Pharmaceuticals, Inc., New Haven CT have become parties to the membership. Additionally, The Dow Chemical Company, Midland, MI has decided not to withdraw participation as previously announced.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and BRDC intends to file additional written notification disclosing all changes in membership.

On April 12, 1988, BRDC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on May 12, 1988, 53 FR 16919. The last notification was filed June 12, 1995.

Constance K. Robinson,
Director of Operations, Antitrust Division.
[FR Doc. 96-21903 Filed 8-27-96; 8:45 am]
BILLING CODE 4410-01-M

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Biotechnology Research and Development Corporation ("BRDC")

Notice is hereby given that, on June 12, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. *et seq.* ("the Act"), Biotechnology Research and Development Corporation ("BRDC") filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in the membership and project status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, that Amoco Technology Company, Naperville, IL has withdrawn from participation and The Dow Chemical Company plans to withdraw from BRDC, effective April 1, 1996. In addition to undertaking original research, BRDC may also acquire interests in existing inventions which require further research and

development before they can be commercialized.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and BRDC intends to file additional written notification disclosing all changes in membership.

On April 12, 1988, BRDC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to Section 6(b) of the Act on May 12, 1988, 53 FR 16919. The last notification was filed September 17, 1993. A notice was published in the Federal Register on December 2, 1993, 58 FR 63586.

Constance K. Robinson,
Director of Operations, Antitrust Division.
[FR Doc. 96-21904 Filed 8-27-96; 8:45 am]
BILLING CODE 4410-01-M

FOREIGN CLAIMS SETTLEMENT COMMISSION

[F.C.S.C. Meeting Notice No. 7-96]

Sunshine Act Meetings; Announcement in Regard to Commission Meetings and Hearings

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR Part 504), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings and oral hearings for the transaction of Commission business and other matters specified, as follows:

Date and Time: Mon., October 7, 1996, 10:00 a.m.

Subject Matter: Consideration of Proposed Decisions on claims against Albania.

Status: Open.

Subject matter not disposed of at the scheduled meeting may be carried over to the agenda of the following meeting.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street, NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting may be directed to: Administrative Officer, Foreign Claims Settlement Commission, 600 E Street, NW., Room 6029, Washington, DC 20579. Telephone: (202) 616-6988.

Dated at Washington, DC on August 23, 1996.

Jeanette Matthews,
Administrative Assistant.
[FR Doc. 96-22081 Filed 8-26-96; 12:44 pm]
BILLING CODE 4410-01-P

[F.C.S.C. Meeting Notice No. 8-96]**Sunshine Act Meetings;
Announcement in Regard to
Commission Meetings and Hearings**

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR Part 504), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings and oral hearings for the transaction of Commission business and other matters specified, as follows:

Date and Time: Mon., October 7, 1996, approximately 11:30 a.m.

Subject Matter: Consideration of Proposed Decisions on claims of Holocaust survivors against Germany.

Status: Closed.

Subject matter not disposed of at the scheduled meeting may be carried over to the agenda of the following meeting.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street, NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Administrative Officer, Foreign Claims Settlement Commission, 600 E Street, NW., Room 6029, Washington, DC 20579. Telephone: (202) 616-6988.

Dated at Washington, DC on August 23, 1996.

Jeanette Matthews,
Administrative Assistant.

[FR Doc. 96-22082 Filed 8-26-96; 12:44 pm]

BILLING CODE 4410-01-P

**NUCLEAR REGULATORY
COMMISSION**

[Docket NO. 50-255]

**Consumers Power Company; Notice of
Consideration of Issuance of
Amendment to Facility Operating
License, Proposed No Significant
Hazards Consideration Determination,
and Opportunity for a Hearing**

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-20 issued to Consumers Power Company (the licensee) for operation of the Palisades Plant located in Van Buren County, Michigan.

The proposed amendment would revise the requirements of technical specification (TS) 3.1.9.3 to permit a filled refueling cavity to serve as a backup means of decay heat removal.

Before issuance of the proposed license amendment, the Commission will have made findings required by the

Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the three standards of 10 CFR 50.92(c). The staff's review is presented below.

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed changes emulate the Standard Technical Specifications by allowing use of a filled reactor cavity as the required backup capability for decay heat removal; only an operable train of shutdown cooling is currently allowed to fulfill this function. The decay heat removal backup capability need not provide forced flow through the reactor core. This is because Action 2.a of TS 3.1.9.3 currently requires discontinuation of all operations involving a reduction in primary coolant system (PCS) boron concentration if loss of the inservice system caused flow to be reduced below that required. The proposed changes do not affect the requirements for the inservice train of shutdown cooling. Since the proposed changes do not affect the requirements for equipment that would be in operation, allowing use of an alternate decay heat removal backup capability cannot alter any plant operating conditions, equipment settings, or capabilities or operating equipment. Therefore, operating the facility in accordance with the proposed changes would not increase the probability or consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any previously evaluated?

As discussed in the response to question 1, above, the proposed changes would not affect the plant configuration or the capability of equipment required to be in operation. The changes simply allow substitution of one means of

decay heat removal for another as a backup capability. The equipment used as a backup capability is only actuated after occurrence of an event that disables the decay heat removal equipment that is required to be in operation. Because the backup capability for decay heat removal, either as currently required or as proposed, would not be placed into service until after an event had occurred, operating the facility in accordance with the proposed changes would not create the possibility of a new or different kind of accident from any previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

The objectives of TS 3.1.9.3 are to ensure that the PCS is mixed by forced flow to avoid the potential for development of pockets of unborated or diluted coolant, and to ensure that sufficient decay heat removal capability is available to withstand loss of the operating decay heat removal system due to equipment failure or personnel error. These objectives are fulfilled by requiring (1) forced flow through the reactor core, (2) one operable system capable of decay heat removal to be in operation, and (3) another operable system capable of decay heat removal to provide a backup capability.

The proposed changes allow use of a filled refueling cavity as the required backup capability for decay heat removal; only an operable train of shutdown cooling is currently allowed to fulfill this function. The proposed changes do not affect the requirements for flow through the reactor core or the inservice train of shutdown cooling. The decay heat removal backup capability need not provide forced flow through the reactor core. This is because Action 2.a of TS 3.1.9.3 requires discontinuation of all operations involving a reduction in PCS boron concentration if loss of the inservice system caused flow to be reduced below that required. Since the proposed changes only allow substitution of an alternate method of meeting the third objective for that currently specified, all objectives of the specification are still met. Therefore, operating the facility in accordance with the proposed changes would not involve a significant reduction in a margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received

within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By September 27, 1996, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Van

Wylen Library, Hope College, Holland, Michigan 49423. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to

matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248-5100 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Mark Reinhart, Acting Director, Project Directorate III-1: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to Judd L. Bacon, Esquire Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated January 5, 1996, as supplemented July 12, 1996, which are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Van Wylen Library, Hope College, Holland, Michigan 49423.

Dated at Rockville, Maryland, this 22nd day of August 1996.

For the Nuclear Regulatory Commission.
Robert G. Schaaf,
*Project Manager, Project Directorate III-1,
Division of Reactor Projects—III/IV, Office of
Nuclear Reactor Regulation.*
[FR Doc. 96–21937 Filed 8–27–96; 8:45 am]
BILLING CODE 7590–01–P

[Docket No. 50–397]

Washington Public Power Supply System, Unit 2; Notice of Consideration of Issuance of Amendment To Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity For a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF 21 issued to Washington Public Power Supply System (WPPSS, also the licensee) for operation of the WPPSS Nuclear Project No. 2 located on the Hanford Reservation in Benton County, Washington.

The proposed amendment would revise Technical Specification (TS) Section 6.3, Unit Staff Qualifications, by changing the operations manager qualification requirements associated with operations knowledge from meeting ANSI/ANS N18.1–1971 (holding a senior reactor operator's license at the time of appointment) to (1) Holding a senior reactor operator's license at the time of appointment; (2) having held a senior reactor operator's license; or (3) having been certified for equivalent senior reactor operator knowledge.

Before issuance of the proposed license amendment, the Commission

will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed amendment provides an alternate qualification criterion for the operations manager in lieu of a senior reactor operator's license at the time of appointment to the position. The alternate criterion ensures that the operations manager has certified knowledge equivalent to that of a senior reactor operator. The position of operations manager is not identified as an initiator for, or contributor to, a previously analyzed accident or transient. Additionally, either the assistant operations manager or the operations manager will maintain a senior reactor operator's license such that the on shift personnel routinely report to someone not normally on shift that has a license. The proposed change involves no change to the plant design or the manner in which the plant is operated. As such, the proposed change will not result in a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed amendment provides an alternate qualification criterion for the operations manager in lieu of a senior reactor operator's license at the time of appointment to the position. The alternate criterion ensures that the operations manager has certified knowledge equivalent to that of a senior reactor operator. The proposed change involves no change to the plant design or the manner in which the plant is operated. Either the assistant operations manager or the operations manager will maintain a senior reactor operator's license such that the on shift personnel routinely report to someone not normally on shift that has a license. Since the operations manager will continue to have the knowledge necessary to perform the functions of the position, and since sufficient licensed personnel will be available in accordance with other Technical Specification and 10 CFR 50.54(m)(2) requirements, the proposed change will not create the possibility of a new or different

kind of accident from any accident previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The plant margins of safety are established through LCOs [limiting conditions for operation], limiting safety system settings, and safety limits specified in the Technical Specifications. There will be no changes to either the physical design of the plant, the manner in which the plant is operated, or to any of these settings or limits as a result of the proposed change. As such, the proposed amendment does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

The filing of requests for hearings and petitions for leave to intervene is discussed below.

By September 27, 1996, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Richland Public Library, 955 Northgate Street, Richland, Washington 99352. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wished to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the

proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide reference to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or act. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by

the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248-5100 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to William H. Bateman, Director, Project Directorate IV-2: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to M. H. Phillips Jr., Esq., Winston & Strawn, 1400 L Street NW., Washington, DC 20005-3512, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated August 9, 1996, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Richland Public Library, 955 Northgate Street, Richland, Washington 99352.

Dated at Rockville, Maryland, this 23rd day of August 1996.

For the Nuclear Regulatory Commission.

Timothy G. Colburn,

Senior Project Manager, Project Directorate IV-2, Division of Reactor Projects—III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 96-21938 Filed 8-27-96; 8:45 am]

BILLING CODE 7590-01-P

Advisory Committee on Reactor Safeguards; Meeting Notice

In accordance with the purposes of Sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards will hold a meeting on September 12-13, 1996, in Conference Room T-2B3, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in

the Federal Register on Monday, November 27, 1995 (60 FR 58393).

Thursday, September 12, 1996

8:30 A.M.–8:45 A.M.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding conduct of the meeting and comment briefly regarding items of current interest. During this session, the Committee will discuss priorities for preparation of ACRS reports.

8:45 A.M.–10:45 A.M.: Adequacy of the Codes to Analyze Steam Generator Tube Temperature Distributions During Severe Accidents (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the adequacy of the NRC codes to analyze steam generator tube temperature distributions during severe-accident conditions.

Representatives of the industry will participate, as appropriate.

11:00 A.M.–11:15 A.M.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss responses from the NRC Executive Director for Operations (EDO) to comments and recommendations included in recent ACRS reports. The EDO responses are expected to be provided in writing to the ACRS prior to the meeting.

11:15 A.M.–11:45 A.M.: Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will hear a report of the Planning and Procedures Subcommittee on matters related to the conduct of ACRS business, and organizational and personnel matters relating to ACRS.

A portion of this session may be closed to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of this Advisory Committee, and matters the release of which would constitute a clearly unwarranted invasion of personal privacy.

11:45 A.M.–12:15 P.M.: Future ACRS Activities (Open)—The Committee will discuss recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the full Committee during future meetings.

1:15 P.M.–2:45 P.M.: Indian Point Unit 3 (Open)—The Committee will hear presentations by and hold discussions with representatives of the Indian Point Unit 3 licensee (New York Power Authority) regarding the resolution of issues that led to the shutdown of Indian Point Unit 3, and the status of resolution of new issues since the restart of the plant in June 1995.

Representatives of the NRC staff will participate.

3:00 P.M.–5:00 P.M.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting.

5:15 P.M.–7:00 P.M.: Strategic Planning (Open)—The Committee will continue its discussion of items that are of significant importance to NRC, including rebaselining of the Committee activities for FY 97.

Friday, September 13, 1996

8:30 A.M.–8:35 A.M.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding conduct of the meeting.

8:35 A.M.–10:30 A.M.: Meeting with the Director of the NRC Office of Nuclear Regulatory Research (RES) (Open)—The Committee will hear a presentation by and hold discussions with Mr. David Morrison, RES Director, on items of mutual interest including:

- Overview of the NRC research program and budget.
- Research priorities.
- NRC Thermal Hydraulic Code Activities.
- International cooperative research program.
- RES plans and priorities for providing information necessary for the development of risk-informed and performance-based regulations by expanding the scope of NUREG-1150 work to include Level 3 PRA for shutdown modes of operation, fire, and other external events; rationale for these plans and priorities; ongoing and planned research to do such PRAs for other modes of operation.

10:45 A.M.–12:00 NOON: Loss of Feedwater Event at Arkansas Nuclear One Unit 1 (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the findings and conclusions of the Augmented Inspection Team, which investigated the May 19, 1996 loss of feedwater event at Arkansas Nuclear One Unit 1.

Representatives of the licensee will participate, as appropriate.

1:15 P.M.–3:00 P.M.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting.

Procedures for the conduct of and participation in ACRS meetings were published in the Federal Register on September 27, 1995 (60 FR 49925). In accordance with these procedures, oral or written statements may be presented by members of the public, electronic recordings will be permitted only during the open portions of the meeting, and questions may be asked only by

members of the Committee, its consultants, and staff. Persons desiring to make oral statements should notify Mr. Sam Duraiswamy, Chief, Nuclear Reactors Branch, at least five days before the meeting, if possible, so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during this meeting may be limited to selected portions of the meeting as determined by the Chairman.

Information regarding the time to be set aside for this purpose may be obtained by contacting the Chief of the Nuclear Reactors Branch prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Chief of the Nuclear Reactors Branch if such rescheduling would result in major inconvenience.

In accordance with Subsection 10(d) Pub.L. 92-463, I have determined that it is necessary to close portions of this meeting noted above to discuss matters that relate solely to the internal personnel rules and practices of this Advisory Committee per 5 U.S.C. 552b(c)(2), and to discuss matters the release of which would constitute a clearly unwarranted invasion of personal privacy per 5 U.S.C. 552b(c)(6).

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting Mr. Sam Duraiswamy, Chief, Nuclear Reactors Branch (telephone 301/415-7364), between 7:30 A.M. and 4:15 P.M. EDT.

ACRS meeting notices, meeting transcripts, and letter reports are now available on FedWorld from the "NRC MAIN MENU." Direct Dial Access number to FedWorld is (800) 303-9672; the local direct dial number is 703-321-3339.

Dated: August 22, 1996.

John C. Hoyle

Acting Advisory Committee Management Officer.

[FR Doc. 96-21939 Filed 8-27-96; 8:45 am]

BILLING CODE 7590-01-P

Advisory Committee on Reactor Safeguards, Subcommittee Meeting on Thermal Hydraulic Phenomena; Notice of Meeting

The ACRS Subcommittee on Thermal Hydraulic Phenomena will hold a meeting on September 18-19, 1996,

Room T-2B3, 11545 Rockville Pike, Rockville, Maryland.

A portion of this meeting may be closed to discuss the proposed NRC thermal hydraulic research program budget. Discussion of the impact of possible budget reduction on continuing and proposed research contracts, if held in public session, might result in premature disclosure of information which would in turn frustrate the Commission's ability to effectively implement the affected programs.

The agenda for the subject meeting shall be as follows:

Wednesday, September 18, 1996—8:30

a.m. until the conclusion of business

Thursday, September 19, 1996—8:30

a.m. until the conclusion of business

The Subcommittee will: (1) Begin its review of the NRC-RES Program to revise/replace the current suite of NRC-RES thermal hydraulic codes and (2) discuss the status of the RES thermal hydraulic research program and associated budget. The purpose of this meeting is to gather information, analyze relevant issues and facts, and to formulate proposed positions and actions, as appropriate, for deliberation by the full Committee.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Electronic recordings will be permitted only during those portions of the meeting that are open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the cognizant ACRS staff engineer named below five days prior to the meeting, if possible, so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the scheduling of sessions which are open to the public, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting the cognizant ACRS staff engineer, Mr. Paul A. Boehnert (telephone 301/415-

8065) between 7:30 a.m. and 4:15 p.m. (EDT). Persons planning to attend this meeting are urged to contact the above named individual one or two working days prior to the meeting to be advised of any potential changes to the agenda, etc., that may have occurred.

Dated: August 21, 1996.

Sam Duraiswamy,

Chief, Nuclear Reactors Branch.

[FR Doc. 96-21940 Filed 8-27-96; 8:45 am]

BILLING CODE 7590-01-P

Biweekly Notice

Applications and Amendments to Facility Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law 97-415, the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. Public Law 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from August 3, 1996, through August 16, 1996. The last biweekly notice was published on August 14, 1996 (61 FR 42274).

Notice Of Consideration Of Issuance Of Amendments To Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, And Opportunity For A Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this

proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By September 27, 1996, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for

Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the

petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 248-5100 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to (Project Director): petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear

Regulatory Commission, Washington, DC 20555-0001, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room for the particular facility involved.

Carolina Power & Light Company, et al., Docket No. 50-400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of amendment request: July 19, 1996

Description of amendment request: The proposed amendment would revise Technical Specification (TS) Section 3/4.6.2, Containment Spray System, to extend the surveillance interval for performance of an air or smoke flow test through containment spray nozzles from once per 5 years to once per 10 years. This change is consistent with the guidance in NRC Generic Letter 93-05, "Line Item Technical Specifications Improvements to Reduce Surveillance Requirements for Testing During Power Operations," and NUREG-1366, "Improvements To Technical Specifications Surveillance Requirements."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed extended testing frequency of containment spray nozzles will not affect any initiators of any previously evaluated accidents or change the manner of operation for any system or component. The containment spray system serves a mitigating function by removing heat and fission products from a post accident containment atmosphere. Increasing the surveillance test interval will not affect the system's ability to provide this function. Therefore, there would be no increase in the probability or consequences of an accident previously evaluated.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Since the proposed change affects only a surveillance frequency, it will not involve any physical alterations to plant equipment or alter the manner in which any safety-related system performs its function. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed amendment does not involve a significant reduction in the margin of safety.

The proposed change does not affect any Final Safety Analysis Report (FSAR) Chapter 15 accident analyses or impact the margin of safety for the containment spray system as defined in the Bases to the Technical Specifications. Therefore, the proposed change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room

location: Cameron Village Regional Library, 1930 Clark Avenue, Raleigh, North Carolina 27605

Attorney for licensee: William D. Johnson, Vice President and Senior Counsel, Carolina Power & Light Company, Post Office Box 1551, Raleigh, North Carolina 27602

NRC Project Director: Eugene V. Imbro

Commonwealth Edison Company, Docket Nos. 50-254 and 50-265, Quad Cities Nuclear Power Station, Units 1 and 2, Rock Island County, Illinois

Date of amendment request: June 10, 1996

Description of amendment request: To change the technical specifications to reflect the transition from General Electric Company (GE) to Siemens Power Corporation (SPC) as the fuel supplier for the Quad Cities Nuclear Power Station, Units 1 and 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1) Involve a significant increase in the probability or consequences of an accident previously evaluated.

The probability of an evaluated accident is derived from the probabilities of the individual precursors to that accident. The consequences of an evaluated accident are determined by the operability of plant systems designed to mitigate those

consequences. Limits will be established consistent with NRC approved methods to ensure that fuel performance during normal, transient, and accident conditions is acceptable. The proposed Technical Specifications amendment reflects previously approved SPC methodology used to analyze normal operations, including anticipated operational occurrences (AOOs), and to determine the potential consequences of accidents.

Licensing Methods and Models

The proposed amendment is to support operation with NRC approved fuel and licensing methods supplied from Siemens Power Corporation. In accordance with FSAR Chapter 15, the same accidents and transients will be analyzed with the new fuel and methods as were analyzed by GE for GE fuel. The analysis methods and models are NRC approved. These approved methods and models are used to determine the fuel thermal limits (e.g., LHGR, APLHGR, MCPR). The SPC core monitoring code enables the site to monitor k_{eff} as well as rod density to perform the reactivity anomaly surveillance. This is consistent with GE methodology. The support systems for minimizing the consequences of transients and accidents are not affected by the proposed amendment. Therefore, the change in licensing analysis methods and models does not significantly increase the probability of an accident or the consequences of an accident previously identified.

New Fuel Design

The use of ATRIUM 9B fuel at Quad Cities does not involve a significant increase in the probability or consequences of any accident previously evaluated in the FSAR. The ATRIUM-9B fuel is generically approved for use as a reload BWR fuel type (Reference: ANF-89-014(P)(A) Rev. 1 Supplement 1, General Mechanical Design for Advanced Nuclear Fuels 9X9-IX and 9X9-9X BWR Reload Fuel). Limiting postulated occurrences and normal operation have been analyzed using NRC-approved methods for the ATRIUM 9B fuel design to ensure that safety limits are protected and that acceptable transient and accident performance is maintained.

The reload fuel has no adverse impact on the performance of in-core neutron flux instrumentation or CRD response. The ATRIUM-9B fuel design will not adversely affect performance of neutron instrumentation nor will it adversely affect the movement of control blades relative to the GE fuel. The exterior dimensions of the ATRIUM-9B fuel have been evaluated by ComEd; the SPC fuel provides adequate clearances relative to the GE10 fuel installed at Quad Cities. Thus, no increased interactions with the adjacent control blade and nuclear instrumentation are created. Additionally, given the above mentioned overall envelope similarities, no problems are anticipated with other station equipment such as the fuel storage racks, the new fuel inspection stand and the spent fuel pool fuel preparation machine. Therefore, the probability of adverse interactions between the Siemens fuel and components in the core and fuel handling equipment is not significantly increased.

The ATRIUM 9B design is neutronicallly compatible with the existing fuel types and

core components in the Quad Cities core. SPC tests have demonstrated that the ATRIUM-9B fuel design is hydraulically compatible with the GE9/GE10 fuel. The bundle pressure drop characteristics of the ATRIUM 9B bundle are similar to those of the GE9/GE10 fuel design, hence core thermal-hydraulic stability characteristics are not adversely affected by the ATRIUM 9B design. Cycle stability calculations are performed by SPC. Therefore, the probability of thermal hydraulic instability is not significantly increased.

An evaluation of the Emergency Procedures is being performed to ensure that the use of the ATRIUM-9B fuel at Quad Cities does not alter any assumptions previously made in evaluating the radiological consequences of an accident at Quad Cities Station. Therefore, the radiological consequences of accidents are not significantly increased.

Methods approved by the NRC are being used in the evaluation of fuel performance during normal and abnormal operating conditions. The ComEd and SPC methods to be used for the cycle specific transient analyses have been previously NRC approved. The proposed methodologies are administrative in nature and do not significantly affect any accident precursors or accident results; as such, the proposed incorporation of the SPC methodologies for Quad Cities does not significantly increase the probability or consequences of any previously evaluated accidents. The description of the fuel is modified to include the water box design of the NRC approved ATRIUM-9B fuel. This change is administrative.

Review of the above concludes that the probability of occurrence and the consequences of an accident previously evaluated in the safety analysis report have not been significantly increased.

* * * * *

2) Create the possibility of a new or different kind of accident from any accident previously evaluated:

Creation of the possibility of a new or different kind of accident would require the creation of one or more new precursors of that accident. New accident precursors may be created by modifications of the plant configuration, including changes in allowable modes of operation.

Licensing Methods and Models

The proposed Technical Specification amendment reflects previously approved SPC methodology used to analyze normal operations, including AOOs, and to determine the potential consequences of accidents. In accordance with FSAR Chapter 15, the same accidents and transients will be analyzed with the new fuel and methods as were analyzed by GE for GE fuel. As stated above, the proposed changes do not permit modes of operation which differ from those currently permitted; therefore, the possibility of a new or different kind of accident is not created. Plant support equipment is not affected by the proposed changes; therefore, no new failure modes are created.

New Fuel Design

The basic design concept of a 9x9 fuel pin array with an internal water box has been used in various lead assembly programs and in reload quantities in Europe since 1986.

WNP-2 has loaded reload quantities since 1991. Approximately 650 water box assemblies have been irradiated in the United States through 1995, with a substantially higher number being irradiated overseas. The NRC has reviewed and approved the ATRIUM-9B fuel design (Reference: ANF-89-014(P)(A) Rev. 1 Supplement 1, Generic Mechanical Design for Advanced Nuclear Fuels 9X9-IX and 9X9-9X BWR Reload Fuel). The similarities in fuel design and operation between GE and SPC, and the previous Boiling Water Reactor experience with both vendors' fuel indicate there would be no new or different types of accidents for Quad Cities than have been considered for the existing fuel. Therefore, the use of ATRIUM-9B fuel at Quad Cities does not create the possibility of a new or different kind of accident from any accident previously evaluated.

* * * * *

3) Involve a significant reduction in the margin of safety for the following reasons:

The existing margin to safety is provided by the existing acceptance criteria (e.g., 10CFR50.46 limits). The proposed Technical Specification amendment reflects previously approved SPC methodology used to demonstrate that the existing acceptance criteria are satisfied. The revised methodology has been previously reviewed and approved by the USNRC for application to reload cores of GE BWRs. References for the Licensing Topical Reports which document this methodology, and include the Safety Evaluation Reports prepared by the USNRC, are added to the Reference section of the Technical Specifications as part of this amendment.

Licensing Methods and Models

The proposed amendment does not involve changes to the existing operability criteria. NRC approved methods and established limits (implemented in the COLR) ensure acceptable margin is maintained. The ComEd and SPC reload methodologies for the ATRIUM-9B reload design are consistent with the Technical Specification Bases. The Limiting Conditions for Operation are taken into consideration while performing the cycle specific and generic reload safety analyses. NRC approved methods are listed in Section 6 of the Technical Specifications.

Analyses performed with NRC-approved methodology have demonstrated that fuel design and licensing criteria will be met during normal and abnormal operating conditions. The same margins of safety are utilized by SPC as GE (e.g., limits on peak cladding temperature, cladding oxidation, plastic strain). Therefore, there is not a significant reduction in the margin of safety.

New Fuel Design

The exterior dimensions of the ATRIUM-9B fuel assembly result in equivalent clearances relative to the GE10B. Thus, no increased interactions with the adjacent control blade and nuclear instrumentation are created. The change does not adversely impact equipment important to safety; therefore, the margin of safety is not significantly reduced.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff

proposes to determine that the requested amendments involve no significant hazards consideration.

Local Public Document Room

location: Dixon Public Library, 221 Hennepin Avenue, Dixon, Illinois 61021
Attorney for licensee: Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60603

NRC Project Director: Robert A. Capra
Duke Power Company, Docket Nos. 50-269, 270 and 50-287, Oconee Nuclear Station, Units 1, 2 and 3, Oconee County, South Carolina

Date of amendment request: August 12, 1996

Description of amendment request:

The proposed change would implement the performance-based containment leak rate testing provisions of Option B to 10 CFR Part 50 Appendix J for the Type A (containment) testing program.

Basis for proposed no significant hazards consideration determination:
As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The following analysis is presented, pursuant to 10 CFR 50.91, to demonstrate that the proposed change will not create a Significant Hazard Consideration.

1. The proposed change will not involve a significant increase in the probability or consequences of an accident previously evaluated.

Containment leak rate testing is not an initiator of any accident; the proposed change does not affect reactor operations or accident analysis, and has no significant radiological consequences. Therefore, this proposed change will not involve an increase in the probability or consequences of any previously-evaluated accident.

2. The proposed change will not create the possibility of any new accident not previously evaluated.

The proposed change does not affect normal plant operations or configuration, or change any design basis. The proposed changes will not affect the response of [the] containment during a design basis accident.

3. There is no significant reduction in a margin of safety.

The proposed changes are based on NRC-accepted provisions, and maintain necessary levels of reliability of containment integrity. The performance-based approach to leakage rate testing recognizes that historically good results of containment testing provide appropriate assurance of future containment integrity; this supports the conclusion that the impact on the health and safety of the public as a result of extended test intervals is negligible.

Based on the above, no significant hazards consideration is created by the proposed change.

The NRC has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10

CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room

location: Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina 29691

Attorney for licensee: J. Michael McGarry, III, Winston and Strawn, 1200 17th Street, NW., Washington, DC 20036
NRC Project Director: Herbert N. Berkow

Entergy Operations, Inc., Docket No. 50-313, Arkansas Nuclear One, Unit No. 1, Pope County, Arkansas

Date of amendment request: May 31, 1996

Description of amendment request:

The proposed amendment revises the surveillance test interval for the reactor protection system reactor trip breakers, reactor trip modules, and electronic trip relays from 1 month to 6 months. In addition to requesting a change to the Arkansas Nuclear One, Unit 1 Technical Specifications, the request also proposes the same changes to NUREG-1430, Standard Technical Specifications - Babcock and Wilcox Plants.

Basis for proposed no significant hazards consideration determination:
As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Criterion 1 - Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

The accident mitigation features of the plant are not affected by the proposed test interval extension. The results of the B&W Owners Group Topical Report BAW-10167, Supplement 3, "Justification for increasing The Reactor Trip System On-Line Test Intervals," show that the test interval extension of the reactor protection system trip devices is not a significant contributor to trip system unavailability or the risk of core damage.

Therefore, this change does not involve a significant increase in the probability or consequences of any accident previously evaluated.

Criterion 2. Does Not Create the Possibility of a New or Different Kind of Accident from any Previously Evaluated.

The reactor trip device surveillance test interval is not, in and of itself, considered to be an accident initiator. Failure of a trip device to function is an analyzed condition and does not constitute a new or different kind of accident.

Therefore, this change does not create the possibility of a new or different kind of accident from any previously evaluated.

Criterion 3. Does Not Involve a Significant Reduction in the Margin of Safety.

The results of the B&W Owners Group Topical Report BAW-10167, Supplement 3, "Justification for Increasing The Reactor Trip

System On-Line Test Intervals," show that the test interval extension of the reactor protection system trip devices is not a significant contributor to trip system unavailability or the risk of core damage. In addition, the uncertainty analysis contained in BAW-10167 confirms the robustness of the results by demonstrating that even with an order of magnitude change in the failure data, the incremental increase due to an increased test interval is insignificant. Entergy Operations has reviewed BAW-10167 and found it applicable to ANO-1.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, AR 72801
Attorney for licensee: Nicholas S. Reynolds, Esquire, Winston and Strawn, 1400 L Street, N.W., Washington, DC 20005-3502

NRC Project Director: William D. Beckner

Entergy Operations, Inc., Docket Nos. 50-313 and 50-368, Arkansas Nuclear One, Unit Nos. 1 and 2 (ANO-1&2), Pope County, Arkansas

Date of amendment request: May 9, 1996

Description of amendment request: The proposed amendment changes the name of Arkansas Power and Light Company (AP&L) to Entergy Arkansas, Inc. in both the Operating License and the Technical Specifications. AP&L is licensed to own and possess Arkansas Nuclear One (ANO). The company licensed to operate ANO, Entergy Operations, Inc. is unaffected by this change.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does Not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

The proposed change documents changing the legal name of the company. The proposed change will not affect any other obligations. The company will continue to own all of the same assets, will continue to serve the same customers, and will continue to honor all existing obligations and commitments. Therefore, this change does not involve a significant increase in the probability or consequences of any accident previously evaluated.

2. Does Not Create the Possibility of a New or Different Kind of Accident from any Previously Evaluated.

The administrative changes in the operating license requirements do not

involve any change in the design of the plant. Therefore, this change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does Not Involve a Significant Reduction in the Margin of Safety.

The proposed change is administrative in nature and does not reduce the margin of safety imposed by any current requirements. Therefore, this change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, AR 72801
Attorney for licensee: Nicholas S. Reynolds, Esquire, Winston and Strawn, 1400 L Street, N.W., Washington, DC 20005-3502

NRC Project Director: William D. Beckner

Florida Power and Light Company, Docket Nos. 50-250 and 50-251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Dates of amendment request: July 17, 1996

Description of amendment request: The licensee proposed to change the Turkey Point Units 3 and 4 Technical Specifications (TS) to implement 10 CFR 50, Appendix J, Option B, for containment leakage testing. Changes include relocating the details for containment testing to the "containment leakage rate testing program" and adding the requirements of the containment leakage rate testing program to TS 6.8.4, which describes facility programs.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below.

(1) Operation of the facility in accordance with the proposed amendments would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed amendments do not involve a significant increase in the probability or consequences of an accident previously evaluated because:

a) These proposed changes are all consistent with NRC requirements and guidance for implementation of 10 CFR 50, Appendix J, Option B.

b) Based on industry and NRC evaluations performed in support of developing Option B, these changes potentially result in a minor increase in the consequences of an accident previously evaluated due to the expanded

testing intervals. However, the proposed changes do not result in an increase in the core damage frequency since the containment system is used for mitigation purposes only.

c) These changes are expected to result in increased attention to components with poor leakage test history as part of the performance-based nature of Option B, such that the marginally increased consequences from the expanded testing intervals may be further reduced or negated.

Therefore, these changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Operation of the facility in accordance with the proposed amendments would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The use of the modified specifications can not create the possibility of a new or different kind of accident from any previously evaluated since the proposed amendments will not change the physical plant or the modes of plant operation defined in the facility operating license. No new failure mode is introduced due to the implementation of a performance-based program for containment leakage rate testing, since the proposed changes do not involve the addition or modification of equipment, nor do they alter the design or operation of affected plant systems, structures, or components.

(3) Operation of the facility in accordance with the proposed amendments would not involve a significant reduction in a margin of safety.

The operating limits and functional capabilities of the affected systems, structures, and components are basically unchanged by the proposed amendments due to the following reasons:

a) The acceptance criteria for total integrated containment leakage of 1.0 L_a is consistent with the current technical specifications and is within the design basis accident assumptions, and therefore does not reduce the margin of safety.

b) The increase in intervals between leak-test surveillances will not significantly reduce the margin of safety as shown by findings in NUREG 1493, "Performance-Based Containment Leak-Test Program", which was based on implementation of the performance-based testing of Option B.

Therefore these changes do not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Florida International University, University Park, Miami, Florida 33199

Attorney for licensee: J. R. Newman, Esquire, Morgan, Lewis & Bockius, 1800 M Street, N.W., Washington, DC 20036

NRC Project Director: Frederick J. Hebdon

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-321 and 50-366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: May 21, 1996

Description of amendment request: The proposed change to the condensate storage tank (CST) level indication would ensure that the water level is sufficient to provide 50,000 gallons of water for core spray makeup to the reactor pressure vessel.

Technical Specification (TS) Surveillance Requirement (SR) 3.5.2.2.b for ECCS - Shutdown states:

"Condensate storage tank (CST) water level is [greater than or equal to] 12 feet." The corresponding Bases state: "...the CST contains [greater than or equal to] 150,000 gallons of water, equivalent to 12 feet, ensures that the CS System can supply at least 50,000 gallons of makeup water to the RPV."

Subsequent licensee analyses confirmed that Plant Hatch Units 1 and 2 CST configurations are different; that is, for both CSTs, a water level of 12 feet is not equivalent to the required capacity of 150,000 gallons of water. Based on these calculations, the correct level for the Unit 1 CST is 13 feet, and the correct level for the Unit 2 CST is 15 feet.

The proposed change would revise Unit 1 and Unit 2 SR 3.5.2.2.b to require a CST water level of greater than or equal to 13 feet and greater than or equal to 15 feet, respectively, to ensure at least 50,000 gallons of water are available for core spray (CS) makeup to the reactor pressure vessel (RPV).

The associated Bases for each unit will be revised accordingly.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:

1. The proposed TS change does not involve a significant increase in the probability or consequences of an accident previously evaluated, because this administrative change to the CST water level does not alter the operation of any plant system or component. The proposed change does not involve a physical modification to any structure, system, or component. The minimum CST water level for each unit is being increased to account for the height of the CS suction standpipe within each CST and the differences in the Unit 1 and

Unit 2 CST diameters (gallons/ft of water) as follows:

a. Unit 1 - The proposed minimum water level is calculated as: CS suction standpipe height of 9 ft + (50,000 gallons divided by 12,704 gallons/ft) = 12.93 ft or 13 ft.

b. Unit 2 - The proposed minimum water level is calculated as: CS suction standpipe height of 10 ft + (50,000 gallons divided by 11,343 gallons/ft) = 14.4 ft or 15 ft.

The revised minimum levels ensure at least 50,000 gallons of water are provided above the top of the standpipe in each unit's CST and are available for CS makeup to the RPV, as stated in the applicable Bases. The TS Limiting Conditions for Operation (LCO) remain unaffected by the proposed change.

2. The proposed TS change does not create the possibility of a new or different kind of accident from any accident previously evaluated. Revising Surveillance Requirement acceptance criteria does not result in any physical modification to the plant or operation of any existing equipment.

3. The proposed TS change does not involve a significant reduction in a margin of safety, since this administrative change only ensures the existing TS Bases are satisfied by increasing the minimum CST water level requirement to ensure at least 50,000 gallons of water are available for CS injection to the RPV. The proposed change does not involve a physical modification to any structure, system or component, and does not modify the operation of any existing equipment.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Appling County Public Library, 301 City Hall Drive, Baxley, Georgia 31513

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037

NRC Project Director: Herbert N. Berkow

Houston Lighting & Power Company, City Public Service Board of San Antonio, Central Power and Light Company, City of Austin, Texas, Docket Nos. 50-498 and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: July 8, 1996

Description of amendment request: The proposed amendment would clarify that the component cooling water system surge tank level instrumentation can be demonstrated operable by performing a channel calibration test during any plant mode of operation.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or

consequences of an accident previously evaluated.

The proposed change to Technical Specification Surveillance Requirement 4.7.3.b.3 will not effect any accident initiators or precursors and will not alter the design assumptions for the systems or components used to mitigate the consequences of an accident. Calibration is performed on level instrumentation of Component Cooling Water System trains that are out of service for scheduled maintenance. Isolation redundancy is provided by instrumentation associated with the trains that are in service during the calibration. Since the surveillance will continue to be performed at the specified interval, this proposed change will not increase the probability of occurrence of an accident previously evaluated. The surveillance does not differ from those previously performed; therefore, there is no impact on the consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Clarifying the surveillance interval for surge tank level instrumentation does not involve installation or operation of new or different kinds of equipment. There is no change in the procedures as described in the Technical Specifications. The change only clarifies the interval at which the subject calibration will be performed. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The specified surveillance will remain as stated in the Technical Specifications. Consequently, there is no reduction in the effectiveness of the surveillance in ensuring equipment operability. Calibration is performed on level instrumentation of Component Cooling Water System trains that are out of service for scheduled maintenance. Isolation redundancy is provided by instrumentation associated with the trains that are in service during the calibration. Consequently, clarifying the interval at which the calibration is performed will have no significant impact on the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, TX 77488

Attorney for licensee: Jack R. Newman, Esq., Morgan, Lewis & Bockius, 1800 M Street, N.W., Washington, DC 20036-5869

NRC Project Director: William D. Beckner

Houston Lighting & Power Company, City Public Service Board of San Antonio, Central Power and Light Company, City of Austin, Texas, Docket Nos. 50-498 and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: August 8, 1996

Description of amendment request: The proposed amendment would allow the transition from Mode 4 to Mode 3 with the turbine-driven auxiliary feedwater pump inoperable and allow a 72-hour period after the entry into Mode 3 to complete all necessary operability testing.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change will allow entry into Mode 3 with an inoperable Turbine Driven Auxiliary Feedwater pump. Since the operability test on the Turbine Driven Auxiliary Feedwater pump can only be performed once steam pressure is greater than or equal to 1000 psig, this change will allow the plant to reach the Mode where steam pressure greater than or equal to 1000 psig is available to perform the operability testing on the Turbine Driven Auxiliary Feedwater pump. The allowance of 72 hours to complete the surveillance testing will make the surveillance requirements consistent with the allowed outage time already established in the Action Statements. The proposed change does not affect the probability of an accident. The Turbine Driven Auxiliary Feedwater pump is not assumed to be an initiator of any analyzed event. The consequences of an accident previously evaluated remain unchanged by allowing the pump to be inoperable until suitable conditions exist to perform the operability testing. The operability testing will continue to demonstrate that the Turbine Driven Auxiliary Feedwater pump will perform as required prior to entry into Mode 2. This change will not alter assumptions relative to the mitigation of an accident or transient event. Therefore, this change will not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

This change will not physically alter the plant (no new or different type of equipment will be installed). The changes in methods governing normal plant operation are consistent with current safety analysis assumptions. The proposed change will allow entry into Mode 3 with the Turbine Driven Auxiliary Feedwater pump inoperable in order to perform the pump Operability Test on the turbine driven AFW [Auxiliary

Feedwater] pump once steam pressure is greater than or equal to 1000 psig. Therefore, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed change will allow entry into Mode 3 with the Turbine Driven AFW pump inoperable in order to perform the pump Operability Test on the turbine driven AFW pump once steam pressure is greater than or equal to 1000 psig. This will allow time for the plant to obtain suitable test conditions with steam pressure greater than or equal to 1000 psig. The margin of safety is not affected by this change. The operability testing will continue to maintain assurance that the AFW Pumps will perform as required prior to entry into Mode 2. The safety analysis assumptions will still be maintained, thus, no question of safety exists. Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, TX 77488

Attorney for licensee: Jack R. Newman, Esq., Morgan, Lewis & Bockius, 1800 M Street, N.W., Washington, DC 20036-5869

NRC Project Director: William D. Beckner

North Atlantic Energy Service Corporation, Docket No. 50-443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire

Date of amendment request: June 4, 1996

Description of amendment request: The proposed amendment would modify the Seabrook Station, Unit No. 1 Technical Specifications to implement Option B to 10 CFR Part 50, Appendix J by referring to Regulatory Guide 1.163, "Performance-Based Containment Leak-Test Program. The following Technical Specifications would be affected by the proposed amendment:

1. Definitions: Definition 1.7, Containment Integrity (Item d.) would be revised to reflect that leakage rates would be in accordance with the Containment Leakage Rate Testing Program.

2. Limiting Conditions for Operation and Surveillance Requirements:

a. Containment Integrity: Surveillance Requirement 4.6.1.1.c would be deleted because the specific guidance would be contained in the Containment Leakage Rate Testing Program.

b. Containment Leakage: Limiting Condition for Operation 3.6.1.2.a through 3.6.1.2.c and Surveillance Requirements 4.6.1.2.a through 4.6.1.2.h would be revised to replace specific guidance with a reference to the Containment Leakage Rate Testing Program.

c. Containment Leakage: The Action for Limiting Condition for Operation 3.6.1.2 would be revised to include the equivalent Action as required for Limiting Condition for Operation 3.6.1.1 when the overall integrated containment leak rate exceeds 1.0 L_a.

d. Containment Air Locks: Limiting Conditions for Operation 3.6.1.3.a and 3.6.1.3.b would be deleted and Surveillance Requirements 4.6.1.3.a and 4.6.1.3.b would be revised to replace specific guidance with a reference to the Containment Leakage Rate Testing Program. The footnote addressing the exemption to Appendix J regarding testing the air locks prior to establishing containment integrity would be maintained in the Containment Leakage Rate Testing Program.

e. Containment Vessel Structural Integrity: Surveillance Requirement 4.6.1.6 would be revised to replace specific guidance with a reference to the Containment Leakage Rate Testing Program.

f. Containment Ventilation System: Limiting Condition for Operation 3.6.1.7, Action b. would be revised to replace specific guidance with a reference to the Containment Leakage Rate Testing Program. Surveillance Requirement 4.6.1.7.1 would be revised to replace specific guidance with a reference to the Containment Leakage Rate Testing Program.

g. Containment Enclosure Building: Limiting Condition for Operation 3.6.5.3 and Surveillance Requirement 4.6.5.3 would be revised to include a reference to the requirements in the Containment Leakage Rate Testing Program.

3. Bases: Sections 3/4.6.1.2, Containment Leakage; 3/4.6.1.7, Containment Ventilation System; and 3/4.6.5.3, Containment Enclosure Building Structural Integrity, would be revised to reflect the above changes including a reference to the Containment Leakage Rate Testing Program. In addition, a statement would be added to Section 3/4.6.1.2 to clarify the operability of containment regarding allowable leakage rates.

4. Administrative Controls: Section 6.15 would be added to establish a Containment Leakage Rate Testing Program, as specified in Regulatory Guide 1.163, dated September 1995.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the

licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

A. The changes do not involve a significant increase in the probability or consequences of an accident previously evaluated (10 CFR 50.92(c)(1)) because the proposed changes merely revise the testing criteria for containment penetrations. The revised criteria will be based on the guidance in Regulatory Guide 1.163, "Performance-Based Containment Leak-Test Program."

This guidance allows for the use of relaxed testing frequencies for containment penetrations that have performed satisfactorily on a historical basis.

To support consideration of Option B to Appendix J, the NRC staff reviewed the potential impact of performance-based testing frequencies for containment penetrations. The NRC staff review is documented in NUREG-1493 "Performance-Based Containment Leak-Test Program." One of the staff's conclusions was that reducing the frequency of Type A tests (Integrated Leak Rate Tests) from three per 10 years to one per 10 years leads to a marginal increase in risk. For Type B and C testing (Local Leak Rate Tests), the change in testing frequency will not have significant impact since, under existing requirements, leakage contributes less than 0.1 percent of the overall accident risk. The use of a performance-based testing program will continue to provide assurance that the accident analysis assumptions remain bounding.

B. The changes do not create the possibility of a new or different kind of accident from any accident previously evaluated (10 CFR 50.92(c)(2)) because they do not affect the manner by which the facility is operated or involve changes to structures, systems, or components that affect the operational characteristics of the facility. The changes merely revise the testing criteria for the containment penetrations, and establish a Containment Leakage Rate Testing Program to ensure that the performance history of each penetration is satisfactory prior to changing any test frequency. Since there is no change to the facility or the way in which the facility is operated, there is no possibility of creating a new or different kind of accident than previously analyzed.

C. The changes do not involve a significant reduction in a margin of safety (10 CFR 50.92(c)(3)). During the development of 10 CFR Part 50, Appendix J, Option B, the NRC staff determined the reduction in safety associated with the implementation of the performance-based testing program. The staff concluded that reducing the frequency of Type A tests (Integrated Leak Rate Tests) from three per 10 years to one per 10 years would have an imperceptible impact upon risk. For Type B and C testing (Local Leak Rate Tests), the change in testing frequency will not have significant impact since this leakage contributes less than 0.1 percent of the overall risk based on the existing regulations. The use of Option B will have minimal impact on the radiological release rates since most penetration leakage is well below the specified limits. The staff noted

that the accident risk is relatively insensitive to containment leakage rate because accident risk is dominated by accident sequences that result in failure of or bypass of the containment. The use of a performance-based testing program will continue to provide assurance that the accident analysis assumptions remain bounding.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room

location: Exeter Public Library, Founders Park, Exeter, NH 03833

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Cuoco, Esquire, Northeast Utilities Service Company, Post Office Box 270, Hartford CT 06141-0270

NRC Project Director: Phillip F. McKee

Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of amendment request: May 17, 1996

Description of amendment request:

The proposed amendment would revise the technical specifications (TS) to relocate the operability requirements for shock suppressors (snubbers) from the TS to the Updated Safety Analysis Report (USAR) and incorporate snubber examination and testing requirements into TS 3.3.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change will relocate operability requirements for shock suppressors (snubbers) from the Technical Specifications (TS) to the Updated Safety Analysis Report (USAR) and/or plant procedures. On July 16, 1993, the NRC issued a Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors. The Final Policy Statement contains four criteria which can be used to determine which constraints on the design and operation of nuclear power plants are appropriate for inclusion in TS. The NRC has incorporated these criteria into 10 CFR 50.36, "Technical specifications." Snubbers do not meet any of the four criteria for inclusion as a Limiting Condition for Operations within the TS, and therefore it is proposed that these requirements be relocated from the TS. The proposed change would not reduce or revise any of the current requirements for snubber operability, only relocate the requirements. Any changes to the requirements contained in the USAR and/or plant procedures can be made without NRC approval only when the

changes meet the criteria of 10 CFR 50.59.

Changes to the snubber operability requirements that do not meet the criteria of 10 CFR 50.59 must be approved by the NRC by license amendment. Therefore, the relocation of the requirements on snubber operability from the TS to the USAR does not increase the probability or consequences of any accident previously analyzed.

The proposed change also deletes sections of the TS which are redundant or in conflict with the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code. Snubbers are required to be examined and tested in accordance with ASME Section XI by 10 CFR 50.55a. The proposed change will ensure that the TS implement ASME Section XI examination and testing requirements for snubbers in accordance with 10 CFR 50.55a. Where differences between the deleted sections of the TS and ASME Section XI requirements exist, the Section XI requirements are similar or more conservative than the TS. For example, although the functional test sample size differs between the methodologies, both ensure that a very high percentage of the snubbers in the plant are operable within acceptance limits. Therefore, the proposed revision does not reduce the effectiveness of snubber examination and testing.

The proposed change would not reduce the operability requirements, acceptance criteria, or examination and testing of snubbers. Therefore, the proposed change would not increase the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

There will be no physical alterations to the plant configuration, changes to setpoint values, or changes to the implementation of setpoints or limits as a result of this proposed change.

The proposed change deletes duplicate or conflicting requirements between the TS and the ASME Section XI. In these areas, the proposed deletions would remove the TS requirements and testing would be conducted in accordance with ASME Section XI as directed by 10 CFR 50.55a. Although the requirements of ASME Section XI differ from the TS in some cases, the differences do not decrease the effectiveness of testing and examination as compared to the TS requirements. Other areas, such as snubber operability requirements and service life monitoring, which are presently addressed by TS, but are not covered under ASME Section XI, will be maintained in the USAR so that these requirements cannot be deleted without NRC approval.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed change does not reduce the operability, examination, or testing requirements for snubbers. Snubbers will still be required to meet the requirements of ASME Section XI and 10 CFR 50.55a except where specific written relief has been granted by the NRC. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room

location: W. Dale Clark Library, 215 South 15th Street, Omaha, Nebraska 68102

Attorney for licensee: Perry D.

Robinson, Winston & Strawn, 1400 L Street, N.W., Washington, DC 20005-3502

NRC Project Director: William H. Bateman

Omaha Public Power District, Docket No. 50-285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska

Date of amendment request: May 20, 1996

Description of amendment request:

The proposed amendment would revise the technical specifications (TS) to clarify surveillance test requirements of TS 3.1, Tables 3-1, 3-2, 3-3, 3-3A, and 3-5.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The changes to the Table of Contents are administrative in nature to reflect the removal of incore instrumentation (Specification 2.10.3) from the TS by Amendment 167 and for consistency. Amendment 169 inadvertently reinserted incore instrumentation back into the Table of Contents.

The change to Specification 2.1.7(1)b is necessary because the requirement to test the signal to alarm meter relay located in Specification 3.1, Table 3-3, Item 6 is being deleted. The test, which verifies the high and low pressurizer level alarm settings and the pressurizer heater cutout function is unnecessary. Operating experience has shown that a shiftily pressurizer level verification as proposed for Specification 3.1, Table 3-3, Item 6.a is sufficient to detect any level deviation and verify that operation is within safety analyses assumptions. The level alarms serve as early warning devices but do not provide an accident mitigation function. Replacing the monthly test with a channel check is in accordance with NUREG-1432, Combustion Engineering (CE), Standard Technical Specifications (STS), Surveillance Requirement (SR) 3.3.11.1 (post accident monitoring instrumentation). The monthly channel check supplements the shiftily level verification.

The Basis of Specification 3.1 is revised to clarify expectations regarding a channel

check of channels that are normally off scale when the surveillance is required. In this situation, the channel check only verifies that they are off scale in the same direction. Off scale low current loop channels are verified to be reading at the bottom of the range and not failed downscale. These statements are taken from the Bases of CE STS SR 3.3.4.1 Engineered Safety Features Actuation System (ESFAS) Instrumentation (Analog).

In addition, the Basis of Specification 3.1 is revised to clarify that power operated relief valve (PORV) actuation is not required during the channel functional test of the PORV low temperature setpoint (Table 3-3, Item 18.a). PORV actuation is not required because it could depressurize the reactor coolant system. This clarification is modeled after a similar statement from the Bases of SR 3.4.12.6 (Low Temperature Overpressure Protection (LTOP) System) of the CE STS.

Changing Specification 3.1, Tables 3-1, 3-2, 3-3, and 3-3A by using defined terms to enable the Surveillance Method to match the Surveillance Function is an administrative change designed to simplify the tables. Removal of the extraneous text does not alter the surveillance because the defined terms are equivalent in meaning to the deleted text.

The reordering of several items in the tables into a Check-Test-Calibrate sequence adds consistency to the tables. Text revisions in the Channel Description or Surveillance Function columns of Tables 3-1 and 3-2 add clarity and/or consistency. Footnote No. 1 in Table 3-1 concerning the bistable trip tester was deleted because it is unnecessary.

The Surveillance Function of Table 3-1, Item 1.c (Power Range Safety Channels) is being changed to "Test" from "Calibrate and Test." It is not necessary for Item 1.c to require both because Item 1.b already requires the power range safety channel adjustment (calibration) to be performed daily. As stated in the Basis of Specification 3.1, "The minimum calibration frequencies of once-per-day for the power range safety channels, ...are considered adequate." To further clarify the issue, the Basis of Specification 3.1 is being revised to note that the daily calibration is a heat balance adjustment only.

Changing Table 3-1, Item 4 (Thermal Margin/Low Pressure (TM/LP)) to use the defined term CHANNEL CALIBRATION will allow OPD to relax the current TM/LP calibration requirements with a negligible impact on safety. Calibration of the temperature input and pressure input will still require calibration to known standards (i.e., resistance and pressure), but will allow the calibrations to be done separately instead of coincidentally. The channel functional test that follows the channel calibration verifies proper function of the TM/LP circuitry.

Removing the word "Instruments" from the Channel Description of Table 3-2, Item 14 makes the Channel Description consistent with the Surveillance Method. Table 3-2, Item 14 is not intended to verify safety injection tank (SIT) instrumentation operability but rather that the parameters level and pressure are within limits. Generic Letter (GL) 93-05, Item 7.4, states that the operability of SIT instrumentation is not directly related to the capability of a SIT to perform its safety function. GL 93-05 concludes that the surveillance should only

confirm that the parameters defining SIT operability are within their specified limits.

Items 22 & 24 are being added to Table 3-2 to clearly state the requirement for testing manual actuation of the Engineered Safety Features (ESF) channels for Off-site Power Low Signal (OPLS) and Auxiliary Feedwater. Although testing manual actuation of these channels is done via the existing Specifications, the requirement to do so is not clearly stated. Reordering Table 3-2, Item 23 into a Check-Test-Calibrate Surveillance Frequency sequence adds clarity and consistency.

The addition of Footnote No. 7 to Table 3-2 clarifies that the refueling frequency ESF channel functional test pertains to the backup channels such as derived circuits and equipment that cannot be tested when the plant is at power. Operating certain relays during power operation could cause plant transients or equipment damage.

The revisions to Table 3-3, Item 6, clarify that pressurizer level is the parameter to be verified and not the pressurizer level instruments. The revision to Item 6.a is consistent with CE STS SR 3.4.9.1 (pressurizer water level). Reordering Item 6 into a Check-Test-Calibrate Surveillance Function sequence makes Item 6 consistent with the ordering of the other items in Table 3-3. The requirement to test the signal to alarm meter relay currently located in Specification 3.1, Table 3-3, Item 6.c is unnecessary. Operating experience has shown that a shiftily pressurizer level verification as proposed for Specification 3.1, Table 3-3, Item 6.a is sufficient to detect any level deviation and verify that operation is within safety analyses assumptions. Thus, the monthly "Test" requirement will be replaced with a "Check" to supplement the less formal but more frequent shiftily level verification of Item 6.a.

Table 3-3, Items 21 (PORV Operation & Acoustic Position Indication Channel) and 23 (Safety Valve Acoustic Position Indication Channel) should be revised to a channel functional test from a channel/circuit check. An oscillator and installed impactors are used to generate noise signals and therefore, this surveillance is more accurately described as a channel functional test rather than a channel check.

Table 3-3, Items 21 and 22 (PORV Block Valve Operation & Position Indication) should have the requirement to verify operation on the emergency power supply deleted. Permanent Class 1E power supplies the PORV and PORV Block Valve. Therefore, verification of PORV or PORV Block Valve operability while powered from the emergency power supply system provides no additional benefit. (Operability of the emergency power supply system is tested in accordance with Specification 3.7.) The proposed revision is in accordance with the exception for plants with a permanent Class 1E power supply to these valves as stated in CE STS, SR 3.4.11.4.

Deletion of the requirement of TS 3.2, Table 3-5, Item 15, to test spent fuel pool surveillance coupons for a change in hardness corrects an oversight in the Application for Amendment dated December 7, 1992.

As stated in the Safety Evaluation Report enclosed with Amendment 155, "Each

coupon, upon its removal from the mounting jacket, will be analyzed according to the following tests:

visual observation and photography
neutron attenuation
dimensional measurements (length, width, and thickness)
weight and specific gravity."

The tests listed above are sufficient to detect degradation of the Boral—material and do not require that the surveillance coupons be tested for hardness.

Based on the above discussion, the proposed changes clarify and standardize existing surveillance requirements, remove redundant requirements, correct minor oversights from previous amendment requests or are in accordance with CE STS. Thus, none of the requested changes involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed revisions will not result in any physical alterations to the plant configuration, changes to setpoint values, or changes to the application of setpoints or limits. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed changes clarify existing surveillance requirements, remove redundant requirements, correct minor oversights from previous amendment requests or are in accordance with CE STS. Thus, none of the requested changes involves a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: W. Dale Clark Library, 215 South 15th Street, Omaha, Nebraska 68102

Attorney for licensee: Perry D. Robinson, Winston & Strawn, 1400 L Street, N.W., Washington, DC 20005-3502

NRC Project Director: William H. Bateman

Pennsylvania Power and Light Company, Docket No. 50-388
Susquehanna Steam Electric Station, Unit 2, Luzerne County, Pennsylvania

Date of amendment request: May 20, 1996, as supplemented by letter dated July 25, 1996

Description of amendment request: This amendment request would modify the Technical Specifications for the unit by: changing the Minimum Critical Power Ratio safety limit values, adding

a reference to reflect the use of the ANF-B Critical Power Correlation, and modifying the associated Bases.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The change to the ANFB correlation and corresponding MCPR Safety Limits does not physically change the plant systems, structures, or components. Thus, the probability of an event evaluated in the SAR is not increased. The acceptance criterion for the MCPR Safety Limit (i.e., 99.9% of the fuel rods expected to avoid boiling transition) is not changed. Only the methodology used to demonstrate compliance is changed.

Therefore, the consequences of anticipated operational occurrences (which must show the Safety Limit is not violated) are not changed. Results of incorporating this change will not significantly increase the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

As stated above, this methodology change does not impact the acceptance criteria for the MCPR Safety Limits and does not physically change the plant systems, structures, or components. Since no changes to the physical plant are being made, this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

A cycle specific MCPR Safety Limit analysis was performed by SPC [Siemens Power Corporation]. This analysis used NRC approved methods described in the SPC report: ANF-524(P)(A), Revision 2 and Supplement 1, Revision 2. The MCPR Safety Limit value is calculated such that at least 99.9% of the fuel rods are expected to avoid boiling transition during normal operation or anticipated operation occurrences. Both the existing analysis using XN-3 and the new analysis using ANFB utilize NRC approved methods to accomplish this same objective. Therefore, the change to an ANFB based Safety Limit does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, PA 18701

Attorney for licensee: Jay Silberg, Esquire, Shaw, Pittman, Potts and

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NRC Project Director: John F. Stolz
TU Electric Company, Docket Nos. 50-445 and 50-446, Comanche Peak Steam Electric Station (CPSES), Units 1 and 2, Somervell County, Texas

Date of amendment request: July 31, 1996

Brief description of amendments: Based on analyses of the core configuration and expected operation for CPSES Unit 1, Cycle 6, the proposed amendments would revise core safety limit curves and Overtemperature N-16 reactor trip setpoints. In addition, the TU Electric Small Break LOCA Topical Report on the Core Operating Limits Report Technical Specification is incorporated. The topical report change is applicable to both Units.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1.a. Revision to the Unit 1 Core Safety Limits

Analyses of reactor core safety limits are required as part of reload calculations for each cycle. TU Electric has performed the analyses of the Unit 1, Cycle 6 core configuration to determine the reactor core safety limits. The methodologies and safety analysis values result in new operating curves which, in general, permit plant operation over a similar range of acceptable conditions. This change means that if a transient were to occur with the plant operating at the limits of the new curve, a different temperature and power level might be attained than if the plant were operating within the bounds of the old curves. However, since the new curves were developed using NRC approved methodologies which are wholly consistent with and do not represent a change in the Technical Specification BASES for safety limits, all applicable postulated transients will continue to be properly mitigated. As a result, there will be no significant increase in the consequences, as determined by accident analyses, of any accident previously evaluated.

1.b. Revision to Unit 1 Overtemperature N-16 Reactor Trip Setpoints, Parameters and Coefficients

As a result of changes discussed, the Overtemperature N-16 reactor trip setpoint has been recalculated. These trip setpoints help ensure that the core safety limits are maintained and that all applicable limits of the safety analysis are met.

Based on the calculations performed, the safety analysis value for Overtemperature N-16 reactor trip setpoint has changed. This essentially means if a transient were to occur, the actual temperature and power level achievable prior to initiating a reactor trip could be slightly higher. However, the analyses performed show that, using the TU Electric methodologies, all applicable limits of the safety analysis are met. This setpoint

provides a trip function which allows the mitigation of postulated accidents and has no impact on accident initiation. Therefore, the changes in safety analysis values do not involve an increase in the probability of an accident and, based on satisfying all applicable safety analysis limits, there is no significant increase in the consequences of any accident previously evaluated.

In addition, sufficient operating margin has been maintained in the overtemperature setpoint such that the risk of turbine runbacks or reactor trips due to upper plenum flow anomalies or other operational transients will be minimized, thus reducing potential challenges to the plant safety systems.

1.c. Incorporation of TU Electric Small Break LOCA Topical Report, RXE-95-0001-P.

TU Electric has submitted the topical report "Small Break Loss of Coolant Accident Analysis Methodology," RXE-95-001-P and plans to use the report to support Unit 1 Cycle 6. In order to accomplish this activity, it is necessary to include the topical report in the list of NRC-approved methodologies in Technical Specification 6.9.1.6b. Use of this topical report is contingent upon NRC approval; therefore, inclusion of this report in Section 6 of the Technical Specifications is administrative in nature and does not change the probability or consequences of an accident.

2. The proposed changes involve the use of revised safety analysis values and the calculation of new reactor core safety limits and reactor trip setpoints. As such, the changes play an important role in the analysis of postulated accidents but none of the changes effect plant hardware or the operation of plant systems in a way that could initiate an accident. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. In reviewing and approving the methods used for safety analyses and calculations, the NRC has approved the safety analysis limits which establish the margin of safety to be maintained. While the actual impact on safety is discussed in response to question 1, the impact on margin of safety is discussed below:

3.a.

Revision to the Unit 1 Reactor Core Safety Limits

The TU Electric reload analysis methods have been used to determine new reactor core safety limits. All applicable safety analysis limits have been met. The methods used are wholly consistent with Technical Specification BASES 2.1 which is the bases for the safety limits. In particular, the curves assure that for Unit 1, Cycle 6, the calculated DNBR is no less than the safety analysis limit and the average enthalpy at the vessel exit is less than the enthalpy of saturated liquid. The acceptance criteria remains valid and continues to be satisfied; therefore, no change in a margin of safety occurs.

3.b. Revision to Unit 1 Overtemperature N-16 Reactor Trip Setpoints, Parameters and Coefficients

Because the reactor core safety limits for CPSES Unit 1, Cycle 6 are recalculated, the Reactor Trip System instrumentation setpoint values for the Overtemperature N-16 reactor

trip setpoint which protect the reactor core safety limits must also be recalculated. The Overtemperature N-16 reactor trip setpoint helps prevent the core and Reactor Coolant System from exceeding their safety limits during normal operation and design basis anticipated operational occurrences. The most relevant design basis analysis in Chapter 15 of the CPSES Final Safety Analysis Report (FSAR) which is affected by the change in the safety analysis value for the CPSES Unit 1 Overtemperature N-16 reactor trip setpoint is the Uncontrolled Rod Cluster Control Assembly Bank Withdrawal at Power (FSAR Section 15.4.2). This event has been re-analyzed with the revised safety analysis value for the Overtemperature N-16 reactor trip setpoint to demonstrate compliance with event specific acceptance criteria. Because all event acceptance criteria are satisfied, there is no degradation in a margin of safety.

The nominal Reactor Trip System instrumentation setpoints values for the Overtemperature N-16 reactor trip setpoint (Technical Specification Table 2.2-1) are determined based on a statistical combination of all of the uncertainties in the channels to arrive at a total uncertainty. The total uncertainty plus additional margin is applied in a conservative direction to the safety analysis trip setpoint value to arrive at the nominal and allowable values presented in Technical Specification Table 2.2-1. Meeting the requirements of Technical Specification Table 2.2-1 assures that the Overtemperature N-16 reactor trip setpoint assumed in the safety analyses remains valid. The CPSES Unit 1, Cycle 6 Overtemperature N-16 reactor trip setpoint is different from previous cycles which provides more operational flexibility to withstand mild transients without initiating automatic protective actions. Although the setpoint is different, the Reactor Trip System instrumentation setpoint values for the Overtemperature N-16 reactor trip setpoint are consistent with the safety analysis assumption which has been analytically demonstrated to be adequate to meet the applicable event acceptance criteria. Thus, there is no reduction in a margin of safety.

3.c. Revise 6.9.1.6b to include Topical Report RXE-95-001-P, "Small Break Loss of Coolant Accident Methodology"

TU Electric has submitted the topical report "Small Break Loss of Coolant Accident Analysis Methodology," RXE-95-001-P and plans to use the report to support Unit 1 Cycle 6. In order to accomplish this activity, it is necessary to include the topical report in the list of NRC-approved methodologies in Technical Specification 6.9.1.6b. Use of this topical report is contingent upon NRC approval; therefore, inclusion of this report in Section 6 of the Technical Specifications is administrative in nature and does not reduce the margin of safety.

Using the NRC approved TU Electric methods, the reactor core safety limits are determined such that all applicable limits of the safety analyses are met. Because the applicable event acceptance criteria continue to be met, there is no significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are

satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: University of Texas at Arlington Library, Government Publications/Maps, 702 College, P.O. Box 19497, Arlington, TX 76019

Attorney for licensee: George L. Edgar, Esq., Morgan, Lewis and Bockius, 1800 M Street, N.W., Washington, DC 20036
NRC Project Director: William D. Beckner

TU Electric Company, Docket Nos. 50-445 and 50-446, Comanche Peak Steam Electric Station (CPSES), Units 1 and 2, Somervell County, Texas

Date of amendment request: July 31, 1996

Brief description of amendments: The proposed amendments would revise the Technical Specifications by (1) changing the battery charger ratings; (2) by clarifying the meaning of the term "associated inverter"; and by (3) deleting the protection channel and the vital bus ratings for the instrument busses identified for Mode 1 through 4. These changes are associated with a plant modification in which the inverters and battery chargers are being replaced and an installed spare inverter is being added for each safety train. These changes are equally applicable to CPSES Units 1 and 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. DO THE PROPOSED CHANGES INVOLVE A SIGNIFICANT INCREASE IN THE PROBABILITY OR CONSEQUENCES OF AN ACCIDENT PREVIOUSLY EVALUATED?

CHANGE TO IDENTIFY BATTERY CHARGER RATINGS

The first proposed change replaces the test amperes with the design value for the replacement battery charger and allows a voltage range (greater than or equal to 130 volts) instead of a single value. The intent of the surveillance requirement or the surveillance frequency is not changed. The replacement inverters and battery chargers will continue to provide the capacity needed to perform the required safety functions. The revised surveillance will continue to assure that the battery chargers are capable of performing as designed. Therefore this change does not impact the probability or the consequences of an accident previously evaluated.

CLARIFICATION TO DEFINE ASSOCIATED INVERTER

The second proposed change adds a foot note to clarify the term "associated inverter" by describing it as, "... the dedicated inverter or installed spare inverter." Also the Bases

for this specification is revised to reflect the basis for this change. This change allows use of an installed spare inverter (for each train) having the capability to energize the Instrument Bus for the protection channel or the vital bus. Procedural controls and interlocks ensure that the spare is available to feed only one of the protection channel or vital bus Instrument Bus at a time, in the event the dedicated inverter is not available. Procedural controls and interlocks also ensure that the installed spare inverter is fed from the same power source as that of the dedicated inverter not in service and whose loads are being fed by the spare inverter. This proposed design only allows the spare inverter for a safety train to be manually aligned to replace only one of the four inverters in that train at a time.

The installation of a spare inverter for each train and the associated design configuration increases the availability of energized Instrument Bus for the protection channel and vital bus. These changes do not involve an increase in the probability or consequences of an accident previously evaluated.

DELETION OF THE PROTECTION CHANNEL AND VITAL BUS RATINGS FOR INSTRUMENT BUS

The third proposed change deletes specifying of the protection channel and vital bus KVA ratings for the Instrument Bus. The ratings of inverter that feeds these instrument buses are being described in other Licensing Bases Documents or Design Basis Documents. There is no change proposed to the intent of the action statements.

This is considered an administrative change and does not impact the probability or consequences of an accident previously evaluated.

2. DO THE PROPOSED CHANGES CREATE THE POSSIBILITY OF A NEW OR DIFFERENT KIND OF ACCIDENT FROM ANY ACCIDENT PREVIOUSLY EVALUATED?

CHANGE TO IDENTIFY BATTERY CHARGER RATINGS

Replacing the inverters and battery chargers and changing the parameters of the battery charger surveillance test to match the replacement chargers does not alter the functional modes of this portion of the design and does not result in any new failure modes. As such, it does not create the possibility of a new or different accident from any previously evaluated.

CLARIFICATION TO DEFINE ASSOCIATED INVERTER

The second proposed change allows use of an installed spare inverter for each train to energize the one of the Instrument Bus for the protection channel and vital bus at a time for the respective safety train while its dedicated inverter is not available. The spare inverter is such that it has the capability to support the maximum load for the protection channel or vital bus. Manually aligning the installed inverter to replace on[e] of the dedicated inverters is essentially equivalent to a repair activity which replaces a faulted inverter with a new inverter. In addition, procedural controls and interlocks are provided to ensure the proper alignment of the installed spare when it is used. The proposed changes do not create the possibility of a new or different accident from any previously evaluated.

DELETION OF THE PROTECTION CHANNEL AND VITAL BUS RATINGS FOR INSTRUMENT BUS

The third proposed change as discussed earlier does not change intent of the Technical Specifications action statements. This is an administrative change which does not introduce new failure modes and has no new or different accidents from any previously evaluated are created.

3. DO THE PROPOSED CHANGES INVOLVE A SIGNIFICANT REDUCTION IN MARGIN OF SAFETY?

The relevant Technical Specification sections proposed for changes: (1) ensure that the battery charger is capable of charging the battery by performing the surveillance at 18 month frequency; (2) establish operability requirements of the Instrument Bus for the protection channel and vital bus in MODES 1 through 6; and (3) identify the actions required for not meeting item 2.

These proposed changes do not alter the intent of the above requirements; however replacement of the currently installed inverters with inverters which are expected to be more reliable and available and the addition of a spare inverter per safety train to energize Instrument Bus for protection channel and vital bus does increase the reliability of the instrument busses for the train. Allowing credit for this spare inverter in meeting the operability requirements of Instrument Bus for the protection channel and vital bus, minimize potential plant shutdowns due to non-energized instrument from its dedicated inverter. These changes do not involve a significant reduction in margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: University of Texas at Arlington Library, Government Publications/Maps, 702 College, P.O. Box 19497, Arlington, TX 76019

Attorney for licensee: George L. Edgar, Esq., Morgan, Lewis and Bockius, 1800 M Street, N.W., Washington, DC 20036

NRC Project Director: William D. Beckner

Vermont Yankee Nuclear Power Corporation, Docket No. 50-271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of amendment request: August 9, 1996

Description of amendment request: The proposed amendment would revise the Safety Limits for Minimum Critical Power Ratio (MCPR) based upon a Vermont Yankee plant and cycle specific analysis, performed by General Electric. The revised MCPR Safety Limits are needed to accommodate Vermont Yankee's core design for upcoming refueling cycle number 19.

Specifically, the MCPR Safety Limits of 1.07 and 1.08 in the Vermont Yankee Technical Specifications (TS) section 1.1.A are proposed to be increased to 1.10 and 1.12 for two loop and single loop operation, respectively.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) The Safety Limit Minimum Critical Power Ratio (MCPR) is defined to ensure that during normal operation and Anticipated Operational Transients (AOTs), at least 99.9% of the fuel rods in the core do not experience transition boiling. Core MCPR operating limits are developed to ensure these Safety Limits are maintained in the event of the worst case transient. Since the Safety Limit MCPR will be maintained at all times, operation under the proposed changes will ensure at least 99.9% of the fuel rods in the core do not experience transition boiling and no significant radiological release will result. Therefore, this Safety Limit MCPR change does not affect the probability or consequences of a previously evaluated accident.

(2) The proposed changes do not involve any new modes of operation or any plant modifications. Establishment and monitoring of the operating limits will continue as per established procedure. The proposed changes to these limits do not result in the creation of any new precursors to an accident. Therefore, the proposed change does not create the possibility of a new or a different kind of accident from any previously analyzed.

(3) The Safety Limit MCPR values were evaluated by General Electric based upon a cycle specific Vermont Yankee analysis, using NRC approved methods. The resulting limits are more conservative than the previous generic limits and will continue to assure that at least 99.9% of the fuel rods in the core do not experience transition boiling during analyzed transients. This acceptance criteria ensures the safety design limit of "no damage to a nuclear system process barrier shall result from forces associated with AOTs." Therefore, the implementation of the proposed change does not involve a significant reduction in [a] margin of safety.

The NRC staff has reviewed the licensee's analysis. The staff notes that, although the proposed change does not involve a plant modification, the reason for the proposed higher safety limit MCPRs is the cycle-specific core design and the local power distribution in the slightly higher enriched fresh GE-9B fuel bundles. This new fuel will be loaded during the September/October 1996 refueling outage. In conjunction with the proposed safety limit MCPRs and the core operating limits determined in accordance with Vermont Yankee TS 6.7.A.4, the new fuel load will not involve a significant increase in the probability or consequences of an

accident previously evaluated nor a significant reduction in a margin of safety. In addition, the new fuel load does not create the possibility of a new or different kind of accident from any accident previously evaluated. Based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room
location: Brooks Memorial Library, 224 Main Street, Brattleboro, VT 05301

Attorney for licensee: R. K. Gad, III, Ropes and Gray, One International Place, Boston, MA 02110-2624

NRC Project Director: Jocelyn A. Mitchell, Acting Director

Notice Of Issuance Of Amendments To Facility Operating Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the Federal Register as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the

local public document rooms for the particular facilities involved.

Boston Edison Company, Docket No. 50-293, Pilgrim Nuclear Power Station, Plymouth County, Massachusetts

Date of application for amendment: May 1, 1996

Brief description of amendment: The proposed amendment will modify the definition of "Core Alteration," and the limiting condition for operation, Surveillance conditions and Bases section associated with Technical Specification 3.7.C, "Secondary Containment."

Date of issuance: August 12, 1996

Effective date: August 12, 1996

Amendment No.: 166

Facility Operating License No. DPR-35: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: June 5, 1996 (61 FR 28606) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 12, 1996. No significant hazards consideration comments received: No

Local Public Document Room
location: Plymouth Public Library, 11 North Street, Plymouth, Massachusetts 02360.

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: July 17, 1995, as supplemented May 2, 1996, and July 1, 1996.

Brief description of amendment: The change revises technical specification (TS) section 3.8 to specify that the spent fuel building refueling filter fan and at least one containment purge fan shall be shown to operate within plus or minus 10 percent of the design flow.

Date of issuance: August 6, 1996

Effective date: August 6, 1996

Amendment No. 172

Facility Operating License No. DPR-23: Amendment revises the Technical Specifications.

Date of initial notice in Federal Register: September 13, 1995 (60 FR 47615). The May 2, and July 1, 1996, letters provided clarifying information that did not affect the proposed no significant hazards consideration. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 6, 1996. No significant hazards consideration comments received: No

Local Public Document Room
location: Hartsville Memorial Library, 147 West College Avenue, Hartsville, South Carolina 29550

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: June 6, 1996

Brief description of amendment: The amendment revises technical specifications (TS) Section 4.2.3 to allow the licensee to defer the ultrasonic inspection of the reactor coolant pump flywheel for one operating cycle.

Date of issuance: August 9, 1996

Effective date: August 9, 1996

Amendment No. 173

Facility Operating License No. DPR-23: Amendment revises the Technical Specifications.

Date of initial notice in Federal Register: July 3, 1996 (61 FR 34888) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 9, 1996. No significant hazards consideration comments received: No

Local Public Document Room
location: Hartsville Memorial Library, 147 West College Avenue, Hartsville, South Carolina 29550

Carolina Power & Light Company, et al., Docket No. 50-400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of application for amendment: May 31, 1996

Brief description of amendment: The amendment revises Technical Specifications (TS) Table 3.3-7, Seismic Monitoring Instrumentation, and TS Table 4.3-4, Seismic Monitoring Instrumentation Surveillance Requirements, to correct the location described for one of the three Triaxial Peak Accelerograph recorders.

Date of issuance: August 7, 1996

Effective date: August 7, 1996

Amendment No. 66

Facility Operating License No. NPF-63: Amendment revises the Technical Specifications

Date of initial notice in Federal Register: July 3, 1996 (61 FR 34888) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 7, 1996. No significant hazards consideration comments received: No

Local Public Document Room
location: Cameron Village Regional Library, 1930 Clark Avenue, Raleigh, North Carolina 27605.

Commonwealth Edison Company, Docket Nos. 50-373 and 50-374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois

Date of application for amendments: April 16, 1996

Brief description of amendments: The amendments revise the Technical

Specifications (TSs) to eliminate selected response time testing requirements based on analyses performed by the Boiling Water Reactor Owners' Group as documented in NEDO-32291. The affected TS sections are 3/4.3.1, "Reactor Protection System Instrumentation;" 3/4.3.2, "Isolation Actuation Instrumentation;" and 3/4.3.3, "Emergency Core Cooling System Actuation Instrumentation."

Date of issuance: August 14, 1996

Effective date: Immediately, to be implemented within 60 days.

Amendment Nos.: 114 and 99

Facility Operating License Nos. NPF-11 and NPF-18: The amendments revised the Technical Specifications.

Date of initial notice in Federal Register: May 22, 1996 (61 FR 25702) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 14, 1996. No significant hazards consideration comments received: No

Local Public Document Room location: Jacobs Memorial Library, Illinois Valley Community College, Oglesby, Illinois 61348.

Detroit Edison Company, Docket No. 50-341, Fermi-2, Monroe County, Michigan

Date of application for amendment: December 21, 1995

Brief description of amendment: The amendment revises the Technical Specifications (TS) to implement 10 CFR Part 50, Appendix J - Option B, by referring to Regulatory Guide 1.163, "Performance-Based Containment Leak-Test Program." Specifically, changes have been made to TS Section 3/4.6.1.2, "Primary Containment Leakage," TS 3/4.6.1.3, "Primary Containment Air Locks," TS 3/4.6.1.5, "Primary Containment Structural Integrity," TS 6.0, "Administrative Controls," and their associated Bases.

Date of issuance: August 8, 1996

Effective date: August 8, 1996, with full implementation within 45 days.

Amendment No.: 108

Facility Operating License No. NPF-43. Amendment revises the Technical Specifications.

Date of initial notice in Federal Register: February 28, 1996 (61 FR 7551) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 8, 1996. No significant hazards consideration comments received: No

Local Public Document Room location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161

Florida Power and Light Company, Docket Nos. 50-250 and 50-251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of application for amendments: April 19, 1996, and supplements dated May 10 and May 28, 1996.

Brief description of amendments: The amendment changes the Technical Specifications to address frequency extension on a periodic basis, deletes separate notification requirements for an inoperable startup transformer, and allows the operating residual heat removal loop to be removed from operation, under certain conditions, during refueling.

Date of Issuance: August 6, 1996

Effective Date: August 6, 1996

Amendment Nos.: 189 and

183 Facility Operating Licenses Nos. DPR-31 and DPR-41: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: July 3, 1996 (61 FR 34892) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 6, 1996. No significant hazards consideration comments received: No

Local Public Document Room location: Florida International University, University Park, Miami, Florida 33199.

Florida Power and Light Company, Docket Nos. 50-250 and 50-251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of application for amendments: July 26, 1995, and supplemented March 13, May 3, and May 9, 1996.

Brief description of amendments: Change TS 6.9.1.7, Core Operating Limits Report, resulting from a reanalysis of the small break loss-of-coolant accident for the Turkey Point Units using the NOTRUMP code including the COSI safety injection (SI) condensation model.

Date of issuance: August 13, 1996

Effective date: August 13, 1996

Amendment Nos. 190 and 184 Facility Operating Licenses Nos. DPR-31 and DPR-41: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: September 13, 1995 (60 FR 47618). The supplements dated March 13, May 3, and May 9, 1996 provided clarifying information that did not change the initial proposed no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 13, 1996. No significant hazards consideration comments received: No

Local Public Document Room location: Florida International

University, University Park, Miami, Florida 33199.

Houston Lighting & Power Company, City Public Service Board of San Antonio, Central Power and Light Company, City of Austin, Texas, Docket Nos. 50-498 and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: May 1, 1996

Brief description of amendments: The amendments changed the technical specifications to implement 10 CFR Part 50, Appendix J, Option B, by referring to Regulatory Guide 1.163, "Performance-Based Containment Leak-Test Program." Part of the requested change, that regarding the frequency of leakage rate testing the normal containment purge valves and the supplementary containment purge valves, was denied.

Date of issuance: August 13, 1996

Effective date: August 13, 1996

Amendment Nos.: 84 and 71

Facility Operating License Nos. NPF-76 and NPF-80. The amendments revised the Technical Specifications.

Date of initial notice in Federal Register: June 5, 1996 (61 FR 28616) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 13, 1996. No significant hazards consideration comments received: No

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, TX 77488

IES Utilities Inc., Docket No. 50-331, Duane Arnold Energy, Center, Linn County, Iowa

Date of application for amendment: November 30, 1995

Brief description of amendment: The amendment implements the Option I-D long-term stability solution and removes the existing SIL-380 Rev. 1-based specifications. In addition, the amendment requires a plant scram be initiated should the plant enter natural circulation conditions and prohibits restarting a recirculation pump while in natural circulation. Finally, this amendment deletes Technical Specification (TS) actions and surveillance requirements related to core plate differential pressure noise while in single recirculation pump operation (SLO).

Date of issuance: August 7, 1996

Effective date: August 7, 1996

Amendment No.: 215

Facility Operating License No. DPR-49: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: March 13, 1996 (61 FR 10394) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 7, 1996. No significant hazards consideration comments received: No.

Local Public Document Room location: Cedar Rapids Public Library, 500 First Street, S. E., Cedar Rapids, Iowa 52401

IES Utilities Inc., Docket No. 50-331, Duane Arnold Energy, Center, Linn County, Iowa

Date of application for amendment: November 15, 1995, as supplemented April 9, 1996

Brief description of amendment: The amendment revises the requirements for the End of Cycle Recirculation Pump Trip logic to match more closely the assumptions applicable to the turbine trip events for which it was installed. The surveillance requirements are also revised, based on those same assumptions.

Date of issuance: August 8, 1996

Effective date: August 8, 1996

Amendment No.: 216

Facility Operating License No. DPR-49: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: January 22, 1996 (61 FR 1629) The April 9, 1996, submittal was clarifying in nature and did not affect the no significant hazards determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 8, 1996. No significant hazards consideration comments received: No.

Local Public Document Room location: Cedar Rapids Public Library, 500 First Street, S. E., Cedar Rapids, Iowa 52401

IES Utilities Inc., Docket No. 50-331, Duane Arnold Energy, Center, Linn County, Iowa

Date of application for amendment: January 18, 1996

Brief description of amendment: The amendment revises the setpoint at which the Reactor Water Cleanup (RWCU) system isolates, based on reactor vessel water level. In particular, the amendment changes the Group 5 isolation from isolating on "reactor water level low" to "reactor water level low-low."

Date of issuance: August 8, 1996

Effective date: August 8, 1996, and shall be implemented prior to startup from RFO 14.

Amendment No.: 217

Facility Operating License No. DPR-49: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: February 14, 1996 (61 FR 5814) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 8, 1996. No significant hazards consideration comments received: No.

Local Public Document Room location: Cedar Rapids Public Library, 500 First Street, S. E., Cedar Rapids, Iowa 52401

Indiana Michigan Power Company, Docket Nos. 50-315 and 50-316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of application for amendments: January 12, 1996 (AEP:NRC:1233)

Brief description of amendments: The amendments modify the Technical Specifications to delete the surveillance requirement demonstrating operability of the emergency power supply for the pressurizer power operated relief valves and block valves.

Date of issuance: August 15, 1996

Effective date: August 15, 1996, with full implementation within 45 days

Amendment Nos.: 211 and 196

Facility Operating License Nos. DPR-58 and DPR-74. Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: February 28, 1996 (61 FR 7554) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 15, 1996. No significant hazards consideration comments received: No.

Local Public Document Room location: Maud Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of application for amendment: February 7, 1996, as supplemented July 26, 1996.

Brief description of amendment: The amendment revises the operating license, TSs and associated Bases to implement Option B "Performance-Based Requirements" of Appendix J to 10 CFR Part 50 for Type A, B, and C leakage rate testing.

Date of issuance: August 13, 1996

Effective date: As of the date of issuance to be implemented within 30 days.

Amendment No.: 74

Facility Operating License No. NPF-69: Amendment revises the Technical Specifications and operating license.

Date of initial notice in Federal Register: May 8, 1996 (61 FR 20849) The Commission's related evaluation of the amendment is contained in a Safety

Evaluation dated August 13, 1996. No significant hazards consideration comments received: No

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Northeast Nuclear Energy Company, et al., Docket No. 50-336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of application for amendment: July 3, 1996

Brief description of amendment: The amendment removes, on a one-time basis during the cycle 13 mid-cycle offload/reload activities, the Technical Specification (TS) requirement that the boron concentration in all filled portions of the reactor coolant system be "uniform." The requested change also adds a footnote indicating that it is acceptable for the boron concentration of the water volumes in the steam generators and the connecting piping to be as low as 1300 parts per million. The TS Bases are also updated to reflect the one-time TS change.

Date of issuance: August 12, 1996

Effective date: As of the date of issuance, to be implemented within 30 days.

Amendment No.: 201

Facility Operating License No. DPR-65. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 11, 1996 (61 FR 36583) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 12, 1996. No significant hazards consideration comments received: No.

Local Public Document Room location: Learning Resources Center, Three Rivers Community-Technical College, 574 New London Turnpike, Norwich, CT 06360, and Waterford Library, ATTN: Vince Juliano, 49 Rope Ferry Road, Waterford, CT 06385

Pennsylvania Power and Light Company, Docket Nos. 50-387 and 50-388 Susquehanna Steam Electric Station, Units 1 and 2, Luzerne County, Pennsylvania

Date of application for amendments: February 29, 1996

Brief description of amendments: These amendments relocate Specification 3/4.9.6, "Refueling Platform," to the Susquehanna Steam Electric Station Technical Requirements Manual, a document which is controlled under the requirements of 10 CFR 50.59.

Date of issuance: August 13, 1996

Effective date: August 13, 1996
Amendment Nos.: 159 and 130

Facility Operating License Nos. NPF-14 and NPF-22. The amendments revised the Technical Specifications.

Date of initial notice in Federal Register: April 10, 1996 (61 FR 15992) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated August 13, 1996. No significant hazards consideration comments received: No

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.

Tennessee Valley Authority, Docket Nos. 50-259, 50-260, and 50-296, Browns Ferry Nuclear Plant, Units 1, 2, and 3, Limestone County, Alabama

Date of application for amendments: May 20, 1996 (TS 373)

Brief description of amendment: The amendments incorporate the guidance of Generic Letter 87-09 in the technical specifications, allowing a 24-hour delay in implementing action requirements due to a missed surveillance requirement.

Date of issuance: August 5, 1996

Effective Date: August 5, 1996

Amendment Nos.: 230, 245 and 205 *Facility Operating License Nos.* DPR-33, DPR-52 and DPR-68: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: June 19, 1996 (61 FR 31185) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 5, 1996. No significant hazards consideration comments received: None

Local Public Document Room location: Athens Public library, South Street, Athens, Alabama 35611

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: May 29, 1996

Brief description of amendment: The amendment authorizes revision of the Final Safety Analysis Report (FSAR) to incorporate a modification to the facility that will reduce the single failure trip potential for the main feedwater and bypass valves.

Date of issuance: August 13, 1996

Effective date: August 13, 1996

Amendment No.: 115

Facility Operating License No. NPF-30: The amendment revised the Final Safety Analysis Report.

Date of initial notice in Federal Register: July 3, 1996 (61 FR 34900) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 13, 1996. No significant hazards consideration comments received: No.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Wisconsin Public Service Corporation, Docket No. 50-305, Kewaunee Nuclear Power Plant, Kewaunee County, Wisconsin

Date of application for amendment: June 4, 1996

Brief description of amendment: The amendment revises the Technical Specifications by reducing the surveillance test frequencies for the radiation monitoring system (Table TS 4.1-1) and the control rods (Table TS 4.1-3) in accordance with the guidance of Generic Letter 93-05, "Line-Item Technical Specifications Improvements to Reduce Surveillance Requirements for Testing During Power Operation," dated September 27, 1993.

Date of issuance: August 7, 1996

Effective date: August 7, 1996

Amendment No.: 125

Facility Operating License No. DPR-43: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: July 3, 1996 (61 FR 34901) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 7, 1996. No significant hazards consideration comments received: No.

Local Public Document Room location: University of Wisconsin, Cofrin Library, 2420 Nicolet Drive, Green Bay, Wisconsin 54311-7001

Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: July 29, 1994, as superseded by letter dated September 15, 1995, and subsequently supplemented by letters dated March 8, 1996, April 18, 1996, June 14, 1996, and July 12, 1996.

Brief description of amendment: The amendment revises TS 3/4.8.1, "Electric Power Systems - A.C. Sources," and its associated Bases to achieve an overall improvement in emergency diesel generator reliability and availability.

Date of issuance: August 9, 1996

Effective date: August 9, 1996, to be implemented within 90 days of the date of issuance.

Amendment No.: 101

Facility Operating License No. NPF-42. The amendment revised the Technical Specifications.

Date of initial notice in Federal Register: May 22, 1996 (61 FR 25716) The June 14, 1996, and July 12, 1996, supplemental letters provided Bases page changes and did not change the

initial no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated August 9, 1996. No significant hazards consideration comments received: No.

Local Public Document Room locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621
Dated at Rockville, Maryland, this 21st day of August 1996.

For the Nuclear Regulatory Commission
Steven A. Varga,

*Director, Division of Reactor Projects - I/II
Office of Nuclear Reactor Regulation*
[Doc. 96-21813 Filed 8-27-96; 8:45 am]

BILLING CODE 7590-01-F

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 22160; 811-3925]

Alliance Growth Fund, Inc.; Notice of Application

August 21, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the "Act").

APPLICANT: Alliance Growth Fund, Inc.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant requests an order declaring that it has ceased to be an investment company.

FILING DATES: The application was filed on July 26, 1996.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on September 16, 1996, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicant, 1345 Avenue of the Americas, New York, New York 10105.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus, Paralegal Specialist, at (202) 942-0584, or Alison E. Baur, Branch Chief, at (202) 942-0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is an open-end, non-diversified management investment company incorporated under the laws of Maryland. On December 9, 1983, applicant filed a notification of registration on Form N-8A under section 8(a) of the Act, and filed a registration statement on Form N-1A under section 8(b) of the Act.

Applicant's registration statement was never declared effective, and applicant has made no public offering of its shares.

2. Applicant never issued or sold any securities. Applicant has no shareholders, assets, or liabilities. Applicant is not a party to any litigation or administrative proceeding.

3. Applicant is not now engaged, and does not propose to engage, in any business activities other than those necessary for the winding-up of its affairs.

4. Applicant intends to file Articles of Dissolution with the State Department of Assessments and Taxation of Maryland terminating its existence.

For the SEC, by the Division of Investment Management, under delegated authority.
Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 96-21896 Filed 8-27-96; 8:45 am]

BILLING CODE 8010-01-M

[Investment Company Act Release No. 22161; 811-7550]

Focus Investment Trust Series 1; Notice of Application

August 21, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the "Act").

APPLICANT: Focus Investment Trust Series 1.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant requests an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on July 25, 1996.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on September 16, 1996, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicant, Morgan Keegan & Co., Inc., Morgan Keegan Tower, 50 N. Front Street, Memphis, Tennessee 38103.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus, paralegal Specialist, at (202) 942-0584, or Alison E. Baur, Branch Chief, at (202) 942-0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is a registered unit investment trust under the Act. According to SEC records, on March 4, 1993, applicant filed a notification of registration on Form N-8A pursuant to section 8(a) of the Act, and a registration statement on Form N-8B-2 pursuant to section 8(b) of the Act. On the same date, applicant filed a registration statement on Form S-6 under the Securities Act of 1933 to register its shares.

2. By letter dated February 22, 1994, applicant requested that its registration statement be withdrawn. Applicant's registration statement was withdrawn by order of the SEC on March 22, 1994, and applicant ceased to exist. Applicant has received no funds nor made any distribution to securityholders due to the fact that applicant was never effectively in operation.

3. Applicant has no securityholders, debts, liabilities or assets. Applicant is not a party to any litigation or administrative proceeding. Applicant is not now engaged, nor does it propose to engage, in any business activities other than those necessary for the winding up of its affairs.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 96-21886 Filed 8-27-96; 8:45 am]

BILLING CODE 8010-01-M

[Investment Company Act Release No. 22159; 811-6676]

Seligman Henderson Emerging Companies Interval Fund, Inc.; Notice of Application

August 21, 1996.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the "Act").

APPLICANT: Seligman Henderson Emerging Companies Interval Fund, Inc.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant requests an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on August 7, 1996.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on September 16, 1996, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, 100 Park Avenue, New York, New York 10017.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus, Paralegal Specialist, at (202) 942-0584, or Alison E. Baur, Branch Chief, at (202) 942-0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is an open-end, diversified management investment

company organized as a Maryland corporation. On May 15, 1992, applicant, then known as "Seligman Henderson Small Capitalization Interval Fund, Inc.," filed a notification of registration on Form N-8A pursuant to section 8(a) of the Act. On September 23, 1992, applicant filed a registration statement on Form N-1A pursuant to section 8(b) of the Act, as well as an amended notification of registration changing its name. Applicant's registration statement has not been declared effective and the applicant has not made a public offering of its shares.

2. Applicant has not issued or sold any securities. As of the date of filing of the application, applicant has no security holders, liabilities, or assets. Applicant is not a party to any litigation or administrative proceeding.

3. Applicant is not now engaged, nor does it propose to engage, in any business activities other than those necessary for the winding-up of its affairs.

4. Applicant is in the process of dissolving its existence under Maryland law, including filing Articles of Dissolution with the Maryland Department of Assessment and Taxation.

For the SEC, by the Division of Investment Management, under delegated authority.
Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 96-21887 Filed 8-27-96; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-37589; International Series Release No 1015; File No. SR-CHX-96-12]

**Self-Regulatory Organizations;
Chicago Stock Exchange, Inc.; Order
Approving Proposed Rule Change and
Notice of Filing and Order Granting
Accelerated Approval of Amendment
No. 2 Thereto Relating to Listing
Standards for Investment Company
Units**

August 21, 1996.

I. Introduction

On March 27, 1996, the Chicago Stock Exchange, Inc. ("CHX" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend Article XXVIII of its rules governing the listing requirements of securities on the CHX, as well as Article XXX of the CHX's rules governing specialists. On April 12,

1996, the CHX filed Amendment No. 1 to the proposal.³ Notice of the proposed rule change and Amendment No. 1 thereto appeared in the Federal Register on April 23, 1996.⁴ No comments were received by the Commission. The CHX submitted Amendment No. 2 ("Amendment No. 2") to the proposal on August 20, 1996 to address issues related to Exchange Trading of the Investment Company Units.⁵ This order approves the proposal, as amended, and solicits comments on Amendment No. 2.

II. Description of the Proposal

A. Introduction

The Exchange is proposing listing standards for units of trading ("Units") that represent an interest in a registered investment company ("Investment Company") that could be organized as a unit investment trust ("UIT"), an open-end management investment company, or a similar entity. The Investment Company would hold securities comprising, or otherwise based on or representing an investment in, an index or portfolio of securities. The Investment Company either could hold the securities directly or could hold another security representing the index or portfolio of securities (such as shares of a UIT that holds shares of an open-end management investment company).

Under the proposed rules, the Investment Company would be required either to: (i) Hold securities comprising or otherwise based on or representing an interest in an index or portfolio of securities, or (ii) hold securities in another registered investment company.⁶ The Investment Company would then issue Units in a specified aggregate number in return for a deposit of either: (i) Shares of securities comprising or otherwise based on the relevant index or portfolio, or (ii) shares of an Investment Company. In addition to or instead of the "in-kind" deposit, the Investment Company might require

a cash deposit. Thus, Units could be structured as series of an open-end management investment company investing in a portfolio of securities ("Fund-only structure"). Alternatively, Units could be structured as UITs that have as their assets shares of an open-end management investment company holding a portfolio of securities ("Fund/UIT structure"). Unit holders would receive periodic cash payments corresponding to the regular cash dividends or distributions declared with respect to the securities held by the Investment Company (after subtracting applicable expenses and charges).

Units would be distributed in "Creation Transactions." To effect a Creation Transaction in a Fund-only structure, an entity would be shares from the investment company ("Fund") in "Creation Unit" size aggregations in exchange for a deposit of a basket of securities reflecting the securities underlying the Fund and/or a cash deposit. To effect a Creation Transaction in a Fund/UIT structure, an entity would buy a Fund share from the open-end management investment company with a similar deposit and exchange it with the UIT for a Creation Unit.⁷ The owner of a Creation unit could then subdivide the Creation Unit into a specific number of identical fractional non-redeemable sub-units, the Units, that would constitute the securities traded. Units could be recombined into Creation Unit aggregations, and redeemed for the securities underlying the Fund and/or an amount of cash, either directly, or indirectly, depending on the structure chosen. The securities would not be redeemable other than in Creation Unit aggregations.⁸

Dealing in Units on the Exchange will be conducted pursuant to the Exchange's general agency-auction trading rules. The Exchange's general dealing and settlement rules will apply, including its rules on clearance and settlement of securities transactions and its equity margin rules. Other generally applicable Exchange equity rules and procedures also will apply. Unless the prospectus for a specific security states otherwise, the Units trading on the Exchange will have one vote per share; however, as with other securities issued by registered investment companies, there will not be a "pass-through" of the voting rights on the actual index securities held by a fund or directly or indirectly by a trust.

With respect to specialist dealings, Article XXX, Rule 23(a) of the Exchange's Rules precludes certain business relationships between an

³ Amendment No. 1 serves to supersede entirely the Exchange's initial rule filing. Letter from Charles R. Haywood, Foley Lardner, to Francois Mazur, Attorney, Office of Market Supervision ("OMS"), Division of Market Regulation ("Division"), Commission, dated April 11, 1996 ("Amendment No. 1").

⁴ See Securities Exchange Act Release No. 37121 (April 17, 1996), 61 FR 17932.

⁵ See Letter from David Rusoff, Foley & Lardner, to Michael Walinskas, SEC, dated August 20, 1996. Specifically, Amendment No. 2 amends Interpretation and Policy .01 of Article XXVIII, Rule 23 to require that for the Japan Series, 500,000 Units (as defined below) be outstanding prior to the commencement of trading of a series of Units on the Exchange.

⁶ Telephone Conversation between David T. Rusoff, Foley & Lardner, and Francois Mazur, Attorney, OMS, Division, Commission, on April 12, 1996.

⁷ *Id.*

⁸ *Id.*

¹ 15 U.S.C. § 78s(b)(1) (1988).

² 17 CFR 240.19b-4.

issuer of an "exclusive issue" and the specialist in that exclusive issue.⁹ Rule 23(a) could be interpreted to prevent a specialist from engaging in Creation Transactions with the issuer of Units. The Exchange believes, however, that such market activities could enhance liquidity in the Units and facilitate the specialist's market-making responsibilities. In addition, since the specialist will be able to engage in Creation Transactions and redemptions only according to the same terms and conditions as every other investor (and only at net asset value), the Exchange believes that there is no potential for abuse.

Therefore, the Exchange proposes amending Article XXX, Rule 23(a) to permit specialists to engage in these types of transactions if such transactions would facilitate the maintenance of a fair and orderly market in Units. Any Creation Transactions in which the specialist engages, however, will have to be effected through the Distributor (as defined herein), and not directly with the issuer. This requirement will make clear that the specialist is purchasing Units in Creation Unit-size aggregations only to facilitate normal specialist trading activity.

With respect to investor disclosure, the Exchange notes that pursuant to the requirements of the Securities Act of 1933 ("1933 Act") all investors in Units will receive a prospectus regarding the Units. Because the Units will be in continuous distribution, the prospectus delivery requirements of the 1933 Act will apply to all investors in Units. It is possible, however, that an exemption from the prospectus delivery requirement may be obtained at some point in the future with respect to Units listed or traded on the Exchange. In the event of such an exemption the Exchange will discuss with Commission staff the appropriate level of disclosure that should be required with respect to the Units being listed or traded, as appropriate, and will file any necessary rule change to provide for such disclosure.

Upon the initial listing of any class of Units or trading of such Units pursuant to unlisted trading privileges ("UTP"), the Exchange will issue a circular to its membership explaining the unique characteristics and risks of this type of security. The circular will, among other things, inform member organizations of

their responsibility to deliver a prospectus to investors. The circular also will note that before an Exchange member undertakes to recommend a transaction in Units, it should make a determination that it is in compliance with applicable rules of other self-regulatory organizations of which it is a member, including applicable suitability and know-your-customer rules.

With respect to trading halts, the trading of Units would be halted, along with the trading of all other listed stocks, in the event the "circuit breaker" thresholds of Article IX, Rule 10A are reached.

The Exchange proposes that Units trade either in certificated form or solely through the use of a global certificate. Permitting the use of global certificates would be consistent with expediting the processing of transactions in Units and would minimize the costs of engaging in transactions in these securities.

One existing form of Units are CountryBaskets ("CBs"),¹⁰ which are created pursuant to a Fund-only structure. In March 1996, the New York Stock Exchange ("NYSE") received Commission approval to list and trade CountryBaskets.¹¹ CHX currently will not list CountryBaskets, but rather seeks to trade CountryBaskets pursuant to unlisted trading privileges ("UTP") once the generic listing standards set forth herein are approved.

Pursuant to Rule 12f-5 under the Act,¹² prior to trading a particular class or type of security pursuant to UTP, CHX must have listing standards comparable to those of the primary exchange on which the security is listed. The NYSE has adopted listing standards for Units, and CHX's proposed rule change is designed to create similar standards for Unit listing and/or trading on CHX. As stated above, CHX intends to trade CountryBaskets pursuant to UTP upon approval of this rule filing.

B. CountryBaskets Generally

CountryBaskets are issued as series of an open-end management investment company that invest in a portfolio of securities ("Index Securities") included in a corresponding index.¹³ Each series of the investment company is designed

to provide investment results that substantially correspond to the price and yield performance of a corresponding FT/S&P-Actuaries World Index ("Index" or "FT/S&P").¹⁴ The nine series of Funds that currently exist are based on the following Indices: Australia, France, Germany, Hong Kong, Italy, Japan, South Africa, United Kingdom, and the United States.

C. Distribution of Units

Units are distributed through Creation Transactions. To effect a Creation Transaction, a person buys Fund shares from the Fund at their net asset value ("NAV") next computed. The sales will be in Creation Unit-size aggregations in exchange for a deposit ("Deposit") of Index Securities (a "Fund Basket") and a specified amount of cash sufficient to equal the NAV of such shares.

Units in Creation Unit-size aggregations may be redeemed, at NAV, generally for an in-kind distribution of Index Securities comprising the Fund shares, plus a cash payment. A Creation Unit-size aggregation of Fund shares represents securities with approximately \$2 to \$9.5 million in market value. The Creation Unit is disaggregated into the individual Units that trade on an Exchange, currently the NYSE.¹⁵ For the nine initial CountryBasket securities, there are the following number of Units per Creation Unit:

¹⁴ According to Amendment No. 1 to SR-NYSE-95-23, the Indices are a continuation of the FT-Actuaries World Indices, which were jointly founded by The Financial Times Limited ("FT"), Goldman, Sachs & Co. ("Goldman"), and NatWest Securities Limited ("NatWest," and each a "Founding Member"). In May 1995, Standard & Poor's ("S&P"), a division of The McGraw-Hill Companies, Inc., joined FT and Goldman as co-publishers of the predecessor to the Indices. As part of the new arrangement, NatWest withdrew from the management of those Indices, but continues to be recognized as a Founding Member. The Indices are now jointly owned by S&P, FT and Goldman. Following a transition period, FT and S&P will jointly calculate the Indices. In November 1995, FT transferred its ownership rights in the Indices to FT-SE International, a new company jointly owned by the FT and the London Stock Exchange. By the end of 1996, it is expected that FT-SE International will assume responsibility for calculating the European and Asia-Pacific Indices and S&P will calculate the U.S. Index.

¹⁵ If a Fund/UIT structure instead had been used, a "Redeemable Unit" would represent the functional equivalent of the Creation Unit. The owner of a Redeemable Unit could separate it into a specific number of identical fractional non-redeemable sub-units that would constitute the Units traded on the Exchange. In the case of the Germany CountryBasket series, for example, there would be 100,000 Units per Redeemable Unit. These Units could be recombined into Redeemable Units and then redeemed, at NAV, for the appropriate number of Fund shares. In turn, the Fund shares could be redeemed for the Index Securities and cash. The Units would not be redeemable other than in the Creation Unit aggregations.

⁹ Interpretation and Policy .01 of Article XXX, Rule 23 defines "exclusive issue" as the stock of any company traded on the Exchange not otherwise traded on the NYSE, American Stock Exchange, or NASDAQ/NMS, and, where there exists another market for such issue, the Exchange has executed 15% or more of the volume in the issue during the three previous months.

¹⁰ CHX understands that "CountryBaskets" and "The CountryBaskets Index Fund" are service marks of Deutsche Morgan Grenfell/C.J. Lawrence, Inc. ("DMG"), the investment adviser to the fund.

¹¹ Securities Exchange Act Release No. 36923 (March 5, 1996), 61 FR 10410.

¹² 17 CFR 240.12f-5.

¹³ The information describing the structure and mechanics of CountryBaskets has been restated from File No. SR-NYSE-95-23. See Securities Exchange Act Release No. 36923, *supra* note 11.

Australia	100,000
France	100,000
Germany	100,000
Hong Kong	100,000
Italy	100,000
Japan	250,000
South Africa	100,000
United Kingdom	100,000
United States	100,000

D. Exchange Trading of Units

The Exchange will require that there be at least 300,000 tradable Units outstanding before trading can begin.¹⁶ The Exchange will consider the suspension of trading of a series of Units if:

- after the first year of trading, there are fewer than 50 record or beneficial holders of the Units for 30 or more consecutive trading days;
- the value of the underlying index or portfolio of securities no longer is calculated or available; or
- there occurs another event that makes further dealings in the Units on the Exchange inadvisable.¹⁷

E. The FT/S&P-Actuaries World Indices

Deutsche Bank Securities Corporation, formerly investment adviser to the Funds, provided the NYSE with certain information describing the FT/S&P-Actuaries World Indices, contained within NYSE filing SR-NYSE-95-23, as amended.

1. Establishing an Index

The FT/S&P are jointly compiled by The Financial Times Limited, Goldman, Sachs & Co., and Standard & Poor's, a division of The McGraw-Hill Companies, Inc., in conjunction with the Institute of Actuaries (together, the "Consortium").¹⁸ The aim of the Consortium is to create and maintain a series of high quality equity indices for use by the global investment community. Specifically, the Consortium seeks to establish and

maintain the FT/S&P so that with respect to their corresponding markets, they are comprehensive, consistent, flexible, accurate, investible, and representative.

The World Index Policy Committee ("WIPC") makes all policy decisions concerning the FT/S&P, including objectives, selection criteria, liquidity requirements, calculation methodologies, and the timing and disclosure of additions and deletions. The WIPC makes those decisions in a manner that is consistent with the stated aims and objectives of the Consortium. In general, the WIPC aims for a minimum of 70 percent coverage of the aggregate value of all domestic exchange-listed stocks in every country, region and sector in which it maintains an index.

The WIPC consists of one representative of each Consortium member, one member nominated by each of the parties as representing an actual or prospective main user group of the World Indices, and a Chairman and additional member who are members of the Institute of Actuaries or the Facility of Actuaries.

A country must satisfy the following criteria for the WIPC to include it in the FT/S&P-Actuaries World Indices: (1) Direct equity investment by non-nationals must be permitted; (2) accurate and timely data must be available; (3) no significant exchange controls should exist that would prevent the timely repatriation of capital or dividends; (4) significant international investor interest in the local equity market must have been demonstrated; and (5) adequate liquidity must exist.

Securities in the FT/S&P are subject to the following "investibility screens": (1) Securities comprising the bottom five percent of any market's capitalization are excluded; (2) securities must be eligible to be owned by foreign investors; (3) 25 percent or more of the full capitalization of eligible securities must be publicly available for investment and not in the hands of a single party or parties "acting in concert"; and (4) securities that fail to trade for more than 15 business days within each of two consecutive quarters are excluded.

The WIPC seeks to select constituent stocks that capture 85 percent of the equity that remains in any market (known as the "investible universe") after applying the investibility screens. Securities are selected with regard to economic sector and market capitalization to make a given FT/S&P highly representative of the overall economic sector make-up and market capitalization distribution of the investible universe of a market.

2. Maintaining an Index

The WIPC may add securities to the FT/S&P for any of the following reasons:

- (1) The addition would make the economic sector make-up and market capitalization distribution of the FT/S&P component more representative of its investible universe;
- (2) a non-constituent security has gained in importance and replaces an existing constituent security under the rules of review established by the WIPC;
- (3) the FT/S&P component represents less than its targeted percentage of the capitalization of its investible universe (usually in cases where the investible universe has grown faster than the corresponding FT/S&P);
- (4) a new, eligible security becomes available whose total capitalization is one percent or more of the current capitalization of the relevant FT/S&P;
- (5) an existing constituent "spins off" a part of its business and issues new equity to the existing shareholders; or
- (6) changes in investibility factors lead to a stock becoming eligible for inclusion and that stock now qualifies on other grounds.

The WIPC may adjust the FT/S&P for any of the following reasons: (1) The component comprises too high a percentage of its representative universe; (2) a review by the WIPC shows that a constituent security has declined in importance and should be replaced by a non-constituent security; (3) the deletion of a security that has declined in importance would make the FT/S&P more representative of the economic make-up of its investible universe; (4) circumstances regarding investibility and free float change, causing the constituent security to fail the FT/S&P screening criteria; (5) an existing constituent security is acquired by another entity; or (6) the stock has been suspended from trading for a period of more than ten working days. Generally, but not in all cases, changes resulting from review by the WIPC occur at the end of a calendar quarter. Changes resulting from merger or "spin-off" activity will be effectuated as soon as practicable.

3. Dissemination of Changes to the Constituent Stocks in the Indices

Changes to an Index made during a calendar quarter are noted at the foot of the tables containing the Indices that are published daily in the FT. Consistent with the FT publication policy, these changes also are shown prior to the actual day of implementation (unless for reasons beyond the control of FT this is not possible). Decisions regarding the addition of new eligible constituent stocks that are unrelated to existing stocks in an Index, or weighting changes

¹⁶ For the Japan series, 500,000 worth of DBs, representing two Creation Units, will be required to be outstanding prior to commencing trading. See Amendment No. 2.

¹⁷ The Commission notes that the fund must invest at least 95% of its net assets in the securities of the appropriate Index and that the weighting of the portfolio securities of each series will substantially correspond to their proportional representation in each Index, helps to reduce concerns that Units could become a surrogate for trading in a single or a few unregistered stocks. See Securities Exchange Act Release No. 36923, *supra* note 11. In the unlikely event, however, that this were to occur, the Commission would expect the CHX to suspend trading in the securities to ensure compliance with the Act.

¹⁸ In Amendment No. 1 to SR-NYSE-95-23, the NYSE stated that certain modifications had occurred to the Indices. The CHX's filing has incorporated the additional information, and operates under the assumption that the original information detailed in SR-NYSE-95-23 continues to be accurate to the extent not modified by the NYSE's amendment.

to existing constituent stocks, are announced in the FT at least four working days before they are implemented. Monday editions of the FT also show all constituent changes made during the previous week, together with base values for each Index. Changes to be made in an Index at the end of a calendar quarter are published as soon as is practicable following the quarterly meeting of the World Indices Policy Committee, but before the quarter-end.

4. Calculation and Dissemination of an Index

The FT/S&P are calculated through widely accepted mathematical formulae, with the effect that the Indices are weighted arithmetic averages of the price relatives of the constituents—as produced solely by changes in the marketplace—adjusted for intervening capital changes. The FT/S&P are base-weighted aggregates of the initial market capitalization, the price of each issue being weighted by the number of shares outstanding, modified to reflect only those shares outstanding that are eligible to be owned by foreign investors.

For each constituent security, the implied annual dividend is divided by 260 (an accepted approximation for the number of business days in a calendar year). This dividend is then reinvested daily according to standard actuarial calculations. Distributions affect adjustments to the base capital or the price per share in accordance with prescribed FT/S&P standards. The Indices' values and related performance figures for various periods of time are calculated daily and are disseminated to the public.

The FT/S&P are valued in terms of local currency, U.S. dollars, and U.K. pounds sterling, thereby allowing the effect of currency value on the Index value to be measured. Changes to the Indices are announced as soon as possible, and on Mondays the Financial Times publishes a list of changes to each Index implemented during the previous week, if any. The FT/S&P are calculated once a day on weekdays when one or more of the constituents markets are open; the Indices are syndicated and published in the financial sections of several newspapers worldwide. FT/S&P data also may be purchased electronically.

F. Indicative Values

Recognizing the importance of having current information on the value of the Indices, DMG has arranged for Telesphere Corporation (formerly Telekurs (North America) Inc.) ("Telesphere") to calculate "indicative

values" for the nine Indices on which CountryBaskets are based. CHX understands that the NYSE provides for the dissemination of these indicative values through the facilities of the Consolidated Tape Association ("CTA").

In calculating "indicative values," Telesphere uses the most currently available stock price information for the constituent stocks in an Index (based on home currency prices) and prevailing currency exchange rates to translate the Index value into U.S. dollars.

Telesphere also uses the same pricing algorithm and methodology as the Index calculators in calculating the indicative values. These values are disseminated every 30 seconds by the NYSE during regular trading hours of 9:30 A.M. to 4:00 P.M. Eastern time. Because trading hours in the markets for the stocks underlying the Indices differ, the calculation of the indicative values are effected as follows:

- *Pacific Rim.* Australia, Hong Kong, and Japan. There is no overlap between the NYSE trading hours and the home-country trading hours. Thus, the indicative values always reflect the closing prices of the underlying securities on the most recently completed trading day, but are updated every 30 seconds to reflect changes in exchange rates.

- *Europe.* France, Germany, Italy, and the United Kingdom. There is some overlap between NYSE trading hours and home-country trading hours. Thus, the 30-second updates for these Indices reflect changes in both current stock price information and currency exchange rates while the relevant market is open; it reflects only changes in exchange rates once the home-market closes.

- *United States.* Each 30-second update reflects the current price of U.S. component stocks.

- *South Africa.* During Eastern Standard Time there is no overlap between NYSE and South African trading hours. During Eastern Daylight Savings Time there is a half-hour overlap. Thus, during Standard Time, the disseminated Index values reflect the closing South African prices. During Daylight Savings Time, there is a real-time feed of stock prices from the Johannesburg Stock Exchange and there is a real-time calculation of the indicative value of the index at 30-second intervals during the half-hour overlap.

While these indicative values are not the official values of the Indices (which continue to be calculated and disseminated once each day), the Exchange believes that these values provide investors with accurate, timely

information on the values of the Indices. Providing standardized information through CTA facilities should help ensure that all investors have equal access to this market information. While some market participants may be able to perform these calculations for their own trading purposes during the business day, many participants lack sufficient resources to do so. Of course, it cannot be guaranteed that the indicative value will at all times be a completely accurate reflection of the value of the underlying Index.¹⁹

Although the CHX operates under Central Time, its trading hours coincide with those of the NYSE. Therefore, the time zone difference will not affect the ability to trade CountryBaskets on the CHX with full price information.

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6(b)(5) of the Act.²⁰ The Commission believes that the Exchange's proposal to establish listing standards for Units and to trade CountryBaskets pursuant to UTP will provide investors with a convenient way to participate in domestic and foreign securities markets. The Exchange's proposal should help to provide investors with increased flexibility in satisfying their investments with increased flexibility in satisfying their investment needs by allowing them to purchase and sell at negotiated prices throughout the business day securities that replicate the performance of several portfolios of stocks.²¹ Accordingly, the Commission finds that the Exchange's proposal will facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, and is not designed to permit unfair discrimination between

¹⁹In the unlikely event that Telesphere determines that it no longer will calculate the indicative value of the Indices, according to the NYSE, DMG will seek to find another entity to provide such values on substantially the same basis as Telesphere. If this were to occur, the NYSE has represented that it will consult with the staff of the Division to ensure that the staff finds any proposed new arrangements acceptable, including the possibility of ending trading in the securities.

²⁰15 U.S.C. 78f(b)(5) (1988).

²¹The Commission notes that unlike typical open-end management investment companies, where investors have the right to redeem their fund shares on a daily basis, investors in Units only could redeem Units in Creation Unit size aggregations.

customers, issuers, brokers, or dealers.²² The Commission also believes that the Exchange's proposal is consistent with Section 12(f) of the Act²³ relating to trading securities pursuant to UTP.

The CHX seeks to trade CBs pursuant to UTP. In approving the NYSE's proposal to list and trade CBs, the Commission noted that the estimated cost of an individual CB security, approximately \$20 to \$50, should make it attractive to individual retail investors who wish to hold a security replicating the performance of a portfolio of foreign or domestic stocks. The Commission also stated that it believes that CBs will provide investors with several advantages over standard open-end management investment companies specializing in such stocks, and in particular, investors will be able to trade CBs continuously throughout the business day in secondary market transactions at negotiated prices.²⁴ In contrast, Investment Company Act Rule 22c-1²⁵ limits holders and prospective holders of open-end management investment company shares to purchasing or redeeming securities of the fund based on the net asset value of the securities held by the fund as designated by the board of directors. Thus, the Commission stated that CBs should allow investors to: (1) Respond quickly to market changes through intra-day trading opportunities; (2) engage in hedging strategies not currently

available to retail investors; and (3) reduce transaction costs for trading a portfolio of securities.

Although the value of CBs will be based on the value of the securities and cash held in the Fund, CBs are not leveraged instruments.²⁶ In essence, CBs are equity securities that represent an interest in a portfolio of stocks designed to reflect substantially the applicable FT/S&P Index. Accordingly, it is appropriate to regulate CBs in a manner similar to other equity securities. Nevertheless, in approving the CHX's proposal to trade CBs, the Commission believes that the unique nature of CBs requires that certain product design, disclosure, trading, and other issues be addressed.

A. CountryBaskets Generally

As stated in the approval of the NYSE's proposal to list and trade CBs,²⁷ the Commission believes that the CBs are reasonably designed to provide investors with an investment vehicle that substantially reflects in value the Index it is designed upon, and, in turn, the performance of the specified U.S. or foreign market. In this regard, the Commission notes that the WIPC imposes specific criteria in its selection of Index countries and components. For a market to be eligible for inclusion in an FT/S&P Index, it must allow direct equity investment by non-nationals, make timely and accurate data available, impose no significant exchange controls, demonstrate significant international investment interest, and be sufficiently liquid. For a security to be included in a given Index, it may not be in the bottom 5% of a market's capitalization, it must be eligible to be owned by foreigners, 25% of its full capitalization must be publicly available for investment, and it may not fail to trade for more than 15 business days within each of two consecutive quarters. The aim of component selection is to make Index components highly representative of the over-all economic sector make-up and market capitalization of a given market. The Commission believes that these criteria should serve to ensure that the underlying securities of these Indices are well capitalized and actively traded.

The Commission also notes that the CB series' investment policies require that at least 95% of a CB series' investments be in the equity securities that are the constituent securities of the relevant FT/S&P Index. In addition, the weighting of the portfolio securities of each series substantially correspond to their proportional representation in the corresponding FT/S&P Index.²⁸ This will help to ensure that an investment in CBs is substantially similar to an investment in the securities comprising the related FT/S&P Index.

B. Disclosure

The Commission believes that the Exchange's proposal should ensure that investors have information that will allow them to be adequately apprised of the terms, characteristics, and risks of trading Units, including CBs.²⁹ As noted above, all Unit investors, including investors purchasing CBs in the secondary market at the CHX pursuant to UTP, will receive a prospectus regarding the product. Because Units, including CBs trading on the CHX pursuant to UTP, will be in continuous distribution, the prospectus delivery requirements of the Securities Act of 1933 will apply both to initial investors, and to all investors purchasing such securities in the secondary market at the CHX. The prospectus will address the special characteristics of a particular Unit, including a statement regarding that Unit's redeemability, and method of creation. With respect to CBs, the prospectus will state specifically that CBs individually are not redeemable.

The Commission also notes that upon the initial listing of or extension of unlisted trading privileges to any class of Units, including CBs, the Exchange will issue a circular to its members explaining the unique characteristics and risks of this type of security. The circular will note that before an Exchange member undertakes to recommend a transaction in Units, it should make a determination that it is in compliance with applicable rules of other self-regulatory organizations of which it is a member, including applicable suitability and know-your-

²² Pursuant to Section 6(b)(5) of the Act, the Commission must predicate approval of exchange trading for new products upon a finding that the introduction of the product is in the public interest. Such a finding would be difficult with respect to a product that served no investment, hedging or other economic function, because any benefits that might be derived by market participants would likely be outweighed by the potential for manipulation, diminished public confidence in the integrity of the markets, and other valid regulatory concerns.

²³ 15 U.S.C. § 78s(l) (1994).

²⁴ Because of potential arbitrage opportunities, the Commission believes that CBs should not trade at a material discount or premium in relation to their net asset value. The mere potential for arbitrage should keep the market price of CBs comparable to their net asset values; therefore, arbitrage activity likely will not be significant. In addition, the Fund will redeem in-kind, thereby enabling the Fund to invest virtually all of its assets in securities comprising the FT/S&P Indices.

²⁵ 17 CFR 270.22c-1. Investment Company Act Rule 22c-1 generally provides that a registered investment company issuing a redeemable security, its principal underwriter, and dealers in that security may sell, redeem, or repurchase the security only at a price based on the net asset value next computed after receipt of an investor's request to purchase, redeem, or resell. The net asset value of an open-end management investment company generally is computed once daily Monday through Friday as designated by the investment company's board of directors. The Commission granted CBs an exemption from this provision to allow them to trade in the secondary market at negotiated prices. See Investment Company Act Release No. 21802; International Series Release No. 943, March 5, 1996.

²⁶ In contrast, proposals to list exchange-traded derivative products that contain a built-in leverage feature or component raise additional regulatory issues, including heightened concerns regarding manipulation, market impact, and customer suitability. See e.g., Securities Exchange Act Release No. 36165 (August 29, 1995), 60 FR 46653 (relating to the establishment of uniform listing and trading guidelines for stock index, currency, and currency index warrants).

²⁷ Securities Exchange Act Release No. 36923, *supra* note 11.

²⁸ The actual components, component capitalization, and component weightings for each series as of December 29, 1995, were submitted as part of a Form N-1A registration statement of The CountryBaskets Index Fund, Inc. under the Securities Act of 1933 and the Investment Company Act of 1940. Registration Nos. 33-85710; 811-8734.

²⁹ The CHX states that it may, in the future, seek to obtain an exemption from the prospectus delivery requirement with respect to Units trading on the Exchange. In the event it obtains such an exemption, the Exchange will discuss with Commission staff the appropriate level of disclosure that should be required with respect to the Units being listed, and will file any necessary rule change to provide for such disclosure.

customer rules. The circular also will address members' responsibility to deliver a prospectus to all investors as well as highlight the characteristics of purchases in Units, including CBs, including that they only are redeemable in Creation Unit size aggregations.

C. Trading of CBs

The Commission finds that adequate rules and procedures exist to govern the trading of Units, including the trading of CBs by the CHX pursuant to UTP. In this regard, the Commission notes that Units are deemed equity securities subject to CHX rules applicable to the trading of equity securities. Accordingly, the Exchange's existing general rules that currently apply to the trading of equity securities also will apply to Units, including CBs. These rules include those governing: the auction market (including trading halt provisions pursuant to CHX Article IX, Rule 10A); priority, parity and precedence of orders; members dealing for their own accounts; specialist, odd-lot broker, and registered trader responsibilities; handling of orders and reports; publications of transactions and changes; comparisons and exchange of contracts; marking to the market; settlement of contracts; dividends, interests, and rights; reclamations; closing contracts; and lending securities.³⁰ The CHX also will consider suspending trading in a series of Units if it deems that an event or condition exists that makes further dealings on the Exchange inadvisable.

In addition, the Exchange has proposed specific listing and delisting criteria to accommodate the trading of Units. These criteria should help to ensure that a minimum level of liquidity will exist in each series of Units to allow for the maintenance of fair and orderly markets. The delisting criteria also allows the Exchange to consider the suspension of trading and the delisting of a series of Units, including suspending trading in CBs traded on the Exchange pursuant to UTP, if an event were to occur that made further dealings in such securities inadvisable. This will give the Exchange flexibility to suspend trading and delist Units, if circumstances warrant such action. For example, as noted above, suspending trading in CBs might be appropriate if Telesphere no longer were able to calculate indicative values, and no acceptable alternative arrangements could be found.³¹ In addition, as noted above, in the unlikely event that CBs become a surrogate for trading a single or few securities, such an event could

raise issues pursuant to the Act that would require suspending trading in CBs so as to ensure compliance with the Act.³² Accordingly, the Commission believes that the rules governing the trading of Units provide adequate safeguards to prevent manipulative acts and practices and to protect investors and the public interest.

D. Indicative Indices

The Commission believes that given that the NYSE is disseminating the indicative values for the nine Indices upon which CBs are based, investors are provided with timely and accurate information concerning the value of the FT/S&P. The Commission understands that the information is disseminated through the facilities of the CTA and will reflect currently-available stock price information. Moreover, it is calculated based upon the same pricing algorithm and methodology used by the FT/S&P calculators and is disseminated every 30 seconds during the regular NYSE trading day.³³ In addition, since it is expected that the market value of the CBs will closely track the performance of the applicable FT Index,³⁴ the Commission believes that the indicative values provide investors with adequate information to determine the intra-day value of a given CB series.³⁵

E. Specialists

The Commission finds that it is consistent with the Act to allow a specialist registered in a security issued by an Investment Company to purchase or redeem the listed security from the issuer as appropriate to facilitate the maintenance of a fair and orderly market in that security. The Commission believes that such market activities should enhance liquidity in such securities and facilitate a specialist's market-making responsibilities. In addition, because the specialist only will be able to purchase and redeem Units on the same terms and conditions as any other investor (and only at NAV), and Creation

Transactions must occur through the distributor and not directly with the issuer, the Commission believes that concerns regarding potential abuse are minimized. As noted below, the Exchange's existing surveillance procedures also should ensure that such purchases are only for the purpose of maintaining fair and orderly markets, and not for any other improper or speculative purposes. Finally, the Commission notes that its approval of this aspect of the Exchange's rule proposal does not address any other requirements or obligations under the federal securities laws that may be applicable.³⁶

F. Surveillance

The Commission believes that the CHX's existing surveillance procedures should be adequate to address any concerns associated with specialists purchasing and redeeming Creation Units. The Exchange has represented that its existing surveillance procedures should allow it to identify situations where specialists purchase or redeem Creation Units to ensure compliance with the rule.³⁷

G. Scope of the Commission's Order

The Commission is approving in general the Exchange's proposed listing and delisting standards for Units representing an interest in an Investment Company that would hold a Fund Basket, and specifically the Exchange proposal to trade the nine series of CountryBaskets described herein pursuant to UTP. The Commission notes that Rule 12f-5 under the Act requires that a national securities exchange not extend unlisted trading privileges to any security unless it has in effect a rule or rules providing for transactions in the class or type of security to which the exchange extends unlisted trading privileges.³⁸ The Commission believes that the Exchange's proposed listing standards for Units are consistent with this requirement and will allow the CHX to trade, pursuant to UTP, the nine CBs currently trading on the NYSE. Other similarly structured products would require review by the Commission pursuant to Section 19(b) of the Act prior to being listed on the CHX or

³² See note 17, *supra*.

³³ See Securities Exchange Act Release No. 36923, *supra* note 11.

³⁴ See Form N-1A, *supra* note 28. Each CB series is required to invest the largest proportion of its assets as is practicable, and in any event at least 95% of its net assets, in the securities of the corresponding FT/S&P Index, and the weighting of the portfolio securities of each CB series should substantially correspond to their proportional representation in the relevant FT/S&P Index. *Id.*

³⁵ In addition, each series calculates its NAV per share at the close of the regular trading session for the NYSE on each day that the NYSE is open for business. NAV generally will be based on the last quoted sales price on the securities exchange or national securities market on which a given series' component securities are quoted. *Id.*

³⁶ The Commission notes that with respect to CBs, broker dealers and other persons are cautioned in the prospectus and/or the Fund's statement of additional information that some activities on their part may, depending on the circumstances, result in their being deemed statutory underwriters and subject them to the prospectus delivery and liability provisions of the Securities Act of 1933.

³⁷ Letter from J. Craig Long, Foley & Lardner, to Sharon Lawson, Senior Special Counsel, OMS, Division, dated June 22, 1996.

³⁸ 17 CFR 240.12f-5.

³⁰ See CHX Rules, Parts II & III *passim*.

³¹ See *supra* note 19.

traded pursuant to UTP. Moreover, CBs based on FY/S&P Indices not described herein, would require consultation with the Commission as to whether a filing pursuant to Section 19(b) of the Act is required prior to being listed on the Exchange, or traded pursuant to UTP.

The Commission finds good cause for approving Amendment No. 2 prior to the thirtieth day after the date of publication of notice of filing thereof in the Federal Register. Amendment No. 2 amends Interpretation and Policy .01 of Article XXVIII, Rule 23 to require that the Japan Series have a minimum of 500,000 CBs outstanding prior to the commencement of trading on the Exchange. As discussed above, CHX must have listing standards comparable to those of the primary exchange on which the security is traded. The Commission notes that this Amendment brings CHX's listing standards into conformity with those of the NYSE. Accordingly, the Commission does not believe Amendment No. 2 raises any new or unique regulatory issues. Therefore, the Commission believes it is consistent with Sections 6(b)(5) and 19(b)(2) of the Act to approve Amendment No. 2 to the proposal on an accelerated basis.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendment No. 2. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to the file number in the caption above and should be submitted by September 18, 1996.

V. Conclusion

For the reasons discussed above, the Commission finds that the proposal, as amended, is consistent with the Act, and, in particular, Section 6 of the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,³⁹ that the proposed rule change (File No. SR-CHX-96-12), as amended is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁴⁰

Margaret H. McFarland,

Deputy Secretary.

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[Release No. 34-37590; File No. SR-PSE-96-28]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Pacific Stock Exchange Incorporated Relating to Its Rule on the Evaluation of Its Equity Specialists

August 21, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on August 18, 1996, the Pacific Stock Exchange Incorporated ("PSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to adopt a pilot program amending its rule on the evaluation of its equity specialists.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to adopt a pilot program amending its rule relating to specialists evaluations for a nine month period from October 1, 1996 to June 30, 1997. Currently, PSE Rule 5.37(a) provides that the Equity Allocation Committee ("EAC") shall evaluate all registered specialists on a quarterly basis and that each registered specialist shall receive an overall evaluation rating based on the following three measures of performance: (1) Specialist Evaluation Questionnaire Survey ("Questionnaire"); (2) SCOREX Limit Order Acceptance Performance; and (3) National Market System Quote Performance.

The Exchange is proposing to modify PSE Rule 5.37(a) by adding three new measures of performance and eliminating one measure of performance. The new measures are: (1) Executions; (2) Book Display Time; and (3) Post 1-P.M. Parameters. The Exchange is also proposing to: add more questions to the Questionnaire and to expand the National Market System Quote Performance measure (for the nine month pilot, this criterion will be referred to as "Quote Performance")¹ to include a performance measure for bettering the quote. In addition, the Exchange is proposing to eliminate SCOREX Limit Order Acceptance Performance as a measure of specialist performance. The Exchange's new rule for the evaluation of specialists will therefore consist of five separate measures of performance, as specified below:

a. Executions. This category, on which 50% of each specialist evaluation is based, consists of four subcategories: (a) Turnaround Time; (b) Holding Orders Without Action; (c) Trading Between the Quote; and (d) Executions in Size Greater Than BBO.

"Turnaround Time" calculates the average number of seconds for all eligible orders up to 1,099 shares based upon the number of seconds between the receipt of a market or marketable limit order in P/COAST and the execution, partial execution, stopping, or cancellation of the order. An order that is moved from the auto-ex screen to the manual screen will accumulate time until it is executed, partially executed, stopped, or canceled. This measurement begins after the stock opens for the day on the primary market. Only those orders received by P/COAST after the

³⁹ 15 U.S.C. 78s(b)(2) (1988).

⁴⁰ 17 CFR 200.30-3(a)(12).

¹ See *infra* text accompanying note 4.

stock opens will be counted. If there is a trading halt or period when the P/COAST system is experiencing problems, Turnaround Time will not be included for those blocks of time. A specialist will be awarded points based on the average number of seconds between the receipt of eligible market or marketable limit orders and any of the actions specified above being taken upon such orders. This category will count for 15% of the overall score. The parameter ranges and corresponding points for Turnaround Time are listed below:

Number of seconds parameter range	Points
1-8	10
9-10	9
11-12	8
13-14	7
15-16	6
17-18	5
19-20	4
21-22	3
23-24	2
25-26	1
27+	0

“Holding Orders Without Action” measures the number of market and marketable limit orders up to 10,099 shares that are held without action for greater than 25 seconds. As in the Turnaround Time calculation, a cancellation, a stop, an execution, or partial execution stops the clock. This measurement begins after the stock opens for the day on the primary market. Only those orders received by P/COAST after the stock opens will be counted. If there is a trading halt or period when the P/COAST system is experiencing problems, those blocks of time will be excluded from the Holding Orders Without Action calculation. The specialist will be awarded points based on the percentage of orders that are held under the established time period.² This category will count for 15% of the overall score. The parameter ranges and corresponding points for Holding Orders Without Action are listed below:

Percent of orders parameter range	Points
1-3	10
4-6	9
7-9	8
10-12	7
13-15	6
16-18	5
19-21	4
22-24	3
25-27	2
28-30	1
31+	0

“Trading Between the Quote” measures the number of market and marketable limit orders that are executed between the best primary market bid and offer. For this criterion to count toward the overall evaluation score, ten orders or more must have been executed during the quarter the specialist is being evaluated. If less than ten orders are executed, this criterion will not be counted and the rest of the evaluation criteria will be given more weight.

When a market or marketable limit order is executed, the execution price is compared to the primary bid and offer. The specialist will be awarded points based on the percentage of orders the specialist receives that are executed between the primary bid and offer. If the execution price falls between the primary bid and the primary offer, the trade is counted as one that traded between the quote at the time of execution. Each time a trade is executed, the primary market quote will be noted. If the spread of that quote is two or more trading fractions apart, that trade will count as one eligible for the comparison of the execution price to the quote. If there is a trading halt or period when the P/COAST system is experiencing problems, those blocks of time will not be included in the Trading Between the Quote calculation.

This category will count for 10% of the overall score. The parameter ranges and corresponding points for Trading Between the Quote are listed below:

Percent of orders parameter range	Points
51+	10
46-50	9
41-45	8
36-40	7
31-35	6
26-30	5
21-25	4
16-20	3
11-15	2
5-10	1
0-4	0

“Executions in Size Greater Than BBO” measures the number of market and marketable limit orders which exceed the best bid and offer (“BBO”) size. When a market or marketable limit order is executed, the order must meet two tests to be counted: first, the original order size must be greater than the BBO size; and second, the execution size must be greater than the BBO size. If the execution size is greater than the bid size (for a sell order) or offer size (for a buy order), the trade is counted as one that was executed in size greater than the BBO. If there is a trading halt or period when the P/COAST system is experiencing problems, those blocks of

time will not be included in the Executions in Size Greater Than BBO calculation. For this criterion to count toward the overall evaluation score, ten orders or more must have been executed during the quarter the specialist is being evaluated. If less than ten orders are executed, this criterion will not be counted and the rest of the evaluation criteria will be given more weight.

The specialist will be awarded points based on the percentage of orders that are executed that exceed the BBO size. This category will count for 10% of the overall score. The parameter ranges and corresponding points for Executions In Size Greater than BBO are listed below:

Percent of orders parameter range	Points
98-100	10
95-97.999	9
92-94.999	8
89-91.999	7
86-88.999	6
83-85.999	5
80-82.999	4
77-79.999	3
74-76.999	2
71-73.999	1
0-70.999	0

b. *Specialist Evaluation Questionnaire Survey.* The Questionnaire is filled out by equity floor brokers on a quarterly basis. The Questionnaire responses will count for 15% of the overall score. Each question in the Questionnaire has a possible rating of 1 to 10. Each question will be weighted equally and will count for 1.875% of the overall evaluation score.

The Questionnaire currently solicits from floor brokers ratings in the following categories: the quality of markets maintained by the specialist; the specialist's effectiveness in his (her) handling of orders; communication; and the specialist's handling of clerical and administrative matters. The Questionnaire will be expanded to solicit from floor brokers ratings on the specialist's: handling of manual orders for a size greater than that provided for in the BBO; failure trade on displayed quotes; representation of the broker's orders in his (her) quotes; and facilitation of crosses.

The new questions proposed to be added to the Questionnaire are the following: Does the specialist handle manual orders from floor brokers for greater than the BBO size? Does the specialist fail to trade on his (her) displayed quotes? Does the specialist adequately represent brokers' orders in the quotes? and Does the specialist allow for each facilitation of crosses?

c. *Book Display Time.* This criterion calculates the percentage of the book shares at the best price in the book that

² I.e., a specialist will receive fewer points the larger the percentage of orders that he (she) holds for greater than 25 seconds.

are displayed in the specialist's quote, by symbol, and the duration of time that each percentage is in effect. This criterion rates the P/COAST book displayed 100% of the time. The sizes of all open buy limit orders at the best price for the symbol in the specialist's book will be totaled and compared to the bid size quote. The sizes of all open sell limit orders at the best price for the symbol in the book will be totaled and compared to the offer size quote. This will be done for each symbol traded by the specialist, and only for those orders priced within the primary quote. Limit orders in the book which are priced beyond the primary quote will not be included; they will not be executed until they reach the price in the primary quote, so the specialist should not be required to cover them in his (her) quote sizes.

The specialist will be awarded points on the basis of the percentage of the book that the specialist displays. This category will count for 15% of the overall score. The parameter ranges and corresponding points for Book Display Time are listed below:

Percent of book parameter range	Points
80+	10
75-79	9
70-74	8
65-69	7
60-64	6
55-59	5
50-54	4
45-49	3
40-44	2
35-39	1
0-34	0

d. *Post-1 P.M. Parameters.* This criterion measures the specialist's quote performance in the post-1 p.m. (Pacific Time) auction market ("Extended Trading Session").³ The Post-1 P.M. Parameters criterion has the following features:

1. Specialists' activity is recorded in post-1 p.m. files, where there is one record for each quote and trade per post and symbol as they occur during the extended trading session.

2. Specialists are not subject to the post-1 p.m. quote-spread parameters until after 1:10 p.m. This allows the specialists time to do any primary market runoff business that is necessary.

3. The specialist's quote prices in effect ten minutes past the beginning of the Extended Trading Session must be within the defined number of trading fractions of the primary closing quote.

A. If the primary exchange is the NYSE, and the primary bid price at

closing on that day for the stock is under \$1.00, the trading fraction is $\frac{1}{16}$; if the price is at or over \$1.00, it is $\frac{1}{8}$.

B. If the primary exchange is the Amex, and the primary bid price at closing on that day for the stock is under \$10.00, the trading fraction is $\frac{1}{16}$; if the price is at or over \$10.00, it is $\frac{1}{8}$.

4. The specialist's quote sizes in effect ten minutes past the beginning of the Extended Trading Session must be 500 shares or more if the primary bid price is less than \$50.00, or 200 shares if the primary bid price is \$50.00 or more.

5. The specialist's quote-spread parameters must apply to a minimum of 25% of the stocks traded at the post to receive full credit on the evaluation (i.e., 10 points).

6. If the specialist executes any trades after ten minutes of the Extended Trading Session and they are priced within the allowable trading fraction of the primary closing quote price, the quantity of the trade is deducted from the required quote size.

7. If the specialist changes his (her) quote at any time on the same day for that symbol while the required quote size is not zero, his (her) quote price must be within the allowable trading fraction from the primary closing bid price and his (her) quote size must be at least the remaining quote size required (as adjusted for trades, as explained in item 6). If either the price or size on either side of the quote for that symbol does not comply, the symbol is not counted as adhering to the parameters for that day.

8. If, at the end of the Extended Trading Session, the required quote size is still not zero (after adjusted for trades) for bid and/or ask, but the specialist has complied with the quote price and size guidelines on both bid and ask, the symbol is counted as one that adhered to the parameters.

This category will count for 10% of the overall score. The parameter ranges and corresponding points for Post-1 P.M. Parameters are listed below:

Percent of book parameter range	Points
25+	10
22-24.999	9
19-21.999	8
16-18.999	7
13-15.999	6
10-12.999	5
7-9.999	4
4-6.999	3
0-3.999	0

e. *Quote Performance.* This category, on which 10% of each specialist evaluation is based, consists of two subcategories: (a) Equal or Better Quote Performance; and (b) Better Quote Performance.

"Equal or Better Quote Performance" calculates for each issue traded, the percentage of time in which a specialist's bid or offer is equal to or better than the primary market quote with a 500-share market size or the primary market size, whichever is less, with a 200-share minimum. This category will count for 5% of the overall score. The parameter ranges and corresponding points for Equal or Better Quote Performance are listed below:

Percent of time parameter range	Points
40+	10
36-39	9
32-35	8
28-31	7
24-27	6
20-23	5
16-19	4
12-15	3
8-11	2
4-7	1
0-3	0

"Better Quote Performance" calculates for each issue traded, the percentage of time in which a specialist's bid or offer, is better than the primary quote with a 500-share market size or the primary market size, whichever is less, with a 200-share minimum. This category will count for 5% of the overall score. The parameter ranges and corresponding points for Better Quote Performance are listed below:

Percent of time parameter range	Points
4+	10
3-3.999	9
2-2.999	8
1-1.999	7
0-0.999	0

The Exchange notes that the pilot program only modifies the performance criteria of PSE Rule 5.37(a). Consequently, during the pilot the EAC will evaluate the performance of specialists in accordance with the standards and procedures found in PSE Rule 5.37. During the nine month pilot, the Exchange will re-program its computer program so that the following three criteria are based upon the national best bid and offer instead of the primary market bid and offer: Trading Between the Quote, Book Display Time, and Quote Performance.⁴ Also, during the pilot, the Exchange will establish an overall passing score for the performance evaluation as well as individual passing scores for each criterion. The exchange will file a proposed rule change with the Commission pursuant to Rule 19b-4 of

³ The PSE's Extended Trading Session is an auction market trading session that runs from 1:00-1:50 p.m. (Pacific Time).

⁴ See *supra* note 1.

the Act that will include these changes by May 1, 1997.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)(5) of the Act⁵ in that it is designed to prevent fraudulent and manipulative acts and practices and to perfect the mechanism of a free and open market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W.,

Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR-PSE-96-28 and should be submitted by September 18, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96-21891 Filed 8-27-96; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-37593; File No. SR-Phlx-96-32]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating to Index Option Exercise Advices

Pursuant to Section 19(b)(1) of the Securities and Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 29, 1996, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx, pursuant to Rule 19b-4 of the Act, proposes to amend Exchange Rule 1042A, Exercise of Option Contracts, and Floor Procedure Advice ("Advice") G-1, retitled Index Option Exercise Advice Forms, to provide that the deadline for submitting a memorandum to exercise and an exercise advice form will be "no later than 4:30 p.m. or fifteen minutes after the close of trading, if trading hours are modified or extended beyond 4:15 p.m." Currently, the deadline for such submissions is "no later than 4:30 p.m." In addition, the Phlx proposes to codify that anyone intending to exercise index options must complete a memorandum to exercise and/or an exercise advice form in compliance with the exercise cut-off time and must exercise that amount of option contracts indicated on such forms.

¹ 15 U.S.C. 78s(b)(1) (1988).

² 17 CFR 240.19b-4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Exchange Rule 1042A and Advice G-1 govern the exercise of index options.³ Specifically, Exchange Rule 1042A(a)(i) requires that a memorandum to exercise any American-style index option contract must be received or prepared by the Phlx member organization no later than 4:30 p.m. on the day of exercise. In addition, Exchange Rule 1042A(a)(ii) requires the submission of an exercise advice form to the Exchange no later than 4:30 p.m. when exercising American-style index option contracts.⁴

In this regard, the Exchange has attempted to create a level playing field among option investors by maintaining a cut-off time to ensure that all exercise decisions occur promptly after the close of trading. Consequently, to prevent fraud and unfairness, a long option holder is prohibited from exercising index options on non-expiration days

³ The Exchange notes that with respect to index option contracts, clearing members are also required to follow the procedures of the Options Clearing Corporation ("OCC") for tendering exercise notices. Exercise notices are the exercise instructions required by OCC and are distinct from exercise advices which are required by Exchange rules.

⁴ The Phlx notes that Exchange Rule 1042A previously allowed the submission of a memorandum to exercise and an exercise advice form until five minutes after the close of trading. See Securities Exchange Act Release No. 32991 (September 30, 1993), 58 FR 52337 (October 7, 1993) (File No. SR-Phlx-92-31). Specifically, the exercise cut-off time for narrow-based index options was 4:15 p.m. or five minutes after the close of trading, and for broad-based index options it was 4:20 pm or five minutes after the close of trading. When the exercise cut-off time was changed to 4:30 p.m., however, the language "or five minutes after the close of trading" was deleted. See Securities and Exchange Act Release No. 37077 (April 5, 1996), 61 FR 16156 (April 11, 1996) (File No. Phlx-95-86). As such, the Phlx's current proposal resurrects this concept.

⁵ 15 U.S.C. 78f(b)(5).

based on information obtained after the cut-off.⁵

The Exchange currently proposes to amend these provisions such that the exercise cut-off time would be 4:30 p.m. or fifteen minutes after the close of trading, where trading hours are modified or extended beyond 4:15 p.m. For instance, on certain days prior to a holiday, the Exchange may cease trading broad-based index options at 1:15 p.m. Under the current rule, however, the exercise cut-off time would remain at 4:30 p.m., regardless of when trading ceased. In comparison, under the proposal, the exercise cut-off time in the above example would change to 1:30 p.m.

With respect to trading hours extending beyond 4:15 p.m., the Exchange notes that in certain situations a trading rotation may occur after the ordinary 4:10 or 4:15 p.m. close of trading. For instance, if a halt in the trading of a component issue causes an index option to halt trading, and if the index option re-opens at 4:00 p.m., an opening rotation may need to be conducted. Because such rotation may result in extended trading hours, the exercise cut-off time under the proposal would be fifteen minutes after the end of the rotation. In this manner, a cut-off of fifteen minutes after the close of trading will ensure that index option traders and investors have adequate time to make exercise decisions.

In addition, the Exchange proposes to adopt an amendment procedure to facilitate changes in exercise decisions prior to the cut-off time. The amended exercise advice form and amendment procedure should add certainty to the exercise process by clarifying how a change in a decision to exercise should be indicated to the Exchange. In this manner, when amending an exercise decision, a new exercise advice form must be filed with the Exchange, listing all exercise decisions, not just the one being amended. Omitting one series means that no exercise of that series is intended and a violation of the rule occurs if that series is exercised. Further, all exercise advice forms, whether original or those amending previous submissions, must be filed prior to the exercise cut-off time.

⁵ Pursuant to Exchange Rule 1042A(b), however, these requirements are not applicable on the last business day before expiration, generally an "expiration Friday." The above requirements are also not applicable to European-style index options which, by definition, cannot be exercised prior to expiration. Lastly, the Exchange notes that the procedures for exercising equity option contracts, contained in Exchange Rule 1042, are not affected by this rule proposal.

2. Statutory Basis

The Phlx believes that its proposal is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5), in particular, in that it is designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts and practices, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, and processing information with respect to securities, as well as to protect investors and the public interest, by allowing a reasonable amount of time to submit an exercise decision when trading hours are modified or extended.

B. Self-Regulatory Organization's Statement on Bruden on Competition

The self-regulatory organization does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Comments were neither solicited nor received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve the proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule changes that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the

provisions of 5 U.S.C. § 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filings also will be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR-Phlx-96-32 and should be submitted by September 18, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.⁶

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 96-21888 Filed 8-27-96; 8:45 am]

BILLING CODE 8010-01-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Bangladesh

August 22, 1996.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: August 26, 1996.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-5850. For information on embargoes and quota re-openings, call (202) 482-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Uruguay Round Agreements Act.

The current limits for certain categories are being adjusted, variously, for swing and carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 60 FR 65299, published on December 19, 1995). Also

⁶ 17 CFR 200.30-3 (a)(12).

see 60 FR 65290, published on December 19, 1995.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

August 22, 1996.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 13, 1995, by the Acting Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Bangladesh and exported during the twelve-month period which began on January 1, 1996 and extends through December 31, 1996.

Effective on August 26, 1996, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit ¹
237	374,228 dozen.
335	182,806 dozen.
336/636	375,691 dozen.
338/339	1,243,490 dozen.
347/348	2,095,780 dozen.
363	23,850,858 numbers.
641	805,735 dozen.

¹The limits have not been adjusted to account for any imports exported after December 31, 1995.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C.553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc.96-21916 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-DR-F

Adjustment of an Import Restraint Limit and Guaranteed Access Level for Certain Cotton and Wool Textile Products Produced or Manufactured in Guatemala

August 22, 1996.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs increasing a limit and guaranteed access level.

EFFECTIVE DATE: August 26, 1996.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-5850. For information on embargoes and quota re-openings, call (202) 482-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Uruguay Round Agreements Act.

The current limit for Category 448 is being increased for carryforward. Also, the Government of the United States has agreed to increase the 1996 guaranteed access level for Categories 347/348.

A description of the textile and apparel categories in terms of HTS numbers is available in the **CORRELATION:** Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 60 FR 65299, published on December 19, 1995). Also see 60 FR 62398, published on December 6, 1995.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

August 22, 1996.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 29, 1995, by the Chairman, Committee for the Implementation

of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textile products, produced or manufactured in Guatemala and exported during the twelve-month period beginning on January 1, 1996 and extending through December 31, 1996.

Effective on August 26, 1996, you are directed to increase the limit for Category 448 to 48,992 dozen¹, as provided for by the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing.

Also, you are directed to increase the 1996 guaranteed access level (GAL) for Categories 347/348 to 1,800,000 dozen. The GAL for Category 448 remains unchanged.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 96-21917 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-DR-F

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Pakistan

August 22, 1996.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: August 26, 1996.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-6714. For information on embargoes and quota re-openings, call (202) 482-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Uruguay Round Agreements Act.

The current limits for Categories 338 and 339 are being increased for special shift, reducing the limit for Categories 638/639 to account for the increases.

A description of the textile and apparel categories in terms of HTS numbers is available in the **CORRELATION:** Textile and Apparel

¹ The limit has not been adjusted to account for any imports exported after December 31, 1995.

Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 60 FR 65299, published on December 19, 1995). Also see 60 FR 62393, published on December 6, 1995.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

D. Michael Hutchinson,
Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

August 22, 1996.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 29, 1995, by the Acting Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton and man-made fiber textile products, produced or manufactured in Pakistan and exported during the twelve-month period which began on January 1, 1996 and extends through December 31, 1996.

Effective on August 26, 1996, you are directed to amend the November 29, 1995 directive to adjust the limits for the following categories, as provided for under the terms of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit ¹
338	5,023,112 dozen.
339	1,330,701 dozen.
638/639	52,187 dozen.

¹The limits have not been adjusted to account for any imports exported after December 31, 1995.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C.553(a)(1).

Sincerely,

D. Michael Hutchinson,
Acting Chairman, Committee for the Implementation of Textile Agreements.
[FR Doc.96-21915 Filed 8-27-96; 8:45 am]

BILLING CODE 3510-DR-F

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Meeting of the Investment and Services Policy Advisory Committee

AGENCY: Office of the United States Trade Representative.

ACTION: Notice that the September 17, 1996 meeting of the Investment and Services Policy Advisory Committee will be held from 10:00 a.m. to 2:00 p.m. The meeting will be closed to the public from 10:00 a.m. to 1:30 p.m. The meeting will be open to the public from 1:30 p.m. to 2:00 p.m.

SUMMARY: The Investment and Services Policy Advisory Committee will hold a meeting on September 17, 1996, from 10:00 a.m. to 2:p.m. The meeting will be closed to the public from 10:00 a.m. to 1:30 p.m. The meeting will include a review and discussion of current issues which influence U.S. trade policy. Pursuant to Section 2155(f)(2) of Title 19 of the United States Code, I have determined that this portion of the meeting will be concerned with matters the disclosure of which would seriously compromise the development by the United States Government of trade policy, priorities, negotiating objectives or bargaining positions with respect to the operation of any trade agreement and other matters arising in connection with the development, implementation and administration of the trade policy of the United States. The meeting will be open to the public and press from 1:30 p.m. to 2:00 p.m. when trade policy issues will be discussed. Attendance during this part of the meeting is for observation only. Individuals who are not members of the committee will not be invited to comment.

DATE: The meeting is scheduled for September 17, 1996, unless otherwise notified.

ADDRESS: The meeting will be held at the Jefferson Hotel in the Monticello Room at 16th and M Streets, N.W., Washington, D.C., unless otherwise notified.

FOR FURTHER INFORMATION CONTACT:

Suzanna Kang, Office of the United States Trade Representative, (202) 395-6120.

Charlene Barshefsky,

Acting United States Trade Representative.

[FR Doc. 96-21985 Filed 8-27-96; 8:45 am]

BILLING CODE 3190-01-M

Notice of Meeting of the Advisory Committee for Trade Policy and Negotiations

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of the September 12, 1996, meeting of the Advisory Committee for Trade Policy and Negotiations will be held from 10:00 a.m. to 2:00 p.m. The meeting will be closed to the public from 10:00 a.m. to 1:30 p.m. and open to the public from 1:30 p.m. to 2:00 p.m.

SUMMARY: The Advisory Committee for Trade Policy and Negotiation will hold a meeting on September 12, 1996 from 10:00 a.m. to 2:00 p.m. The meeting will be closed to the public from 10:00 a.m. to 1:30 p.m. The meeting will include a review and discussion of current issues which influence U.S. trade policy. Pursuant to Section 2155(f)(2) of Title 19 of the United States Code, I have determined that this meeting will be concerned with matters the disclosure of which would seriously compromise the development by the United States Government of trade policy, priorities, negotiating objectives or bargaining positions with respect to the operation of any trade agreement and other matters arising in connection with the development, implementation and administration of the trade policy of the United States. The meeting will be open to the public and press from 1:30 p.m. to 2:00 p.m. when trade policy issues will be discussed. Attendance during this part of the meeting is for observation only. Individuals who are not members of the committee will not be invited to comment.

DATE: The meeting is scheduled for September 12, 1996, unless otherwise notified.

ADDRESS: The meeting will be held at the Sheraton Carlton Hotel in the Potomac Room, located at 16th and K Streets, Washington, D.C., unless otherwise notified.

FOR FURTHER INFORMATION CONTACT:

Suzanna Kang, Office of the United States Trade Representative, (202) 395-6120.

Charlene Barshefsky,

Acting United States Trade Representative.

[FR Doc. 96-21986 Filed 8-27-96; 8:45 am]

BILLING CODE 3190-01-M

DEPARTMENT OF TRANSPORTATION**Office of the Secretary****Reports, Forms and Recordkeeping Requirements Agency Information Collection Activity Under OMB Review**

AGENCY: Office of the Secretary, Department of Transportation (DOT).

ACTION: Notice and request for Comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended) this notice announces the Department of Transportation's (DOT) intention to request a reinstatement, without change, of a previously approved information collection for which approval has expired. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. The Federal Register Notice with a 60-day comment period soliciting comments on the following collection of information was published on April 8, 1996 [FR 61, page 15556-15557].

DATES: Comments on this notice must be received on or before September 26, 1996.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725-17th Street, NW, Washington, DC 20503, Attention OST Desk Officer.

FOR FURTHER INFORMATION CONTACT: Ms. Judith Street, Federal Aviation Administration, Corporate Information Division, ABC-100, 800 Independence Ave., SW., (202) 267-9895, Washington, DC 20591.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Airplane Operator Security—FAR 108.

OMB Control Number: 2120-0098.

Type of Request: Reinstatement without change, a previously approved information collection for which approval has expired.

Affected Entities: Air carriers.

Abstract: FAR Part 108 requires air carriers to check radiation leakage on x-

ray equipment used for property security screening at least annually, evaluate and record personal dosimeter readings monthly, and report aircraft piracy as part of the required security program, and maintain security training records.

Number of Respondents: 266.

Estimated Total Burden on Respondents: 10,823 hours.

Issued in Washington, DC, on August 23, 1996.

Phillip A. Leach,

Clearance Officer, United States, Department of Transportation.

[FR Doc. 96-21927 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-62-P

Coast Guard

[CGD08-96-033]

Houston/Galveston Navigation Safety Advisory Committee Meeting

AGENCY: Coast Guard, DOT.

ACTION: Notice of subcommittee meetings.

SUMMARY: The two Subcommittees (Waterways and Navigation) of the Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC) will meet to discuss waterway improvements, aids to navigation, current meters, and various other navigation safety matters affecting the Houston/Galveston area. Both meetings will be open to the public.

DATES: The meeting of the Navigation Subcommittee will be held on Thursday, September 5, 1996 at 9:30 a.m. and immediately following, the Waterways Subcommittee will meet. Members of the public may present written or oral statements at the meetings.

ADDRESSES: The subcommittee meetings will be held at the Port of Houston Authority, 111 East Loop North, Houston, Texas.

FOR FURTHER INFORMATION CONTACT: Captain Kevin Eldridge, Executive Director of HOGANSAC, Telephone (713) 671-5101, or Commander Paula Carroll, Executive Secretary of HOGANSAC, telephone (713) 671-5164.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agendas of the Meetings

Subcommittee on Navigation. The tentative agenda includes the following:

(1) Presentation by each work group of its accomplishments and plans for the future.

(2) Review and discuss the work completed by each work group.

Subcommittee on Waterways. The tentative agenda includes the following:

(1) Presentation by each work group of its accomplishments and plans for the future.

(2) Review and discuss the work completed by each work group.

Procedural

All meetings are open to the public. Members of the public may make oral presentations during the meetings.

Information on Services for the Handicapped

For information on facilities or services for the handicapped or to request special assistance at the meetings, contact the Executive Director as soon as possible.

Dated: July 24, 1996.

T.W. Josiah,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 96-21936 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-14-M

Federal Aviation Administration

[Summary Notice No. PE-96-42]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR Part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR Chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before September 10, 1996.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC-

200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, D.C. 20591.

Comments may also be sent electronically to the following internet address: nprmcmts@mail.hq.faa.gov.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rule Docket (AGC-200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 267-3132.

FOR FURTHER INFORMATION CONTACT:

Mr. Federal Haynes, (202) 267-3939, or Ms. Marisa Mullen, (202) 267-9681, Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, D.C., on August 23, 1996.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Dispositions of Petitions

Docket No.: 26048.

Petitioner: National Test Pilot School.

Sections of the FAR Affected: 14 CFR 91.319(a) (1) and (2).

Description of Relief Sought/

Disposition: To extend and amend Exemption No. 5778 to permit the National Test Pilot School to operate aircraft that have experimental certificates to train flight test students who are pilots and flight engineers through the demonstration and practice of flight test techniques, and to teach these students flight test data acquisition methods for compensation. *GRANT, August 6, 1996, Exemption No. 5778B.*

Docket No.: 26710.

Petitioner: Skydive DeLand, Inc.

Sections of the FAR Affected: 14 CFR 105.43(a).

Description of Relief Sought/

Disposition: To permit nonstudent parachutists who are foreign nationals (foreign parachutists) to participate in parachute jumping events sponsored by Skydive DeLand without complying with the FAA parachute equipment and packing requirements. *GRANT, August 7, 1996, Exemption No. 5542B.*

Docket No.: 26896.

Petitioner: Boeing Commercial Airplane Group.

Sections of the FAR Affected: 14 CFR 21.325(b)(3).

Description of Relief Sought/

Disposition: To extend and amend

Exemption No. 5942 to allow the petitioner to issue export air worthiness approvals for not only Class II and Class III products located in England, Singapore, and Belgium, but also for products located in China, and any future location the petitioner may establish under the control of its existing FAA Production certificate and Organizational Designated Airworthiness Representative authority. *DENIAL, July 22, 1996, Exemption No. 6481.*

Docket No.: 28373.

Petitioner: Executive Jet Sales, Inc.

Sections of the FAR Affected: 14 CFR 43.9(a)(4), 43.11(a)(3), appendix B to part 43, 135.443(b)(3) and (c), and 145.57(a).

Description of Relief Sought/

Disposition: To allow the petitioner to use "electronic signatures" in lieu of physical signatures to satisfy the airworthiness release and/or approval for return-to-serve signature requirements. *GRANT, July 31, 1996, Exemption No. 6483.*

Docket No.: 28400.

Petitioner: Skydive, Inc.

Sections of the FAR Affected: 14 CFR 105.43(a).

Description of Relief Sought/

Disposition: To permit Skydive's employees, representatives, and customers to make tandem parachute jumps while wearing a dual-harness, dual-parachute pack, having at least one main parachute and one approved auxiliary parachute packed in accordance with § 105.43(a); and permit pilots in command of aircraft involved in these operations to allow such persons to make these parachute jumps. *GRANT, July 1996, Exemption No. 6482.*

Docket No.: 28459.

Petitioner: Biplane Adventure Tours, LTD.

Sections of the FAR Affected: 14 CFR 119.1(e)(2).

Description of Relief Sought/

Disposition: To allow the petitioner to conduct sightseeing flights beyond the 25-statute-mile radius of Old Bridge Airport, New Jersey, without meeting the part 135 requirements. *DENIAL, August 9, 1996, Exemption No. 6495.*

Docket No.: 28546.

Petitioner: The Ranch Club, Ltd.

Sections of the FAR Affected: 14 CFR 105.43(a).

Description of Relief Sought/

Disposition: To permit nonstudent parachutists who are foreign nationals (foreign parachutists) to participate in parachute jumping events sponsored by The Ranch Parachute Club, Ltd. without complying with the FAA parachute equipment and packing requirements. *GRANT, August 7, 1996, Exemption No. 6494.*

Good Cause

Docket No.: 26914.

Petitioner: Air Transport Association of America.

Sections of the FAR Affected: 14 CFR 121.583(b) (c) and (d).

Description of Relief Sought: To allow ATA member airlines and other similarly situated part 121 certificate holders to continue to carry Federal Aviation Administration (FAA) air traffic controllers and certain technical representatives in the cockpit observer's seat of all-cargo aircraft without meeting the passenger-carrying requirements of part 121, except as described in § 121.583(b), (c), and (d).

Docket No.: 28639

Petitioner: Peninsula Airways, Inc.

Sections of the FAR Affected: 14 CFR 121.574(a) (1) and (3).

Description of Relief Sought: To allow PenAir to carry and operate oxygen storage and dispensing equipment for medical use by passengers requiring emergency or continuing medical attention when the equipment is furnished and maintained by the hospital treating the passenger.

[FR Doc. 96-21990 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-13-M

RTCA, Inc. Special Committee 186; Automatic Dependent Surveillance—Broadcast (ADS-B)

Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (P.L. 92-463, 5 U.S.C., Appendix 2), notice is hereby given for Special Committee 186 meeting to be held September 17-18, 1996, beginning at 9:00 a.m. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, N.W., Suite 1020, Washington, DC, 20036.

The agenda will include: (1) Chairman's Introductory Remarks/ Review of Meeting Agenda; (2) Review and Approval of Minutes of the Previous Meeting; (3) Report of Working Group Activities: a. Working Group 1 Report (Operations Working Group); b. Working Group 2 Report (Technical Working Group); c. Working Group 3 Report (CDTI Working Group); (4) Review of Chapter 2 of the MASPS; (6) Other Business; (7) Date and Place of Next Meeting.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, N.W., Suite 1020, Washington, DC, 20036; (202) 833-9339 (phone) or (202)

833-9434 (fax). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on August 22, 1996.

Janice L. Peters,

Designated Official.

[FR Doc. 96-21991 Filed 8-27-96; 8:45 am]

BILLING CODE 4810-13-M

Federal Highway Administration

[FHWA Docket No. MC-96-32]

Notice of Request for Reinstatement of an Expired Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, 3506(c)(2)(A)), the FHWA solicits comment on its intent to request the Office of Management and Budget (OMB) to reinstate expired information collections that prove that motor carriers of property and passengers have obtained and have in effect the required minimum levels of financial responsibility.

DATES: Comments must be submitted on or before October 28, 1996.

ADDRESSES: All signed, written comments should refer to the docket number that appears at the top of this document and must be submitted to HCC-10, Room 4232, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard/envelope.

FOR FURTHER INFORMATION CONTACT: Mr. Peter C. Chandler, Office of Motor Carrier Research and Standards, (202) 366-5763, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Endorsement for Motor Carrier Policies of Insurance.

OMB Number: 2125-0074.

Background: Sections 29 and 30 of the Motor Carrier Act of 1980 (codified at 49 U.S.C. 31139) require the Secretary of Transportation to promulgate

regulations which establish minimal levels of financial responsibility for motor carriers of property to cover public liability, property damage, and environmental restoration. The Endorsement for Motor Carrier Policies of Insurance for Public Liability (Form MCS-90) and the Motor Carrier Public Liability Surety Bond (Form MCS-82) contain the minimum amount of information necessary to document that a motor carrier of property has obtained and has in effect the minimum levels of financial responsibility as set forth in 49 CFR 387.9. The information within these documents is used by the FHWA and the public to verify that a motor carrier of property has obtained and has in effect the required minimum levels of financial responsibility.

Respondents: Insurance and surety companies of motor carriers of property.

Average Burden per Response: 2 minutes to complete the Endorsement for Motor Carrier Policies of Insurance for Public Liability or the Motor Carrier Public Liability Surety Bond; 1 minute to file the Motor Carrier Public Liability Surety Bond; 1 minute to have either document on board the vehicle (foreign-domiciled motor carriers only).

Estimated Total Annual Burden: 3,555 hours.

Frequency: Upon creation, change, or replacement of an insurance policy or surety bond.

Title: Financial Responsibility for Motor Carriers of Passengers.

OMB Number: 2125-0518.

Background: Sections 18 of the Bus Regulatory Reform Act of 1982 (codified at 49 U.S.C. 31138) requires the Secretary of Transportation to establish regulations to require minimal levels of financial responsibility for for-hire motor carriers of passengers to cover public liability and property damage. The Endorsement for Motor Carrier Policies of Insurance for Public Liability (Form MCS-90B) and the Motor Carrier Public Liability Surety Bond (Form MCS-82B) contain the minimum amount of information necessary to document that a motor carrier of passengers has obtained and has in effect the minimum levels of financial responsibility as set forth in 49 CFR 387.33. The information within these documents is used by the FHWA and the public to verify that a motor carrier of passengers has obtained and has in effect the required minimum levels of financial responsibility.

Respondents: Insurance and surety companies of motor carriers of property.

Average Burden per Response: 2 minutes to complete the Endorsement for Motor Carrier Policies of Insurance for Public Liability or the Motor Carrier

Public Liability Surety Bond; 1 minute to file the Motor Carrier Public Liability Surety Bond; 1 minute to have either document on board the vehicle (foreign-domiciled motor carriers only).

Estimated Total Annual Burden: 103 hours.

Frequency: Upon creation, change, or replacement of an insurance policy or surety bond.

Interested parties are invited to send comments regarding any aspect of this information collection, including, but not limited to: (1) The necessity and utility of the information collection for the proper performance of the functions of the FHWA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information.

Authority: 23 U.S.C. 315; 44 U.S.C. 3506(c)(2)(A); 49 CFR 1.48.

Issued on: August 21, 1996.

Diana Zeidel,

Deputy Associate Administrator for Administration.

[FR Doc. 96-21931 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-22-P

[Docket Number MC-96-40]

Motor Carrier Regulatory Relief and Safety Demonstration Project

AGENCY: Federal Highway Administration, DOT.

ACTION: Notice; request for comments.

SUMMARY: With this notice, the Federal Highway Administration (FHWA) is proposing to implement a motor carrier regulatory relief and safety demonstration project, as mandated by Congress in section 344 of the National Highway System Designation Act of 1995 (NHS Act). The FHWA is utilizing this project as a means of furthering the objectives of the President's Regulatory Reinvention Initiative. Through this project, motor carriers operating commercial motor vehicles (CMVs) with a gross vehicle weight rating (GVWR) between 10,001 and 26,000 pounds in interstate commerce may qualify for exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs) if they exhibit exemplary safety records. Motor carriers participating in this Project would have the opportunity to demonstrate that they can maintain or improve their safety records when they are given greater latitude to select the means by which their safety performance is attained. The FHWA seeks the comments of all interested parties, especially comments aimed at

aiding the FHWA in designing this project so that it advances safety to the highest degree possible. A Notice of Final Determination will be published as soon as the comments on this Project which are received in a timely manner can be reviewed and carefully considered.

DATES: Written comments on this Project must be received on or before September 27, 1996. Written comments on the information collection requirements of this Project must be received on or before October 28, 1996.

ADDRESSES: Submit written, signed comments to FHWA Docket No. MC-96-40, Room 4232, HCC-10, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, D.C. 20590. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Robert F. Schultz, Jr., Office of Motor Carrier Research and Standards, (202) 366-4009, or Ms. Grace Reidy, Office of the Chief Counsel, (202) 366-0834, Federal Highway Administration, DOT, 400 Seventh Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: On November 28, 1995, the President signed the NHS Act (Pub. L. 104-59, 109 Stat. 568 (1995)). Section 344 of the NHS Act requires the FHWA to implement a pilot program under which motor carriers operating CMVs with a GVWR between 10,001 and 26,000 pounds in interstate commerce could qualify for exemptions from the FMCSRs (49 CFR Part 325 *et seq.*). In accordance with the NHS Act, notice is hereby given that the FHWA is proposing the Motor Carrier Regulatory Relief and Safety Demonstration Project. The purpose of the comment period is to provide the public with the opportunity to assist the FHWA in designing the Project. The details of the Project which follow are proposed details; the FHWA is seeking all points of view before defining the final parameters of the Project. The FHWA will carefully scrutinize all timely suggestions and weigh carefully the facts upon which they are based.

The FHWA proposes that in order to participate in the Project, a motor carrier would have to meet the criteria for admission developed by the Secretary and outlined later in this notice. Motor carriers seeking to participate would also be required to develop a written Safety Control Plan for the Project. This plan would outline the measures which

the motor carrier will undertake to ensure that the current level of safety is not compromised by the operation of the exemptions. The motor carrier would also enter into a written Agreement of Participation with the Administrator of the FHWA in which it agrees to abide by its Safety Control Plan and to work with the FHWA in generating and monitoring certain Project data. The FHWA would grant, for the term of the Project only, an exemption to the motor carrier from certain requirements of the current FMCSRs, but such exemption would apply only to the eligible CMVs and drivers designated in the motor carrier's application. The FHWA would evaluate the Project data throughout the Project, with particular focus upon the significance of the data with regard to FHWA's regulatory reinvention and zero-base initiatives. In addition, at the conclusion of the Project, the FHWA, in accordance with the NHS Act, will use this data to conduct a zero-base review of the need for, and the costs and benefits of, all the FMCSRs.

The proposed requirements for participation in the Project would include several information collection requirements which must be approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Generally, OMB has 60 days to review proposed collections of information. However, since Congress mandated that this Project begin no later than August 23, 1996, the FHWA will request that OMB authorize emergency processing of FHWA's submission of these information collection requirements as provided for in OMB's regulations implementing the Paperwork Reduction Act. The OMB regulation regarding emergency processing provides, in part, that an agency may request expedited processing if use of normal procedures is reasonably likely to cause a statutory deadline to be missed. 5 CFR 1320.13(a)(2)(iii). The FHWA will request that OMB approve this request within 20 days.

Analysis of Project data will occur throughout the Project, and only at such time as that analysis is complete will the FHWA be in a position to consider other performance-based initiatives in this area. Given the Project parameters, the FHWA believes that three years of continuous, sustained motor carrier operations is the minimum amount of time necessary to draw conclusions about operational safety. In view of the customary level of activity for a motor carrier, the FHWA, after three years, should be able to assert, with reasonable

certainty, that the data accumulated with respect to the activity of the class of motor carriers in this Project is representative of future behavior.

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I. The New Era at FHWA

The FHWA is entering a new era of highway safety. The President's initiatives in reinventing government and regulatory reform have challenged the FHWA to re-examine the way in which it operates. Internally, the FHWA has begun to orient its systems more toward performance-based standards and to reward its employees who set and attain performance goals. Externally, the FHWA is approaching its duty to advance the safety of the public, and particularly the motor carrier industry, in a new manner. We are de-emphasizing prescriptive, "red tape" requirements, and focusing upon allowing the motor carrier industry a greater role in promoting highway safety. In particular, the new era at FHWA is characterized by:

Greater FHWA Emphasis upon Safety Performance, and Less Emphasis Upon the Specific Procedures Employed to Achieve Safety. In order to improve highway safety, the FHWA is focusing more upon the results of the operational controls of motor carriers, and less upon the specific design of those controls. To monitor the safety of motor carriers, the FHWA is increasingly utilizing "performance-based" systems; that is, systems which employ performance standards to measure safety. This approach provides the motor carrier greater flexibility to conduct its business in the manner which best meets its organizational and operational needs. Rather than sacrificing operational efficiency in order to conform its procedures to specific regulatory requirements, the motor carrier is better able to capitalize upon opportunities to exercise creativity in developing those countermeasures which work best for it. In turn, the economic vitality of the motor carrier industry is promoted.

Greater Reliance upon our Partners. In this environment, the FHWA relies increasingly upon its partners in the motor carrier industry to share the burden of promoting safety. The States are assuming greater responsibility for ensuring compliance by interstate motor carriers with the FMCSRs, and this Project will provide the FHWA with further opportunities to work with State enforcement officials in developing new approaches to improving highway safety. In addition, motor carriers are recognizing that, hand-in-hand with the increased opportunities presented by the greater emphasis upon performance, comes an

increased responsibility on their part for safety. As long as a motor carrier demonstrates by its safety performance that it recognizes this responsibility, it will experience less operational oversight from the FHWA. This enables the FHWA to focus more of its limited resources upon those carriers, and drivers, who adversely affect highway safety.

Greater Reliance Upon Technology to Achieve Safety. The FHWA is encouraging greater implementation of technology as a tool in the effort to improve motor carrier safety. One benefit of the greater flexibility of the new environment will be that motor carriers will be better able to explore "high tech" solutions to operational safety.

The FHWA recently sought information from the motor carrier community with regard to advanced driver, vehicle, and inspection technology in CMV operations (Notice and Request For Information, 60 FR 46682, Sep. 7, 1995). Eight responses were received to this Notice—three from private industry, three from trade associations, and two from state or local agencies. None of them brought to light any significant developments on these topics. However, technology progresses rapidly, and the FHWA wishes to capitalize on every opportunity to explore new ways in which technology can ease the burden on all parties. Is there a greater role which technology could play in addressing the needs of this Project?

Greater Emphasis Upon Regulatory Reinvention and "Zero-Base" Reform. The FHWA is currently at the halfway point of the multi-year "Zero-Base Regulatory Review Program." This program is redesigning the FMCSRs into a performance-based "Rulebook of the Future." The new design is evolving from a close examination of each FMCSR from the ground up, or "zero-base." This examination will ensure that each requirement of our regulations is either supported by sound data, or represents the best professional judgment possible. The NHS Act directs the FHWA to conduct a zero-base review at the conclusion of the Project. This review, drawing upon the various zero-base resources of the FHWA, will examine the need for, as well as the cost and benefits of, each provision of the FMCSRs, as applied to this class of motor carriers.

For purposes of this Project, the new era at the FHWA means that participants in the Project will be able to exercise a high degree of innovation, consistent with highway safety, in designing and implementing their safety controls. Motor carriers will also be challenged to demonstrate that they can fulfill their responsibility for safety when regulatory relief is granted.

II. Proposed Exemptions of the Project

In accordance with the NHS Act, interstate motor carriers participating in the Project will be exempt from certain sections of the FMCSRs. The FHWA proposes the regulations described below as the particular FMCSRs from which motor carriers participating in the Project would be exempt. All motor

carriers participating in the Project would be exempt from the same regulations. Applicant motor carriers would not be authorized to pick and choose the regulations from which they would be exempt. In this way, all motor carriers in the Project would be operating under the same conditions. The FHWA believes that any weakening of this uniformity would compromise the Project data and impair the evaluation phase of the Project.

In selecting specific FMCSRs to propose for exemption, the FHWA believes that relief from those regulations related to the physical requirements of drivers, the parts and accessories necessary for safe operation, and the number of hours which drivers may operate CMVs would not be in the public interest. The regulations which are proposed for exemption are those whose purposes could easily be served by the safety control plans to be developed by participating motor carriers and monitored by the FHWA.

The FHWA proposes that Project motor carriers would be exempt from the following regulations:

Driver Qualifications

The FHWA proposes that newly-hired drivers would not be required to prepare, or furnish to the employing motor carrier, a list of violations of motor vehicle laws, or a certificate in lieu thereof. Drivers would also not be required to successfully complete a Driver's Road Test, or furnish an Application For Employment. 49 CFR 391.11(b)(8), 391.11(b)(10), and 391.11(b)(11). In addition, motor carriers would not have to maintain "Driver Qualification Files" on each driver in accordance with 49 CFR § 391.51. Driver Hours Of Service

The FHWA proposes that Project drivers would not be required to comply with record of duty status provisions, whether this entails maintenance of a logbook in accordance with 49 CFR 395.8, use of a timecard in accordance with 49 CFR 395.1(e), or the use of an automatic on-board recording device in accordance with 49 CFR 395.15. However, Project motor carriers and drivers would have to continue to observe the provisions governing maximum driving time, and the use of ill or fatigued operators. 49 CFR 395.3 and 392.3. Project motor carriers, and their drivers, would not forfeit any other exemptions currently available under FHWA regulations.

CMV Inspections

While participating in the Project, motor carriers would be exempt from the requirements pertaining to CMV inspection records and their retention.

In addition, exemption would be granted from the requirements pertaining to driver vehicle inspection reports and the driver vehicle inspection. 49 CFR 396.3 (b) and (c), 396.11, and 396.13 (b) and (c). Finally, the FHWA proposes that driveaway-towaway inspections would not be required, nor would the periodic inspection and the periodic inspection report. 49 CFR 396.15, 396.17 and 396.21.

Accident Information

The FHWA proposes to exempt Project motor carriers from the requirement that they maintain an accident register in accordance with 49 CFR 390.15 (b)(1) and (b)(2). This exemption would allow motor carriers to maintain their records during the Project in the manner which they deem best.

The FHWA seeks public comment on whether these exemptions are appropriate and whether other regulations ought to be included. We ask that you consider which of the current FMCSRs most readily lend themselves to exemption. That is, which are most amenable to being replaced by a standard or standards based upon performance? The NHS Act requires the FHWA to ensure that the Project is designed to achieve a level of operational safety "equal to or greater than" that under the current requirements of the FMCSRs. In considering additional exemptions under this Project, the FHWA will carefully weigh whether adequate safety measures exist to ensure that the exemptions do not cause a decline in motor carrier safety.

III. Criteria for Administration to the Project

In selecting the criteria which motor carriers must satisfy to be admitted to this Project, the FHWA will be guided by the principles of the new era at FHWA. The FHWA proposes the following criteria for admission because the agency believes they will advance the development of an environment which rewards results and fosters technology-based applications. At the same time, this Project will generate data which will assist the agency's zero-base initiatives.

The criteria for admission to the Project which the FHWA proposes (numbered 1 through 7) follow:

1. A motor carrier would be eligible for the project if:

- (a) It operates in interstate commerce, and
- (b) Its operations include CMVs having a GVWR between 10,001 and 26,000 pounds.

Specifically excluded are CMVs designed to transport more than 15

passengers (including the driver), and CMVs used in transporting hazardous materials in placardable quantities, as defined in regulations issued by the Secretary of Transportation under the Hazardous Materials Transportation Act (49 U.S.C. 5101, et seq.). These requirements are dictated by the NHS Act.

2. The FHWA intends that this Project include only motor carriers and drivers with exemplary safety records. To serve that end, the FHWA proposes that a motor carrier would be eligible for the Project only if:

(a) It does not have a current Safety Rating of Unsatisfactory, AND

(b) Its police reported accident rate is no more than 1.6 per million vehicle miles traveled for the most recent 36 month period.

An applicant motor carrier would have to satisfy BOTH of these criteria to be eligible to participate in the Project. The FHWA would exclude those motor carriers which have a Safety Rating of Unsatisfactory from participating in the program. Those which have a rating of Satisfactory, or Conditional, or have no rating, would be eligible for the Project only if they also satisfy the accident rate criterion.

Although the FHWA is entering a new era of performance-based regulation, it must continue to ensure that the motor carrier industry is operating safely on our nation's highways. As proposed, this Project would allow us to examine the question: Does the safety performance of motor carriers with exemplary safety histories change when they are permitted to operate exempt from certain FMCSRs? The exclusion of interstate motor carriers with either Unsatisfactory Safety Ratings or poor accident rates permits the FHWA to explore the role of such exemptions while ensuring the safety of CMVs operations.

Participation would be limited to those motor carriers which have exemplary safety histories. An example of an exemplary history would be that of a motor carrier with an accident rate equal to or better than that of the top 25% of all motor carriers. The FHWA estimates this accident rate to be 1.6, or fewer, crashes per 1,000,000 miles of travel, based on analysis of the nationwide police reported crash experience of the types of vehicles that are expected to participate in this Project, and the FHWA's estimates of the miles traveled annually by such vehicles.

This suggested crash rate is more particularly derived from the most recent three years of information for straight trucks included in the General Estimates System (GES) of the National Highway Traffic Safety Administration, and from mileage statistics found in the

FHWA's 1994 Highway Statistics, Publication No. FHWA-PL-95-042. The FHWA employed data on straight trucks from the GES to ensure that all types of police reported crashes were taken into consideration. The FHWA believes that in order to definitively pinpoint those motor carriers with exemplary safety histories, all types of crashes, not just those which may be defined as preventable or recordable, must be taken into account. In addition, this approach nearly doubles the number of crashes available for consideration.

The FHWA believes that many of the motor carriers which will volunteer for the Project will have operations in urban areas. Using a measure of 1.6 police reported crashes per million miles of travel is consistent with the methods which the FHWA employs to determine the Safety Rating of motor carriers with urban operations. When combined with the exclusion of those motor carriers with an Unsatisfactory Safety Rating, participation in the Project is effectively limited to motor carriers with exemplary safety histories.

The FHWA seeks public comment on these proposed criteria. Is a crash rate of no more than 1.6 crashes per 1,000,000 miles of travel a prudent requirement in view of the need to limit participation to those motor carriers with exemplary safety histories? Are there other tenable approaches, and if so, what is the rationale behind them?

3. Project motor carriers will submit the name, driver's license number, and date of employment for each of its drivers whom it proposes for participation in the Project. The FHWA proposes that a driver would not be eligible for the Project if:

(a) He or she operates, AT ANY TIME, CMVs other than those which have a GVWR between 10,001 and 26,000 pounds, inclusive,

OR if

(b) He or she has been convicted, in the past three years, of:

(i) an offense that directly arose out of a fatal traffic accident;

(ii) Driving a CMV while under the influence of alcohol. This shall include:

(A) Driving a CMV while the person's alcohol concentration is 0.04 percent or more;

(B) Driving under the influence of alcohol, as prescribed by State law;

(C) Refusal to undergo such testing for alcohol or controlled substances required by any State or jurisdiction;

(iii) Driving a CMV while under the influence of a controlled substance;

(iv) Leaving the scene of an accident involving a CMV; and

(v) A felony involving the use of a CMV, including use of a CMV in the commission of a felony involving manufacturing, distributing, or dispensing a controlled substance.

The FHWA proposes that a motor carrier applicant would certify that its

Project drivers operate eligible CMVs exclusively. We believe that drivers who cross over, and operate, for example, CMVs in excess of 26,000 pounds GVWR (whether for the same employer or a different one), create difficulties in analyzing the results of the Project. At the conclusion of this Project, we wish to provide an analysis of the Project's effect upon the operation of CMVs in the 10,001 to 26,000 pounds GVWR range. By excluding drivers who cross over to operate other CMVs, we would ensure that the Project data would not be compromised by the driving experience developed while operating other kinds of vehicles.

In addition, the FHWA proposes that each motor carrier would submit the names of the drivers whom it wishes to place in the Project. The motor carrier would also provide the driver's license numbers, and the dates on which each driver's employment with the motor carrier began. Owner-operators would be eligible to volunteer to participate in the Project if they satisfy all entrance criteria.

The FHWA believes that the exclusion of drivers who have these types of convictions, in the past three years, is consistent with Criterion 2 which confines the Project to the safest motor carriers. The Project must be consistent in limiting its findings to a finite class engaged in specific activities; unnecessary ambiguity in the classifications employed in this Project will limit the reliability of the findings and recommendations of the Project.

The FHWA would like to know if there are other means of limiting this Project to exemplary drivers and would welcome any ideas which the public may have on how these issues could be handled in a different manner. In responding to this request, please explain the rationale supporting your suggestions.

4. Project motor carriers would be required to submit ALL eligible drivers and ALL eligible motor vehicles for participation in the Project.

The FHWA was directed by Congress, in the NHS Act, to ensure that the participants represent a broad cross-section of fleet size and drivers. See Public Law No. 104-59, 344(2)(E)(i), 109 Stat. at 611 (codified at 49 U.S.C. 31136(e)(2)(E)(i)(1996)). The FHWA believes that if motor carriers are permitted to submit less than all of their eligible drivers, or vehicles, to the Project, the findings or conclusions of the Project relative to their performance during the Project will be subject to questions about why these particular drivers, or vehicles, were selected. The proposed approach allows the FHWA to

analyze all of a motor carrier's Project vehicles and drivers instead of a select portion of them.

The FHWA is mindful of the fact that some motor carriers with larger operations may desire to volunteer a particular terminal, or a particular geographic region, or state, for this Project. The FHWA anticipates no difficulty in affording motor carriers flexibility with this form of selection for participation; however, the FHWA will carefully scrutinize any suggested subunits to be certain that they advance the Congressional mandate, particularly the requirement that this Project examine a broad cross-section of the motor carrier industry. Any ideas which the public may have on how this issue could be handled in a different manner would be welcome. The rationale which supports such a suggestion should be explained.

5. Project motor carriers would have to be active on a year-round basis.

The FHWA further proposes that each interstate motor carrier applying for participation in the Project would have to certify that it is actively engaged in interstate commerce *at all times of the year*.

Thus seasonal motor carriers would be excluded. The FHWA proposes to collect Project data for a relatively short period of time (three years). Consequently, we believe that a Project motor carrier must generate a regular flow of Project data on a year-round basis in order to provide the FHWA with a true picture of the effect of the Project exemptions upon the motor carrier's operational safety. The FHWA believes that it should avoid issues which cloud the evaluation of this Project, such as what weight to give to the spotless accident record of a motor carrier which only operates for three months of the year, vis-a-vis the spotless record of a year-round motor carrier. The FHWA believes that it must have a consistent pattern of motor carrier activity in order to reach sound conclusions regarding the Project. This pattern is customarily absent from the profile of the seasonal motor carrier. The agency invites public comment on this proposed criterion and on whether or not the misgivings of the FHWA are well-founded. The FHWA would also appreciate suggestions regarding other methods the agency could employ to deal with the problems which seasonal motor carriers present.

6. Project motor carriers would be required to have vehicle maintenance records which reflect the systematic inspection, repair, and replacement of all Project CMVs.

The FHWA proposes this criterion as a means of monitoring and selectively

evaluating the performance of Project motor carriers in maintaining their CMVs in safe operating condition. The FHWA believes that these records are indicative of the importance which the motor carrier assigns to its vehicle maintenance activities. Project motor carriers would have to certify that they have maintained these records for the 12 months immediately preceding entry into the Project. This data would serve as the benchmark for comparison to data generated during the Project. Consequently, the Project motor carrier would also have to agree to maintain these records on a continuing basis throughout the Project.

Please provide comments regarding this criterion. Are there better methods of measuring the particulars of fleet maintenance? Please explain the rationale underlying your suggestion.

7. Project motor carriers would be required to develop a safety control plan (SCP).

The FHWA proposes that all Project participants would develop a Safety Control Plan prior to admission to the Project. Under the NHS Act, an applicant to the Project must agree to implement such safety management controls as are necessary to carry out the objectives of the Project, while at the same time achieving a level of operational safety equal to or greater than that resulting from compliance with the regulations. See Public Law 104-59, section 344(2) (A) and (B), 109 Stat. at 610-11 (codified at 49 U.S.C. 31136(e)(2) (A) and (B) (1996)).

After the FHWA reviews the timely comments to this Notice, it will publish a Notice of Final Determination finalizing all aspects of this Project. Only at that time will motor carriers be able to examine the final Project admission criteria and the regulations from which the FHWA proposes to grant exemption under this Project. From this information, motor carriers will be able to develop their Safety Control Plan (SCP) and application for admission to the Project.

Until the Notice of Final Determination is issued, specific criteria for the SCP are unavailable. However, we propose that, in general, the SCP would provide the answers to the following questions: During the Project, how will the motor carrier applicant ensure:

That Project drivers are qualified to operate commercial motor vehicles,

That Project vehicles are in safe operating condition,

That Project drivers are complying with the maximum hours of service requirements of the FMCSRs, and

That it will receive a timely warning if Project drivers are violating the FMCSRs or the Agreement?

The FHWA believes that the preparation of the SCP will be straightforward for most motor carriers which have the exemplary safety history required in order to qualify for this Project. Experience has shown that the vast majority of motor carriers who have exemplary safety histories also have a well-defined set of safety controls. For this Project, the FHWA proposes that an existing set of company operating instructions, whether currently included in a manual or set of policy documents, could be used to satisfy the SCP requirement, if a motor carrier directed the FHWA to the sections which satisfy the SCP requirements. Where an initial SCP must be created, the FHWA believes that simple explanations of the day-to-day safety practices and controls which the motor carrier employs, or will employ, would suffice. Upon review of a motor carrier, the FHWA would need to be able to comprehend from the SCP what safety controls are in place, and be able to evaluate them in terms of the level of compliance they could be expected to produce. For those motor carriers which would like assistance in developing their SCP, the FHWA proposes to develop and make available a suggested outline for the document. Comments and suggestions as to the substance and form this outline should take would be welcome. The FHWA also welcomes the comments of the public on the following question: Should the SCP be submitted to the FHWA? Why, or why not?

IV. The Agreement

The FHWA proposes that an eligible interstate motor carrier would volunteer for the Project by submitting an application for admission. Thereafter, the FHWA would approve or deny the application within 120 days. If approved, a written agreement with the FHWA would be executed, in which the FHWA would grant the motor carrier exemption from certain requirements of the FMCSRs. The motor carrier would agree to be responsible for maintaining its safety performance while participating in the Project, and to make data on its operations available to the FHWA. A Project motor carrier would also agree to abide by the remaining FMCSRs, and all changes which may occur to the FMCSRs, as the Project progresses.

The FHWA proposes that each Project motor carrier would, as a condition of its Agreement with the FHWA, agree to provide the FHWA, on a quarterly basis each year, with the following:

(a) Details of all police reported accidents involving Project vehicles and/or drivers, including nonconfidential insurance-related

information, sufficient to enable the FHWA to locate the corresponding State police accident report;

(b) The miles traveled by Project vehicles, and the calculation of crashes per 1,000,000 vehicle miles traveled;

(c) Changes in the initial roster of Project drivers, including the names of those no longer employed by the motor carrier, and the names, driver's license numbers, and dates of employment of all new hires proposed for the Project (this information would enable the FHWA to monitor the driving records of Project drivers); and

(d) Vehicle maintenance records reflecting the frequency of replacement or repair of safety-related parts. (This information would enable the FHWA to compare this information to the records which reflect the 12 months preceding the motor carrier's entrance into the Project.)

The FHWA would like public comment upon this proposal. The FHWA will require data in order to evaluate this Project. What is the best method of providing this data to the FHWA? Is some form of periodic reporting necessary? If periodic reports are necessary: (a) Does the industry believe that they ought to be submitted quarterly, or at some other interval; and (b) could such information be made available in electronic format, or by means of on-line service? The FHWA is interested in other suggestions of methods by which the Agency could satisfy its duty to monitor and evaluate this Project while minimizing the paperwork burden on the motor carrier.

In addition, the FHWA proposes that each motor carrier admitted to the Project would agree to notify the FHWA immediately if any of the following occur:

(1) The motor carrier is sold, goes out of business, changes its name, ceases to operate in interstate commerce, or in any way alters its operation in such a manner;

(2) The motor carrier ceases to conduct active operations on a year-round basis;

(3) The motor carrier ceases to operate CMVs with GVWRs between 10,001 and 26,000 pounds;

(4) The motor carrier is rated "Unsatisfactory;"

(5) The accident rate of the motor carrier exceeds 1.6 per million vehicle miles traveled for the most recent thirty-six month period;

(6) The motor carrier is unable, for any reason, to carry out the terms of the Safety Control Plan which it developed for this Project;

(7) The motor carrier is unable to maintain Vehicle Maintenance Records which reflect the inspection, repair and maintenance history; or

(8) A Project driver ceases to exclusively operate CMVs with GVWRs between 10,001 and 26,000 pounds.

The FHWA also believes that some form of identification card or form should be furnished by the FHWA to

those selected to participate in the Project. We propose that a single-page document executed by the FHWA would serve this purpose. Any card or form furnished to drivers would be surrendered upon termination of employment with the motor carrier that nominated them for the Project. We invite public comment on this proposal, and encourage the development of alternative methods of providing appropriate identification of drivers and CMVs included in the Project.

V. Coordination With the States

The Motor Carrier Safety Assistance Program (MCSAP) was established by Congress in 1982, and has subsequently been amended several times. The program provides grants to States which agree to adopt and enforce minimum Federal safety standards for interstate and intrastate CMVs and drivers. The MCSAP funds are used to support salaries, equipment, and training of State enforcement officers. The data collected by the States are shared on a national basis and used by the FHWA as the basis for its safety rating, review, and enforcement programs. Through the MCSAP, the FHWA and its State partners have developed a uniform program of safety compliance and enforcement for CMVs.

The FHWA recognizes that this Project presents new challenges for this partnership. We are asking our State partners to support this program because of the long-term benefit which it can bestow upon the regulatory environment. This Project will serve as a major step toward a permanent performance-based revision of the FMCSRs. Through the implementation of a demonstration project instead of the initiation of a rulemaking, the FHWA will avoid burdening the States, and motor carriers, with frequent amendments to the FMCSRs driven by the preliminary results of performance-based regulation. Currently there are 26 states and territories that automatically adopt any revisions to the FMCSRs. This demonstration project would minimize the disruption to the States and motor carriers and would preserve the existing standards of highway safety, while permitting examination of the effect of performance-based standards on a controlled group of motor carriers. This Project should provide data which will serve as the foundation for performance-based rules.

VI. Disqualification

The FHWA does not anticipate that any motor carrier which has satisfied the stringent admission criteria of this Project will experience any deterioration of its safety record.

However, should this occur, the FHWA would, consistent with its duty under the NHS Act, take all steps necessary to protect the public interest, as well as the integrity of the Project. Participation in this Project is voluntary, and the FHWA retains the right to revoke a motor carrier's exemption and participation in the Project if its safety performance poses a threat to highway safety. Participating motor carriers will not be exempt from compliance reviews or enforcement actions on the remaining regulations from which they are not exempt, or on those portions of its operations (such as those involving CMVs with a GVWR in excess of 26,000 pounds) which are not a part of the Project. Also, Project drivers who pose a threat to highway safety would, at a minimum, be subject to immediate revocation of their privilege to participate in the Project.

The FHWA proposes that if it finds that the highway operations of a Project motor carrier have placed the safety of the public in jeopardy, it would, at a minimum, declare the motor carrier disqualified and remove it from the Project. The FHWA also proposes that an increase in the police reported accident rate of a Project motor carrier such that it exceeds 1.6 per million vehicle miles traveled (see Criteria For Admission, Item 2(b) above) would be grounds for immediate disqualification of the motor carrier. In addition, the FHWA proposes that any Project driver convicted of any of the offenses enumerated under 3(b) of the Criteria for Admission above would be immediately disqualified from further participation in the Project. We propose that such a conviction would not necessarily result in the disqualification of the motor carrier who placed the convicted driver in the Project.

VII. The Final Evaluation

The NHS Act requires the FHWA to conduct an evaluation at the conclusion of the Project. The principal objective of the evaluation is to provide input to a zero-base review of the need for, and the cost and benefits of, the FMCSRs as they apply to interstate motor carriers operating CMVs in the 10,001 to 26,000 pound GVWR class.

The FHWA proposes that the evaluation would focus upon operational safety by comparing the collective experience of Project motor carriers and drivers during the Project with that prior to the Project. The evaluation would also compare the collective experience of Project motor carriers and drivers with the collective experience of motor carriers and drivers not participating in the Project.

VIII. Paperwork Reduction Act of 1995

As proposed, this voluntary program would impose information collection requirements which are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number. The FHWA has requested that OMB authorize emergency processing of these proposed information collections through an alternative procedure provided in OMB's regulations for cases where, among other things, use of normal procedures is reasonably likely to cause a statutory deadline to be missed. 5 CFR § 1320.13. The FHWA has asked OMB to approve this request within 20 days. However, the FHWA anticipates that this approval will be for a period of not more than 90 days, pursuant to OMB regulations. Thus, the FHWA also intends to submit a request to OMB through the usual procedures for approval under the Paperwork Reduction Act of 1995 for a three year period.

In general, Federal agencies must provide 60 days of notice in the Federal Register concerning each collection of information. Comments on the information collections proposed in this Notice will be considered by the FHWA in its request for long-term approval. With respect to the collections of information described below, the FHWA invites comments on: (1) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collections of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of these collections of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The title used to identify the information collections proposed in this notice and submitted for OMB's approval is—Motor Carrier Regulatory Relief and Safety Demonstration Project.

This Federal Register notice proposes a voluntary pilot project. In return for receiving exemption from certain Federal Motor Carrier Safety Regulations, each Project motor carrier would be required to develop and/or furnish certain information about its

operations. It is anticipated that the initial application will require about one-half hour to complete on average. This document is necessary to identify those motor carriers who believe they are eligible to participate in the Project, and to indicate their desire to be included in the Project. The Safety Control Plan, outlining the safety management measures the motor carrier would have in place to ensure that it would achieve the appropriate level of operational safety during the Project, would require, on average, one and one-half hours to prepare. This document would be subject to examination by the FHWA, and would be necessary to assist the FHWA in ensuring that Project participants did not neglect those aspects of motor carrier safety which are normally addressed by the regulations from which they are temporarily exempt. In addition, participating motor carriers would be required to submit to the FHWA: (1) For each of its Project drivers, the name, driver's license identification number, and date of employment and (2) for each Project vehicle, the vehicle identification number. On a quarterly basis, the motor carrier would have to advise the FHWA of any changes in this information. In addition, during the Project, motor carriers would be required to maintain, but not submit, a record of the maintenance performed upon Project vehicles. These collections and submissions of information are necessary in order to effectively grant Project exemption to identifiable CMVs and operators of CMVs and to permit the performance of each to be monitored and evaluated. It is estimated that the reporting and recordkeeping burden for these items would be one hour and fifteen minutes on the average.

In addition, it is proposed that each accident involving Project drivers and/or Project vehicles would be reported to the FHWA on a quarterly basis. Each Project motor carrier would also calculate its accident rate per million vehicle miles traveled on a quarterly basis, and advise the FHWA if that rate exceeds 1.6. This information is necessary in order to detect those motor carriers whose safety performance is declining during the Project and would also be used to assist in comparing the performance of the exempt motor carriers with the performance of those which remain subject to the FMCSRs. The annual reporting and recordkeeping burden for this information is estimated to be one-half hour on the average.

The most likely respondents to this information collection will be motor carriers operating commercial motor vehicles (CMVs) with a gross vehicle

weight rating (GVWR) between 10,001 and 26,000 pounds in interstate commerce, with a Safety Rating of satisfactory or unrated, and with an accident rate of fewer than 1.6 per million miles traveled. The approximate number of motor carriers currently eligible to participate in the Project is 33,000. Therefore, it is estimated that the total annual reporting and recordkeeping burden will be 2,214,250 hours. Comments on these proposed information collections may be submitted either to OMB or the FHWA (Docket # MC-96-40).

IX. Conclusion

The FHWA welcomes comment on any and all aspects of this Project from trade associations, public interest groups, the States, interstate motor carriers, drivers, and all others.

Issued on: August 2, 1996.

Rodney E. Slater,

Federal Highway Administrator.

[FR Doc. 96-21928 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-22-P

National Highway Traffic Safety Administration

[Docket Number 96-092; Notice 1]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for public comment on proposed collections of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under new procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes two collections of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before October 28, 1996.

ADDRESSES: Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted to Docket Section, Room 5109, NHTSA, 400 Seventh Street, Southwest, Washington, D.C. 20590. Please identify the proposed collection of information for which a comment is provided, by referencing its OMB Clearance Number. It is requested, but

not required, that one original plus two copies of the comments be provided. The Docket Section is open on weekdays from 9:30 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT:

Complete copies of each request for collection of information may be obtained at no charge from Mr. Edward Kosek, NHTSA Information Collection Clearance Officer, NHTSA, 400 Seventh Street, Southwest, Room 6123, Washington, D.C. 20590. Mr. Kosek's telephone number is (202) 366-2590. Please identify the relevant collection of information by referring to its OMB Clearance Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the Federal Register providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1230.8(d)), an agency must ask for public comment on the following:

- (i) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (iii) how to enhance the quality, utility, and clarity of the information to be collected; and
- (iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

49 CFR Part 575—Consumer Information Regulations

Type of Request—Reinstatement of OMB Clearance.

OMB Clearance Number—2127-0049.
Form Number—This collection of information uses no standard forms.

Requested Expiration Date of Approval—September 30, 1999.

Summary of the Collection of Information—NHTSA must ensure that motor vehicle manufacturers comply

with 49 CFR Part 575, Consumer Information Regulation Part 575.103—Truck-camper loading and Part 575.105—Utility Vehicles. Part 575.103 (Truck-camper loading) requires that manufacturers of light trucks that are capable of accommodating slide-in campers to provide information on the cargo weight rating and the longitudinal limits within which the center of gravity for the cargo weight rating should be located. Part 575.105 (Utility vehicles) requires that manufacturers of utility vehicles affix a sticker in a prominent location alerting drivers that the particular handling and maneuvering characteristics of utility vehicles require special driving practices when these vehicles are operated.

Description of the need for the information and proposed use of the information—In order to ensure that motor vehicle manufacturers are complying with 49 CFR Part 575, NHTSA needs consumer information from mabeing introduced.

Estimate of the total annual reporting and recordkeeping burden resulting from the collection of information—The light truck manufacturers are required to gather only pre-existing data for the purposes of this regulation. NHTSA estimates that each motor vehicle manufacturer will incur a total reporting and recordkeeping burden of 15 hours. Thus, the total estimated reporting and recordkeeping burden hours a year on motor vehicle manufacturers (15 motor vehicle manufacturers multiplied by 15 hours (gathering data, printing, and distributing copies of this consumer information) is 300, at a total cost of \$2,240,000.

Patricia Breslin,

Director, Office of Planning and Consumer Programs Safety Performance Standards.

[FR Doc. 96-21992 Filed 8-27-96; 8:45 am]

BILLING CODE 4910-59-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 941-M

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the

Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 941-M, Employer's Monthly Federal Tax Return.

DATES: Written comments should be received on or before October 28, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, (202) 622-3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Employer's Monthly Federal Tax Return.

OMB Number: 1545-0718.

Form Number: Form 941-M.

Abstract: Form 941-M is used by certain employers to report payroll taxes on a monthly rather than quarterly basis. Employers who have failed to file Form 941 or who have failed to deposit taxes as required are notified by the District Director that they must file Form 941-M monthly.

Current Actions: There are no changes being made to this form.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals or households.

Estimated Number of Respondents: 1,000.

Estimated Time Per Respondent: 147 hr., 50 min.

Estimated Total Annual Burden Hours: 147,840.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

- (a) Whether the collection of

information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 21, 1996.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 96-21987 Filed 8-27-96; 8:45 am]

BILLING CODE 4830-01-P

Proposed Collection; Comment Request for Form 3206

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 3206, Information Statement by United Kingdom Withholding Agents Paying Dividends From U.S. Corporations to

Residents of the United States and Certain Treaty Countries.

DATES: Written comments should be received on or before October 28, 1996, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, (202) 622-3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Information Statement by United Kingdom Withholding Agents Paying Dividends From U.S. Corporations to Residents of the United States and Certain Treaty Countries.

OMB Number: 1545-0153.

Form Number: Form 3206.

Abstract: Form 3206 is used to report dividends paid by U.S. corporations through United Kingdom nominees to beneficial owners who are residents of countries other than the United Kingdom with which the U.S. has a tax treaty providing for reduced withholding rates on dividends. The data is used by IRS to determine whether the proper amount of income tax was withheld.

Current Actions: There are no changes being made to this form.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals or households.

Estimated Number of Respondents: 5,000.

Estimated Time Per Respondent: 2 hr., 55 min.

Estimated Total Annual Burden Hours: 14,570.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: August 20, 1996.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 96-21988 Filed 8-27-96; 8:45 am]

BILLING CODE 4830-01-P

August 28, 1996
Book 1 of 2 Books

Part II

**Department of
Health and Human
Services**

Food and Drug Administration

**21 CFR Part 801, et al.
Regulations Restricting the Sale and
Distribution of Cigarettes and Smokeless
Tobacco to Protect Children and
Adolescents; Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 801, 803, 804, 807, 820, and 897**

[Docket No. 95N-0253]

RIN 0910-AA48

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents.

The regulations prohibit the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18; require manufacturers, distributors, and retailers to comply with certain conditions regarding the sale and distribution of these products; require retailers to verify a purchaser's age by photographic identification; prohibit all free samples and prohibit the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time; limit the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format; prohibit the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts; prohibit sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permit such sponsorship in a corporate name; and require manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising.

These regulations will address the serious public health problems caused by cigarettes and smokeless tobacco products. They will reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and will significantly decrease the amount of positive imagery that makes these products so appealing to that age group.

The regulations are predicated on the agency's assertion of jurisdiction under the Federal Food, Drug, and Cosmetic Act over cigarettes and smokeless

tobacco as delivery devices for nicotine, incorporated as part of the regulations for purposes of, and to facilitate, congressional review under the Small Business Regulatory Enforcement Fairness Act of 1996.

DATES: *Effective date.* The regulation is effective August 28, 1997, except that § 897.14(a) and (b) are effective February 28, 1997 and § 897.34(c) is effective February 28, 1998.

Compliance dates. Manufacturers and distributors are required to comply with the requirements of 21 CFR parts 803 and 804 August 28, 1997; manufacturers are required to comply with the requirements of 21 CFR parts 807 and 820 February 28, 1998.

ADDRESSES: References listed in the footnotes of this document have been placed on public display at the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nancy Yeates, Office of Policy (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0867.

SUPPLEMENTARY INFORMATION:
Preamble Outline

I. Introduction

- A. Purpose and Overview of the Rule
- B. Background
- C. Provisions of the Rule

II. Legal Authority

- A. Legal Principles Applicable to Combination Drug/Device Products
 - 1. The SMDA Recognized Combination Products for the First Time
 - 2. The SMDA Leaves to FDA's Discretion the Determination of Which Regulatory Authorities to Apply to Particular Combination Products
 - 3. Interpreting the SMDA to Allow the Agency to Determine Which Regulatory Scheme Best Serves the Public Health is Consistent With 50 Years of Case Law
 - 4. The Implementing Regulations and the Delegations of Authority Reflect FDA's Interpretation That Section 503(g) of the Act Authorizes the Agency to Determine the Appropriate Regulatory Authorities
 - 5. The Intercenter Agreements and Administrative Precedent Recognize That FDA May Determine Which Regulatory Authority to Apply to a Particular Product
 - B. Cigarettes and Smokeless Tobacco Have Both a Drug and a Device Component and Are Therefore Combination Products
 - C. FDA's Choice of Legal Authorities
 - 1. FDA Will Regulate Cigarettes and Smokeless Tobacco Under the Act's Device Authorities
 - 2. Cigarettes and Smokeless Tobacco Will be Subject to the Full Range of Device Authorities

- 3. The Restricted Device Provision Authorizes FDA to Establish Access and Advertising Restrictions

- 4. Application of Other Device Authorities

- 5. FDA Will Classify Cigarettes and Smokeless Tobacco Under Section 513 of the Act

- D. The Fact That the Act's Drug Authorities Authorize the Imposition of Similar Restrictions Supports the Reasonableness of the Restrictions That the Agency Has Imposed

- E. Constitutional Issues Regarding Authority

- 1. Separation of Powers
- 2. Nondelegation Doctrine

- III. Overview of Comments, Smoking Prevalence Rates Among Minors, Scope, Purpose, and Definitions

- A. Overview of Comments

- B. Smoking Prevalence Rates Among Minors

- C. Scope

- D. Purpose (§ 897.2)

- E. Definitions (§ 897.3)

IV. Access

- A. General Comments

- B. General Responsibilities of Manufacturers, Distributors, and Retailers (§ 897.10)

- C. Additional Responsibilities of Manufacturers (§ 897.12)

- 1. Removal of Manufacturer-Supplied or Manufacturer-Owned Items That Do Not Comply With the Regulations

- 2. Visual Inspections by a Manufacturer's Representative at Each Point of Sale

- D. Additional Responsibilities of Retailers (§ 897.14)

- 1. Use of Photographic Identification to Verify Age

- 2. Minimum Age

- 3. Restrictions Against "Impersonal" Modes of Sale

- 4. Restrictions Against the Sale of Individual Cigarettes

- 5. Additional Comments

- E. Conditions of Manufacture, Sale, and Distribution (§ 897.16)

- 1. Restrictions on Nontobacco Trade Names on Tobacco Products

- 2. Minimum Package Size

- 3. Maximum Package Size

- 4. Impersonal Modes of Sale

V. Label

- A. Established Name (§ 897.24)

- B. Package Design

- C. Ingredient Labeling

- D. Labeling for Intended Use

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I. Introduction

A. Purpose and Overview of the Rule

This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing FDA's determination that it has jurisdiction over these products under the Federal Food, Drug, and Cosmetic Act (the act). As described in "Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination" (the 1996 Jurisdictional Determination), annexed hereto, FDA has determined that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, within the meaning of the act's definitions of "drug" and "device." The nicotine in cigarettes and smokeless tobacco is a "drug," which produces significant pharmacological effects in consumers, including satisfaction of addiction, stimulation, sedation, and weight control. Cigarettes and smokeless tobacco are combination products consisting of the drug nicotine and device components intended to deliver nicotine to the body.

FDA has chosen to regulate cigarettes and smokeless tobacco under the act's device authorities. This rule allows the continued marketing of these products, while employing measures to prevent future generations of Americans from becoming addicted to them. As discussed in section I.B. of this document, most people who use cigarettes and smokeless tobacco begin their use before the age of 18 and, therefore, before they fully understand the addictive nature and serious health risks of these products. Even though the sale of tobacco products to minors is illegal in 50 States, the tobacco industry has adopted extensive marketing campaigns which appeal to children and adolescents. Therefore, the rule effects measures that would both complement the existing State restrictions on access and prevent

tobacco companies from marketing their products to children and adolescents.

In determining the best course of action, the agency considered the highly addictive nature of cigarettes and smokeless tobacco and the fact that these products have previously been lawfully marketed to millions of adult Americans. The agency has determined that the approach outlined in this document—restrictions to reduce the use of cigarettes and smokeless tobacco by individuals under the age of 18 while leaving these products on the market for adults—is the available option that is the most consistent with both the act and the agency's mission to protect the public health.

The agency intends to assist affected entities, including retailers, distributors, and manufacturers, in complying with the rule. The agency also will issue a small entities guide in easy to understand language. In addition, the agency will conduct workshops throughout the country to assist affected entities in complying with the rule.

B. Background

Approximately 50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco.¹ In the Federal Register of August 11, 1995 (60 FR 41314), FDA published a proposed rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents" (the 1995 proposed rule). As stated in the preamble to the 1995 proposed rule, tobacco use is the single leading cause of preventable death in the United States.² More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths.³ Tobacco alone kills

more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined.⁴

Tobacco products have historically been legal and widely available in this country. It was only after millions of people became addicted to the nicotine in cigarettes and smokeless tobacco that health experts became fully aware of the extraordinary health risks involved in the consumption of these products. Consequently, tobacco use has become one of the most serious public health problems facing the United States today. Because of the grave health consequences of the use of tobacco products, some have argued that they should be removed from the market.

However, a ban would have adverse health consequences and would not be likely to prevent individuals from gaining access to these products. Of the 50 million people who use cigarettes, 77 to 92 percent are addicted.⁵ Data suggest that almost as many smokeless tobacco users may be addicted.⁶ Adverse health consequences could result if these people were suddenly deprived of the nicotine these products deliver. As stated in the preamble to the 1995 proposed rule:

Because of the high addiction rates and the difficulties smokers experience when they attempt to quit, there may be adverse health consequences for many individuals if the products were to be withdrawn suddenly from the marketplace. Our current health care system and available pharmaceuticals may not be able to provide adequate or sufficiently safe treatment for such a precipitous withdrawal.

(60 FR 41314 at 41348)

A similar situation would exist for addicted smokeless tobacco users.

It is probable also that a black market and smuggling would develop to supply addicted users with these products. As stated in the preamble to the 1995 proposed rule, and discussed further in section II.C.5. of this document, "[t]he products that would be available through a black market could very well be more dangerous (e.g., cigarettes containing more tar or nicotine, or more toxic additives) than products currently on the market" (60 FR 41314 at 41349). Thus, the agency has concluded that, while taking cigarettes and smokeless tobacco off the market could prevent some people from becoming addicted and reduce death and disease for others,

the record does not establish that such a ban is the appropriate public health response under the act.

To effectively address the death and disease caused by tobacco products, addiction to cigarettes and smokeless tobacco must be eliminated or substantially reduced. The evidence demonstrates that this can be achieved only by preventing children and adolescents from starting to use tobacco. Most people who suffer the adverse health consequences of using cigarettes and smokeless tobacco begin their use before they reach the age of 18, an age when they are not prepared for, or equipped to, make a decision that, for many, will have lifelong consequences. These young people do not fully understand the serious health risks of these products or do not believe that those risks apply to them. They are also very impressionable and therefore vulnerable to the sophisticated marketing techniques employed by the tobacco industry, techniques that associate the use of tobacco products with excitement, glamour, and independence. When cigarette and smokeless tobacco use by children and adolescents results in addiction, as it so often does, these youths lose their freedom to choose whether or not to use the products as adults.

The facts on underage use confirm this pattern. As stated in the preamble to the 1995 proposed rule, approximately 3 million American adolescents currently smoke and an additional 1 million adolescent males use smokeless tobacco.⁷ Eighty-two percent of adults who ever smoked had their first cigarette before the age of 18, and more than half of them had already become regular smokers by that age.⁸ Among smokers ages 12 to 17 years, 70 percent already regret their decision to smoke and 66 percent say that they want to quit.⁹

Moreover, children and adolescents are beginning to smoke at younger ages than ever before. Despite a decline in smoking rates in most segments of the American adult population, the rates among children and adolescents have recently begun to rise.¹⁰ Data reported

¹ "National Household Survey on Drug Abuse: Population Estimate 1993, Department of Health and Human Services (DHHS), Public Health Service (PHS), Substance and Mental Health Services Administration (SAMHSA), Office of Applied Studies, Rockville, MD, Pub. No. (SMA) 94-3017, pp. 89 and 95, 1994.

² "Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990," *Mortality and Morbidity Weekly Report*, (MMWR) CDC, DHHS, vol. 42, No. 33, pp. 645-649, 1993; Lynch, B. S., and R. J. Bonnie, editors, *Growing Up Tobacco Free—Preventing Nicotine Addiction in Children and Youths*, Committee on Preventing Nicotine Addiction in Children and Youths, Division of Biobehavioral Sciences and Mental Disorders, Institute of Medicine, National Academy Press, Washington, DC, p.3, 1994, (hereinafter cited as "IOM Report").

³ "Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990," *MMWR*, CDC, DHHS, vol. 42, No. 33, pp. 645-649, 1993.

⁴ IOM Report, pp. 3-4.

⁵ See authorities cited at 1996 Jurisdictional Determination, Section II(B)(2)(a).

⁶ *Id.*

⁷ "Preventing Tobacco Use Among Young People: A Report of the Surgeon General," DHHS, PHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, the Office on Smoking and Health (OSH), Atlanta, GA, p. 5, 1994, (hereinafter cited as "1994 SGR").

⁸ 1994 SGR, p. 65.

⁹ "Teen-Age Attitudes and Behavior Concerning Tobacco," The George H. Gallup International Institute, p. 54, September 1992.

¹⁰ "Cigarette Smoking Among Adults—United States, 1991," *MMWR*, DHHS, CDC, vol. 42, No. 12,

in December 1995, after publication of the 1995 proposed rule, showed increases in 30-day prevalence rates of cigarette smoking for 4 consecutive years for 8th- and 10th-graders, and 3 consecutive years for high school seniors.¹¹ Daily use of cigarettes by 8th-, 10th-, and 12th-graders has also increased in each of the last 3 years.¹² The percentage of 8th- and 10th-graders who reported smoking in the 30 days before the survey had risen by one-third since 1991 to about 19 percent and 28 percent, respectively.¹³ Similarly, the percentage of high school seniors saying that they had smoked in the 30 days before the survey had increased by more than one-fifth since 1991, to about 33.5 percent or one in three.¹⁴

An adolescent whose cigarette use continues into adulthood increases his or her risk of dying from cancer, cardiovascular disease, or lung disease.¹⁵ Moreover, the earlier a young person's smoking habit begins, the more likely he or she will become a heavy smoker and therefore suffer a greater risk of diseases caused by smoking.¹⁶

pp. 230–233, 1993; Johnston, L. D., P. M. O'Malley, and J. G. Bachman, "National Survey Results on Drug Use from the Monitoring the Future Study 1975–1993, vol. I: Secondary School Students," Rockville, MD, DHHS, PHS, National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), NIH Pub. No. 94–3809, pp. 9 and 19, 79, 80, and 101, 1994; "Smoking Rates Climb Among American Teen-agers, Who Find Smoking Increasingly Acceptable and Seriously Underestimate the Risks," The University of Michigan News and Information Service, Table 1., July 17, 1995.

¹¹ "Results from the 1995 Monitoring the Future Survey," National Institute on Drug Abuse Briefing for Donna E. Shalala, Ph.D., Secretary of Health and Human Services, December 13, 1995.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ McGinnis, J. M., and W. H. Foege, "Actual Causes of Death in the United States," *Journal of the American Medical Association (JAMA)*, vol. 270, No. 18, pp. 2207–2212, 1993; "Reducing Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General," DHHS, PHS, CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), OSH, DHHS Pub. No. 89–8411, p. 5, 1989, (hereinafter cited as "1989 SGR"); See generally "The Health Consequences of Smoking: Chronic Obstructive Lung Disease: A Report of the Surgeon General," DHHS, PHS, OSH, 1984, (hereinafter cited as "1984 SGR"); "The Health Consequences of Smoking: Cardiovascular Disease—A Report of the Surgeon General," DHHS, PHS, OSH, 1983 (hereinafter cited as "1983 SGR"); "The Health Consequences of Smoking: Cancer—A Report of the Surgeon General," DHHS, PHS, OSH, 1982, (hereinafter cited as "1982 SGR").

¹⁶ Taioli, E., and E. L. Wynder, "Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood," *The New England Journal of Medicine*, vol. 325, No. 13, pp. 968–969, 1991; Escobedo, L. G., et al. "Sports Participation, Age at Smoking Initiation, and the Risk of Smoking Among

Approximately one out of every three young people who become regular smokers each day will die prematurely as a result.¹⁷

Similar problems exist with underage use of smokeless tobacco. As stated in the 1995 proposed rule, the market for smokeless tobacco has shifted dramatically toward young people since 1970 (60 FR 41314 at 41317). School-based surveys in 1991 estimated that 19.2 percent of 9th to 12th-grade boys use smokeless tobacco.¹⁸ Among high school seniors who had ever tried smokeless tobacco, 73 percent did so by the 9th grade.¹⁹

As long as children and adolescents become addicted to cigarette and smokeless tobacco use in these numbers, there is little chance that society will be able to reduce the toll of tobacco-related illnesses. If, however, the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin.²⁰

On the basis of this evidence, the agency has determined that establishing restrictions to substantially reduce the number of children and adolescents who become addicted to cigarettes and smokeless tobacco best serves its public health obligations. Because such a small percentage of the U.S. population begins tobacco use after the age of 18, limiting the use of these products to the adult population would substantially reduce the principal source of new users. Thus, the appropriate emphasis is on reducing the use of tobacco products by children and adolescents.

Evidence in the administrative record demonstrates that the most effective

U.S. High School Students," *JAMA*, vol. 269, No. 11, pp. 1391–1395, 1993; see also 1994 SGR, p. 65.

¹⁷ Memorandum from Michael P. Eriksen (CDC) to Catherine Lorraine (FDA) August 7, 1995 and CDC Fact Sheet (based on J. P. Pierce, M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, "Trends in Cigarette Smoking in the United States: Projections to the Year 2000," *JAMA*, vol. 261, pp. 61–65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, Jr., "Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from National Vital Statistics," Oxford University Press, Oxford, 1994).

¹⁸ Kann, L., W. Warren, J. L. Collins, J. Ross, B. Collins, and L. J. Kolbe, "Results from the National School-Based 1991 Youth Risk Behavior Survey and Progress Toward Achieving Related Health Objectives for the Nation," *Public Health Reports*, vol. 108, (Supp. 1), pp. 47–54, 1993.

¹⁹ 1994 SGR, p. 101.

²⁰ *Id.*, pp. 5, 58, and 65–67.

way to achieve such a reduction is by limiting the access to, and attractiveness of, cigarettes and smokeless tobacco to young people. FDA concludes that the act provides sufficient authority to issue regulations that, while leaving these products on the market for adult use, restrict access to and promotion of cigarettes and smokeless tobacco to those under 18 years of age.

C. Provisions of the Rule

After considering numerous comments submitted in response to the 1995 proposed rule, the agency is adopting the rule in modified form. New part 897 is being added to Title 21 of the Code of Federal Regulations and contains the regulations governing the labeling, advertising, sale, and distribution of cigarettes and smokeless tobacco to children and adolescents.

FDA is regulating nicotine-containing cigarettes and smokeless tobacco as restricted devices within the meaning of the section 520(e) of the act (21 U.S.C. 360j(e)). While leaving these products on the market for adults, the final rule prohibits the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18 and requires manufacturers, distributors, and retailers to comply with certain conditions regarding access to, and promotion of, these products. Among other things, the final rule requires retailers to verify a purchaser's age by photographic identification. It also prohibits all free samples and prohibits the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time. The rule also limits the advertising and labeling to which children and adolescents are exposed. The rule accomplishes this by generally restricting advertising to which children and adolescents are exposed to a black-and-white, text-only format. In addition, billboards and other outdoor advertising are prohibited within 1,000 feet of schools and public playgrounds. The rule also prohibits the sale or distribution of brand-identified promotional, nontobacco items such as hats and tee shirts. Furthermore, the rule prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name. This rule is intended to complement the regulations issued by SAMHSA implementing section 1926 of the Public Health Service Act (42 U.S.C. 300x–26) regarding the sale and

distribution of tobacco products to individuals under the age of 18 (the SAMHSA rule).

In this document, FDA: (1) Presents its analysis of its authority to issue regulations that impose the enumerated restrictions on the sale and promotion of cigarettes and smokeless tobacco to those under the age of 18, while leaving cigarettes and smokeless tobacco on the market for adults; and (2) responds to comments on the proposed rule.

II. Legal Authority

In the 1996 Jurisdictional Determination, annexed hereto, the Food and Drug Administration (FDA)²¹ has determined that cigarettes and smokeless tobacco are combination products consisting of a drug (nicotine) and device components intended to deliver nicotine to the body. The agency may regulate a drug/device combination product using the Federal Food, Drug, and Cosmetic Act's (the act's) drug authorities, device authorities, or both. The agency exercises its discretion to determine which authorities to apply in the regulation of combination products to provide the most effective protection to the public health. FDA has determined that tobacco products are most appropriately regulated under the device provisions of the act, including the restricted device authority in section 520(e) of the act (21 U.S.C. 360j(e)).

A. Legal Principles Applicable to Combination Drug/Device Products

The agency's discretion to choose the appropriate regulatory tools under the act is based, in part, on the authority provided under the Safe Medical Devices Act of 1990 (the SMDA). FDA's interpretation, supported by the language of the statute and its legislative history, is embodied in the agency's implementing regulations codified at part 3 (21 CFR part 3), the delegations of premarket approval authority to FDA's Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Biologics Evaluation and Research (CBER) that enable all three Centers to administer statutory authority for drugs, devices, and biologics (56 FR 58758, November 21, 1991), and the "intercenter agreements" that guide the agency in allocating Center

responsibility for various categories of combination products (56 FR 58760, November 21, 1991). In addition to the authority provided by the SMDA, the agency's discretion is also based on the principles recognized by the Supreme Court in cases such as *United States v. An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784 (1969). In *Bacto-Unidisk*, for example, the Supreme Court upheld the agency's decision to regulate a diagnostic test kit under its drug authorities on the grounds that "[i]t is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health * * *." (*Bacto-Unidisk* 394 U.S. at 791-792.)

The discussion that follows describes in more detail FDA's interpretation of the combination product provisions of the SMDA, the agency's understanding of combination products, and the way in which the agency has exercised its discretion in determining the most appropriate authorities to apply to regulate combination products.

1. The SMDA Recognized Combination Products for the First Time

Congress enacted the SMDA's combination product provisions to recognize combination products as distinct entities subject to regulation under the act and to alleviate the difficulty the agency had experienced in regulating such products, especially those consisting of components of both a drug and a device. First, the SMDA explicitly recognized the existence of products that "constitute a combination of a drug, device, or biological product" (section 503(g)(1) of the act (21 U.S.C. 353(g)(1))). Second, the statute provided a mechanism for determining which agency component would be assigned the administrative responsibility of regulating a particular combination product (*Id.*).

In accordance with its recognition of combination products, the SMDA changed the statutory definitions of "drug" and "device" at section 201(g) and (h) of the act (21 U.S.C. 321(g) and (h)). Before the enactment of the SMDA, section 201(g) of the act provided that a drug "does not include devices or their components, parts, or accessories." The SMDA removed this language from the definition of "drug" so that the terms "drug" and "device" were no longer mutually exclusive, thereby making it possible for a combination product consisting of both a drug and device to be regarded as an independent entity subject to regulation. The legislative history indicates that this

definitional change was made "to accommodate the principle of [combination products in] section 20" (S. Rept. 101-513, 101st Cong. 2d sess., at 30 (1990)). For the first time it was possible, as a legal matter, for a single product to have both drug and device components.

The SMDA also permitted a wider range of products to meet the definition of a device. Prior to its amendment by the SMDA, section 201(h) of the act defined a "device" as an instrument or other item that, among other things, "does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes." The SMDA changed the phrase "any of its principal intended purposes" in the definition to read, "its primary intended purposes." This change broadened the definition of device and allowed more products to be categorized as devices.

2. The SMDA Leaves to FDA's Discretion the Determination of Which Regulatory Authorities to Apply to Particular Combination Products

Having recognized combination products, the SMDA also provided a clear mechanism for determining which agency component a particular combination product should be directed to for review. Under the SMDA, the agency must:

[d]etermine the primary mode of action of the combination product. If the [agency] determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(Section 503(g)(1) of the act)

This section of the SMDA "provide[d] the [agency] with firm ground rules to direct products promptly to that part of FDA responsible for reviewing the article that provides the primary mode of action of the combination product" (S. Rept. 101-513, 101st Cong., 2d sess., 30 (1990)).

Although the SMDA provided a mechanism for determining which agency component, i.e., a Center, should review a particular combination product, the legislation left to FDA the discretion to decide which statutory authorities it would use in regulating a particular combination product. The

²¹ The Secretary of the Department of Health and Human Services (DHHS) (the Secretary) has the authority to carry out functions under the act through the Commissioner of Food and Drugs (the Commissioner). (See section 903 of the act (21 U.S.C. 393); 21 CFR 5.10 and 5.11.) Throughout this document, references to FDA include the Secretary and the Commissioner.

language of the SMMA makes this clear, as does the legislative history of the statute. Indeed, an earlier version of the bill, S. 3006, would arguably have removed this discretion by requiring the agency to regulate a product based only on its Center assignment. Thus, for example, if the primary mode of action were that of a drug, the product would be subject to regulation by CDER under the act's drug authorities. The earlier version's language, which Congress chose to strike from the final enactment, provided in relevant part:

The [agency] shall require only one market clearance route for an article that constitutes a combination of a device, drug, or biological product. If the [agency] determines that the primary mode of action of the combination article is that of—

(A) a drug (other than a biological product), neither the combination article nor any part of the article shall be treated as a device or as a biological product for market clearance purposes;

(B) a device, neither the combination article nor any part of the article shall be treated as a drug or a biological product for market clearance purposes; or

(C) a biological product, neither the combination article nor any part of the article shall be treated as a drug or a device for market clearance purposes.

(136 Congressional Record, S.12493, 101st Cong., 2d sess., August 4, 1990)

The omission of this language from the statute indicates that while Congress considered dictating which regulatory authority must be applied to particular combination products, and knew how to craft language to accomplish such a result, Congress ultimately chose to rely on FDA's expertise in determining the most appropriate regulatory tools needed to ensure the safety and effectiveness of the combination products that it regulates.

Moreover, Congress enacted language that recognizes that the agency may choose the appropriate regulatory authority for a particular combination product. Section 503(g)(2) of the act provides that nothing "shall prevent the [Agency] from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article." Since the enactment of the SMMA, the agency has interpreted the phrase "any agency resources" to include administrative resources and all applicable statutory authorities. See Drug/Device Intercenter Agreement, p. 2, contemporaneous interpretation that:

[u]nder the provisions of the Safe Medical Devices Act of 1990 and regulations promulgated to implement the combination product provisions of the Act, [the Center for

Drug Evaluation and Research] and [the Center for Devices and Radiological Health] each may use both the drug and device provisions of the Federal Food, Drug, and Cosmetic Act as appropriate to regulate a combination product.

(See 21 CFR Part 3).

(See also 56 FR 58754 at 58759, November 21, 1991 (FDA amending its procedural regulations at part 5 by adding delegations of authority relating to the premarket review of combination products to state that those specified officials in CBER, CDRH, or CDER "who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products: * * *") (21 CFR 5.33).) Thus, when a combination product, a single entity, consists of a component that may be regulated as a drug, the act's drug provisions and device provisions are "resources" available to the agency for regulating the product.

(1) One comment disputed the agency's interpretation of section 503(g)(2) of the act, stating that the language of section 503(g)(2) can be construed to mean only "people, laboratories, and other agency support. The term 'Agency resources' does not mean 'legal authorities' as FDA would like to believe."

FDA disagrees with this comment. The agency notes that there is nothing in the statute itself or the legislative history that suggests any reason that the expansive phrase "any FDA resources" should be narrowly interpreted given the important public health benefit ("ensuring an adequate premarket review") that is the goal of this section of the SMMA. The agency's interpretation of this language is supported by the SMMA's legislative history, which is discussed more fully in section II.A.2. of this document. More importantly, as discussed previously, the agency has the discretion under the statute as enacted to choose the regulatory authorities most appropriate to the specific product at issue.

3. Interpreting the SMMA to Allow the Agency to Determine Which Regulatory Scheme Best Serves the Public Health is Consistent With 50 Years of Case Law

Construing the act as allowing the agency discretion to choose the most appropriate regulatory tools for a particular combination product is consistent with over 50 years of judicial precedent. The importance of

interpreting the act in a manner that is consistent with the public health purposes of the act was recognized by the Supreme Court in *United States v. Dotterweich*, 320 U.S. 277 (1943). This case, decided shortly after substantial changes were made to expand the agency's authority by the 1938 act, addressed the breadth of the term "person" in determining who was subject to prosecution for violations of the act. The Court described the spirit in which the statute should be interpreted:

By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

(*Id.* at 280)

The approach in *Dotterweich* was followed by a number of cases in which FDA's interpretation of the statute, especially in the area of selecting how to regulate a product to achieve a public health purpose, has been granted deference and has been upheld. In *United States v. An Article of Drug * * * Bacto-Unidisk*, 394 U.S. 784 (1969), FDA's interpretation of the definition of the term "drug" and the applicability of the premarket review requirements were at issue. The Court upheld the agency's expansive interpretation of the definition of "drug" to include a laboratory screening product, in large part because this interpretation resulted in greater protection of the public health by virtue of the premarket review that the product would be subject to as a drug. As the Court reasoned:

It is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health, for we are hardly qualified to second-guess the Secretary's medical judgment.

(*Bacto-Unidisk*, 394 U.S. at 791-792)

The Court further stated:

The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow * * *. But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is

to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with 'efficacy' and 'safety.'

(*Id.* at 798); (See also *U.S. v. 25 Cases, More or Less, of An Article of a Device*, * * * *Sensor Pads*, 942 F.2d 1179 (7th Cir. 1991) (upholding FDA's determination that a latex bag filled with a layer of silicone lubricant that was intended to aid women in self-examinations for early detection of breast cancer was a device, because, among other reasons, the court deferred to the agency's discretion to interpret its own statute based on the legislative history of the act and on the principles announced in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)); *AMP, Inc. v. Gardner*, 389 F.2d 825, 830 (2d Cir.), *cert. denied, sub nom. AMP, Inc. v. Cohen*, 393 U.S. 825 (1968) (upholding FDA's classification of appellant's product for tying off severed blood vessels as a drug because, in part, the court was reluctant to give a narrow construction to the act, "touching the public health as it does").

These cases stand for two principles: (1) FDA's interpretations of its own statute should be given deference, and (2) the act should be interpreted expansively to achieve its primary purpose, protecting the public health. These principles support the agency's determinations, carefully made after applying its considerable scientific expertise to the evaluation of the evidence before it, that cigarettes and smokeless tobacco are drug delivery devices and that these combination products are most appropriately regulated using the device authorities of the act. The agency's decision regarding tobacco products is consistent with other determinations that the agency has made, which have been upheld and endorsed by the courts, to regulate products in the most reasonable manner that will result in the best protection of the public health.

4. The Implementing Regulations and the Delegations of Authority Reflect FDA's Interpretation That Section 503(g) of the Act Authorizes the Agency to Determine the Appropriate Regulatory Authorities

FDA's implementing regulations and delegations of authority, adopted shortly after passage of the SMDA, reflect the agency's contemporaneous interpretation of section 503(g) of the act as authorizing the agency to apply the most appropriate regulatory authorities to any given combination product. In

§ 3.2(e)(1), FDA defined a combination product to include, in relevant part:

A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity[.]

In a final rule that published in the Federal Register of November 21, 1991 (56 FR 58754), the agency explained that "the term combination product means a product comprised of two or more different regulated entities, e.g., drug, device, or biologic * * *" or that are produced together as a single entity, packaged together, or used together to achieve the intended effect. Thus, the fact that a single product contains elements of two or more regulated entities does not change the regulatory status of the individual elements. Each "different regulated entity[y]" of the combination continues to satisfy the criteria of its relevant statutory definition; that is, a drug component must satisfy the definition in section 201(g) of the act, and a device component must comply with the definition in section 201(h) of the act. Because the elements of a combination product meet more than one jurisdictional definition, the agency may apply one or more sets of regulatory provisions to the product.

In the same issue of the Federal Register in which the agency published the final regulations governing combination products, the agency published delegations of authority that allow the officials in CDER, CDRH, and CBER to utilize the premarket approval authorities for any product that is a drug, device, biologic, or any combination of two or more of these (56 FR 58758, November 21, 1991 (21 CFR 5.32)). These delegations allow the officials of one Center to conduct a premarket review of a product under another Center's regulatory authority, thereby making it possible, for example, for CDER to review a drug/device combination product under the device authorities. While the combination product regulations created the procedure for making the proper Center assignment, the delegations were necessary in order for FDA to exercise its discretion to determine which regulatory authority is most appropriate and to make it possible to apply that authority to review a particular product. If the primary mode of action of a combination product having drug and device components resulted in the assignment of the product to CDER, for example, but the agency determined

that the device component of the product presented the most important regulatory and scientific questions, the delegations make it possible for CDER officials to conduct the premarket review of the product under the device provisions of the act.

The regulations and the delegations of authority constitute the agency's contemporaneous interpretation of section 503(g) of the act as granting the agency discretion to choose the premarket approval authority that provides the best public health protection. Such contemporaneous interpretations by an agency are entitled to considerable deference by the courts. (See *Young v. Community Nutrition Institute*, 476 U.S. 974 (1986).)

5. The Intercenter Agreements and Administrative Precedent Recognize That FDA May Determine Which Regulatory Authority to Apply to a Particular Product

In addition to the regulations and delegations of authority implementing section 503(g) of the act, FDA has also adopted and made public three guidance documents, entitled "Intercenter Agreements," that describe the agreements reached among the Centers about regulatory pathways for specified products or classes of products as of October 31, 1991. (See Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health; Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (the Drug/Device Agreement); and Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.)

These documents detail which Center generally will have the lead responsibility for regulating particular types of products. The Intercenter Agreements also state which regulatory authority usually will be applied to specific products. For example, the Drug/Device Agreement provides that a device with the primary purpose of delivering or aiding in the delivery of a drug (i.e., "prefilled delivery system") will be regulated by "CDER using drug authorities and device authorities, as necessary" (Drug/Device Agreement, p. 6). Examples given of such combination products include a nebulizer, prefilled syringe, and transdermal patch (Drug/Device Agreement, p. 6). The Drug/Device Agreement specifically provides that such combination products may be regulated under either the drug or

device authorities, whichever is more appropriate for a particular product.²²

FDA's implementation of the Intercenter Agreement reflects these understandings. For example, one drug delivery product that has been regulated under the device authorities under the Drug/Device Agreement is the prefilled, intravenous infusion pump, manufactured by two companies. These are pumps designed to be sold prefilled with a diluent, either a sodium chloride solution or a dextrose solution. FDA regulates the diluents in the pumps as drugs under section 201(g)(1)(B) of the act because they are intended for use in the treatment of disease. The pumps are combination products consisting of a device component, the pump, and a drug component, the diluent; and the product's purpose is to deliver the diluent to be mixed by the doctor or other health care provider attending the patient with another drug substance for infusion into the patient. These pumps prefilled with diluents are clearly "a device containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose" that would be regulated as a drug according to the general principle stated in the Drug/Device Agreement (Drug/Device Agreement, p. 14). However, the agency exercised its discretion and determined that these drug delivery products should be regulated under the device authorities.

The agency based its determination on the fact that the drugs that were delivered by the products, saline and dextrose, are two ingredients very commonly used in intravenous infusions about which the agency had a wealth of scientific information and thorough regulatory experience. The pumps, the device component of this combination, however, operated on novel design principles. Because the device components of these combination products were new and raised significant regulatory questions, the agency determined that the products would receive the most appropriate premarket review if the device authorities were applied.

Another example of the agency's use of its discretion and its ability under the guidance in the Intercenter Agreements to make a sensible decision about product assignment is its decision regarding regulation of a catheter flush solution containing a blood-thinning drug and an antibiotic. The solution is intended as a flush solution to prevent the catheter (or tube) inserted into a patient's body from becoming clogged with blood and to prevent dangerous bacteria from growing in the catheter. Under the Drug/Device Agreement, this product would appear to fit into the category of a "liquid * * * or other similar formulation intended only to serve as a component * * * to a device with a primary mode of action that is physical in nature [and] will be regulated as a device by CDRH" (see Drug/Device Agreement, p. 13). The agency did determine that the product's premarket review would be conducted under the device authorities, but it assigned the review responsibility to CDER. The decision to follow an approach different from the one generally suggested in the Drug/Device Agreement was based on the fact that the inclusion of the blood-thinning and anti-infective drugs in the flush solution represented an innovation in such solutions and raised important scientific and regulatory questions that were most properly reviewed by the scientists in CDER. Because CDER was assigned the lead, the sponsor of this product was informed that the clinical investigations of this product should proceed under the investigational drug provisions of the act (section 505(i) of the act (21 U.S.C. 355(i))). This determination tailored the act's premarket review provisions, incorporating the most appropriate sections of both the drug and device authorities without being redundant, to the special features of this original product.

The agency has thus in the past made its jurisdiction decisions by determining the most reasonable course of action to protect public health given the scientific questions presented by each product. FDA considers essential its ability to continue to assess the individual circumstances of particular products. This will allow the agency to respond to technological developments, expanded scientific understanding, or additional factual information concerning a specific product or class of products.

B. Cigarettes and Smokeless Tobacco Have Both a Drug and a Device Component and Are Therefore Combination Products

As discussed in detail in the 1996 Jurisdictional Determination, the agency has concluded that the nicotine in cigarettes and smokeless tobacco is a drug within the meaning of section 201(g)(1)(C) of the act. The agency has also concluded that cigarettes and smokeless tobacco contain, in addition to the drug nicotine, delivery device components that deliver a controlled amount of nicotine to the body. Thus, cigarettes and smokeless tobacco are combination products that contain both a "drug" and a "device."

The agency further concluded that processed loose cigarette tobacco, which is used by smokers who roll their own cigarettes, is a combination product.

C. FDA's Choice of Legal Authorities

1. FDA Will Regulate Cigarettes and Smokeless Tobacco Under the Act's Device Authorities

Having established that cigarettes and smokeless tobacco are combination products consisting of both a drug component and device components, the agency has the discretion to choose whether it will regulate these products under the act's drug authorities, device authorities, or both if appropriate. Making this determination requires FDA to consider how the public health goals of the act can be best accomplished.

The act's drug and device provisions have a common objective: To ensure the safety and effectiveness of regulated products. They also provide the agency with similar authorities to regulate drugs and devices. In certain ways, however, the device provisions offer FDA more flexibility. The Medical Device Amendments of 1976 (the Medical Device Amendments) were enacted nearly 40 years after the act itself. During that period of time, Congress observed FDA's efforts to regulate devices under the authority of the act, noting that the agency's authority over devices became increasingly inadequate as the nature of the devices on the market changed (H. Rept. 94-853, 94th Cong., 2d sess., 6-10 (1976)).

In 1938 most of the devices in use were "relatively simple items which applied basic scientific concepts * * *" (H. Rept. 94-853, 6). However, by the time the Medical Device Amendments were enacted, the universe of device products had evolved from primarily simple products, such as tongue depressors and bandages, to include a

²² A later section of the Drug/Device Agreement states that a "device containing a drug substance as a component with the primary purpose of the combination product being to fulfill a drug purpose is a combination product and will be regulated as a drug by CDER." While this is the approach that FDA will usually take with such products, the earlier language of the Drug/Device Agreement expressly recognizes that FDA may use its device authorities where appropriate, and as discussed in the text, there are several examples of this type of prefilled delivery system being regulated using the device authorities.

variety of scientifically and technologically sophisticated products, such as cardiac pacemakers, lasers, and magnetic resonance imaging equipment. This wide range of technology posed many more varied regulatory concerns than those posed by drugs, which as a group of products are less diverse in nature.

Congress recognized the need for specific authority for devices that would take into account "the great diversity among the various medical devices and their varying potentials for harm as well as their potential benefit to improved health" (S. Rept. 94-33, 94th Cong., 1st sess., 10 (1975)). Thus, with the Medical Device Amendments, Congress enhanced FDA's authority to tailor regulatory controls, from an array of statutory tools, to fit the particular safety and effectiveness issues presented by individual devices.

Because of this additional flexibility, the agency has determined that the device authorities provide the most appropriate basis for regulating cigarettes and smokeless tobacco. Because millions of Americans are addicted to cigarettes and smokeless tobacco, regulation of these products presents unique safety problems that require careful, tailored solutions. The Medical Device Amendments provide the agency with regulatory options that are well suited to the unique problems presented by cigarettes and smokeless tobacco.

Although the agency has determined that the device authorities are the most appropriate authorities for regulating cigarettes and smokeless tobacco, the agency disagrees with the comments that suggest that the agency could not regulate cigarettes and smokeless tobacco as drugs. To the contrary, as discussed in section II.D. of this document, the agency could have used its drug authorities to implement similar types of controls on cigarettes and smokeless tobacco as it is imposing under the somewhat more flexible device authorities.

2. Cigarettes and Smokeless Tobacco Will be Subject to the Full Range of Device Authorities

In regulating cigarettes and smokeless tobacco, FDA will follow the regulatory scheme created by Congress for devices. Because the universe of devices is extremely diverse, presenting a broad spectrum of safety and effectiveness issues, the Medical Device Amendments include a wide range of regulatory controls. Some of these controls, such as the adulteration and misbranding requirements, are applicable to all

devices, while others, such as premarket approval and restrictions on sale, distribution, and use, are to be applied only where FDA concludes that they are necessary to provide reasonable assurance of safety and effectiveness for particular devices. The Medical Device Amendments are thus designed to allow the agency to regulate individual devices with controls that are tailored to address the safety and effectiveness problems raised by those devices.

As devices, cigarettes and smokeless tobacco will be subject to all mandatory provisions of the act, except where exemption is permitted by statute and is appropriate for these products. In addition, cigarettes and smokeless tobacco will be subject to other discretionary provisions of the act that the agency has concluded are necessary to address the special safety issues posed by these products.

The basic requirements of the act applicable to all devices include: Adulteration and misbranding provisions (sections 501 and 502 of the act (21 U.S.C. 351 and 352)), labeling requirements (section 502), establishment registration, device listing, and premarket notification (section 510 (21 U.S.C. 360)), recordkeeping and reporting requirements (section 519 (21 U.S.C. 360i)), and good manufacturing practice (GMP) requirements (section 520(f)). As described in more detail in section II.C.4. of this document, FDA intends to apply these requirements, where appropriate, to cigarettes and smokeless tobacco at a future time. In addition, the act requires the agency to classify devices into one of three classes. Depending on the class into which a product is classified, additional regulatory requirements may apply: Class I (general controls), class II (special controls), and class III (premarket approval). As described in more detail in section II.C.5. of this document, as the act contemplates, FDA intends to classify cigarettes and smokeless tobacco at a future time, and will impose any additional requirements that apply as a result of their classification.

The agency has determined that the safety of cigarettes and smokeless tobacco cannot be assured without restrictions on the sale, distribution, and use of these products to children and adolescents. Accordingly, FDA is imposing restrictions under the authority granted in section 520(e) of the act.

(2) Several comments argued that the regulatory requirements proposed by

FDA for cigarettes and smokeless tobacco distort the regulatory scheme for devices established by Congress. These comments contended that FDA has: (1) Selectively applied the provisions of the Medical Device Amendments; (2) inappropriately relied on section 520(e) of the act (restrictions on sale, distribution, or use) while ignoring other mandatory provisions of the act, such as classification; and (3) determined that cigarettes and smokeless tobacco are unsafe and yet failed to invoke provisions of the act that, according to the comments, require the agency to remove them from the market.

FDA disagrees with these comments. As already described, FDA intends to apply to cigarettes and smokeless tobacco all of the mandatory provisions of the Medical Device Amendments. Thus, FDA is neither selectively applying the provisions of the act nor ignoring mandatory provisions.

Although FDA intends to impose on cigarettes and smokeless tobacco all requirements applicable to devices, the act does not provide that these requirements should all be imposed immediately. Classification serves the purpose of identifying which devices need to be subject to special controls (class II) or premarket approval (class III) in addition to the general controls applicable to all devices. Classification requires FDA to institute a separate rulemaking proceeding. The act does not require the agency to classify a device before general controls become applicable to it. Rather, the general controls provisions of the act apply to all devices both before and after classification and irrespective of the class into which a device is ultimately classified. Because the classification process involves many steps and can take years to complete, FDA does not ordinarily complete the classification process before regulating the device under its general controls.

Moreover, the statute contains no requirement that the agency complete a classification rulemaking before invoking the general controls that apply to all devices. For example, each of the literally thousands of medical devices that have been classified by rulemaking under section 513 of the act (21 U.S.C. 360c) were subject to the general controls of the statute—such as the provisions on adulteration, misbranding, registration, investigational device controls, and GMP—in advance of the completion of the classification rulemaking proceedings. (See, e.g., *Contact Lens*

Mfrs. Association v. FDA, 766 F.2d 592, 603 (D.C. Cir. 1985), *cert. denied* 474 U.S. 1062 (1986).) Indeed, in some cases, the general controls provisions were applicable to marketed devices for many years before completion of classification.

Consistent with the agency's practice, FDA has made a decision to apply the general controls provisions of the act to cigarettes and smokeless tobacco, including restrictions on their distribution, sale, and use under section 520(e) of the act, before classifying cigarettes and smokeless tobacco. As described in section II.C.5. of this document, FDA will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with the procedures in section 513 of the act. In the meantime, the general controls will apply.

FDA also disagrees that the act requires the agency to remove cigarettes and smokeless tobacco from the market. As described in the preamble to the 1995 proposed rule (60 FR 41314), although cigarettes and smokeless tobacco pose very grave risks, the agency cannot conclude that removing them from the market would most effectively meet the statutory goal of providing reasonable assurance of safety and effectiveness. Because millions of Americans are addicted to cigarettes and smokeless tobacco, the consequences of their removal from the market, as discussed in greater detail in section II.C.5. of this document, would include adverse health effects from sudden withdrawal, the likely development of a black market, and the possibility that the products that would be available through a black market would pose greater risks than those currently on the market. None of the statutory sections cited by the comments require the agency to remove products from the market where the agency concludes that such action would be contrary to the public health. Here, FDA has determined that the unique safety issues presented by highly addictive and long-marketed products like cigarettes and smokeless tobacco can most effectively be addressed by actions to prevent new users from becoming addicted to these devices.

In section II.C.3. of this document, FDA discusses its authority to impose restrictions on sale, distribution, and use to prevent children and adolescents from becoming addicted to cigarettes and smokeless tobacco. In section II.C.4 of this document, FDA discusses imposition of other general controls, and, in section II.C.5 of this document,

FDA discusses classification of cigarettes and smokeless tobacco.

3. The Restricted Device Provision Authorizes FDA to Establish Access and Advertising Restrictions

Congress provided FDA with authority to prevent the use of a device by those not competent to use it safely in the restricted device provision (section 520(e) of the act). Specifically, section 520(e) of the act states in part:

(1) The [agency] may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the [agency] may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the [agency] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

Section 520(e) is one of the act's "general controls" (see section 513(a)(1)(A) of the act). As a general control, section 520(e) of the act can be used by FDA to regulate any class of device (section 513(a) of the act). Because its applicability does not depend upon the outcome of the classification process, 520(e) of the act—like the other general controls—can be used by FDA to regulate a device prior to the classification of the device.

In applying section 520(e) of the act to restrict the sale, distribution, or use of a device, FDA must find that without the restriction "there cannot otherwise be reasonable assurance of its safety and effectiveness." This provision requires FDA to find that the restrictions in section 520(e) of the act are necessary to assure the safety and effectiveness of the device, but FDA does not have to find that the restrictions are sufficient to assure safety and effectiveness. During the classification process, FDA determines whether additional controls beyond section 520(e) of the act and the other general controls applicable to all devices are needed to assure the safety and effectiveness of the device.

The restricted device provision in section 520(e) of the act authorizes FDA to adopt regulations that ensure that children and adolescents, who by State law are not competent to use cigarettes and smokeless tobacco, will not be able to obtain them. In particular, FDA has determined that section 520(e) of the act authorizes the access and advertising restrictions in the final rule because without these restrictions "there cannot otherwise be reasonable assurance of * * * safety * * *."

As described more fully later in this section of this document, the agency's use of section 520(e) of the act in this rule is consistent with the plain language of section 520(e), the legislative history, and the agency's prior use of section 520(e) in, for example, restricting the sale, distribution, and use of hearing aids (42 FR 9285, February 15, 1977, as amended at 47 FR 9397 through 9398, March 5, 1982).

As discussed in section II.C.5. of this document, the agency intends to classify cigarettes and smokeless tobacco under the procedures contained in section 513 of the act. The classification process is the time at which the agency determines what degree of regulation is necessary to provide a "reasonable assurance of safety and effectiveness" for a particular product, such as tobacco products. However, the act does not specify the timing of the application of device authorities, and the agency is therefore able to issue restrictions under section 520(e) of the act prior to initiating the classification process. The agency also did so in its regulation of hearing aids. In 1977, FDA adopted regulations under section 520(e) of the act containing restrictions on the sale, distribution, and use of hearing aids (42 FR 9285, February 15, 1977, as amended at 47 FR 9397 and 9398, March 5, 1982), but did not classify these products until 1986 (51 FR 40378 at 40389, November 6, 1986).

FDA is following a similar course here. The agency has determined that unless measures are taken now to prohibit the sale and promotion of these products to young people under the age of 18, there cannot otherwise be reasonable assurance of safety. Therefore, FDA is acting under section 520(e) of the act to restrict the sale, distribution, and use of cigarettes and smokeless tobacco.

a. *The restricted device provision authorizes FDA to prevent access to persons who cannot use a device safely or effectively.* Section 520(e) of the act is in part the device counterpart to section 503(b), the act's prescription drug provision. Section 503(b)(1) of the act, for instance, authorizes FDA to restrict access to potentially dangerous drugs by requiring that they be dispensed "only upon a * * * prescription of a practitioner licensed by law to administer such a drug * * *." Similarly, section 520(e)(1)(A) of the act authorizes FDA to restrict access to potentially dangerous medical devices "only upon the * * * authorization of a practitioner licensed

by law to administer or use such device * * *.”

The restricted device provision, however, is significantly broader than the prescription drug provision. Not only may FDA restrict sale, distribution and use by prescription, but it may do so upon “such other conditions as [it] may prescribe in such regulation” (section 520(e)(1)(B) of the act (emphasis added)). There is no counterpart to this “other conditions” authority in the prescription drug provisions.

Section 520(e) of the act was designed to deal with the risks that are created by improper use of a device. The legislative history of the Medical Device Amendments specifically states that section 520(e) of the act was intended to “supersede[]” and “add[]” to the prescription authority derived from section 503(b) of the act (H. Rept. 94–853, 94th Cong. 2d sess., 24–25 (1976)). This confirms that Congress intended to give FDA broad authority to restrict access to potentially dangerous devices. (See also “Medical Device Regulation: The FDA’s Neglected Child,” Report of the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, 98th Cong., 1st sess., 31 (1985).)

Congress’ use of the phrase “could include” indicates that this discussion was intended to be illustrative rather than exhaustive. The examples of possible restrictions described in the legislative history demonstrate that Congress intended to give the agency authority to restrict access to devices in a variety of ways, depending upon the type of risk posed by the device and the measures needed to ensure that the device is not used inappropriately. In short, the legislative history supports the statutory language and establishes that Congress intended FDA’s authority to restrict the sale, distribution, and use of devices “upon such other conditions as the [agency] may prescribe” to be a flexible authority that allows FDA to tailor restrictions on sale, distribution, and use according to the circumstances posed by the device being regulated.

b. *The restricted device provision also authorizes FDA to restrict promotional activities that encourage uses that are inconsistent with the regulatory scheme.* Section 520(e) of the act is a broad grant of authority. The Secretary, and by delegation FDA, is authorized to restrict the sale, distribution, or use of a device “upon such other conditions as the [agency] may prescribe in such regulation.” This broad grant of

authority covers all aspects of the sale of a device, including the offer of sale.

How a device is sold involves many elements. It involves not only the circumstances surrounding the exchange of money for the device, but also whether the device must be sold only on the authorization of a practitioner, whether age limits on users are appropriately established, and how the device is represented to potential users. It is in the latter regard that advertising plays a role and may be restricted under section 520(e) of the act.

The Supreme Court cases on commercial speech recognize that a State’s interest in regulating sales extends to advertising promoting the sale. In *Edenfield v. Fane*, 507 U.S. 761, 767 (1993), the Supreme Court said that commercial transactions are “linked inextricably” with the commercial speech that proposes the transaction, and that the State’s interest in regulating the underlying transaction may give it a concomitant interest in the expression itself. Likewise, under section 520(e) of the act, the sale of a device is “linked inextricably” to the advertising that promotes the sale, giving FDA concomitant authority to impose necessary restrictions on the advertising.

FDA’s regulation of hearing aids exemplifies this aspect of section 520(e) of the act. One of the most important purposes of the restrictions on sale, distribution, and use imposed on hearing aids was to respond to widespread inappropriate promotion of hearing aids to consumers for whom the devices are not effective (see 41 FR 16756 at 16757 (April 21, 1976)). In that regulation, in addition to restricting sales to persons who had been medically evaluated for hearing aids, FDA relied upon section 520(e) of the act to require that an instructional brochure be distributed to each prospective hearing aid user. These brochures described the adverse reactions and side effects associated with hearing aids and encouraged prospective users to seek medical evaluations. The distribution of the brochure was required as a means of ensuring that advertising for hearing aids did not inappropriately induce persons who had not been medically evaluated to purchase the hearing aids.

The agency’s authority to use section 520(e) of the act to restrict advertising is especially strong when limits on advertising are necessary to ensure that advertising does not undermine the conditions on sale, distribution, or use

that the agency adopts under section 520(e). The agency should not be—and under section 520(e) of the act is not—powerless to prevent advertising that encourages sales that the agency has barred under section 520(e). Rather, the agency may use its authority to impose “such other conditions as the [agency] may prescribe” to restrict advertising that directly undercuts the agency’s restrictions on sale, distribution, and use.

c. *The restricted device provision authorizes FDA’s restrictions on youth access and on advertising designed to make cigarettes and smokeless tobacco appealing to youth.* The restricted device provision authorizes the restrictions on youth access and on advertising in this final rule. Section 520(e) of the act contemplates these types of restrictions on sale and distribution. Moreover, they are necessary if FDA ever were to be able to find that there is a reasonable assurance of the safety of cigarettes and smokeless tobacco under the act. As section 520(e) of the act provides, without these restrictions “there cannot otherwise be reasonable assurance of safety and effectiveness.”

The provisions in the final rule that restrict the access of minors to cigarettes and smokeless tobacco are clearly restrictions on “sale, distribution, or use” of a device within the meaning of section 520(e) of the act. FDA’s access restrictions are designed to ensure that children and adolescents are unable to have access to cigarettes and smokeless tobacco. These restrictions directly limit the sale of cigarettes and smokeless tobacco by, for instance, banning the sale of these products to persons under 18. They also directly limit the distribution of cigarettes and smokeless tobacco by, for instance, banning the distribution of free samples. Hence, these access restrictions are within the plain language of section 520(e) of the act.

The advertising restrictions in the final rule are also among the types of restriction that section 520(e) of the act authorizes. As in the case of the restrictions imposed on hearing aids, the advertising restrictions are designed to address inappropriate promotion of cigarettes and smokeless tobacco to individuals for whom the potentiality for harm is particularly great. The advertising restrictions are necessary to prevent advertising by the manufacturers of cigarettes and smokeless tobacco from undercutting the access restrictions. The effectiveness of the restrictions on youth access

would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions. In this circumstance, restrictions on advertising are properly treated as restrictions on "sale, distribution, or use" within the meaning of section 520(e) of the act.

The final requirement of section 520(e) of the act is that the agency establish that without the restrictions on the device "there cannot otherwise be reasonable assurance of its safety and effectiveness." This requirement is plainly met in the case of the access and advertising restrictions for cigarettes and smokeless tobacco. Without effective restrictions on sale and distribution of cigarettes and smokeless tobacco to children and adolescents under 18, young people will continue to become addicted to these products and, once addicted, will as adults continue to use them in spite of their potential for harmful effects. As stated in section I.B. of this document, the earlier tobacco use begins, the greater the risk of disease caused by, or associated with, the use of these products. Thus, there can be no doubt that without the access and advertising restrictions imposed in this final rule, no finding that there is a reasonable assurance of safety for cigarettes and smokeless tobacco would be possible.

Although FDA finds that the restrictions under section 520(e) of the act are *necessary* for providing a reasonable assurance of safety, FDA is not required under section 520(e) of the act to show that the restrictions are *sufficient* by themselves to provide a reasonable assurance of safety or effectiveness. Under section 520(e) of the act, all that FDA must establish is that without the section 520(e) restrictions, the device could not be found to be safe.

It is in the classification process—not in the application of section 520(e) of the act—that FDA must determine what controls are necessary if the agency is to find that there is a reasonable assurance that a device is safe and effective for its intended use. As discussed in section II.C.5. of this document, FDA intends to classify cigarettes and smokeless tobacco in a future rulemaking.

d. *Response to other comments.* FDA received several comments on whether section 520(e) of the act authorizes restrictions on youth access and advertising. Most of the comments were from tobacco trade associations, tobacco companies, and advertisers, arguing that section 520(e) of the act does not provide authority for either the access or

advertising restrictions. A comment from a public interest group, however, fully supported FDA's reliance on section 520(e). FDA also received a large number of comments from a broad cross-section of the public that expressed support for, or opposition to, the proposed restrictions without delving into the legal issues analyzed in the 1995 proposed rule.

(3) One comment said that FDA uses the term "conditions" in section 520(e)(1)(B) of the act to mean any regulatory imposition that the agency believes would bring about an improvement in safety in some way related to the device in question. The comment argued that FDA has used this term in such an overinclusive way that it would authorize FDA to impose many of the requirements that Congress imposed in other provisions of the act. For example, the comment argued that under FDA's interpretation it could require premarket approval of a device with a potentiality for harmful effect as a "condition" on the "sale, distribution, or use" of the device, on the theory that without premarket approval it would be impossible for there to be "reasonable assurance of its safety."

FDA disagrees with this comment. FDA's interpretation of section 520(e) of the act does not create any redundancy with the other provisions of the Medical Device Amendments. Most of the general controls authorized under the act, and the major thrust of the provisions on performance standards and premarket approval, are geared toward ensuring that finished devices, when ready for use, will be free from defects and will provide a reasonable assurance of safety and effectiveness for their labeled use. Restrictions under section 520(e) of the act, on the other hand, are imposed because the device's "potentiality for harmful effect or the collateral measures necessary to its use," and the determination that, without such restrictions, there cannot otherwise be a reasonable assurance of safety and effectiveness. The restrictions under section 520(e) of the act on cigarettes and smokeless tobacco focus on those who may *not* purchase and use these products rather than on those who will be using the products. Without successful restrictions on sale, distribution, and use of cigarettes and smokeless tobacco to children and adolescents under 18, there will never be reasonable assurance of the safety of these products because they would continue to be available to these young people, who, by State law, are not competent to use them.

(4) With regard to access, industry comments contended that FDA's authority under the provisions of the act relating to restricted devices was intended to be no broader than its prescription drug authority and, accordingly, could not extend to restrictions such as those in the 1995 proposed rule.

FDA disagrees with this view and believes that it is unsupported by the clear language of the act and the legislative history (see H. Rept. 94-853, 94th Cong., 2d. sess., 24-25 (1976)). Had Congress meant for the authority granted FDA under section 520(e) of the act to be no broader than the authority granted in section 503(b)(1) of the act to limit drugs to prescription use, it could simply have amended section 503(b)(1) of the act to add "or device" after "drug" each time the term is used. Indeed, as discussed in *Becton, Dickinson and Company v. Food and Drug Administration*, 589 F.2d 1175 (2d Cir. 1978) that approach was the one used in early versions of the legislation that became the 1976 amendments but was abandoned in favor of the broader "restricted device" approach that has been a part of the law for 20 years. The plain language of the enacted provision contains no limitation on the types of restrictions that can be imposed and certainly is not limited by its terms to restriction to prescription use. Moreover, as previously discussed, the legislative history specifically states that the agency's authority under section 520(e) of the act is broader than its authority under the prescription drug provisions (H. Rept. 94-853, 94th Cong., 2d sess., 24-25, 1976).

(5) An industry comment contended that "FDA uses what is merely the medical device version of prescription drug status as the sole legal justification for an elaborate system of controls far broader and more intrusive than is authorized even for true medical devices."

As discussed in section II.C.3. of this document, FDA's restricted device authority is significantly broader than suggested by this comment. Given the potentiality for harm from cigarettes and smokeless tobacco, FDA has ample authority to impose the conditions on their sale, distribution, and use that it is adopting.

As is the case with other medical devices, cigarettes and smokeless tobacco are subject to those regulatory controls that are appropriate for medical devices generally (e.g., registration, labeling, and inspection), along with those tailored to the product in question

and the risks that it presents (access restrictions and advertising controls). Thus, FDA is treating cigarettes and smokeless tobacco in a manner that is consistent with how it treats other medical devices.

(6) Turning to the advertising restrictions, several comments argued that section 520(e) of the act authorizes only restrictions on “sale, distribution, or use,” and that it does not include the words “offer for sale.” These comments pointed out that Congress used the words “offer for sale” elsewhere in the act (sections 301(m) and (o) (21 U.S.C. 331(m) and (o)) and 503(c)), and they therefore drew the inference that if Congress had intended section 520(e) of the act to authorize restrictions on how medical devices are offered for sale, it would have made this fact explicit.

FDA is not persuaded by this argument. In each of the instances cited in the comments where Congress has included the phrase “offer for sale” in the act, it was defining a prohibited act, that is, an act whose commission would violate the statute, in which the prohibition focused, at least in part, on the sale of a food, drug, or device. By including the phrase “offered for sale” in these provisions, Congress sought to ensure that the statutory objective of preventing the actual sale of products where advertising or labeling does not meet the statutory requirement would be met by including products merely “offered for sale” within the statute’s coverage. The agency notes that, similarly, the words “offered for sale” appear in section 502(q) of the act, the provision that the agency would use to enforce section 520(e) of the act. Thus, Congress did in fact include “offer for sale” in the scope of conduct regulated under section 520(e) of the act and its enforcement clause, section 502(q). The comment’s argument, however, misses the significance of section 520(e) of the act.

As discussed in section II.C.3. of this document, the authority to restrict the “sale, distribution, or use” of a device includes the authority to restrict the circumstances surrounding the sale and distribution of the device, including the device’s advertising. The use of section 520(e) of the act to restrict advertising is particularly appropriate when the advertising restrictions are necessary to ensure that access restrictions issued under section 520(e) of the act are not undermined by a manufacturer’s advertising. Here, FDA is restricting the sale of cigarettes and smokeless tobacco because of their potential harmful effects on individuals who start using

them before the age of 18 and who lack the competency to decide to do so. FDA has determined, as explained in sections VI.B. and D. of this document, that how cigarettes and smokeless tobacco are advertised plays a material role in the decision of children and adolescents under 18 to purchase and use these products. Thus, if the restrictions on how cigarettes are sold, distributed, and used that FDA is adopting under section 520(e) of the act are to be effective, they must include restrictions on how cigarettes and smokeless tobacco are advertised.

(7) The comments also argued that section 520(e) of the act on its face says nothing about advertising. Thus, according to these comments, FDA’s authority to regulate the advertising of restricted devices is limited by section 502(q)(1) of the act, which prohibits false or misleading advertising, and section 502(r) of the act, which prescribes certain statements in the advertising for these devices. One comment implied that FDA’s interpretation of section 520(e)(1) of the act had rendered section 502(q)(1) and (r) of the act superfluous.

FDA is not persuaded by these comments. The interpretation of section 520(e) of the act that FDA has adopted in this proceeding would not render either section 502(q)(1) or (r) of the act inoperative or superfluous. These sections impose requirements on advertising of the permissible sale, distribution, and use of restricted devices. They set out conditions on advertising to which manufacturers must adhere in offering these devices for sale. Section 520(e) of the act, on the other hand, is the means by which FDA demarcates permissible and nonpermissible conditions of sale, distribution, and use of these devices. In so doing, as has been explained in response to the previous comments, FDA may by regulation impose limits on advertising that it finds are necessary to ensure that advertising is not used to undermine the conditions on sale, distribution, or use that the agency adopts. This is what §§ 897.30, 897.32(a), and 897.34, the regulations that set out the restrictions on advertising, are designed to accomplish. In fact, section 502(q)(1) of the act reinforces this authority because any advertisement that promotes the sale of a device for a use that is inconsistent with a restriction established by FDA would be false and misleading because it would represent that the device is appropriate for that use, which would not be the case.

Thus, Congress clearly intended section 502(q)(1) and (r) of the act and any restrictions that FDA adopts under section 520(e) of the act to be complementary. This intent is further evidenced by the fact that section 502(q)(2) of the act provides that a restricted device is misbranded if it is sold, distributed, or used in violation of regulations prescribed under section 520(e) of the act. Section 502(q)(2) of the act thus complements sections 502(q)(1) and (r) of the act, which, as previously explained, address different aspects of the regulation of restricted devices than does section 520(e) of the act.

FDA’s interpretation of section 520(e) of the act accordingly does not render either section 502(q)(1) or (r) of the act superfluous. Rather, the three provisions support and reinforce each other.

(8) An additional argument advanced by two tobacco trade associations was that the interpretation of section 520(e)(1)(B) of the act, which authorizes FDA to restrict the sale of a device upon such “other conditions” as it deems necessary, is governed and limited by the rule of *ejusdem generis*. This rule of statutory construction provides that, where general words follow an enumeration of persons or things of a particular and specific meaning, such general words are not to be construed in their widest extent but are to be held as applying to only persons or things of the same general kind or class as those specifically mentioned. Thus, the comment argued that here, *ejusdem generis* limits the scope of “other conditions” in section 520(e)(1)(B) of the act to restrictions similar in nature to the restriction to prescription use in section 520(e)(1)(A) of the act. The comment argued that it would be totally inconsistent with the rule of *ejusdem generis* to expand the scope of “other conditions” to include a provision as dissimilar to a prescription requirement as a restriction on advertising. FDA does not agree that *ejusdem generis* is controlling, or that it has any application here. In *Norfolk & Western v. American Train Dispatchers Ass’n*, the Supreme Court held that this canon does not control “when the whole context dictates a different conclusion” (499 U.S. 117, 129 (1991)). The context involving section 520(e) of the act does not support the application of *ejusdem generis* to it. There is no indication that Congress thought that it was providing a list of similar measures in section 520(e)(1)(A) and (e)(1)(B) of the act. In fact, the face of the act is to the contrary. After specifying one means of restricting

the sale, distribution, and use of a device, Congress granted the Secretary broad authority to impose "such other conditions as [she] may prescribe in such regulation." Congress, rather than limiting the Secretary's options, left it to the Secretary to decide what conditions are necessary for a particular device. Nor does the legislative history support the comments. As stated in section II.C.3.a. of this document, Congress intended section 520(e) of the act to add to the agency's authority beyond providing for use by prescription only (H. Rept. 94-853, 94th Cong., 2d sess., 24-25 (1976)).

Moreover, the "or" connecting section 520(e)(1)(A) of the act with section 520(e)(1)(B) is properly read here as disjunctive rather than conjunctive. (See *Garcia v. United States*, 469 U.S. 70, 73 (1984).) Section 520(e) of the act is intended to authorize such conditions on the sale, distribution, or use of a device as are necessary to ensure that the device is not improperly used and without which a reasonable assurance of its safety and effectiveness cannot be provided. There is no basis on the face of the act or in the legislative history to conclude that Congress was trying to limit the conditions that FDA could impose to achieve that end (other than the admonition not to base a physician restriction on board certification).

(9) One comment argued that the interpretation of section 520(e) of the act that FDA is advancing in this proceeding is contrary to the interpretation that the agency offered in imposing restrictions on hearing aids in 1977. The comment pointed out that FDA stated at that time: "The Commissioner notes, however, that the [Act] regulates the safety * * * of the [device] itself" (42 FR 9286 at 9287, February 15, 1977). The comment asserted that, for this reason, FDA concluded that it could not prescribe competency standards for hearing health professionals, fix the price of hearing aids, or control the promotional practices of hearing aid dispensers, all matters that were being handled by the Federal Trade Commission (FTC) (42 FR 9286 at 9287). The comment argued that, for the same reasons, FDA may not, under section 520(e) of the act, regulate attire, contests, or athletic or cultural events.

FDA does not agree that the hearing aid proceeding provides any support for the view that the agency has been inconsistent in its interpretation of section 520(e) of the act. In that proceeding, FDA was aware that FTC had developed a proposed trade

regulation rule that included a prohibition of certain selling techniques (42 FR 9286 at 9287). FDA said that it was avoiding any duplication of effort with FTC. Thus, it was not necessary for FDA to consider the extent of its authority to specifically regulate selling techniques of hearing aid dispensers.

Contrary to the comment's assertion, this proceeding is consistent with the hearing aid proceeding. Although FDA did not duplicate FTC's effort and directly regulate selling techniques, FDA imposed various restrictions that were tailored to restrict inappropriate promotion of hearing aids including requiring a medical evaluation before purchase and distribution of a user instructional brochure. In the case of cigarettes and smokeless tobacco, FDA is imposing restrictions that are tailored to promotion of tobacco products to ensure that advertising does not induce the use of cigarettes and smokeless tobacco by children and adolescents under 18.

(10) Finally, several comments argued that FDA lacks statutory authority for the advertising restrictions that it is imposing. Some of these comments sought to analogize this rulemaking to *American Pharmaceutical Ass'n v. Weinberger*, 377 F. Supp. 824, 831 (D.D.C. 1974), *aff'd sub nom. American Pharmaceutical Ass'n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976) (per curiam). That case involved an attempt by FDA to limit the distribution of methadone to certain designated facilities under the drug authorities of the act. The court held that the statutory drug authority did not authorize the agency to impose these limitations on the distribution of methadone, even though methadone posed unique problems of medical judgement, law enforcement, and public policy.

FDA regards the *American Pharmaceutical Ass'n* case as a questionable precedent. The case predates both the Supreme Court's decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), and the Medical Device Amendments. In *Chevron*, the Court stated that "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer * * *" (467 U.S. at 844). Moreover, when Congress enacted section 520(e) of the act, one of its objectives was to provide FDA with precisely the kind of authority over medical devices that the court found that the agency did not have over drugs in *American Pharmaceutical Ass'n*. Thus, FDA now has explicit

authority under section 520(e) of the act to impose conditions on the sale, distribution, and use of a medical device to prevent its misuse, including the access and advertising restrictions in the final rule. FDA is imposing controls on the sale of cigarettes and smokeless tobacco to ensure that individuals under 18 will not be able to purchase them. Further, to ensure that these controls on sale, distribution, and use are not undermined, FDA has found that they must include restrictions on how these products are advertised, so that individuals under 18 are not encouraged to purchase or use them. These actions are consistent with the language and purpose of section 520(e) of the act.

4. Application of Other Device Authorities

As described in section II.C.2. of this document, FDA intends to follow its normal course and apply the "general controls" provisions of the Medical Device Amendments to cigarettes and smokeless tobacco pending classification of these products. The general controls authorized by the Medical Device Amendments include adulteration and misbranding (sections 501 and 502 of the act), establishment registration, device listing, and premarket notification (section 510), labeling requirements (section 502), recordkeeping and reporting requirements (section 519), and GMP (sections 501 and 520(f)).

(11) Tobacco industry comments claimed that FDA had ignored a number of mandatory provisions of the act applicable to devices, "presumably because they again recognize that those provisions would mean the prohibition of tobacco sales." The comments also asserted that FDA had picked and chosen among statutory provisions and had misinterpreted *Heckler v. Chaney*, 470 U.S. 821 (1985), as authorizing this selective regulatory approach. These comments also argued that FDA had ignored section 520(a) of the act, which provides that the adulteration, misbranding, and records and reports requirements are applicable to devices until the applicability of these requirements is changed by an action under the classification, premarket approval, standard-setting, or investigational device provisions of the act.

The agency disagrees with these comments. FDA is applying to cigarettes and smokeless tobacco the general controls applicable to all devices.

In the following discussion, the agency elaborates on the applicability of the general controls provisions to

cigarettes and smokeless tobacco, and on matters the agency has reconsidered in response to comments (the applicability of labeling requirements to cigarettes and smokeless tobacco is discussed in sections V. and VI. of this document). Overall, FDA believes that it has developed a regulatory system for cigarettes and smokeless tobacco that is consistent with the statutory scheme and the record of this rulemaking.

a. Adulteration and misbranding.

Cigarettes and smokeless tobacco will be subject to the adulteration and misbranding provisions in sections 501 and 502 of the act, and the implementing regulations, with one exception that is permitted by statute. Section 502(f) of the act authorizes the agency to grant exemptions from section 502(f)(1) of the act under certain circumstances. As described in section V.E. of this document, FDA has determined that an exemption from section 502(f)(1) of the act is appropriate for cigarettes and smokeless tobacco. In addition, section VI.E.6. of this document also contains a more detailed description of the applicability of specific labeling requirements to cigarettes and smokeless tobacco.

The adulteration and misbranding provisions are largely self-executing and do not require the agency to impose requirements by regulation.

b. Device registration and listing.

Section 510 of the act and part 807 (21 CFR part 807) of the regulations require that device manufacturers and importers register their establishments with the agency. Every year an annual registration form is sent to all registered establishments to be completed and returned to the agency (§ 807.22(a)). Any significant changes of information to the original must be reported to FDA within 30 days of the change (§ 807.26).

Manufacturers are also required to list their devices that are in commercial distribution in the United States (part 807). Foreign manufacturers may, but are not required to, register (§ 807.40). However, they are required to list their devices (§ 807.40(b)). Manufacturers are required to update their listing if there are significant changes to listing information.

Manufacturers of cigarettes and smokeless tobacco will be subject to the establishment registration and device listing requirements in section 510 of the act and part 807 of FDA's regulations. The application of these provisions to cigarettes and smokeless tobacco derives from their status under the device provisions of the act and

does not require rulemaking by the agency.

Section 510(k) of the act requires submission of a premarket notification to the agency whenever a manufacturer markets a device for the first time, whenever there is a major change in the intended use of an already marketed device, or whenever an already marketed device is to be modified in a way that could significantly alter its safety or effectiveness (§ 807.81). The device may not be commercially distributed unless the agency issues an order finding the device substantially equivalent to one or more predicate devices already legally marketed in the United States for which premarket approval is not required (section 513(i) of the act (§ 807.100)), or unless the agency approves a premarket approval application for a device subject to an approval requirement under section 515 of the act (21 U.S.C. 360(e)). Substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device; or has the same technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness (section 513(i) of the act). The premarket notification submission must include either a summary of the safety and effectiveness information upon which a substantial equivalence determination may be based, or state that safety and effectiveness data will be made available to anyone upon request (section 513(i)(3)(A) of the act (21 U.S.C. 360c(i)(3)(A)), and §§ 807.87(h) and 807.92).

c. Records and reports. Section 519 of the act contains several requirements relating to the keeping of records and making of reports on devices. In addition to implementing the specific requirements of the act, the agency has used its authority under section 519 of the act to issue several regulations. As nicotine delivery devices, which are drug-device combination products that FDA is regulating under its device authorities, cigarettes and smokeless tobacco are subject to the requirements of section 519 of the act and the implementing regulations unless otherwise exempted.

Section 519(a) of the act requires manufacturers, importers, and distributors of devices to establish and maintain records, and make reports and other information available to the agency, to ensure that a device is not adulterated or misbranded and to

otherwise ensure its safety and effectiveness. Similarly, section 519(b) of the act requires medical device user facilities to make reports to device manufacturers and the agency when they become aware of information suggesting that a device has caused or contributed to a death, serious injury, or serious illness. Under this authority, the agency has issued part 803 (21 CFR part 803), on medical device reporting, and part 804 (21 CFR part 804), on medical device distributor reporting (the MDR requirements). These regulations were recently amended by a final rule published in the Federal Register of December 11, 1995 (60 FR 63578) (the 1995 reporting requirements final rule), reflecting changes in the reporting requirements of section 519 of the act that were mandated by the SMDA and the Medical Device Amendments of 1992.

The 1995 proposed rule would have amended parts 803 and 804 to exempt cigarettes and smokeless tobacco from the MDR requirements. These proposed exemptions were based on the fact that "the adverse health effects attributable to cigarettes and smokeless tobacco products are extensive and well-documented" (60 FR 41314 at 41342). The agency stated that it did not anticipate any real benefit in requiring manufacturers and distributors of these products to report such information (*Id.*).

(12) The agency received several comments criticizing this proposed exemption. One comment from a trade association stated that, although it disagreed with the agency's classification of cigarettes as medical devices, the agency had no authority to exempt manufacturers from this reporting requirement. This trade association also stated that, because the agency has concluded that cigarettes are not safe for individual users, this exemption cannot be reconciled with the standard under section 519(c) of the act for exempting this product. (Section 519(c)(3) of the act provides for exemptions upon a finding that compliance with recordkeeping and reporting is not necessary to ensure that a device is not adulterated or misbranded or to otherwise ensure its safety and effectiveness.) Another trade association claimed that the agency did not follow the proper exemption procedures under the act. A trade association also noted that the agency did not propose to require such user facility reports for cigarettes and also noted that such reports are not "suitable" for cigarettes.

In view of these comments, the agency has reconsidered its tentative position regarding the application of the MDR requirements in parts 803 and 804. The adverse health effects attributable to these products are extensive and well-documented. As a result, the cost of processing the enormously high volume of MDR reports related to the use of cigarettes and smokeless tobacco would likely be prohibitive in light of the small benefit to be gained from reports documenting adverse health effects already known to the agency.

Nevertheless, there would be a benefit to receiving information regarding adverse events that are not well-documented and thus, not well-known or anticipated. Therefore, the agency has determined that it will require MDR reporting in certain limited circumstances, and is amending §§ 803.19 and 804.25 of its regulations to make this clear.

In the preamble to the 1995 reporting requirements final rule, the agency clarified that it may grant a written exemption, variance, or alternative to some or all of the MDR requirements "when it determines compliance with all MDR requirements is not necessary to protect the public health" (60 FR 63578 at 63592). The agency cited, as an example for an appropriate exemption, devices for which "adverse events that are known and well documented, are occurring at a normal rate, and do not justify the initiation of remedial action * * * (Id.).

To limit the volume of reports that could otherwise be required, the agency is modifying the MDR requirements for adverse events relating to tobacco. The agency has added § 803.19(f) to the regulation's "Exemption, variances, and alternative reporting requirements" section in order to limit the medical device reports concerning cigarettes and smokeless tobacco; specifically, new paragraph (f) requires reports from manufacturers only for those adverse events related to contamination, a change in any ingredient or any manufacturing process, or any serious adverse event that is not well-known or well-documented by the scientific community.

The agency notes that user facilities are not likely to have direct knowledge of even these limited adverse events required to be reported by manufacturers. Therefore, the agency is adding § 897.19(g) to exempt user facilities from the MDR requirements relating to cigarettes and smokeless tobacco.

For similar reasons, FDA is also modifying the MDR requirements for distributors of cigarettes and smokeless tobacco. Because distributors handle these products, break open cartons, and even affix the tax stamp, the agency believes that distributors could be responsible for, or aware of, contamination of these products. The agency does not believe, however, that distributors are likely to have direct knowledge of any change in ingredient or manufacturing process or any serious adverse event that is not well-known or well-documented by the scientific community. Therefore, the agency is limiting the MDR requirements for distributors to require reports concerning cigarettes and smokeless tobacco only for adverse events relating to contamination.

The agency notes that it has granted similar variances in the past for circumstances that justify modifications to the MDR requirements and has issued guidance that establishes criteria for modified reporting. Examples where reporting has been modified include events involving health care professionals being stuck by needles and certain events involving defibrillators. These modifications were made in order to clarify which events would provide valuable information to the agency given the inherently risky circumstances surrounding the use of these devices. A variance from the MDR requirements has also been granted to the manufacturers of breast implants in order to limit the frequency of reports for events already known to the agency.

(13) Industry comments also questioned why FDA had not proposed to apply device tracking and premarket surveillance provisions to cigarettes and smokeless tobacco. Section 519(e) of the act, governing device tracking, applies only to products that are permanently implantable, life-sustaining or life-supporting, or have been designated by the agency to be tracked. Cigarettes and smokeless tobacco do not fall within the first two categories, and the agency has not designated them for tracking.

For the reasons cited in the previous discussion of 519(e) of the act, postmarket surveillance will not be required unless, at a future date, the agency specifically designates these products under section 522 of the act (21 U.S.C. 360l).

Section 519(f) of the act, which requires FDA to issue regulations to require reports on device removals and corrections, will apply to manufacturers, importers, and distributors of cigarettes and smokeless

tobacco. To implement section 519(f) of the act, FDA issued a proposed rule in the Federal Register of March 23, 1994 (59 FR 13828), that would require manufacturers, importers, and distributors of devices to report promptly to FDA any corrections or removals of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. The agency expects that the final rule will publish in 1996. This rule will apply to removals and corrections of medical devices including cigarettes and smokeless tobacco.

d. *GMP*. In the preamble to the 1995 proposed rule, FDA specifically recognized that the GMP regulations may be appropriate for tobacco products (60 FR 41314 at 41352). In this final rule, FDA is requiring that the manufacturers of cigarettes and smokeless tobacco comply with GMP regulations in part 820 (21 CFR part 820), which the agency is currently revising. (See 58 FR 61952, November 11, 1993.) Application of GMP's to cigarettes and smokeless tobacco will assist the tobacco industry in avoiding such situations as the recall of Marlboros in 1995 because of a contamination mishap in processing and, in such cases, may advance public health by reducing to some degree the overall risk associated with these products.

(14) A comment from a tobacco trade association urged that FDA provide ample time for compliance with GMP and requested a 2-year period for compliance.

FDA recognizes that manufacturers will need an adequate amount of time to comply with GMP requirements and is accepting the suggestion in the comment by adopting a 2-year period for compliance. The tobacco industry already has a sophisticated approach to quality control with the production of their products. Thus, much of what is required to meet the requirements of part 820 appears to be in place already, and therefore, 2 years should be a sufficient time for compliance.

(15) In response to comments from tobacco distributors expressing concern about present or future applicability of the GMP regulations, FDA advises that it is exempting distributors from part 820. The agency has decided to amend part 820 by adding a new § 820.1(f) to exempt distributors from the requirement of complying with GMP regulations because it has concluded that compliance with GMP requirements

by distributors is not necessary to assure that these devices will be safe and effective or otherwise in compliance with the act.

5. FDA Will Classify Cigarettes and Smokeless Tobacco Under Section 513 of the Act

In addition to applying the general device authorities previously described to cigarettes and smokeless tobacco, the agency will classify cigarettes and smokeless tobacco under section 513 of the act. The agency relies on classification to determine what level of control of the device is required to provide a reasonable assurance of safety and effectiveness. For devices classified into class I, general controls (sections 501, 502, 510, 516, 518, 519, and 520 of the act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j, respectively)) are sufficient to provide a reasonable assurance of safety and effectiveness. For devices classified into class II, special controls (such as performance standards under section 514 of the act (21 U.S.C. 360d)) are needed in addition to the general controls to provide a reasonable assurance of safety and effectiveness. For devices classified into class III (premarket approval), neither general nor special controls are sufficient to provide a reasonable assurance of safety and effectiveness, without the added safeguard of premarket approval. Therefore, these devices are subject to "premarket approval" under section 515 of the act.

The process of classification is an important component of device regulation, but it includes numerous procedural steps and thus cannot be part of this final rule. Under section 513 of the act, FDA is required to convene or use a classification panel, which should consist of experts who "possess skill in the use of, or experience in the development, manufacture, or utilization of," the device and who provide "adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions" (section 513(b)(2) of the act). The classification panel is required to "provide an opportunity for interested persons to submit data and views on the classification" and, after consideration of these data and views, to submit to FDA its "recommendation for the classification of the device" (section 513(c)(1) and (c)(2) of the act). Upon receipt of the panel recommendation, FDA must publish in the Federal Register "the panel's recommendation and a proposed regulation classifying

such device" and provide interested persons "an opportunity to submit comments on such recommendation and the proposed regulation" (section 513(d) of the act). After reviewing the comments, FDA must classify the device "by regulation" (*Id.*).

As required by section 513 of the act, FDA will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with the procedures in section 513 of the act. Without prejudging that proceeding, the agency recognizes that it will involve consideration of both the known risks of tobacco products and the public health concerns that could be raised by withdrawal from the market of cigarettes and smokeless tobacco to which many adults are addicted. Moreover, the agency's restrictions on access and advertising in this final rule, which are carefully designed to help prevent young people from becoming addicted, will need to be factored in as well.

Consistent with the statute and the agency's normal practice, however, FDA is not postponing regulation of cigarettes and smokeless tobacco under its general authorities pending classification. Such a postponement would serve no useful purpose, because the general authorities will be applicable to cigarettes and smokeless tobacco regardless of the outcome of the classification proceeding. To the contrary, postponing application of FDA's general authorities would have adverse consequences for public health because, during the several years that it may require to complete classification, the applicability of the controls put in place by this final rule, as well as the registration, GMP, and other general controls discussed in this document, would be delayed with respect to cigarettes and smokeless tobacco. During this period, millions of children and adolescents would be likely to use cigarettes and smokeless tobacco for the first time and, in the absence of FDA regulation under its general authorities, become addicted to these dangerous products.

The tobacco industry argues that FDA cannot classify cigarettes and smokeless tobacco because, given "FDA's view of the health effects" of cigarettes and smokeless tobacco, classification would inevitably lead to a ban of the products. According to the industry, FDA cannot classify cigarettes under class I or class II because neither the general nor the special controls will provide what FDA will regard as a reasonable assurance of safety, leaving FDA with only one option: To classify cigarettes and

smokeless tobacco under class III. According to the industry, classifying cigarettes and smokeless tobacco under class III would lead to a ban of cigarettes and smokeless tobacco because FDA cannot grant premarket approval of a class III device until it is satisfied that there is reasonable assurance that the device is safe. The tobacco industry argues that the inability of FDA to classify cigarettes and smokeless tobacco without triggering a ban of the products demonstrates that the act was never intended to apply to cigarettes and smokeless tobacco.

It would not be appropriate for FDA to make a final determination at this time as to whether the application of all appropriate regulatory controls identified in a classification proceeding would result in a reasonable assurance of safety and effectiveness for cigarettes and smokeless tobacco for any users. This determination must await completion of the classification process and of any regulatory steps identified in the classification process (section 513 of the act). Nonetheless, it seems clear that the best public health result is one that prevents access to tobacco products by children and adolescents while allowing their continued availability for adults. Moreover, the agency disagrees with industry comments that argue that it does not have the authority to permit the sale of tobacco products to adults because the agency has found that tobacco products are unsafe.

In considering this issue, the agency reiterates that tobacco products are dangerous. As discussed more fully in section I. of this document and in the preamble to the 1995 proposed rule, cigarettes and smokeless tobacco cause great pain and suffering from illness, such as cancer, respiratory illnesses, and heart disease. More than 400,000 people die each year as a result of tobacco use.²³

If the act required that the agency limit its consideration to the risks of tobacco products, then it could not find that there is a reasonable assurance of safety. To the contrary, tobacco products are unsafe, as that term is conventionally understood. However, as reflected in the act and in judicial decisions, the determination as to whether there is a "reasonable assurance of safety" involves consideration of not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of

²³ "Cigarette Smoking-Attributable Mortality and Years of Potential Life Lost—United States, 1990," *MMWR*, CDC, vol. 42, No. 33, pp. 645–649, 1993.

not permitting the product to be marketed. Thus, section 513(a)(2)(C) of the act declares that, with respect to safety and effectiveness, the agency must “weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use (see also 21 CFR 860.7(d)(1)). According to the legislative history of the Medical Device Amendments, “[t]he reasonable assurance of safety standard] is predicated upon the recognition that no regulatory mechanism can guarantee that a product will never cause injury” because “[r]egulation cannot eliminate all risks but rather must eliminate those risks which are unreasonable in relation to the benefits derived” (H. Rept. 94–853, 94th Cong., 2d sess., 16, 17 (1976); see also *United States v. Rutherford*, 442 U.S. 544, 555 (1979)).

An example of the balancing of risks of using a product against the risks of not using a product can be found in the agency’s approval of a number of drugs used in the treatment of various cancers. These drugs are highly toxic to patients who receive them, and in approving these drugs for chemotherapy, FDA balances the seriousness of the diseases these drugs were intended to treat against the drugs’ toxicity. In cases where the risks of not treating the cancer outweighed the risks of the drugs, FDA has approved these products.

Similarly, in the case of tobacco products, the agency must weigh the risks of leaving cigarettes and smokeless tobacco on the market against the risks of removing these products from the market. For children and adolescents, the serious health consequences of using tobacco products support an approach designed to reduce their use, as all 50 States and many of the tobacco companies themselves recognize. It is also relevant that many children who use tobacco products are in the period of initiation and are not addicted, and thus a prohibition of the sale and promotion to this segment of the population will effectively reduce their use of tobacco products. Although some children and adolescents are addicted to tobacco products, the agency has concluded that the approach that most effectively takes into account the health of young people is one that prohibits the sale and promotion of tobacco products to children and adolescents under 18 years of age.

The issue is more difficult with respect to adults, particularly adults who are addicted to cigarettes and other tobacco products. There are

approximately 50 million Americans who currently smoke and another 6 million who use smokeless tobacco.²⁴ It is particularly relevant that 77 to 92 percent of all smokers are addicted²⁵ and that a substantial number of all users of smokeless tobacco are addicted.²⁶

The agency believes that these factors must be considered when developing a regulatory scheme that achieves the best public health result for these products. The sudden withdrawal from the market of products to which so many millions of people are addicted would be dangerous. First, there could be significant health risks to many of these individuals. Second, it is possible that our health care system would be overwhelmed by the treatment demands that these people would create, and it is unlikely that the pharmaceuticals available could successfully treat the withdrawal symptoms of many tobacco users. Third, the agency also believes that, given the strength of the addiction and the resulting difficulty of quitting tobacco use, a black market and smuggling would develop to supply smokers with these products.²⁷ It also seems likely that any black market products would be even more dangerous than those currently marketed, in that they could contain even higher levels of tar, nicotine, and toxic additives.²⁸

Whether individuals who use these products have an opportunity to make an informed choice is also relevant. Most individuals who use these products begin as children and adolescents, at an age when they are not prepared for or equipped to make a

decision that for many will have lifelong consequences.

In contrast, adults generally have the capacity to make informed decisions. In the case of cigarette and smokeless tobacco, very few adults who have not used tobacco as children and adolescents choose to use these products as adults.²⁹ Unfortunately, for the many individuals who have become addicted, their capacity to choose whether to use cigarettes or smokeless tobacco in large measure no longer exists. Thus, the agency must take their addiction into consideration when developing its regulatory scheme.

Serious health consequences follow both from the option of leaving tobacco products on the market and from the option of banning tobacco products. However, on balance, an approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, while permitting the sale to adults seems most appropriate. It is consistent with the statutory standard of reasonable assurance of safety and is more effective in achieving public health goals than a ban on all tobacco products. Therefore, FDA is adopting this approach in this final rule.

There is also a basis for finding that these products are “effective” for adults who are addicted to tobacco products because such products sustain with great efficacy the individual’s continued need for the active ingredient nicotine. Tobacco products are effective for preventing withdrawal symptoms in individuals addicted to nicotine in much the same way that methadone is effective in preventing withdrawal.

Section 516 of the act supports this analysis. Section 516 of the act is the provision that gives the agency the authority to ban medical devices. Under that provision, the agency “may” ban a device if it finds that the device presents “an unreasonable and substantial risk of illness or injury.” There are two elements of discretion which plainly allow the agency to leave these products on the market—the word “may” which applies to the entire banned device authority; and the standard of “unreasonable * * * risk of illness or injury,” which gives the agency ample discretion to balance the unique circumstances surrounding this product.

²⁴ “National Household Survey on Drug Abuse: Population Estimate 1993,” DHHS, PHS, SAMHSA, Office of Applied Studies, Rockville, MD, Pub. No. (SMA) 94–3017, pp. 89 and 95, 1994.

²⁵ 1996 Jurisdictional Determination, section II(B)(2)(a).

²⁶ *Id.*

²⁷ That a black market and smuggling will occur can be predicted by examining the current situation with illegal drugs in the United States and past experience with prohibition of respect to alcoholic beverages. In both situations, individuals continued using the products. Moreover, in the case of cigarettes, even increased cost due to tax disparities can lead to smuggling and black markets. S. Rept. 95–962, 95th Cong., 2d Sess., (June 28, 1978); Joossens, L., and M. Raw, “Smuggling and Cross Border Shopping of Tobacco in Europe,” *British Medical Journal*, vol. 310, May 27, 1995.

²⁸ Such has been the case with illegally produced alcohol. See “Elevated Blood Lead Levels Associated with Illicitly Distilled Alcohol—Alabama, 1990–1991,” *MMWR*, CDC, DHHS, vol. 41, No. 17, pp. 294–295, 1992; Pegues, D. A., B. J. Hughes, C. H., Woernle, “Elevated Blood Lead Levels Associated with Illegally Distilled Alcohol,” *Archives of Internal Medicine*, vol. 153, pp. 1501–1504, 1993.

²⁹ 1994 SGR, pp. 5, 58, and 65–67.

D. The Fact That the Act's Drug Authorities Authorize the Imposition of Similar Restrictions Supports the Reasonableness of the Restrictions That the Agency Has Imposed

(16) At least one tobacco industry comment argued that the agency's proposed access and advertising restrictions were an affront to "common sense"—i.e., that the types of restrictions the agency had proposed, under the device provisions of the act, went well beyond what the plain language of the act could be read to support. The agency, however, could have chosen to impose similar restrictions using the act's drug authorities. As this section demonstrates, the agency has restricted the marketing of a number of drug products, using the adulteration, misbranding, and marketing provisions governing drug products. That similar restrictions can be invoked under either the act's device authorities or under the act's drug authorities supports the reasonableness of restrictions adopted in the final rule.

As discussed in the 1995 proposed rule and in sections II.A. and B. of this document, cigarettes and smokeless tobacco are drug delivery systems—i.e., they combine a drug component and a device component in a single combination product (60 FR 41314 at 41347 through 41349). As such, cigarettes and smokeless tobacco are subject to regulation under the device provisions of the act, the drug provisions of the act, or a combination of the two. The agency has determined that it should use the act's device authority to regulate these products because the device provisions of the act offer the agency greater regulatory flexibility than do the drug provisions of the act (see section II.B. of this document and the 1995 proposed rule at 60 FR 41314 at 41347 through 41349). However, if there were no device component to cigarettes and smokeless tobacco, or if the agency had chosen to regulate these combination products under the act's drug authorities, the agency nevertheless could have limited the access to and advertising of these products in order to protect children and adolescents.

Although the agency's authority to impose access restrictions on a drug product is not as explicit as it is under the device provisions of the act (see section 520(e) of the act authorizing controls over the "sale, distribution, or use" of a device to protect against a potentially harmful or unsafe use), the agency has in fact drawn from several

statutory sources to achieve some of the same regulatory results for a drug. The agency routinely imposes restrictions to protect against unsafe uses of drug products—even where those uses are otherwise unlawful, wholly irrational, or in contravention of express warnings. From the time of the product's development and manufacture through its retail sale, the agency is authorized to ensure that drug products are neither unsafe, misbranded, nor adulterated. (See sections 201(n), 301, 501, 502, 503 and 505 of the act; *United States v. Sullivan*, 332 U.S. 689, 696 (1948) (Congress intended "to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer").)

Consistent with this broad grant of authority, Congress also authorized the agency to issue regulations for the "efficient enforcement" of the act, such as regulations that set forth the conditions under which a drug must be marketed to ensure that it will not be deemed violative of the act (see section 701(a) of the act (21 U.S.C. 371); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 246 (2d Cir. 1977); and *Pharmaceutical Manufacturers Association v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980) (FDA has broad authority to issue drug regulations reasonably related to the public health purposes of the act, so long as the regulations further congressional objectives evidenced elsewhere in the act)).

With this authority, the agency has imposed restrictions on the advertising, labeling, and packaging of drug products, as well as restrictions on access to drug products, without which the products could not be lawfully marketed. For example, the agency has used its authority to ensure that drug products are not adulterated to require special packaging requirements for over-the-counter (OTC) drugs, to protect against product tampering (see 47 FR 50442 at 50447, November 5, 1982); § 211.132 (21 CFR 211.132)). Thus, the agency has imposed industry-wide packaging requirements to protect against product contamination as well as unintended, unsafe uses of drug products. (Compare § 897.14(d) (prohibiting retailers from breaking open cigarette and smokeless tobacco packages to sell loose cigarettes or smokeless tobacco).)

Similarly, the agency has authority to control carefully the package size of drug products to protect persons who

fail to follow the directions from taking a lethal dose of the product (see 60 FR 52474 at 52491, 52502, and 52503, October 6, 1995, and § 355.20 (21 CFR 355.20) (final monograph setting package size limitations on OTC anticaries drugs to prevent individuals from ingesting an acutely toxic dose)). (Compare § 897.16(b) (setting minimum package size for cigarettes).)

Along the same lines, the agency has used its authority to ensure that drugs are not misbranded to restrict the marketing of certain drug products where consumers simply were unable or unwilling to heed the warnings on these products. In some instances, the agency has banned altogether the marketing of persistently misused drug products. (See, e.g., 47 FR 41716 at 41719, September 21, 1982 (camphorated oil products deemed misbranded because, despite label warnings, consumers continued to misuse the product); 47 FR 34636, August 10, 1982 (proposing withdrawal of all drugs containing phenacetin because of persistent abuse, and associated health risks, despite label warnings contained on those products).) In other instances, the agency has restricted the product to prescription use. (See, e.g., § 250.12 (21 CFR 250.12) (requiring prescription dispensing of OTC stramonium preparations because, despite package warnings, young people continued to abuse and misuse them); § 250.100 (21 CFR 250.100) (switching amyl nitrite inhalant from OTC to prescription dispensing because of persistent off-label use and abuse); see also 60 FR 38643, July 27, 1995 (proposing to restrict ephedrine drug products to prescription marketing because of the illicit use of OTC ephedrine in the manufacture of certain controlled substances).)

Finally, the agency has approved drug products with strict limits on distribution, to ensure that the drug will be safe for use under the conditions, prescribed, recommended, or suggested in the product's labeling. For example, the drug Clozaril® (clozapine), used in the treatment of schizophrenia, can cause the onset of a potentially fatal blood condition, agranulocytosis. However, early detection of agranulocytosis through routine blood testing can substantially reduce the risk of death. FDA, therefore, approved the drug with labeling that provides that the drug is available "only through a distribution system that ensures weekly [white blood cell] testing prior to delivery of the next week's supply of

medication.”³⁰ This labeling was intended to ensure that Clozaril® would not continue to be administered to those for whom it presents an unreasonable risk of harm. The marketing of Clozaril® in contravention of the labeling would result in the product being deemed misbranded and subject to regulatory action. More recently, the agency issued regulations authorizing generally restrictions on the distribution of drug products in instances where “a drug product shown to be effective can be safely used only if distribution or use is restricted * * *” (see § 314.520 (21 CFR 314.520)). (Compare § 897.16 (setting conditions on the manufacture, sale, and distribution of cigarettes and smokeless tobacco); § 897.14(b)(1) (requiring retailers to verify the consumer’s age to ensure that the product will not be used by minors) § 897.16(c)(1) (prohibiting use of self-service displays at retail establishments).)³¹

These examples illustrate how the agency has interpreted sections 501, 502, 503, and 505 of the act (in conjunction with sections 201(n), 301, and 701(a) of the act) as authorizing an array of controls to prevent unsafe uses of drug products. The minimum age

requirement for cigarettes and smokeless tobacco (see § 897.14(a)), and the controls on packaging (see §§ 897.14(d) and 897.16(b) and (d)), vending machine sales (see §§ 897.14(b) and 897.16(c)), and self-service displays (see §§ 897.14(c) and 897.16(c)), follow this same path. Without these restrictions, cigarettes and smokeless tobacco as drug products could be deemed misbranded or adulterated drug products and could present too great a safety risk to be marketed at all.

The final rule also regulates the advertising used to promote cigarettes and smokeless tobacco (see §§ 897.30, 897.32, and 897.34). While the act’s device provisions provide the most direct and extensive basis for regulating the advertising of these products (see section VI. of this document), the drug provisions of the act also would have allowed the agency to regulate the advertising of these products.

Whether a drug is marketed on a prescription basis or OTC, the agency has authority to prohibit advertising that promotes the product for a use for which it would be unapproved or misbranded (see sections 201(n), 301, 502, and 505 of the act; see also § 201.128 (21 CFR 201.128) (advertising of a drug product may be used to establish that the product is being marketed for a use for which it is neither labeled nor approved)). Though the agency generally will defer to FTC with respect to the advertising of OTC drugs (see Food and Drug Administration and Federal Trade Commission Memorandum of Understanding (36 FR 18539, September 16, 1971)), the agency retains authority to take action against an OTC drug that is promoted for an unapproved use. (See § 330.1(d) (21 CFR 330.1(d)) (for an OTC drug to be generally recognized as safe and effective, and not misbranded, the advertising for the drug must not prescribe, recommend, or suggest its use under conditions not stated in the labeling); see, e.g., § 310.519 (21 CFR 310.519) (prohibiting the marketing of any OTC drug that is “labeled, represented, or promoted as an OTC daytime sedative (or any similar or related indication)”.)

The agency also has authority to require that a drug product not be advertised in a manner that would undercut or counteract the product’s labeling, including label-based warnings. (See *McNeilab, Inc. v. Heckler*, Food Drug Cosm. L. Rep. (CCH 1985) (Transfer Binder) ¶38,317, p. 39, 787 (D.D.C. 1985) (while FDA “cannot rely on advertising to make safe [an

OTC] drug which is deemed too dangerous to be sold with label warnings alone,” it would be “proper for the agency * * * to ensure that ads do not undercut otherwise sufficient labeling”); see also 57 FR 13234 at 13237, April 15, 1992 (preamble to Accelerated Approval Regulations discussing requirement of submission of promotional materials to ensure that the drugs approved under this section will not be put to inappropriate or unsafe uses.) And, irrespective of whether a drug is marketed OTC or by prescription, the agency has authority to prohibit the distribution of “false or misleading” product “labeling” (see section 502(a) of the act).

Last, had the agency chosen to use the act’s drug authorities to regulate these products, one possible means of limiting their access would have been to require some form of prescription dispensing. In that case, the agency’s authority to regulate the advertising of cigarettes and smokeless tobacco would be extensive (see section 502(n) of the act; § 202.1 (21 CFR 202.1); § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i))). The agency, for example, has discretion under the act to regulate both the presentation and format of prescription drug advertising. According to the House Conference Report on section 502(n) of the act, Congress contemplated that:

[I]n administering the requirement contained in the conference substitute that advertisements contain brief summaries of side effects, etc., the Secretary under the conference substitute has sufficient discretion to exercise due regard to the size of the advertisement, the need for protecting the public health, and the conditions for which the drug is offered in the advertisement.

(Report of the Committee of Conference, H. Conf. Rept. 2526, 87th Cong. 2d sess., (Oct. 3, 1962) reprinted in 1962 U.S. Code Cong. and Admin. News 2927, 2934 (emphasis added).) Further, the agency may take action against a prescription drug advertisement to the extent it lacks “fair balance” or is otherwise “false or misleading” (see sections 201(n), 502(a), and (n) of the act; § 202.1 (21 CFR 202.1)). Thus, had the agency chosen to regulate these products as prescription drugs, the agency’s existing prescription drug advertising regulations themselves would require significant changes to the content and format of the tobacco industry’s advertising campaigns.

The final concern—had the agency regulated these products as drugs—is whether cigarettes and smokeless tobacco could continue to be marketed to adults. As discussed in greater detail

³⁰ Clozaril® (clozapine tablets) product labeling, Sandoz Pharmaceuticals, March 1994, in Physician’s Desk Reference, 50th edition, p. 2252, 1996.

³¹ “The Federal Food, Drug, and Cosmetic Act provides authority for FDA to restrict the conditions for use, including the channels of distribution and use, of any drug, or withdraw approval of an NDA, if a drug cannot otherwise safely be used” (H. Rept. No. 93-884, 93d Cong., 2d Sess., p.4, 1974, reprinted in U.S. Cong. & Admin. News, pp. 3029-3032). But see *American Pharmaceutical Ass’n v. Weinberger*, 377 F.Supp. 824, 829 (D.D.C. 1974) (striking down an FDA regulation restricting the distribution of methadone), *aff’d per curiam sub nom. American Pharmaceutical Ass’n v. Mathews*, 530 F.2d 1054 (D.C. Cir. 1976). The *American Pharmaceutical Ass’n* case, however, was decided before the emergence of cases such as *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), in which the Court signaled the importance of deferring to an agency’s interpretation of its own statute, provided the interpretation is sufficiently rational. The case also involved some unique circumstances: the agency had withdrawn approval of the NDA for the drug (methadone), but nevertheless permitted the drug to be marketed under a regulation to certain treatment programs and pharmacies. Also, because methadone is a controlled substance within the provisions of the Controlled Substances Act, the district court concluded that issues regarding restrictions on the distribution of the drug were more properly within the jurisdiction of the Department of Justice than FDA. In most other instances, however, where a drug is not subject to the Controlled Substances Act, and where certain marketing restrictions are necessary to ensure that the drug will be used safely and effectively, under the conditions contemplated in a new drug application, the *American Pharmaceutical Ass’n* case is distinguishable.

in section II.C.5. of this document, there are compelling public health reasons for permitting the continued marketing of these products to adults. The same rationale would apply had these products been regulated as drugs. As is the case with respect to devices, there is a basis for concluding that an approach that prohibits the sale and promotion of cigarettes and smokeless tobacco to children and adolescents, yet allows these products to continue to be marketed to adults who are addicted to these products, could be found to be consistent with the statutory standard of "safe" and "effective" under section 505 of the act for these products.

It is, of course, essential to this analysis that the agency's youth access restrictions in new part 897 be implemented. These restrictions are necessary to help ensure that the most alarming safety issue associated with these products will have been contained. Absent these restrictions, the risks associated with the continued marketing of these products, even to adults, may be overwhelming. The close issue of whether the public health is better served by allowing adults to continue to use these products, such that the agency could find that cigarettes and smokeless tobacco are "safe" and "effective," depends heavily on the agency's ability to prevent the most alarming use of these products, namely, use by substantial numbers of children.

Moreover, the approach of allowing the continued marketing of these products to adults, so long as youth access is carefully controlled, would be consistent with the agency's inherent discretion to take enforcement action against some uses of a drug product, but not others. Such an exercise of discretion would be unreviewable (*Heckler v. Chaney*, 470 U.S. 821 (1985)).³²

In resolving that there is a presumption against judicial review of agency determinations not to take enforcement action, the *Chaney* Court reasoned that an agency's nonenforcement policy generally

involves a complex weighing of factors "peculiarly" within the agency's expertise. (*Id.* at 831). These factors include, "whether agency resources are best spent on this violation or another," "whether the agency has enough resources to undertake the action at all," and "whether the particular enforcement action requested best fits the agency's overall policies." (*Id.* at 831–832).

A decision by the agency to focus its resources on youth access to cigarettes and smokeless tobacco involves the same "ordering of priorities"—i.e., the same balancing of agency-specific factors—on which the rule crafted in *Chaney* rests. Thus, were the agency to enforce the act only with respect to the promotion and sale of these products to children and adolescents, such a decision would enjoy the full force of the *Chaney* Court's presumption of nonreviewability.³³

Thus, while the agency finds that cigarettes and smokeless tobacco are more appropriately regulated as restricted devices, as the discussion in section II.C. of this document demonstrates, the agency could have crafted a serviceable regulatory scheme for these products under the drug provisions of the act. Contrary to the comments that have argued that the act is inherently unfit for regulation of these products, or that the agency's proposed restrictions exceeded the common sense boundaries of the act, both the device provisions and the drug provisions of the act provide sound authority for controlling the access to and promotion of these drug delivery devices.

E. Constitutional Issues Regarding Authority

1. Separation of Powers

The doctrine of Separation of Powers refers to the distribution under the Constitution of the Federal Government's powers among the legislative, executive, and judicial

branches. In particular, under this scheme only Congress has the constitutional authority to make law.

(17) Numerous comments by industry, media, and retailer trade associations and by State legislators and individuals argued that FDA's assertion of jurisdiction over tobacco products supersedes Congress' legislative judgment, and, some argued, therefore violates the doctrine of Separation of Powers. The comments contended that Congress has provided statutory authority over tobacco products to the Executive Branch only under the statutes that it has enacted that expressly apply to tobacco products, such as the Comprehensive Smokeless Tobacco Health and Education Act (the Smokeless Act) (15 U.S.C. 4401 *et seq.*) and the Federal Cigarette Labeling and Advertising Act (the Cigarette Act) (15 U.S.C. 1331 *et seq.*) and not at all under the act. The comments cited the history of proposals in Congress further to regulate tobacco products, none of which came to fruition, as evidence that Congress has exercised its legislative will not to act further on tobacco regulation.

The agency does not agree that the rule violates the Separation of Powers Doctrine. The relevant legal standards are set out in *Youngstown Sheet and Tube Co. v. Sawyer*, 343 U.S. 579 (1952), and *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979), which are cited in the comments. Justice Black's opinion for the Court in *Youngstown* stands for the proposition that the Executive Branch may not act unless authorized by the Constitution or by statute to do so. In particular, lacking Constitutional authority, the Executive Branch may act only under the aegis of a statute passed by Congress under its "law making power" (see *Youngstown*, 343 U.S. at 585–586, 589).

Executive Branch agencies frequently act by rulemaking. In *Chrysler*, the Supreme Court considered the prerequisite for an agency's "legislative" or "substantive" rules to have the "force and effect of law" (see *Chrysler*, 441 U.S. at 301–302). "The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes" (*Id.* at 302). Therefore, for legislative rules to have the "force and effect of law," they must be "reasonably within the contemplation of [the statutory] grant of authority" (*Id.* at 306). The "thread"

³² See *Cutler v. Hayes*, 818 F.2d 879, 893 (D.C. Cir. 1987) ("The FDC act imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety or the efficacy requirements of the Act"); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) (FDA's agreement not to take enforcement action against an unapproved product for a period of 18 months was unreviewable); see also *Cutler v. Kennedy*, 475 F.Supp. 838, 856 (D.D.C. 1979) (while FDA may not formally authorize the sale of drugs that it has found do not comply with the safety and effectiveness provisions of the act, the agency may use its enforcement discretion not to move against these unapproved drug products).

³³ In a number of other contexts, the agency has declined to take enforcement action against particular uses of unapproved drug products. Indeed, the agency has on occasion set forth detailed guidelines outlining the conditions under which it will, as a general matter, refrain from taking regulatory action. (See, e.g., FDA Compliance Policy Guide, (CPG) 7132b.15 (stating that pending completion of the OTC Drug Review, FDA generally will not take regulatory action against unapproved or misbranded OTC drugs prior to completion of a final monograph); CPG 7125.06 (setting conditions exempting extra-label use of new animal drugs from regulatory action); Regulatory Procedures Manual 9–71 (setting conditions under which FDA generally will permit the import of small quantities of unapproved drugs for personal use which are not available domestically).)

between the regulations and the statute relied upon may not be “so strained that it would do violence to established principles of separation of powers to denominate the[] particular regulations ‘legislative’ and credit them with the ‘binding effect of law’” (*Id.* at 307–308).

This is not to say that any grant of legislative authority to a Federal agency by Congress must be specific before regulations promulgated pursuant to it can be binding on courts in a manner akin to statutes. What is important is that the reviewing court reasonably be able to conclude that the grant of authority contemplates the regulations issued.

(*Id.* at 308.)

Youngstown therefore requires that FDA act under a statutory grant by Congress, while *Chrysler* demands a “nexus between [FDA’s] regulations and some delegation of the requisite legislative authority by Congress” (see *Chrysler*, 441 U.S. at 304).

As discussed elsewhere in this document, Congress exercised its lawmaking power to provide FDA with the authority to regulate any product that is a drug or device as defined in section 201 of the act. The evidence cited in both the 1995 Jurisdictional Analysis and the 1996 Jurisdictional Determination annexed hereto demonstrates that cigarettes and smokeless tobacco meet the statutory definitions of drug and device. FDA may therefore act to regulate tobacco products, and in doing so, it is acting “pursuant to an express or implied authorization of Congress,” and the executive branch’s “authority is at its maximum * * *” (see *Youngstown*, 343 U.S. at 635 (Jackson, J., concurring)). Moreover, *Chrysler* does not require that the act specifically refer to tobacco products, as the comments suggested (see *Chrysler*, 441 U.S. at 308). In fact, most products regulated by FDA are not specifically referred to in the act. In addition, as discussed in sections X.A. and X.B. of this document, neither the Smokeless Act nor the Cigarette Act precludes regulation under the act of cigarettes and smokeless tobacco as drug delivery devices. FDA’s assertion of jurisdiction over cigarettes and smokeless tobacco is therefore reasonably contemplated by the laws as enacted by Congress. Consequently, in regulating tobacco products under the act, FDA is not asserting the lawmaking power reserved by the Constitution to Congress.

2. Nondelegation Doctrine

The Nondelegation Doctrine, broadly speaking, imposes constraints on Congress’ authority to delegate to others

the legislative power vested in it by the Constitution.

(18) While maintaining that Congress has not granted FDA the authority to regulate tobacco products, an industry comment argued that FDA seeks to assume authority that, under the Nondelegation Doctrine, Congress could not have delegated to the Executive Branch. In particular, the comment argued that the act requires FDA to approve a new drug as safe and effective, or to ban it, and to classify a device into one of three categories in which it will be required to meet conditions that ensure that it is safe and effective. Because FDA proposed to do neither with respect to nicotine and cigarettes and smokeless tobacco, the comment contended, the agency is free to choose any course it wishes; and had Congress delegated to FDA such unlimited authority, it would have violated the Nondelegation Doctrine. The comment can also be read to suggest that, if FDA has the flexibility to regulate medical devices, and in particular tobacco products, as it proposed, then Congress provided the agency without a standard, that is, with too much discretion.

The agency disagrees with this comment. The act, while vesting FDA with broad discretion to regulate foods, drugs, and devices, does so by precisely defining the agency’s jurisdictional ambit in section 201 of the act and by establishing a range of requirements and enforcement provisions—for example, in sections 301, 302, 303, 304, 501, 502, 505, 510, 513, 514, 515, 516, 517, 518, 519, 520, and 701 of the act (21 U.S.C. 331, 332, 333, 334, 351, 352, 355, 360, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, and 371 respectively)—for it to pursue when, in its discretion, *Heckler v. Chaney*, 470 U.S. 821 (1985), it has found the operative facts established by Congress. The act therefore involves no delegation of Congress’ legislative power that violates the Nondelegation Doctrine, as the courts have repeatedly held. (See, e.g., *United States v. Shreveport Grain and Elevator Co.*, 287 U.S. 77, 85 (1932); *United States v. Garfinkel*, 29 F.3d 451, 457–59 (8th Cir. 1994); *White v. United States*, 395 F.2d 5, 9–10 (1st Cir.), *cert. denied*, 393 U.S. 928 (1968); *United States v. 62 Packages, More or Less, of Marmola Prescription Tablets*, 48 F. Supp. 878, 884 (W.D. Wis. 1943), *aff’d*, 142 F.2d 107 (7th Cir.), *cert. denied*, 323 U.S. 731 (1944).)

The Supreme Court has only infrequently invalidated a congressional delegation to the Executive Branch.

(See, e.g., *Panama Refining Co. v. Ryan*, 293 U.S. 388, 418 (1935) (holding statute authorizing the President to prohibit interstate shipment of “hot oil” determined by State law or regulation to be “excess” to be unconstitutional delegation because “Congress left the matter to the President without standard or rule, to be dealt with as he pleased”); *Schechter Poultry Corp. v. United States*, 295 U.S. 495, 541–542 (1935) (reversing convictions for violations of code of conduct for poultry suppliers because “the discretion of the President in approving or prescribing [such] codes, and thus enacting laws for the government of trade and industry throughout the country, is virtually unfettered”).)

More recently, the courts have applied the Nondelegation Doctrine to reach, or require from an agency, a narrow interpretation of a statutory provision that would otherwise be too broad a delegation. (See, e.g., *Industrial Union Dep’t., AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 646 (1980); *International Union, UAW v. OSHA*, 37 F.3d 665, 668–69 (D.C. Cir. 1994); *International Union, UAW v. OSHA*, 938 F.2d 1310, 1316–17 (D.C. Cir. 1991).)

Unlike the statutes under review in *Panama Refining* and *Schechter*, the act sets standards for FDA to follow. The agency need not narrowly interpret the act to avoid an otherwise over-broad delegation, and courts have repeatedly directed that the act be construed liberally in light of its public health purpose (see sections I.B. and II.A. of this document). The agency’s rulemaking with respect to tobacco products is a legitimate application of those standards to the facts before the agency. The agency therefore concludes that neither the act nor this rulemaking violates the Nondelegation Doctrine.

III. Overview of Comments, Smoking Prevalence Rates Among Minors, Scope, Purpose, and Definitions

A. Overview of Comments

From the time the 1995 proposed rule was published on August 11, 1995 (60 FR 41314), until January 2, 1996, the Food and Drug Administration (FDA) accepted public comments. This comment period was the opportunity for the public to speak to FDA about the matter of regulating nicotine-containing tobacco products. On March 18, 1996, the agency reopened the comment period for 30 days to make additional information relevant to this rulemaking available for public comment.

The 1995 proposed rule generated more responses than the agency had received at any other time in its history on any other subject. Altogether, the agency received more than 700,000 pieces of mail, representing the views of nearly 1 million individuals. Most of the submissions were form letters or post cards. The agency identified more than 500 different types of form letters.³⁴ Others were petitions with sometimes hundreds of signatures. More than 95,000 submissions expressed individual comments on the 1995 proposed rule, including more than 35,000 from children who were overwhelmingly supportive. The individual comments included one from an industry trade association which delivered a single submission of some 45,000 pages on the last day of the announced comment period.

As may be expected, comments differed sharply on the overarching issues of whether FDA should regulate cigarettes and smokeless tobacco, and whether the 1995 proposed rule would have the desired effect of reducing the availability and attractiveness of these products to children and adolescents.

Several Government officials commented, including U.S. Senators and Congressmen, other Federal agencies, State governors and legislators, and law enforcement officials. Comments came from every corner of the country. FDA heard from smokers who could not understand why the Government was meddling in their lives, and from smokers who desperately wanted to quit, but could not. It heard from employers and employees in the affected industries, including tobacco farmers, wholesalers, cigarette manufacturers, and even laborers with the lowest paying jobs who feared that they might lose the only jobs they know. The agency even heard from school children who wanted to be protected from tobacco. "It is not fair," wrote one 13-year-old, "that the tobacco companies try to get kids to use tobacco."

Although many of the comments were addressed to specific portions of the tobacco regulation proposal, tens of thousands of letters commented in general. Thousands of general comments supported the rule. Some, like this one, came from surprising sources: "I support regulations restricting the sale, advertising,

promotion and distribution of cigarettes and chewing tobacco. I grow tobacco, but I know it is wrong to sell death. I really feel sorry for people who are 'hooked' on nicotine." Other supporting comments came from more traditional sources, especially the medical and public health communities. One letter from a coalition of medical associations that was addressed to President Clinton said: "We, the undersigned 125 organizations, representing more than 18 million members and volunteers, urge your strong support for Food and Drug Administration actions to protect children and teenagers from tobacco."

Many expressed strong overall opposition to the rule. One comment said: "I am taking the time to write this letter to express my overwhelming dissatisfaction with the action of the FDA in trying to rewrite the Constitution and take control of the Tobacco Industry."

Although many comments opposed FDA's regulation of tobacco products, there was nearly unanimous agreement—even from the tobacco companies and smokers—that children under the age of 18 should not be using nicotine-containing products, either cigarettes or smokeless tobacco. A few children, however, did write that, even if tobacco use is unhealthy, it should still be their choice, even if they are younger than 18. The agency received thousands of general comments about the addictive and harmful consequences of tobacco use, and they called on the agency to act.

A summary of the general issues reflected in the thousands of comments, and the agency's responses, follows:

(1) The agency received several thousand comments stating that FDA should focus on the products it already regulates. In addition, many comments said that FDA should not expand its responsibilities because the agency's resources already are inadequate. Others stated that the regulation of tobacco is a responsibility that Congress has reserved for itself.

In contrast, many supporters of the 1995 proposed rule argued that it was appropriate for FDA to take action on this issue. One woman wrote: "As the Federal agency designed to protect consumers from harmful consumer products, FDA clearly has both the right and the responsibility to take these actions against the most serious health threat to our young people."

The regulation of drugs and medical devices sold through interstate commerce is central to FDA's established role. Based on recently

available information, as stated in section II. and in the 1996 Jurisdictional Determination annexed hereto, FDA has determined that nicotine is an addictive drug, and that cigarettes and smokeless tobacco are drug delivery devices, which are combination products under section 503(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(g)). As such, these products fall within the traditional scope of FDA's jurisdiction. Therefore, by regulating these products, FDA is carrying out its traditional role.

(2) FDA received thousands of comments about how smoking was an issue of free choice for adults. Most of the comments focused either on the ideological issue of freedom to choose anything, even something dangerous, or on related economic issues, such as the freedom to receive discount or specialty tobacco products by mail. Many comments said the Government must not attempt to regulate human behavior, especially for adults, even when there are health consequences. Letters like this were typical: "As individuals we too have been promised the freedom of choice and this should continue to be. I don't want the government regulating my personal freedoms."

Supporters of the rule countered that because nicotine addiction is a pediatric disease, the choice to start smoking is not being made by adults, but by adolescents who constitute a most vulnerable population. Because they are not yet mature individuals, they are not really expressing a free choice, the comments said. In addition, supporters of the rule stated that adolescents, who are so impressionable, are being manipulated by the tobacco companies, especially through advertising, and therefore, are actually being denied a free choice. Instead, the comments urged that adolescents not be allowed to choose something addictive that may damage their health or shorten their lives.

FDA believes that adults should continue to have the freedom to choose whether or not they will use tobacco products. However, because nicotine is addictive, the choice of continuing to smoke, or use smokeless tobacco, may not be truly voluntary. Because abundant evidence shows that nicotine is addictive and that children are not equipped to make a mature choice about using tobacco products, the agency believes children under age 18 must be protected from this addictive substance.

(3) Numerous comments, many from adult smokers, expressed the fear that FDA's true goal is a total ban of all

³⁴ Opponents and proponents of the rule organized letter-writing campaigns. One, a massive tobacco company-orchestrated campaign, generated some 300,000 pieces of mail—nearly half of all of the mail received by the agency on this topic.

tobacco products. Some asserted that the 1995 proposed rule is a prelude to prohibition. One woman wrote: "The most insidious insight into this proposed regulatory act is the Federal Government's thinly veiled motive of the eventual prohibition of tobacco sales in the United States to appease a small minority of fanatical anti-smoking zealots."

FDA strongly disagrees with these comments and reiterates that it has no intention of banning cigarettes and smokeless tobacco. FDA is aware that at least one tobacco manufacturer, in letters sent to its customers encouraging them to submit comments opposing the rule, claimed that the "real agenda is Backdoor Prohibition of all tobacco products." These allegations are baseless and ignore statements made by the President and FDA to the contrary. For example, when the President announced the proposed FDA regulations on August 10, 1995, one reporter asked whether an outright ban would be more logical than a "regulatory partial step." The President replied:

I think it would be wrong to ban cigarettes outright because, number one, it's not illegal for adults to use them * * * tens of millions of adults do use them. And I think it would be as ineffective as prohibition was. But I do think to focus on our children is the right thing to do.

(Transcript, "Press Conference by the President," dated August 10, 1995) The preamble to the 1995 proposed rule expressed a similar view that removing cigarettes and smokeless tobacco from the market would not be in the best interest of public health (60 FR 41314 at 41348 and 41349).

Rather than instituting prohibition, the agency's rule will inhibit the spread of smoking behavior from one generation to the next. As a result, fewer and fewer adolescents will become addicted to nicotine-containing products. As current smokers either quit or die, the total number of smokers will gradually decline as they are replaced by fewer and fewer new smokers. The agency wants to reassure those who fear that FDA is taking the first steps that would lead inexorably to a ban on the sale of these products to those 18 and over that FDA will not ban these products for adults. Thus, any claim that the rule is a prelude to or would lead to prohibition is totally without merit.

(4) FDA received many comments from politicians, industry representatives, and private citizens who argued that the agency does not need to regulate tobacco because the

product is already highly regulated. Many comments observed that all 50 States have passed their own laws prohibiting the sale of tobacco products to minors younger than 18. Comments on existing State enforcement programs primarily came from those opposed to FDA's proposed regulation, including legislators from more than a dozen States. These comments claimed that this should remain a State matter, that State laws are either sufficient or superior to the 1995 proposed rule, that State officials, unlike FDA, are responsive to the concerns of State citizens, and that States and private groups are more responsible and effective than a Federal agency. Comments like this were common: "Many states have strict restrictions on tobacco sales to minors already and in my State (Maryland) these regulations are being enforced with great success."

Many supporters of the 1995 proposed rule, however, pointed out that State rules generally have failed to stop minors from purchasing tobacco products. One individual wrote: "I currently live in a State where there is absolutely no enforcement of the laws banning sales of tobacco to minors," and numerous other comments referred to specific instances in which they said State laws were not observed. A joint letter sent by attorney generals from 25 States, as well as Guam and Puerto Rico, welcomed the 1995 proposed rule, saying:

Although every State bans the sale of tobacco to minors, studies show that children have easy access to tobacco. * * * We believe the proposed rule, which emphasizes reducing access and limiting the appeal of tobacco products to children, should be a crucial component of a national effort by Federal, State and local officials to help our youngest generation of Americans avoid suffering preventable disease and premature death from the use of tobacco products.

Many comments stated that the tobacco industry has in place guidelines to prevent the sale of tobacco products to minors. Said one comment: "I fail to see why the government is so quick to dismiss voluntary action on the part of the industry." Other comments recommended that voluntary education programs aimed at retailers, or, more specifically, at retail sales clerks, would be sufficient. These educational programs would either be based on voluntary efforts by the affected industries or in-house, employee training programs.

Supporters of the rule, however, expressed widespread distrust of the industry and of its promise to use voluntary programs to prevent minors

from smoking. One woman wrote: "Thirty years of experience in compromising with the tobacco industry has proven that the industry can not be trusted. After the release of the Surgeon General's report in 1964, the tobacco industry promised to abide by a voluntary advertising code, but the code was quickly ignored after the threat of government regulation had passed." Another comment said: "When tobacco companies fear government regulation, they often adopt voluntarily the restrictions the government is considering. However, there is no penalty for violating a voluntary guideline. The tobacco industry has a track record that speaks for itself. Please don't play the tobacco industry's game!"

The agency believes that the comments opposing the rule on the basis that the States already have restrictions have misinterpreted its scope and application. FDA, under the act, regulates human and animal drug products, certain foods, and devices that are, or have been in interstate commerce. The fact that these products move across State lines makes their regulation a Federal matter.

Other statutes and regulations provide further evidence that tobacco regulation is not reserved to States. The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 *et seq.*) (Cigarette Act) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 *et seq.*) (Smokeless Act), among other things, place federally-required statements and warnings on cigarettes and smokeless tobacco and require manufacturers to submit reports to the Federal Government. These products are also subject to Federal taxes (see, e.g., 26 U.S.C. 5701) and Federal, rather than State, laws and regulations intended to guard against contraband cigarettes (see 18 U.S.C. 2341 *et seq.*; 27 CFR part 296, subpart F). Thus, tobacco regulation is clearly both a Federal and State matter.

FDA also disagrees with those comments suggesting that States and private groups may be more responsible or efficient than FDA or that FDA may not be as responsive to citizens' concerns. Federal regulation of these products has several significant advantages over State or private group oversight alone; for example, the rule establishes minimum, national standards for the sale and distribution of these products whereas State or private group efforts may be limited to a specific locality or to group members. FDA's regulations also create enforceable obligations whereas private

group efforts, voluntary codes, and industry policies do not.

FDA notes that this regulation does not necessarily preclude States from enforcing their own laws. In fact, under section 1926 of the Public Health Service Act (the PHS Act) (42 U.S.C. 300x-26), States are expected to enact and to enforce laws to prohibit any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under age 18.

Moreover, States may choose to regulate areas that are not addressed in this rule and not authorized by the act, such as requiring licenses for retailers. FDA agrees with the comments from State attorneys general that effective regulation of cigarettes and smokeless tobacco, in order to protect children and adolescents, will involve cooperation and joint efforts by Federal and State officials and FDA's rule will enhance, rather than hinder, State tobacco control efforts.

Moreover, States are not precluded from taking action in areas that are addressed in this rule. Although some of these requirements may be preempted, the State may petition the agency for an exemption from the act's preemptive effect under section 521(b) of the act (21 U.S.C. 360k(b)). A more detailed discussion of preemption can be found in section X. of this document.

Finally, regarding the comments questioning FDA's response to State or citizen concerns, mechanisms do exist for States and individual citizens to seek regulatory action or changes by FDA. FDA regulations permit any person to petition the agency to request an action (such as issuance, amendment, or revocation of a rule), to reconsider an action, or to stay an administrative action (see §§ 10.30, 10.33, and 10.35 (21 CFR 10.30, 10.33, and 10.35)). Less formal mechanisms for communicating with FDA, such as letters or meetings, exist as well.

(5) Many comments opposing this rule argued that the tobacco industry already is intensely regulated, and that more regulation is unneeded and unjustified. One person wrote: "As you know the tobacco industry is already one of the most heavily regulated industries in the United States. Current laws would accomplish the stated objective of the proposed FDA regulations." Others disagreed: "I believe that the tobacco industry has a long, sorry, and cynical record * * *. It is an industry that greatly deserves to be regulated further."

While it is true that production of tobacco products is regulated, and the industry is heavily taxed, virtually none of these measures is aimed at the product's impact on the health of the individuals using them or on public health. FDA regulation of tobacco products is intended to have a completely different effect than any of the rules that currently applies to the tobacco industry. The agency's regulatory effort will attempt to reduce the number of young people who smoke or use tobacco products, consistent with FDA's mission to protect public health by existing laws.

(6) Many comments objected to the 1995 proposed rule, stating that cigarettes and smokeless tobacco are legal products and should be treated like any other legal consumer product.

FDA believes that the comments misunderstand the regulatory basis for the rulemaking. FDA has determined that these products contain both a drug and device component as defined in section 201(g) and (h) of the act (21 U.S.C. 321(g) and (h)), respectively, because the products, and the nicotine in the products, are intended to affect the structure and function of the body. The agency has further determined that these products should be regulated as devices. Thus, the issue is not merely whether the products themselves have been legally marketed, but how they may be most appropriately regulated to protect the public health, given their status under the act and potential to do harm.

(7) Some comments suggested that if the Government begins regulating tobacco, it will soon regulate many other consumer products that are now legal, but judged to be harmful to health, including alcohol and caffeine. They expressed fear that, once FDA begins to regulate one consumer product, it will be obligated to regulate others. Said one man: "The FDA thinks it is being sly by defining cigarettes as 'nicotine delivery devices.' A shot glass must then be described as a device for alcohol consumption. A coffee mug must be a device for caffeine consumption. Will the FDA be regulating my morning coffee by restricting the size of my cup?" Some supporters of the proposed rule said that FDA should regulate some of the other consumer products associated with medical disorders. Wrote one: "Bud frogs are no different than Joe Camel."

FDA strongly disagrees with these comments and believes that the concerns they express are misplaced. In no way does the agency's regulation of

cigarettes and smokeless tobacco as nicotine delivery devices justify or require the regulation of coffee cups and shot glasses.

First, the agency notes that currently it regulates both caffeine and alcohol under the authority of the act. Caffeine naturally occurs in coffee, tea, and other foods. It is also used as an ingredient in soft drinks. The act defines "food" as "articles used for food or drink for man or other animals" (section 201(f)(1) of the act (21 U.S.C. 321(f)(1))). When caffeine naturally occurs in products that are foods, such as coffee, or when caffeine is used in soft drink products in accordance with section 402 of the act (21 U.S.C. 342), the product is a "food" under section 201(f)(1) of the act and thus explicitly excepted from the definition of "drug" in section 201(g)(1)(C) (21 U.S.C. 321(g)(1)(C)). Caffeine used in soft drinks in accordance with section 402 of the act is appropriately regulated as a food under 201(f)(1) of the act. Caffeine is also used as an active ingredient in several products regulated as drugs by the agency, including over-the-counter stimulants, internal analgesics and menstrual discomfort relief products.

Likewise, alcohol is used as an ingredient in products regulated as drugs under the act, including over-the-counter cough and cold preparations. There is no evidence to suggest that the agency's current regulation of these substances is inappropriate or inadequate to protect the public health. Therefore, there is no factual or scientific basis for the agency to change the manner in which these substances are now being regulated.

FDA's attention was drawn to tobacco rather than caffeine and alcohol because of certain fundamental differences among the substances. Nicotine is a highly addictive drug. As discussed in section I.B. of this document, studies estimate that as many as 92 percent of all smokers are addicted to the nicotine in cigarettes. There is no evidence that either caffeine or alcohol pose this kind of health problem. Moreover, cigarettes and smokeless tobacco are dangerous products that are associated with lung cancer, heart disease, and many other serious illnesses and conditions.

Yet these factors only served to draw FDA's attention to the tobacco problem. What ultimately separates caffeine and alcohol from nicotine and tobacco products is that caffeine and alcohol are currently being appropriately regulated as foods or drugs based on their intended use. Nicotine and tobacco products, on the other hand, are drugs

and medical devices, respectively, that, in large measure, are not being appropriately regulated. FDA is moving to correct this situation, and the public health will undoubtedly benefit as a result.

(8) Several comments argued that it is the responsibility of parents and teachers, not the Federal government, to educate young people about cigarette and smokeless tobacco use. Some comments feared that FDA's effort to reduce the use of nicotine-containing cigarettes and smokeless tobacco by youth might interfere with the relationship between parents and their children. Many comments voiced the argument that this rule is a sign of big Government getting in the way of parents educating their children. One comment stated, "This is obviously a case of misplaced priorities * * *. The battle will really be won on the home front. Parental guidance will go a long way in curbing underage smoking."

Other parents, however, were grateful for any assistance they could get to help protect their children from nicotine addiction. One person said: "The parents cannot do it all alone." Furthermore, most parents who submitted comments stated that a strong national approach to reducing these products' accessibility and appeal would reinforce messages that their children get at home. One comment stated, "While I am in no way an advocate of government in my life, this to me is a totally different circumstance * * * children should not be expected to make these choices." One comment from a middle school student said, "Giving school age children the opportunity to purchase things that will endanger them is inexcusable."

The agency recognizes the unique role that parents and teachers have in educating young people and has no intention of intervening in that relationship. Rather, FDA expects the rule to complement parental and educational efforts by reducing the availability and appeal of tobacco products. The preamble to the 1995 proposed rule contained ample evidence as to how these products are easily accessible to and appeal to young people and how a comprehensive approach, aimed at reducing both access and appeal, will be more effective than an educational approach alone. Educating young people about health risks may deter some young people from trying cigarettes and smokeless tobacco, but educating them and simultaneously reducing their ability to acquire the products, as well as reducing the appeal

of the products themselves, will prevent more young people from using the products.

FDA also emphasizes that cigarettes and smokeless tobacco are combination drug-device products that are subject to regulation under the act. Consequently, the rule properly addresses issues relating to the sale, distribution, and use of these products by children and adolescents. The rule does not adversely affect a parent's or teacher's ability to discuss cigarette and smokeless tobacco use with young people.

(9) Comments suggested that, for some, illegal drugs and crime evoke stronger emotions than tobacco use. Many comments stated that the Government, although not FDA specifically, should spend more of its resources on fighting crime instead of trying to regulate a legal product such as tobacco. One of the form letters stated it this way: "Federal dollars would be much better spent addressing inner-city violence, illegal drug sales, and this country's deteriorating education system."

FDA's authority is defined by the act. FDA lacks the authority to help with other social ills such as crime and illicit drug sales.

(10) One comment urged FDA to institute policies that would facilitate "whistleblowing." The comment said that FDA should encourage tobacco company employees to disclose allegedly illegal or dishonest practices.

Any person, regardless of the industry that employs that person, can provide records and information to FDA for law enforcement purposes with the assurance that his or her identity, and the information and records that he or she provides, will not be publicly disclosed. Current Federal statutes and FDA regulations already protect records or information compiled for law enforcement purposes from public disclosure. For example, the Freedom of Information Act exempts law enforcement records and information from public disclosure. FDA's regulations governing public disclosure elaborate on this exemption, stating, among other things, that the agency may withhold from public disclosure records or information compiled for law enforcement purposes to the extent that disclosure of such records or information could reasonably be expected to disclose the identity of a confidential source and information furnished by a confidential source in the case of a record compiled by FDA or any other criminal law enforcement

authority in the course of a criminal investigation (§ 20.64 (21 CFR 20.64(a))).

B. Smoking Prevalence Rates Among Minors

The agency received some comments stressing the importance of accurately measuring youth consumption of tobacco products, reiterating the problem of growing use among young people, and stressing the need to curb such growth to improve health and to reduce the tremendous health care costs attributable to tobacco-related illnesses. However, several disputed the statistics FDA cited on the number of youth smokers and challenged the data sources used. These comments are discussed below.

(11) One comment objected to FDA's description of smoking as a "pediatric problem," arguing that "TAPS II [Teenage Attitude and Practice Survey II] demonstrates that smoking in any meaningful sense is a phenomenon that occurs in the later teenage years, not in the pre-teen or early teen years." It further charged that the agency's use of the term "pediatric" is intended to serve "emotive and/or political purposes, not to describe the problem of underage smoking in scientific or medical terms."

A comment from a public health association, however, cited the TAPS II survey as showing that "the average teen smoker initiates smoking at age 13, and becomes a regular smoker by age 14.5." It also referred to the Center for Disease Control and Prevention (CDC's) 1992 Youth Risk Behavior Survey, which showed "similar patterns of early initiation rates, with smoking initiation rates rising rapidly between 10 and 14 years of age."

The agency maintains its position that smoking is a pediatric disease. It agrees with the comment citing TAPS II and Youth Risk Behavior Survey data showing that the average teen smoker begins smoking in the early teens or even preteens, rather than later years.

Furthermore, the American Academy of Pediatrics' Council on Child and Adolescent Health states that the purview of pediatrics includes the physical and psychosocial growth, development, and health of the individual beginning before birth through early adulthood, and that "[t]he responsibility of pediatrics may therefore begin with the fetus and continue through 21 years of age." This definition of pediatrics obviously includes the age group FDA has targeted to reduce smoking.

(12) One comment from the tobacco industry charged that FDA's assertion

that smoking has increased among 8th- and 10th-grade students ignored CDC's TAPS II data showing that the incidence of underage smoking declined between 1989 and 1993. TAPS II, the comment maintained, showed that "[a]lthough total smoking in the interview sample [1993] has increased as minors have aged since 1989, comparing the results for minors of a given age indicates that the incidence of underage smoking declined between the two surveys" and that "between the two surveys both daily smoking and any smoking in the past 30 days declined among minors."

The introduction to TAPS II stated that its prevalence findings were comparable to or lower than those of other national surveys. It explained that the survey method used in TAPS II, computer-assisted telephone interviews, had several limitations that may have led to the lower estimates. For example, young people may be fearful of disclosing smoking behavior if a parent is present in the room during the telephone interview. Further, telephone interviews do not afford the same opportunity for building a rapport between the interviewer and the respondent as do in-person interviews. As a result, young people being interviewed in this manner may be less likely to disclose their real smoking behavior. For these reasons, the introduction stated, "prevalence estimates from TAPS II may be lower than they would have been had the entire TAPS I cohort been successfully reinterviewed and therefore, should be interpreted with caution."³⁵

(13) One comment challenged FDA's claim that 3,000 young people become new smokers every day. The comment maintained that "the study from which the '3,000 per day' number was derived did not refer to children at all," but to smokers "aged 20 years old" (Pierce et al., 1989) (emphasis from original).³⁶

The agency agrees that the study surveyed individuals who were 20-years-old, although the agency referred to these individuals in essentially the same terms used by the authors of the study—"young persons."

Any potential confusion is mitigated by the fact that subsequent surveys indicate that the vast majority of 20-year-olds begin smoking at a younger age. For example, according to the

Combined National Health Interview Surveys for 1987 to 1988, 92 percent of 20-year-old smokers started smoking by age 18. Taking into account the comment and these data, the agency believes that it is accurate to state that approximately 3,000 young people begin to smoke each day, regardless of whether young people is defined as under 18, or 20 years and under, although the agency would note that of the 3,000 young people who begin smoking each day, 2,722 are under age 18.

C. Scope

Proposed § 897.1(a) would have stated that "[t]his part is intended to establish the conditions under which cigarettes and smokeless tobacco products that contain or deliver nicotine, because of their potential for harmful effect, shall be sold, distributed, or used under the restricted devices provisions of the Federal Food, Drug, and Cosmetic Act." Proposed § 897.1(b) would have stated that "[r]eferences in this part to regulatory sections to the Code of Federal Regulations are to chapter I of Title 21, unless otherwise noted." The final rule is being amended to explicitly state that failure to comply with any applicable provision would render the product misbranded.

The preamble to the 1995 proposed rule stated that "[t]he proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act" (60 FR 41314 at 41322). The preamble stated that "FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products" (*Id.*).

(14) A comment opposing this provision stated that FDA does not have authority to regulate cigarettes under the restricted device (or any other) provision of the act.

The agency disagrees. A full discussion of the agency's authority can be found in section II. of this document.

(15) Several comments supported the provision. Some comments recommended that the scope of the rule should also apply to adult smokers. One comment stated that:

[I]t is evident from the FDCA [the Federal Food, Drug, and Cosmetic Act] that the FDA has clear and unambiguous authority to regulate and restrict the sale of the subject products not only to minors but also to adults, who suffer equally from the mortality

and morbidity effects of the toxic components of cigarette smoke and tobacco.

As discussed in section I.B. of this document, the agency believes that, on balance, it is better for cigarettes and smokeless tobacco to remain available for use by adults.

(16) Several comments urged that the scope should be expanded to include all nicotine containing products, including cigars and pipes. Another comment expressed concern that the sale and use of big cigars and pipe tobacco by youth may be increasing, and therefore recommended that FDA expand the scope "to include all presently marketed nicotine delivery devices," or to "include regular monitoring of youth's use of these products, and should that use increase, provide a means to extend the FDA's rulings to include those products."

Another comment stated that since "federal regulations often take seven to ten years to enact and enforce, it is essential that the regulation be written pro-actively to adequately address the problem at the outset." The comment stated that "[i]t is therefore, important to write regulations to protect the public from all 'nicotine delivery devices' that in the future, might be placed in something other than tobacco" because "[a]ny product containing the addictive substance of nicotine has a future market because of its addictive nature."

Finally, this comment asserted that FDA should broaden the scope of the rule to include all products that deliver nicotine, because the comment stated that smoking mothers are at greatest risk for reproductive hazards, such as low birth weight babies. The comment stated that "[c]onsidering that over 50% of births are unplanned, and that people believe they can always quit smoking, it is too late to avoid damage by smoking mothers by the time they realize they are pregnant."

The preamble to the 1995 proposed rule stated that "[t]he proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act" (60 FR 41314 at 41322). The preamble stated that "FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products" (60 FR 41314 at 41322).

The agency advises that, at this time, there is insufficient evidence of cigar or pipe tobacco use by children and

³⁵ "1993 Teenage Attitudes and Practices Survey, Public Use DataTape," CDC, OSH, p. 3, 1993 (unpublished data).

³⁶ Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, "Trends in Cigarette Smoking in United States: Projections to the Year 2000," *JAMA*, vol. 261, pp. 61-65, January 6, 1989.

adolescents to support the inclusion of cigar, pipe tobacco, or "all presently marketed nicotine delivery devices" within the scope of the final rule (section III.E. of this document).

In response to the comment stating that the agency should monitor youths' use of products such as cigars or pipe tobacco, and that the agency should provide a means to "extend FDA's rulings to include these products," the agency advises that, as stated in the 1995 proposed rule, the objective of the final rule is to meet the goal of the report "Healthy People 2000," by reducing roughly by half children's and adolescents' use of tobacco products. The agency is not asserting jurisdiction over pipes and cigars at this time because it does not have sufficient evidence that these products satisfy the definitions of drug and device in the act. However, the agency will consider any additional evidence that becomes available, including any new evidence that these products meet the statutory definitions as well as evidence that indicates that cigars and pipe tobacco are used significantly by young people.

FDA also disagrees with the comment claiming that Federal regulations take 7 to 10 years to enact and enforce. While it may be true that rulemaking, in general, can be a time-consuming task, the agency can and has taken prompt action to issue rules with significant public health implications. For example, the proposed rule for this final rule appeared in the Federal Register of August 11, 1995 (60 FR 41314). (See also 56 FR 60366 et al., November 27, 1991, and 58 FR 2066 et al., January 6, 1993 (15 months to issue Nutrition Labeling and Education Act regulations); 60 FR 5530, January 27, 1995, and 60 FR 63372, December 8, 1995 (11 months to issue regulations to facilitate communications between FDA and State and foreign governments in order to enhance regulatory cooperation).) If it is necessary to amend this regulation, the agency will also be able to do so expeditiously.

The agency agrees with the comment stating that smoking mothers are at risk for certain reproductive hazards. FDA has chosen to tailor its regulation to address only children and adolescents. However, other agencies within the Department of Health and Human Services (DHHS) have programs that currently address tobacco use by persons of all ages.

FDA, on its own initiative, has revised § 897.1 to simplify and to clarify the scope of the rule. As revised, § 897.1(a) states that part 897 "sets out the

restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine." This sentence is comparable to proposed § 897.1(a), but more accurate because the 1995 proposed rule only referred to FDA's restricted device authority. FDA has also added a new § 891.1(b) stating that "[t]he failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act." This sentence is intended to remind parties that violations of a regulation for a restricted device and other actions relating to the sale of a device may cause a device to be "misbranded" under the act. Proposed § 897.1(b), which would have stated that regulatory references are to title 21 of the Code of Federal Regulations, has been renumbered as § 891.1(c) in the final rule and has not been changed.

D. Purpose (§ 897.2)

Proposed § 897.2(a) would have stated that:

[t]he purpose of this part is to establish conditions for the sale, distribution, and use of cigarettes and smokeless tobacco products in order to: * * * [r]educe the number of people under 18 years of age who become addicted to nicotine, thus avoiding the life-threatening consequences associated with tobacco use and to provide important information regarding the use of these products to users * * *.

The agency has modified the final rule to provide information regarding the use of these products only to users; it has deleted potential users because the final rule no longer includes an education program for young people. Proposed § 897.2(b) stated that this part of the provision is intended to "[p]rovide important information regarding the use of these products to users and potential users." The agency's response to more specific comments follows.

The preamble to the 1995 proposed rule stated that the proposed rule would reduce "the appeal of and access to cigarettes and smokeless tobacco products by persons under 18 years of age," but "would preserve access to cigarettes and smokeless tobacco products by persons 18 years of age and older" (60 FR 41314 at 41322).

This rule is designed to complement the regulations (sometimes referred to as "the Synar regulations") issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) (the SAMHSA rule) implementing section 1926 of the PHS Act regarding the sale and distribution of tobacco products to

individuals under the age of 18. The SAMHSA rule contains standards for determining State compliance with section 1926 relating to the enactment and enforcement of State laws prohibiting the sale and distribution of tobacco products to individuals under the age of 18. Both sets of regulations are designed to help address the serious public health problem caused by young people's use of nicotine-containing tobacco products. By approaching this pediatric disease from different perspectives, these regulations together will help achieve the Administration's goal of reducing the number of young people who use tobacco products by 50 percent.

(17) One comment opposing this provision stated that "it will have little effect on tobacco use by young people, is beyond FDA'S statutory authority, is unjustified as a matter of policy, and would violate the Constitution."

The agency believes that the comment opposing this provision misinterprets § 897.2. This particular provision merely states the purpose of the entire rule and is not intended, in and of itself, to impose any new restrictions. The agency disagrees that the entire rule will have little effect on tobacco use by young people; that it is beyond the agency's statutory authority; that it is unjustified as a matter of policy; and that it violates the Constitution. All of these issues are discussed in detail elsewhere in this document.

(18) Several comments supported the provision, stating that a national policy is essential because State laws are ineffective and inconsistent.

The agency agrees with these comments and advises that the final rule complements the existing efforts by States to enforce restrictions on young people's access to cigarettes and smokeless tobacco. As stated in the comments, all States currently have laws prohibiting the sale of tobacco products to minors. Section 1926 of the PHS Act creates an incentive for the States to reduce the unlawful sales of tobacco products to young people by "requiring States to have in effect laws which prohibit the sale of tobacco products to minors as a condition of receipt of substance abuse grants." This rule would only preempt individual State requirements that are different from or in addition to these regulations (see section 521(a) of the act (21 U.S.C. 360k(a))). Thus, a State restriction on the sale of cigarettes and smokeless tobacco to individuals under the age of 18 will continue to be enforced by the State. (See preemption discussion,

section X. of this document.) While the agency expects the State laws to reduce smoking among young people, those laws unlike FDA's rule, only reduce access and not the appeal of smoking to young people. Thus, the agency believes that the rule will help States achieve their goals under the substance abuse programs.

(19) One comment supporting the provision stated that although the focus of the rule should be on children, "the needs of adult smokers should not be abandoned." Another comment stated that:

Cigarettes and smokeless tobacco products are nicotine delivery devices and they regularly cause addiction in their users. Because addiction often leads to serious illness and death, it is important to reduce the number of people under 18 years of age who become addicted to nicotine. Similarly, it is important to provide accurate information about the use of these products to users and to potential users.

The agency appreciates the comment's suggestion, but advises that, for reasons explained in section I.B. of this document, the final rule focuses principally on children and adolescents.

FDA, on its own initiative, has revised § 897.2 to state that the purpose of part 897 is "to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use." FDA believes this revision is a simpler and more accurate statement of the rule's purpose.

E. Definitions (§ 897.3)

Proposed § 897.3 would have contained definitions for the terms "cigarette," "cigarette tobacco," "distributor," "manufacturer," "nicotine," "package," "point of sale," "retailer," and "smokeless tobacco." The agency received several comments on the definition section of the proposal, regarding either the specific definitions provided or requesting definitions for additional terms. In response to the comments, the agency has clarified several terms, including "distributor" and "retailer," and has modified the term "cigarette" to exclude little cigars.

Proposed § 897.3(a)(3) would have provided a definition of "cigarette" which included the following language, modeled after the definition of "little cigar" contained in the Cigarette act:

(a) *Cigarette* means * * *

(3) [a]ny roll of tobacco wrapped in leaf tobacco or any substance containing tobacco

* * * and as to which 1,000 units weigh not more than 3 pounds.

(20) Several comments supported the inclusion of "little cigars" in the definition of "cigarette" and suggested that the definition be broadened to include other tobacco products as well. These comments argued that all tobacco, including "snuff," chewing tobacco, cigars, and pipes, should be regulated in the same manner as cigarettes, as these products are also nicotine delivery systems. These comments further stated that there is evidence to show that cigar smoking is becoming increasingly popular among young adults and adolescents.

In contrast, several comments from industry indicated that little cigars are unique products which should not be regulated as cigarettes. One comment stated that the agency has no studies to support the inclusion of little cigars in the rule. Moreover, the U.S. Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) submitted a comment opposing the inclusion of little cigars in the "cigarette" definition, as this would require little cigars to be labeled and advertised as a cigarette under the FDA regulations, but taxed and labeled as a "cigar," under the Internal Revenue regulations enforced by BATF.

The agency has decided, based upon the comments and the record of this proceeding, not to include little cigars in the definition of "cigarettes" for the purposes of the regulation. The differences between little cigars and cigarettes are significant—the products are easily distinguishable, taxed at different levels, and marketed to different consumers. Moreover, little cigars are neither advertised extensively nor sold in vending machines. Most importantly, the agency is not currently aware of sufficient evidence of use of little cigars by children or adolescents to support inclusion of such products in the rule. Therefore, FDA has deleted little cigars from the definition of "cigarette" in § 897.3(a). Moreover, FDA will continue to coordinate definitions with BATF as appropriate.

Additionally, FDA has deleted "components, accessories, or parts" from § 897.3(a). The reference to "components, accessories, or parts" was unnecessary because the statutory definition of "device" includes "any component, part, or accessory."

Proposed § 897.3(b) would have defined "cigarette tobacco" as "any loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette." The proposed

definition also would have stated that "[u]nless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco."

(21) One comment by manufacturers of "roll-your-own" (RYO) cigarette tobacco argued that the inclusion of RYO cigarette tobacco under the 1995 proposed rule was arbitrary and capricious, as the agency had no factual information about RYO's composition, marketing, and usage. This comment also asserted that there is no evidence of RYO tobacco usage by minors.

The agency disagrees that the inclusion of cigarette tobacco in the rule is arbitrary and capricious. RYO tobacco is nothing less than cigarettes that have not yet been assembled.

Unquestionably, RYO cigarettes contain tobacco and are smoked. The comment did not challenge the agency's proposed finding that the smoke from RYO cigarettes is inhaled, that the RYO tobacco is processed, and that RYO cigarettes deliver nicotine. Unlike "little cigars," discussed in paragraph 1 of this section of the document, the agency believes that there is no significant difference in the composition of RYO tobacco or in the reason consumers use it (to deliver nicotine) from cigarettes. The agency believes that, because a RYO cigarette is fundamentally the same product as a commercially manufactured cigarette posing the same risks, it should be subject to the restrictions in this rule in order to protect the public health.

Furthermore, it is important to include RYO tobacco because to exclude it would provide a simple and obvious way to avoid the restrictions in this regulation. If such an exception existed, cigarettes could be packaged and sold in such a way as to be considered RYO products. Tobacco companies would then be free to sell these products using all the marketing and promotion techniques currently used for cigarettes, techniques that are particularly successful with young people. An exception so broad would quickly undermine the entire purpose of the rule. Additionally, FDA has made a minor change to § 897.3(b) to have "cigarette tobacco" mean "any product that consists of loose tobacco * * *." The addition of the words "any product" is intended to make § 897.3(b) conform with the format used for other definitions.

(22) In proposed § 897.3(c), "distributor" would have been defined as "any person who furthers the marketing of cigarettes or smokeless tobacco products * * * from the

original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repack or otherwise change the container, wrapper, or labeling of the * * * products.”

Several comments stated that the definition of “distributor” is vague and over broad, because:

[P]ersons ‘who further the marketing of cigarettes or smokeless tobacco’ [may include] literally everyone involved in the production, shipping, advertising, or promotion of cigarettes. Such ‘distributors’ could thus include, for example, cigarette manufacturers and their employees; truckers and shipping clerks involved in the physical movement of the product; advertising agencies; people involved in promotional activities and the manufacture of promotional materials; retailers and their employees; and conceivably even individuals who ‘deliver’ cigarettes to social acquaintances or family members as ‘ultimate users.’ Including such persons and entities within the definition of ‘distributor’ would, in turn, render them ‘responsible,’ * * * for ensuring that the cigarettes the ‘marketing’ of which they ‘further’ comply with ‘all applicable requirements’ of part 897.

(23) One comment suggested that an individual advocating a particular brand of cigarette would fall within the definition of “distributor.”

The agency recognizes the concerns expressed about the proposed definition of “distributor.” Therefore, based upon the comments received, the agency has determined that the definition should be modified to clarify the term. The definition of “distributor” has been modified to mean “any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption.” The term does not include persons who do not manufacture, fabricate, assemble, process, or label a finished cigarette or smokeless tobacco product, and does not repack or otherwise change the container, wrapper, or labeling of the cigarette or smokeless tobacco product, because such persons would be “manufacturers” under § 897.3(d).

Under this modified definition, one who manufactures cigarettes or smokeless tobacco is not considered a distributor, but is subject to the requirements applicable to manufacturers (see § 897.3(d), definition of “manufacturer”). Similarly, one who “sells or distributes the product to individuals for personal consumption” is not a distributor, but is subject to the requirements applicable to retailers (see § 897.3(h), definition of “retailer”).

Furthermore, the modified definition clearly does not apply to advertising agencies. Although advertising agencies may be said to further the “marketing” of a product they advertise, they do not further the “distribution” of that product. As for truckers and other carriers, section 703 of the act only requires “carriers engaged in interstate commerce” and persons receiving or holding devices in interstate commerce to provide access to records showing the devices’ movement or holding in interstate commerce. Thus, such carriers would not be subject to the requirements applicable to distributors under this part.

(24) Proposed § 897.3(d) would have defined “manufacturer,” in part, “as any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.” One comment suggested that this definition be modified to exclude foreign manufacturers and manufacturers of products that make up less than 1 percent of the total U.S. cigarette market.

The agency disagrees that foreign manufacturers and “small” manufacturers should be excluded from the definition. A company that manufactures a small amount of a product is, nevertheless, a manufacturer. Thus, small manufacturers and foreign manufacturers of products marketed in the United States are included in the definition of “manufacturer” and are subject to the provisions of this rule. Furthermore, as discussed in more detail later, FDA regulates devices as a class without making exceptions for small market share.

Additionally, FDA, on its own initiative, has deleted the part of the definition which would have stated that a “manufacturer” “does not include any person who only distributes finished cigarettes or smokeless tobacco products.” FDA believes this text was unnecessary given the definition of “distributor” in § 897.3(c).

Proposed § 897.3(e) would have defined “nicotine” by its chemical formula, 3-(1-Methyl-2-pyrrolidinyl) pyridine, and would have included any salt or complex of nicotine. FDA did not receive any comments that would warrant a change to § 897.3(e), and has finalized this definition without change.

Proposed § 897.3(f) would have defined “package” as a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco

are offered for sale, sold, or otherwise distributed to consumers.

FDA did not receive any comments that would warrant a change to § 897.3(f) but has, on its own initiative, deleted the word “products” from “smokeless tobacco products” to correspond to similar changes throughout the rule.

(25) Proposed § 897.3(g) would have defined “point of sale” to mean “any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco products for personal consumption.” One comment stated that this definition is unconstitutionally vague and over broad, because “a person can ‘obtain’ cigarettes from a social acquaintance or family member * * * in any number of * * * settings.” The comment suggested that “point of sale” be limited to “commercial establishments where tobacco products are sold in arm’s-length commercial transactions.”

The agency agrees that obtaining a cigarette from a social acquaintance or family member should not render the venue of this “transaction” a “point of sale.” However, the agency does not believe that the definition of “point of sale” is vague or overly broad, or that it needs to be modified. The definition, as proposed, makes it clear that “point of sale” does not contemplate venues where cigarettes are lent or offered to social acquaintances or family members. The definition in § 897.3(d) refers to the “location at which a consumer can purchase or otherwise obtain” the product (emphasis added). The term “consumer,” means “a person who buys goods or services for personal needs and not for resale or to use in the production of other goods for resale.”³⁷ Thus, in its normal use, the term “consumer” implies a commercial relationship and precludes the possibility that, for example, the act of providing a cigarette to a travel partner would render the vehicle in which both are traveling the “point of sale” for that product.

(26) Proposed § 897.3(h) would have defined “retailer” to mean “any person who sells or distributes cigarettes or smokeless tobacco products to individuals for personal consumption.” One comment stated that this definition is unconstitutionally vague and over broad, because a “manufacturer or wholesaler that ‘distributes’ complimentary cigarettes to its employees, or to guests at a private function, would be a ‘retailer,’ as would

³⁷ Webster’s New World Dictionary, edited by V. Neufeldt, Third College Edition, Prentice Hall, New York, p. 299, 1991.

be any individual who gives any other individual a cigarette.”

The agency agrees that, although the intended meaning of the term is clear, a “person who * * * distributes * * * [a product] to individuals for personal consumption” may include transactions that the agency does not intend to regulate (i.e., noncommercial transactions). Therefore, the definition is modified to mean “any person who sells cigarettes or smokeless tobacco to individuals for personal consumption.”

Additionally, under § 897.3(h) as revised, a retailer can be any person “who operates a facility where vending machines and self-service displays are permitted under this part.” This change complements a change to § 897.16(c) which permits vending machines and self-service displays in facilities where no person under age 18 is present, or permitted to enter, at any time. The agency addresses § 897.16(c) in greater detail below.

Proposed § 897.3(i) would have defined smokeless tobacco as “any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity.”

FDA did not receive any comments that would warrant a change to § 897.3(i). However, FDA has revised the definition to refer to “any product that consists of cut, ground, powdered, or leaf tobacco * * *.” The agency made this change because the words “smokeless tobacco” are often understood as meaning a “smokeless tobacco product” or products. Additionally, elsewhere in this rule, FDA has replaced “smokeless tobacco product” with “smokeless tobacco.”

(27) Several comments requested definitions for additional terms. Specifically, one comment requested that “advertising” be defined to distinguish between trade and consumer advertising; several comments requested that “vending machine” be defined to exempt machines which dispense cigarettes to cashiers, machines that dispense individual cigarettes, or machines that scan a driver’s license or age of majority card before dispensing cigarettes; and several comments requested that “playground” be defined for clarity.

The agency disagrees that additional definitions are necessary for the terms “advertising” and “vending machine.” However, the agency has clarified the use of those terms in the relevant sections of the preamble. The agency has determined that a definition for the term “playground” is necessary, and has

added some examples to § 897.30. A discussion of the comments regarding the definition of “playground” can be found in section VI. of this document.

IV. Access

Subpart B of part 897 (now retitled as “Prohibition of Sale and Distribution to Persons Younger than 18 Years of Age”) contains the restrictions on access to cigarettes and smokeless tobacco by individuals under the age of 18. This subpart, by imposing restrictions on manufacturers, distributors, and retailers, is intended to ensure that children and adolescents cannot purchase these products.

In support of proposed subpart B, the preamble to the 1995 proposed rule cited studies showing that the majority of junior high and high school students—from 67 percent of 9th grade students in a 1990 survey to 94 percent of junior high and high school students in a 1986 survey—believed that purchasing cigarettes and smokeless tobacco was easy (60 FR 41314 at 41322, August 11, 1995). Other studies supported that belief. As noted in the preamble to the 1995 proposed rule, the 1994 Surgeon General’s Report entitled “Preventing Use Among Young People: A Report of the Surgeon General” (the 1994 SGR) examined 13 studies of over-the-counter (OTC) sales and determined that approximately 67 percent of minors are able to purchase cigarettes illegally. The 1994 SGR examined nine studies and found that the weighted average rate of illegal sales to children and adolescents from vending machines was 88 percent.³⁸

Significant numbers of children and adolescents successfully purchased smokeless tobacco as well, with the success rate ranging from 30 percent for junior high school students to 62 percent for senior high school students (60 FR 41314 at 41322). Ninety percent of smokeless tobacco users in junior high and high school in a 1986 survey said they bought their own smokeless tobacco (60 FR 41314 at 41322).

Studies indicate that a comprehensive approach to reducing young people’s access to cigarettes and smokeless tobacco would be more effective than relying primarily on retailer education programs about the need to prevent sales to underage persons. For example, the preamble to the 1995 proposed rule cited a comprehensive community intervention in Woodridge, IL, involving retailer licensing, regular compliance checks, and penalties for merchant

violations. The Woodridge program reduced illegal sales from 70 percent to less than 5 percent almost 2 years later (60 FR 41314 at 41322). Rates of both experimentation and regular smoking decreased more than 50 percent among seventh and eighth grade students (60 FR 41314 at 41322).

In contrast, another study cited in the 1995 proposed rule indicated that retailer education programs, alone, may have limited utility. In the study, retailers received informational packages on preventing illegal sales to young people, yet despite these informational packages, young people were able to buy cigarettes in 73 percent of the stores that received these informational packages, and, after a comprehensive retailer educational program was conducted, illegal sales were still found to occur in 68 percent of the stores (60 FR 41314 at 41322). When the program began issuing citations to violative establishments, the illegal sales rate dropped to 31 percent (*Id.*). This study, as well as other studies reviewed by the agency in the 1995 proposed rule and made available for public comment and review, led the Food and Drug Administration (FDA) to draft a comprehensive proposal to reduce young people’s access to cigarettes and smokeless tobacco and to make explicit the responsibility of manufacturers, distributors, and retailers to prevent cigarette and smokeless tobacco product sales to persons under 18 years of age.

Subpart B to part 897 consists of four provisions. Section 897.10 establishes the general responsibilities of manufacturers, distributors, and retailers to ensure that the cigarettes and smokeless tobacco that they manufacture, label, advertise, package, distribute, sell, or otherwise hold for sale comply with the requirements in this subpart. The agency made one minor change to this provision, to change “smokeless tobacco products” to “smokeless tobacco.”

Section 897.12 sets forth additional responsibilities of manufacturers. Proposed § 897.12(a) would have required manufacturers to remove from point of sale all violative self-service displays, advertising, labeling, and other manufacturer-supplied or manufacturer-owned items. In response to comments from manufacturers and sales representatives objecting to their responsibility for items not owned by them, the agency has amended this provision to require manufacturers only to remove from point of sale all violative self-service displays, advertising,

³⁸ 1994 SGR, p. 249.

labeling, and other items owned by the manufacturer.

Proposed § 897.12(b) would have required manufacturers' representatives who visit a point of sale in the normal course of business to visually inspect and ensure that products are labeled, advertised, and distributed in accordance with this subpart. In response to comments questioning the need for and operation of this requirement, FDA has deleted this provision.

Section 897.14 sets forth additional responsibilities of retailers. Many of the comments supported the requirements to verify age and to ban the sale of single cigarettes. Comments were divided on the requirement for a direct transaction. The comments opposing the 1995 proposed rule were taken into account in the modifications to the final rule.

The final rule contains a new § 897.14(a), which states that no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. This new paragraph codifies a concept that was implicit in the 1995 proposed rule.

Proposed § 897.14(a) (now renumbered as § 897.14(b)) would have required that the retailer or an employee of the retailer verify by means of photographic identification showing the bearer's date of birth that no purchaser is younger than 18 years of age. In response to changes made to § 897.16 regarding mail-order and vending machine sales and self-service displays in facilities inaccessible to children and adolescents, the final rule excepts the requirements for proof of age under these limited circumstances. New § 897.14(b)(2) eliminates the verification requirement for consumers 26 years of age or older.

Proposed § 897.14(b) (now numbered as § 897.14(c)) would have required that cigarettes or smokeless tobacco be provided to the purchaser by the retailer or an employee of the retailer, without the assistance of an electronic or mechanical device, such as a vending machine. The final provision has been modified to reflect changes made to § 897.16 permitting vending machines and self-service displays in certain limited circumstances and to correspond more closely to the requirements in § 897.16(c)(1).

Proposed § 897.14(c) (now renumbered as § 897.14(d)) would have prohibited the retailer or an employee from opening any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or any quantity of the product that is smaller than the

quantity in the unopened products. In order to clarify the intent of this provision, the final rule prohibits retailers from breaking or otherwise opening "any cigarette or smokeless tobacco product package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use."

The final rule also adds § 897.14(e) to clarify that each retailer is responsible for removing all violative self-service displays, advertising, labeling, and other items located in the retailer's establishment or for bringing those items into compliance with the requirements in this rule. This provision complements § 897.12 which requires manufacturers to remove manufacturer-owned, violative items from retail establishments.

Section 897.16 establishes the conditions of manufacture, sale, and distribution. Proposed § 897.16(a) would have prohibited the use of a trade or brand name for a nontobacco product as the trade or brand name for a tobacco product "except for tobacco products on which a trade or brand name of nontobacco product was in use on January 1, 1995." The only change to § 897.16(a) has been to clarify the agency's intent by amending the language to restrict manufacturers to those product names "whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995."

Section 897.16(b) would have established a minimum package size of 20 for cigarettes. The final rule was amended only to provide a very limited exception consistent with the changes made to § 897.16(c)(2)(ii), discussed below.

Proposed § 897.16(c) would have prohibited vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale and required direct, face-to-face exchanges between retailers and consumers. In response to comments criticizing the restrictions as inconveniencing adults, the agency has amended this section. The final rule allows mail-order sales (except for mail-order redemption of coupons and the distribution of free samples through the mail). The final rule also allows vending machines (even those selling packaged, single

cigarettes), and self-service displays (merchandisers) in facilities that are inaccessible to persons under the age of 18.

Proposed § 897.16(d) would have prohibited manufacturers, distributors, and retailers from distributing any free samples of cigarettes or smokeless tobacco. FDA made one minor change to this provision, changing the words "manufacturers, distributors, and retailers may not distribute" to "no manufacturer, distributor, or retailer may distribute" free samples.

The final rule adds a new § 897.16(e) to prohibit manufacturers, distributors, and retailers from selling, distributing, or causing to be sold or distributed cigarettes or smokeless tobacco with advertising or labeling that does not comply with the rule's advertising and labeling requirements. This provision is intended to clarify that the rule's advertising and labeling requirements are conditions on the sale, distribution, and use of these products.

A. General Comments

The agency received many general comments both in support of and in opposition to proposed subpart B of part 897. Comments supporting the 1995 proposed rule often stated that the rule, if finalized, would help prevent young people from obtaining or using cigarettes and smokeless tobacco and would eventually lead to a healthier population and lower health care costs. The agency also received comments from attorneys general of more than 25 States concluding that, overall, the 1995 proposed rule "should be a crucial component of a national effort by Federal, State, and local officials to help our youngest generation of Americans avoid suffering preventable disease and premature death from the use of tobacco products."

Comments opposing the 1995 proposed rule, in general, asserted that FDA regulation was unnecessary or unauthorized or that the proposed requirements would be ineffective. The following is an analysis of and response to these general comments.

(1) Several comments stated that the 1995 proposed rule violates the Commerce Clause of the Constitution. The comments argued that there is no equivalent to a congressional finding that the regulated activity at issue—the sale of tobacco products to children and adolescents—affects interstate commerce, nor is the regulation reasonably adapted to an end permitted by the Constitution. They argued that the regulation of tobacco products by

the Federal Government is impermissible based on *United States v. Lopez*, 115 S.Ct. 1624 (1995) (Congress lacked power under Commerce Clause to criminalize possession of a gun within 1,000 feet of a school).

The agency disagrees with these comments. The Constitution gives Congress the power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." Under the Commerce Clause, Congress may "regulate those activities having a substantial relationship to interstate commerce, i.e., those activities that substantially affect interstate commerce" (*Lopez*, 115 S.Ct. at 1629–30 (citation omitted)). The Supreme Court has consistently held that Congress acted within its powers under the Commerce Clause when it enacted and subsequently amended the Federal Food, Drug, and Cosmetic Act (the act). (See *United States v. Sullivan*, 332 U.S. 689, 697–98 (1948); *United States v. Walsh*, 331 U.S. 432, 437–38 (1947); *Weeks v. United States*, 245 U.S. 618, 622 (1918); *Seven Cases of Eckman's Alternative v. United States*, 239 U.S. 510, 514–15 (1916); *McDermott v. Wisconsin*, 228 U.S. 115, 128 (1913); *Hipolite Egg Co. v. United States*, 220 U.S. 45, 58 (1911).) Regulation of tobacco products is a legitimate exercise of FDA's authority under the act to regulate drugs and devices and is therefore within the scope of Congress' power under the Commerce Clause.

The Supreme Court's recent opinion in *Lopez* does not affect this analysis. As the Court noted, "[t]he possession of a gun in a local school zone is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce." (See *Lopez*, 115 S.Ct. at 1634; see also *Id.* at 1640 (Kennedy, J., concurring) ("[H]ere neither the actors nor their conduct have a commercial character, and neither the purposes nor the design of the statute have an evident commercial nexus."))

By contrast, this tobacco regulation affects conduct that is distinctly commercial in character. In particular, the access restrictions—the national minimum age for purchase of tobacco products and the restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays—all involve actors (manufacturers, vendors, and consumers) and conduct (the marketing, sale, and purchase of products that are themselves in interstate commerce) that are quintessentially commercial (see,

e.g., *Katzenbach v. McClung*, 379 U.S. 294, 298–304 (1964) (under the Commerce Clause, Congress may regulate activities of restaurants that serve food, a substantial portion of which has moved in interstate commerce)). In addition, the purpose and design of the regulation—to deter this commercial activity directed at persons under the age of 18 in order to reduce addiction to the nicotine in these products—has the requisite commercial nexus. (See, e.g., *Heart of Atlanta Hotel, Inc. v. United States*, 379 U.S. 241 (1964); *Perez v. United States*, 402 U.S. 146 (1971).) Moreover, because youths alone purchase an estimated \$1.26 billion of tobacco products annually, the regulated activity—sales of tobacco products—substantially affects interstate commerce.³⁹

As noted, tobacco products are in interstate commerce as defined in section 201(b) of the act (21 U.S.C. 321(b)). Cigarettes manufactured in the United States include myriad components that are in interstate commerce. For example, American-type blended cigarettes contain oriental tobacco imported from Greece, Turkey, Russia, Yugoslavia, or Bulgaria, and they may also contain imported flue-cured tobacco from, for example, Zimbabwe or Brazil. In addition, they contain other tobacco and tobacco products, filters, paper, ammonia, sugars, humectant, licorice, and cocoa, among nearly 600 other possible ingredients. (See generally Brown, C. L., *The Design of Cigarettes*, Hoechst Celanese Corp., Charlotte, NC (3d ed. 1990); "Ingredients Added to Tobacco in the Manufacture of Cigarettes by the Six Major American Cigarette Companies," (April 12, 1994)). Similarly, smokeless tobacco is made from tobacco grown in Pennsylvania and Wisconsin or in Kentucky and Tennessee and contains other ingredients from a list of over 560, such as sugar, molasses, and licorice, which are in interstate commerce. (See *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General*, DHHS, PHS, p. 5, 1986; "Smokeless Tobacco Ingredient List as of April 4, 1994, attached to letter of May 3, 1994, from Stuart M. Pape to the Hon. Henry A. Waxman and the Hon. Thomas J. Bliley, Jr.)

(2) The comments also suggested that Congress' Commerce Clause powers do not allow imposition of a national

minimum age for the purchase of tobacco products.

The agency disagrees. The cases cited in these comments, *South Dakota v. Dole*, 483 U.S. 203 (1987) and *Oregon v. Mitchell*, 400 U.S. 112 (1970), do not address the Commerce Clause, and there is no case law suggesting that an agency may not impose regulations on commerce based on the age of people involved, under a statute passed pursuant to Congress' Commerce Clause power, and in particular that an agency may not set a national minimum age for sales of cigarettes and smokeless tobacco in order to reduce the risks of addiction and to health associated with their use by individuals under age 18. In fact, under its authority to regulate commerce, Congress may exclude from interstate commerce goods produced by children workers, *United States v. Darby*, 312 U.S. 100, 115–17 (1941) (overruling *Hammer v. Dagenhart*, 247 U.S. 251 (1918), which held that Congress lacked power to exclude products of child labor from interstate commerce), and criminalize, for example, the transportation in interstate commerce of pornography involving children (18 U.S.C. 2251 through 2259), or the sale of firearms and ammunition to individuals under the age of 18 (18 U.S.C. 922(b)(1)).

Moreover, "[t]he authority of the Federal government over interstate commerce does not differ' * * * 'in extent or character from that retained by the states over intrastate commerce.'" (See *Heart of Atlanta Hotel*, 379 U.S. at 260 (quoting *United States v. Rock Royal Co-op., Inc.*, 307 U.S. 533, 569–70 (1939)).) States may set a minimum age for sales of cigarettes and smokeless tobacco, and these products are in interstate commerce (and as devices, are presumed under section 709 of the act to be in interstate commerce for the purpose of jurisdiction under the act). Thus, it follows that the Federal Government may establish a national minimum age for sales of tobacco products.

In summary, the imposition of a national minimum age for purchase of tobacco products and restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays is within Congress' authority under the Commerce Clause.

(3) Several comments argued that the regulation's imposition of a national minimum age for purchase of tobacco products and its restrictions on impersonal sales, sales from opened packages, package size, vending

³⁹ DiFranza, J. R., and J. B. Tye, "Who Profits from Tobacco Sales to Children?" *JAMA*, vol. 263, No. 20, pp. 2784–2787, 1990.

machine sales, and self-service displays violate the Tenth Amendment to the Constitution. In particular, the comments argued that the regulation of tobacco products and decisions about eligibility and maturity are traditionally State functions, and that this fact required Congress to have made it unmistakably clear by statute that it intended FDA to regulate tobacco products.

The agency believes that this regulation does not violate the Tenth Amendment. The Tenth Amendment provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." It follows that, "[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." (See *New York v. United States*, 505 U.S. 144, 156.) Because FDA is acting under the act, which Congress enacted under its Commerce Clause authority, there is no Tenth Amendment violation.

FDA disagrees that regulation of tobacco sales or decisions about eligibility and maturity are traditional State functions. Even if they were, however, that fact would not implicate the Tenth Amendment. "As long as it is acting within the powers granted it under the Constitution, * * * Congress may legislate in areas traditionally regulated by the States" (*Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991)). Because the agency is acting to regulate cigarette and smokeless tobacco sales in order to eliminate the health risks of those products, and is doing so under a statute passed under Congress' Commerce Clause power, these provisions do not violate the Tenth Amendment.

Further, Congress need not make its intention to regulate in such areas "unmistakably clear in the language of [a] statute," *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 65 (1989) (quotations omitted), as suggested in the comments. This requirement only applies to Federal statutes that "go[] beyond an area traditionally regulated by the States" to affect "decision[s] of the most fundamental sort for a sovereign entity," *Gregory*, 501 U.S. 460, because such statutes "alter the usual constitutional balance between the States and the Federal Government," *Will*, 491 U.S. 65 (quotations omitted); see also *Seminole Tribe of Florida v. Florida*, 116 S.Ct. 1114, 1123-1132 (1996) (holding that, even if Congress,

acting under the Commerce Clause, makes its intention to subject unconsenting States to Federal suits by private parties absolutely clear, the Eleventh Amendment bars such suits). Regulation of the sale of cigarettes and smokeless tobacco does not fundamentally affect the States' prerogatives under the Constitution (such as abrogating the States' sovereign immunity), and so Congress need not have made it unmistakably clear by statute that it intended FDA to regulate their sale.

In summary, the agency is imposing a national minimum age for purchase of tobacco products and restrictions on impersonal sales, sales from opened packages, package size, vending machine sales, and self-service displays in order to eliminate the health risks to young people associated with products in interstate commerce. These provisions therefore do not violate the Tenth Amendment.

(4) A comment from an industry trade association stated that the Ninth Amendment to the Constitution is a "barrier to federal laws that would restrict freedom of adults as well as others to use tobacco products." Several comments from adults expressed similar arguments regarding an adult's "freedom" to purchase or use tobacco products.

The agency disagrees that its imposition of a national minimum age for purchase of tobacco products and its restrictions on hand-to-hand sales, sales from opened packages, package size, vending machine sales, and self-service displays impinge on unenumerated rights protected by the Ninth Amendment.

The Ninth Amendment provides that "[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." Although not a source of rights itself, the Ninth Amendment nevertheless "show[s] the existence of other fundamental personal rights" and that 'liberty' protected by the Fifth * * * Amendment[] from infringement by the Federal Government * * * is not restricted to rights specifically mentioned in the first eight amendments." *Griswold v. Connecticut*, 381 U.S. 479, 493 (1965) (Goldberg, J. concurring).

The final rule regulates commercial transactions involving tobacco products to limit young people's access to them. Young people do not have an unenumerated, fundamental right protected by the Constitution to have commercial access to tobacco products.

(See *Bowers v. Hardwick*, 478 U.S. 186, 190 (1986).) Nor does the agency believe that it is merely a specific manifestation of a broader right, *Id.* at 199 (Blackmun, J., dissenting), whether styled as the right to privacy, *Griswold*, 381 U.S. at 484-485, or to be let alone, *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting), or to individual autonomy, *Carey v. Population Services Int'l*, 431 U.S. 678, 687 (1977).

In particular, the right to privacy does not protect commercial access to tobacco products for young people, because restricting sales of addicting tobacco products to young people "is within the area of governmental interest in protecting public health." (See *Rutherford v. United States*, 616 F.2d 455, 457 (10th Cir.), (right to privacy does not include access to laetrile) *cert. denied*, 449 U.S. 937 (1980); see also *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) ("Constitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of government police power"); *United States v. Horsley*, 519 F.2d 1264, 1265 (5th Cir. 1975), (holding that right of privacy does not protect possession of marijuana with intent to distribute) *cert. denied*, 424 U.S. 944 (1976); *United States v. Kiffer*, 477 F.2d 349, 352 (2d Cir.) (same), *cert. denied*, 414 U.S. 831 (1973).) The agency therefore concludes that this rule does not abridge an unenumerated, fundamental right reserved to the people by the Ninth Amendment to the Constitution.

(5) Several comments suggested that comprehensive regulations were unnecessary. Instead, these comments advocated training programs for retailers and, more specifically, for retail sales clerks. These training programs would be based either on voluntary efforts by the affected industries or on in-house, employee training programs. A few comments argued that any regulations to restrict access to cigarettes and smokeless tobacco would be futile because young people "would get the products anyway."

The agency disagrees with these comments. The preamble to the 1995 proposed rule indicated that informational or training programs, alone or without any enforcement mechanisms, have limited success (60 FR 41314 at 41322). Given the health risks caused by or associated with these products and the evidence that current, voluntary restrictions on youth access are ineffective, FDA believes that it

needs to develop an effective, mandatory program under the act to restrict young people's access to cigarettes and smokeless tobacco. The agency cannot and should not abdicate its public health responsibilities in deference to voluntary efforts to inform employees or other parties on the sale and distribution of these products, given the evidence cited in the preamble to the 1995 proposed rule that such programs must be bolstered by government sanctions and measures like those in subpart B of part 897 in order to be effective.

(6) Other comments, particularly those submitted by a few State legislators, claimed that States should be free to allocate their resources as they wished so that, if a State decided not to address a particular issue, such as access to tobacco products, that decision would be within the State's purview.

In contrast, comments submitted by State and local public health officials were unanimous in recommending strong Federal leadership in reducing young people's access to cigarettes and smokeless tobacco.

The agency believes that the comments opposing the rule misinterpret the rule's scope and application. The rule does not require States to enforce any provision, nor does it require States to allocate resources in any manner. FDA will enforce the rule as it does any other rule, by using FDA's own resources or, where appropriate and with cooperation from State officials, by "commissioning" State officials to perform specific functions on the agency's behalf. FDA is authorized, under section 702(a) of the act (21 U.S.C. 372), to conduct examinations and investigations through any health, food, or drug officer or employee of any State, territory, or political subdivision commissioned as an officer of DHHS. In most cases, a commissioned State or local government official is authorized to perform one or more of the following functions: (1) Conduct examinations, inspections, and investigations under the act; (2) collect and obtain samples; (3) copy and verify records; and (4) receive and review official FDA documents.⁴⁰ The scope of the official's authority depends on his or her qualifications, and the commissioning process involves active and voluntary participation by States in identifying suitable candidates for commissioning

and establishing the scope of the commissioned official's duties.

(7) A few comments claimed that the rule would create friction between States and the Federal Government because, according to these comments, FDA would be interfering in State affairs. Some comments also claimed that the rule would make State efforts less effective because State regulatory or police agencies would defer to FDA.

In contrast, as noted above, several State attorneys general expressed a different view, stating that the rule would strengthen State efforts to reduce cigarette and smokeless tobacco use among young people.

The agency respectfully disagrees with those comments that claim FDA will be interfering in State affairs or that the rule will create friction or undermine the effectiveness of State officials. The agency has a history of cooperative relations with State regulatory officials. For example, as mentioned earlier, section 702(a) of the act authorizes FDA to commission State officials to perform specific functions on FDA's behalf. FDA also works with State officials in implementing statutes such as the Prescription Drug Marketing Act of 1987, the Nutrition Labeling and Education Act of 1990, and the Mammography Quality Standards Act of 1992. Given this history of cooperation between FDA and State regulatory agencies, FDA does not agree that the rule will create friction between FDA and State authorities or undermine the effectiveness of State officials.

(8) Many comments argued that the 1995 proposed rule would restrict an adult's ability to purchase or select cigarettes and smokeless tobacco. Several asserted that regulations would be ineffective because young people would obtain cigarettes and smokeless tobacco anyway. Hence, these comments would eliminate all provisions intended to reduce a young person's access to these products.

In contrast, many comments supported the rule, stating that it would reduce a young person's easy access to and opportunity for early experimentation with cigarettes and smokeless tobacco, help reduce the use of those products by young people, and prevent young people from suffering adverse health effects associated with using these products.

The agency agrees that the rule may have an incidental effect on an adult's ability to purchase cigarettes or smokeless tobacco, but FDA emphasizes that the rule's benefits far outweigh any inconvenience to adults. FDA has

narrowly focused the rule to address those activities and practices that are especially appealing to, or used by, young people and to preserve, to the fullest extent practicable, an adult's ability to purchase these products. Any inconvenience to adults should be slight. For example, although the final rule eliminates self-service displays for cigarette packages in facilities that are accessible to young people, the limited amount of time spent in requesting and receiving a cigarette pack from a retail clerk should not result in hardship on adults. The agency has also amended the rule, as discussed in section IV.E. of this document to retain specific modes of sale that are restricted to—or used almost exclusively by—adults. These amendments respond to comments from adult consumers and retailers that young people cannot or do not use certain modes of sale and so those modes of sale should remain available to adults.

(9) Several comments argued that the 1995 proposed rule "intruded" on private life or "discriminated" against adult cigarette and smokeless tobacco users.

In contrast, other comments agreed that FDA has jurisdiction over cigarettes and smokeless tobacco and that the rule was an appropriate exercise of FDA's authority and properly focused on curtailing access by young people. Several comments suggested amending the rule to add restrictions for adults, to ban smoking, or to provide information to help all smokers to stop smoking.

As stated earlier, the agency has drafted the rule as narrowly as possible to restrict the sale and distribution of these products to children and adolescents, while preserving adults' ability to purchase the products.

As for extending the rule to include adults or to ban smoking, FDA declines to adopt the comments' suggestion. As discussed in section III.A. of this document, the President, and the agency in its preamble to the 1995 proposed rule, have stated that removing cigarettes and smokeless tobacco from the market would not be in the best interests of the public health. The agency adheres to this position.

(10) Many comments urged FDA to refrain from rulemaking and instead rely on voluntary, manufacturer-developed or retailer-developed programs, such as "Action Against Access," "It's the Law," and "We Card," to prevent sales to young people. Some would require retailers and their employees to be trained to comply with existing State and local laws. Several large retail

⁴⁰ FDA Regulatory Procedures Manual, DHHS, PHS, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy, Chapter 3, p. 45, August 1995.

chains described the programs they already have in place.

Other comments expressed skepticism about such programs and, therefore, strongly supported FDA's rulemaking activities.

The agency declines to rely solely on voluntary, manufacturer- or retailer-developed programs to prevent sales to young people. The agency is regulating cigarettes and smokeless tobacco as devices under the act. Voluntary programs cannot serve as a substitute for such regulation and do not provide many of the safeguards that the act provides.

As for retailer programs to train employees not to sell cigarette and smokeless tobacco to young people, FDA believes that such training efforts will help retailers comply with their obligations under § 897.14. However, retailer training programs, alone, will not be as effective as the rule's comprehensive approach because such training would not affect certain activities (such as free samples and advertising) that are used by or appeal to young people.

Similarly, voluntary, manufacturer-developed programs are not sufficient to prevent sales to young people. Such programs purport to deter young people from using cigarettes or smokeless tobacco until they reach legal age, but often omit retail activities or impose no sanctions if a voluntary code or provision is violated. For example, one comment supported the rule, in part, because a retailer gave the author, when he was 15 years old, and other children free cigarettes. A manufacturer-developed program might not be effective at curtailing such practices by retailers, whereas the rule bars distribution of free samples by manufacturers, distributors, and retailers.

(11) One comment suggested amending the rule to include advertisers.

FDA declines to amend the rule as suggested by the comment. The agency's authority attaches to the product and those responsible for its manufacture, distribution, or sale in interstate commerce. Advertisers do not have control over the products and presumably act at the direction of manufacturers, distributors, and retailers. If an advertisement violated the requirements of this part, the agency would hold the appropriate manufacturer, distributor, or retailer responsible for the violative advertisement.

(12) One comment argued that cigarettes should be sold by prescription only. Other comments opposing the rule predicted that the agency would require prescriptions.

The agency declines to amend the rule to require prescriptions. Such a requirement would unduly affect adults and retailers and, FDA expects that the more narrowly tailored provisions in subpart B of part 897 will adequately restrict young people's access to these products.

(13) One comment criticized the 1995 proposed rule for not restricting where cigarettes and smokeless tobacco may be sold. The comment said that pharmacies and health care facilities often sell these products and that such sales undermine the credibility of health warnings related to these products. The comment suggested that FDA prohibit "inappropriate places" from selling these products.

FDA declines to amend the rule as suggested by the comment. The agency has no information or criteria that would permit it to determine whether certain places or types of establishments are not "appropriate" for selling cigarettes and smokeless tobacco.

B. General Responsibilities of Manufacturers, Distributors, and Retailers (§ 897.10)

Proposed § 897.10 would have required each manufacturer, distributor, and retailer to be responsible for ensuring that the cigarettes or smokeless tobacco that it "manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale" comply with the requirements in part 897. FDA proposed this provision setting forth these general responsibilities as part of the agency's comprehensive program to reduce young people's access to cigarettes and smokeless tobacco. Through this provision FDA intended to ensure that these products, from the time of their manufacture to the time of their purchase, comply with part 897 and that manufacturers, distributors, and retailers appreciate their roles, and carry out their legal responsibilities to reduce the accessibility and appeal of these products to young people. The final rule retains § 897.10 without any significant changes.

(14) Many comments interpreted proposed § 897.10 as imposing strict liability on manufacturers, distributors, and retailers. Generally, these comments interpreted the 1995 proposed rule as making a party responsible for violations committed by another party, even if the former was unaware that the

violation had been committed by the latter. Some comments asserted that the agency cannot impose such vicarious liability, under these comments' interpretation of *United States v. Dotterweich*, 320 U.S. 277 (1943), and *United States v. Park*, 421 U.S. 658 (1975). One comment acknowledged that proposed § 897.10, when read literally, would not hold parties responsible for acts committed by other parties, but nevertheless claimed that, despite such language, FDA would hold manufacturers, distributors, and retailers liable for any action committed by any party.

The agency believes that the comments have misinterpreted § 897.10. Section 897.10 holds manufacturers, distributors, and retailers responsible for their own actions; it does not require any party to ensure that another party complied with the regulations, nor does it hold a party responsible criminally or civilly for actions that it did not commit or about which it had no responsibility under the act and no knowledge. This is the most logical and straightforward interpretation of § 897.10, and, as stated earlier, the provision states that "each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes and smokeless tobacco it manufactures, labels, advertises, packages * * * comply with all applicable requirements under this part" (emphasis added). The word "it" refers to the individual manufacturer, distributor, or retailer, while the word "applicable" signifies that a party, depending on the circumstances, is subject only to those requirements for which that party is responsible. This issue is discussed in greater detail later in this section of the document.

In determining which party may be responsible for a regulatory violation, FDA will examine where and when the violation occurred. For example, § 897.14(d), among other things, prohibits retailers from opening any cigarette package and selling individual cigarettes. If a retailer, on its own initiative, opened a package and sold single cigarettes, without the knowledge of a manufacturer or distributor, only the retailer would be responsible because only the retailer engaged in actions that violated the requirements in this part. However, if the manufacturer or distributor supplied single cigarettes to the retailer—contrary to § 897.16(b) which establishes a minimum package size for cigarettes—and the retailer sold the single cigarettes, or if the manufacturer or distributor knew or had reason to know that the retailer sold

single cigarettes and continued to provide cigarettes to the retailer, the manufacturer or distributor, as well as the retailer, would be subject to regulatory action. The manufacturer or distributor would have violated § 897.16(b) and assisted in violating § 897.14(d), while the retailer would be in violation of § 897.14(d). In sum, each manufacturer, distributor, and retailer is responsible for ensuring that its products (whether it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds them for sale) comply with all requirements applicable to it and its products. As such, § 897.10 does not create the problems that the comments suggested it does.

(15) Several comments objected to proposed § 897.10 because it would have each manufacturer, distributor, and retailer responsible for ensuring compliance with the regulatory requirements in part 897. These comments interpreted the provision as having the affected industries, rather than Federal or State Governments, determine compliance. One comment also asserted that the imposition of such responsibility on private persons is a violation of the Due Process Clause of the Fifth Amendment, which prevents unreasonable delegations of governmental authority. Several comments added that manufacturers, distributors, and retailers should not “spy” on each other to ensure compliance. One comment said that the rule would create a “hidden enforcement tax.”

FDA believes that the comments objecting to § 897.10 have misinterpreted its application. Section 897.10 does not make manufacturers, distributors, or retailers solely responsible for ensuring compliance with the regulations nor does it alter or affect any Federal or State enforcement mechanism. Section 897.10 is intended to remind manufacturers, distributors, and retailers that they are responsible for complying with the regulations that are applicable to them. FDA remains primarily responsible, as it does for most FDA regulations, for determining whether parties comply with the regulations. States, of course, remain free to enforce applicable State laws relating to these products.

(16) One comment asserted that proposed § 897.10 would impose vicarious liability in violation of the Eighth Amendment’s Excessive Fines Clause.

As previously discussed, § 897.10 does not impose the sort of vicarious

liability on manufacturers or distributors that the comments suggested it does. The Excessive Fines Clause of the Eighth Amendment states that “excessive fines [shall not be] imposed.” Here, neither § 897.10 nor any other provision of the final rule imposes an excessive fine or any fine at all. Moreover, whether a fine is excessive in a particular case requires a close analysis of the facts of that case. (See, e.g., *United States v. One Parcel Property Located at 427 and 429 Hall Street, Montgomery, Montgomery County, Alabama*, 74 F.3d 1165, 1170–73 (11th Cir. 1996) (adopting and applying proportionality test to *in rem* civil forfeiture); *United States v. Chandler*, 36 F.3d 358, 365–66 (4th Cir. 1994) (adopting and applying three-part instrumentality test to *in rem* civil forfeiture) *cert. denied*, 115 S.Ct. 1792 (1995).)

(17) A few comments implied that manufacturers should be excluded from § 897.10, stating that retailers, rather than manufacturers, should be responsible for preventing sales to young people.

The agency declines to amend the rule to exclude manufacturers. The preamble to the 1995 proposed rule demonstrated how certain practices by manufacturers, such as the distribution of free samples, offer young people easy and inexpensive access to cigarettes and smokeless tobacco. (See 60 FR 41314 at 41326 (free samples).) FDA received several comments that reinforced these views, such as comments from a 12-year old recounting how his classmate acquired free cigarettes from a manufacturer, and a mother whose 14-year old daughter and friends attributed their cigarette use to free samples obtained from manufacturers. Thus, manufacturers play a critical role in making cigarettes and smokeless tobacco accessible and appealing to young people.

In addition, because cigarettes and smokeless tobacco are products subject to the act, regulation of these products properly follows them from the time of their manufacture to their sale to the consumer. Focusing solely on the sale of these products to consumers would deprive the agency of any ability to address problems that may exist at the manufacturer or distributor level. For example, if products were incorrectly packaged or labeled, a rule that concentrated solely on retail sales might permit FDA to restrict sales of those products, but might not permit FDA to require the manufacturer to package or label those products correctly.

(18) Two comments would amend the rule to exempt manufacturers that had 1 or 2 percent of the cigarette or smokeless tobacco product market. One comment came from an association of specialty tobacco companies that either manufacture or import specialty cigarettes and other tobacco products. The comment claimed that specialty cigarettes account for a very small fraction (approximately 400 million cigarettes) of the total cigarettes market, are sold at higher retail prices compared to domestic cigarettes (from \$1.75 for 10 Indonesian cigarettes to \$4.00 for 20 German cigarettes), and are sold in shops that young people normally do not frequent. The comment also stated that the rule would have an adverse effect on foreign products (particularly products in packages containing less than 20 cigarettes), that the companies had little control over foreign manufacturers, and that companies would go out of business or be adversely affected by the rule. The comment sought an exemption either for firms or brands that have 1 percent or less of the total cigarette market in the United States. The comment explained that an exemption would be equitable because, the comment asserted, there is no evidence that specialty cigarettes contribute to underage smoking, and would also be consistent with an exemption granted by the Federal Trade Commission (FTC) for rotating cigarette label warnings and regulations by the U.S. Department of Agriculture (USDA) defining a “domestic manufacturer of cigarettes” for assessing payments under the Agricultural Adjustment Act of 1938.

The other comment came from a firm whose sales focused primarily on smokeless tobacco, with the remainder devoted to cigars and “smoking tobaccos.” The company said that it had approximately 1 percent of the smokeless tobacco market and is the sixth largest smokeless tobacco product manufacturer. The comment sought an exemption for companies with market shares under 2 percent because it claimed the rule would “sound the death knell” for small, family-owned businesses.

Both comments indicated that 80 to 90 percent of their sales occurred through the mail.

The agency declines to accept the comments’ suggestions to create an exemption based solely on market share. The agency believes that subjecting similar or identical products to the same statutory and regulatory standards is both practical and fair to manufacturers

and consumers. A consumer should be able to expect that similar or identical products made by different manufacturers will be regulated in the same fashion. Similarly, manufacturers will not be unfairly advantaged or disadvantaged if they are all subject to the same statutory and regulatory requirements. For example, the final rule prohibits the distribution of free samples. This restriction applies regardless of a manufacturer's market share and, aside from eliminating a free source of cigarettes and smokeless tobacco that people use, also treats manufacturers equally.

FDA is not persuaded by one comment's suggestion that an exemption would be consistent with actions taken by other agencies. FTC's exemption is based on statutory language at 15 U.S.C. 1333(c)(2)(A)(i) and is limited to changes in the label rotation sequence; in other words, the exemption does not relieve the manufacturer from placing warning statements on its packages. USDA's regulation pertaining to "domestic" manufacturers is based on statutory language at 7 U.S.C. 1301(b)(17) as part of the Agricultural Adjustment Act of 1938 that was designed, among other things, to create an incentive for domestic manufacturers to use domestic tobacco leaf. Thus, neither the FTC nor USDA statutes or regulations were intended to relieve foreign products from substantive requirements or to regulate foreign manufacturers.

As for the comments' assertions that their products are either not used by or accessible to young people, the agency has amended the rule to permit specific modes of sale, including mail order sales, that young people cannot or do not use. The agency did not amend the rule, however, to exclude cigarettes and smokeless tobacco or brands that young people do not appear to use or purchase. It would be inappropriate to exempt a particular brand or specialty product simply because a manufacturer claims young people do not purchase that product. (The agency also notes that the \$1.75 price charged for 10 Indonesian cigarettes is lower than the price charged for some domestic brands and creating an exemption for a low cost cigarette product in a "kiddie pack" size would be contrary to the rule's purpose.)

Additionally, FDA traditionally classifies, as a group, device products that are sufficiently similar so that they can be considered the same type of device for purposes of applying the regulatory controls in the act (see

§ 860.3(i) (21 CFR 860.3(i)) (definition of "generic type of device"), using the cumulative evidence from several manufacturers. Reclassification of one product of a particular type results in the reclassification of the entire group. (See 42 FR 46028, September 13, 1977; and 43 FR 32988 July 28, 1978.) The alternative would require FDA to classify individually each manufacturer's device, and to undertake the classification process whenever a new manufacturer marketed a product within an already identified device type. Thus, FDA applies the same regulatory requirements to all devices within an identified device type that are substantially equivalent to one another. This approach is necessary to provide similar regulatory treatment for essentially identical products of different manufacturers and distributors (42 FR 46028 at 46031; and 43 FR 32988 at 32989).

Additionally, assuming that the rule effectively restricts a young person's access to cigarettes and smokeless tobacco, it is reasonable to assume that a young person would turn to alternative products, such as foreign cigarettes that the comment would exempt. Consequently, the agency declines to exempt products with small market shares from the rule.

(19) FDA received several comments from wholesalers or distributors arguing that they should be exempt from the 1995 proposed rule, particularly proposed § 897.10, because they are unable to affect the actions of manufacturers and retailers. Several comments asserted that wholesalers and distributors are "merely a conduit" for transferring products from manufacturers to retailers and have small staffs that would be unable to comply with all requirements in part 897. According to these comments, a wholesaler or distributor would either have to hire additional staff to ensure that products complied with all applicable requirements or be without sufficient staff to ensure that all products supplied to all retailers complied with the regulations. Several comments added that requiring wholesalers and distributors to maintain records, submit reports to FDA, and be subject to inspection by FDA would waste the wholesaler's or distributor's resources and provide FDA with little or no useful information. A minority expressed confusion as to their obligations if they relabel cigarettes or smokeless tobacco.

The agency believes that the comments misinterpret § 897.10. The

provision states that a distributor would be responsible for ensuring that the cigarettes or smokeless tobacco that *it* manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale complies with all *applicable* requirements. For example, the reporting requirement in proposed § 897.40 was directed at manufacturers. Consequently, distributors would not have been required to submit reports to FDA under § 897.40. (Moreover, as discussed in section VIII. of this document, FDA has deleted § 897.40 and exempted distributors from the registration and listing requirements in part 807. Distributors are, however, subject to other reporting requirements, such as medical device distributor reports under part 804.) However, if a distributor acts in a manner that is outside the definition of distributor in § 897.3, it may alter its regulatory status and become subject to other provisions in this part. For example, a distributor who relabels cigarettes would, for those relabeled products, become a "manufacturer" under this rule and be subject to those provisions pertaining to manufacturers. Section 897.3 defines a manufacturer, in part, as any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels finished cigarettes or smokeless tobacco.

(20) Several comments would exempt distributors from the rule because, the comments claimed, the 1995 proposed rule set forth little or no evidence to justify regulating distributors.

FDA declines to exempt distributors from the rule. The agency reiterates that it is regulating cigarettes and smokeless tobacco under its drug and device authority, and that, as it does for other FDA regulated products, FDA's rule follows the products from the time of their manufacture to the time of their sale. Wholesale or distribution operations must be included in any effective regulatory system because products can be contaminated, diverted into illegal channels, or otherwise adulterated or misbranded at the wholesale or distribution level just as they can at the manufacturing and retail levels.

(21) Many comments asserted that, rather than impose responsibilities on manufacturers and distributors, FDA should limit the rule to requiring that retailers verify the age of persons purchasing cigarettes and smokeless tobacco. These comments claimed that no other regulatory provisions would be necessary if retailers, or their sales clerks, verified the purchaser's age.

FDA declines to exclude manufacturers and distributors from the rule. As stated earlier in section IV.B. of this document, cigarettes and smokeless tobacco are products subject to regulation under the act, and, as a result, the rule follows the products from the time of their manufacture, through storage and distribution, to product sale at the consumer level. Excluding manufacturers and distributors would compromise FDA's ability to ensure that these products are not accessible or appealing to young people. Manufacturers engage in activities, such as advertising, labeling, and distributing samples, that make cigarettes and smokeless tobacco accessible and/or appealing to young people. Distributors channel products from manufacturers to retailers, and so the rule includes distributors to ensure, among other things, that the products do not become adulterated or misbranded while held by distributors.

(22) FDA received many comments from retailers stating that FDA regulation was unnecessary because retailers train their staffs to request proof of age or have taken other steps to prevent sales to young people.

The preamble to the 1995 proposed rule provided reasons for not relying on retailer training programs alone. The preamble to the 1995 proposed rule cited a report by 26 State attorneys general stating that industry training films and retailers' programs have not, on their own, prevented illegal sales to young people and that, in some retail sectors, high employee turnover rates complicated training efforts (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also cited studies showing that significant numbers of young people are not asked to verify their age when purchasing cigarettes or smokeless tobacco and that, in some cases, retail clerks even encouraged the young person's purchase by suggesting cheaper brands or offering to make up the difference in the purchase price if the young person lacked sufficient funds (60 FR 41314 at 41323). FDA received some comments that further illustrated the ease with which young people can purchase these products; for example, one comment reflected on the author's own practice, at age 11, of purchasing cigarettes by saying "They are for my Mom." Thus, while training retail clerks to request proof of age should help curtail a young person's access to cigarettes and smokeless tobacco, the reports and studies cited in the 1995 proposed rule, as well as the personal experiences reflected in some

comments, suggest that additional measures are necessary to reduce a young person's access to these products.

(23) Several comments from retailers claimed that the 1995 proposed rule violated their "right" to sell products or arrange their stores in any manner they wished. Many comments added that, if retailers are subject to the rule, many retailers will lose sales and fees associated with cigarettes and smokeless tobacco and could be forced to fire staff. One comment further stated that this would actually harm young people because the retailer would fire its newest staff, and such staff employees are usually young people. Conversely, some comments claimed that, in order to comply with the rule, retailers would be obliged to hire additional staff.

In contrast, FDA received two comments denying that retailers would lose slotting or promotional fees. (Some manufacturers pay retailers to display their products (often referred to as "slotting fees") in a specific fashion or to display signs or other materials provided by the manufacturer.) One comment, based on experience in an area in northern California where self-service displays were prohibited, stated that retailers did not suffer significant economic losses after the displays were banned. Another comment opined that manufacturers would still have an incentive to offer slotting fees or allowances to retailers to ensure advantageous placement of their products behind the counter.

FDA disagrees with the comments asserting an unrestricted "right" to sell products. Section 520(e) of the act (21 U.S.C. 360j(e)) states, in part, that the agency may require that a device be restricted to sale, distribution, or use upon such conditions as the agency may prescribe by regulation. Because FDA has determined that these products should be regulated as restricted devices, the act authorizes FDA to impose controls on their sale and distribution. The agency further notes that, in addition to restrictions authorized under the act, other consumer products are sold subject to various restrictions. For example, under 23 U.S.C. 158(a)(1), the "national minimum drinking age" is 21 years, and the Secretary of Transportation is authorized to withhold certain highway funds from States that have a lower minimum age. Federal law expressly prevents licensed importers, manufacturers, dealers, and collectors from selling firearms and ammunition to any individual that the licensee knows or has reasonable cause to believe to be

under 18 years old (except in specific, limited cases), or, if the firearm is not a shotgun or rifle, prohibits sales to individuals under 21 years of age (18 U.S.C. 922(b)).

Thus, there is no unfettered or unrestricted "right" to sell consumer products. Instead, products are often sold subject to conditions or restrictions, including those based on age, that are designed to protect the integrity of the product, to protect users or other members of the public, or to prevent the product from reaching certain groups of people.

FDA also disagrees with those comments predicting that the rule will result in lower sales and fees and compel retailers to lay off staff. Insofar as retailers are concerned, the rule does not affect sales to adults. It is intended to eliminate illegal sales to young people. Thus, for a retailer to assert that the rule will reduce its sales revenue so much as to require staff reductions, illegal sales would necessarily have to play a significant role in funding staff positions.

With respect to fees, the agency cannot determine whether manufacturers will discontinue paying slotting fees or other allowances to retailers as a result of the rule. The preamble to the 1995 proposed rule did estimate that industry promotional allowances totaled approximately \$1.6 billion in 1993, or \$2,600 per retailer if the sum is evenly distributed among the estimated 600,000 retail outlets (60 FR 41314 at 41369). FDA does note, however, that some comments supported the agency's position that retailers will not suffer significant economic losses. One study cited in the preamble to the 1995 proposed rule stated that, "in the absence of advertising and promotion outlets * * * the cigarette industry may be expected to provide greater incentives to retailers to provide more and better shelf space for their brands in order to provide availability to the buyer in the store" (60 FR 41314 at 41369). Thus, while some manufacturers might stop paying slotting fees, others might continue paying those fees or even increase the fees to obtain favorable placement of their products behind the counter.

Furthermore, as described in greater detail in section IV.E.4.b. of this document, FDA has amended the rule to permit self-service displays (or, more specifically, merchandisers) in facilities that are inaccessible to young people.

As for those comments stating that retailers would have to hire additional staff, it is possible that some retailers

who have relied on modes of sale that the rule will now prohibit or restrict may need to hire additional staff. For example, if a retailer derived a substantial portion of its revenue from vending machines and those machines would not be available under the rule, the retailer might decide to hire staff in order to continue selling cigarettes or smokeless tobacco. However, the comments did not provide sufficient information to enable FDA to determine the number of retailers who might be affected or the extent to which they might be affected.

(24) A few comments challenged the validity of the 1995 proposed rule because it did not impose responsibilities on young people who purchase cigarettes and smokeless tobacco. These comments claimed that omitting young people from the rule, while requiring retailers to comply, was unfair, arbitrary, and capricious. One comment stated, "any effective public policy to restrict sales of tobacco products to minors must go beyond the discouragement of promotion, advertising and merchandising to minors. It must be accompanied by realistic penalties for minors who purchase and possess cigarettes and for adults who purchase for them."

It would be inappropriate for FDA to amend the rule to impose penalties or sanctions on young people who purchase or possess cigarettes or smokeless tobacco or adults who purchase such products for young people. The main focus of the act is on the introduction, shipment, holding, and sale of goods in interstate commerce. Thus, the actions of minors who purchase cigarettes and smokeless tobacco are appropriately a matter for State or local law.

(25) One comment stated that FDA should prohibit young people under 18 years of age from selling tobacco products.

The agency declines to amend the rule to place age restrictions on those who sell these products. FDA has little evidence to suggest that manufacturers', distributors', or retailers' young employees play a significant role in making cigarettes and smokeless tobacco accessible or appealing to young people. Although some evidence indicates that, in certain settings, a young employee might be less likely to check age or to challenge his or her peers (as in situations where the young employee distributed free samples (60 FR 41314 at 41326)), other provisions in this subpart, such as the elimination of

free samples, should reduce the need to place age restrictions on employees.

The agency does note, however, that in response to comments requesting that vending machines and self-service displays be permitted in "adult-only" facilities, FDA has amended the final rule to allow vending machines and self-service displays in facilities that are totally inaccessible to people under 18 and employ no persons below age 18. This is to ensure that an "adults-only" facility is truly restricted to adults rather than to create an age restriction on sellers. These changes to the rule are described in greater detail elsewhere in this document.

The agency is aware that several local governments have statutes or regulations that establish minimum age requirements for persons who sell tobacco products. Because this rule does not contain a minimum age requirement for persons who sell these products, those statutes or regulations are not preempted. The rule's preemptive effect on other State or local statutes or regulations and federalism issues are discussed elsewhere in this document.

(26) Several comments suggested that, instead of issuing regulations, the Federal Government should transfer funds to States for use in preventing cigarette and smokeless tobacco sales to young people.

FDA must decline to accept the comments' suggestion. Federal funding of State prevention efforts is beyond the scope of the rule. The agency does intend to work with State officials and cooperate in enforcement activities where appropriate and to the extent that its resources permit.

(27) Several comments suggested that FDA amend the rule so that the restrictions on the sale and distribution of cigarettes and smokeless tobacco do not apply to locations where young people do not enter or where entry is restricted, such as bars, liquor stores, factories, and prisons.

After consideration of these comments, the agency has amended the rule to allow certain retail practices to continue because those practices are not used by young people or are inaccessible to them. For example, the final rule permits mail-order sales to occur because the evidence does not establish that young people use mail-order sales to acquire these products. The final rule also permits vending machines and self-service displays (merchandisers only) to be used in locations where young people cannot enter, such as locations where proof of age is required in order to enter the

premises or facilities that employ only adults. These changes are described in detail in the discussion of § 897.16 and elsewhere in this document.

C. Additional Responsibilities of Manufacturers (§ 897.12)

1. Removal of Manufacturer-Supplied or Manufacturer-Owned Items That Do Not Comply With the Regulations

Proposed § 897.12(a) would have required manufacturers, in addition to their other obligations under part 897, to remove, from each point of sale, "all self-service displays, advertising, labeling, and other manufacturer-supplied or manufacturer-owned items" that do not comply with the requirements in part 897. In response to comments, the agency has amended the final rule to require the manufacturer to remove only those violative items that the manufacturer owns.

(28) Many comments, including comments from manufacturers' sales representatives and retailers, strongly objected to this provision, particularly as it would apply to self-service displays. In general, the comments claimed that retailers, rather than manufacturers, own the self-service displays. The comments also expressed concern that manufacturers' representatives or retailers' employees might be physically harmed if a manufacturer's representative attempted to remove a self-service display from a retailer. Several comments also interpreted proposed § 897.12(a) as requiring a manufacturer's sales representative to remove self-service displays supplied by another manufacturer; these comments said removing a competitor's self-service display would be unethical and could result in the sales representative being barred from reentering the retail establishment in the future.

In contrast, a few comments supported proposed § 897.12(a) because manufacturers provide the displays to retailers and visit retailers often. One comment added that the burden of removing displays should not rest on retailers alone, but added that retailers should remain ultimately responsible for displays they use or have on site. This comment suggested that retailers be responsible for removing displays if the manufacturer fails to do so.

The agency agrees, in part, with the comments critical of the proposed provision and has amended § 897.12 to clarify that a manufacturer is responsible for removing all self-service displays (which the final rule also clarifies as referring to merchandisers),

advertising, labeling, and other items that it owns that do not comply with the requirements in part 897. FDA has also amended § 897.14 to clarify the obligation of retailers with respect to all other violative items in the retailer's establishment. These changes should eliminate potential conflicts between manufacturers' sales representatives and retailers.

Additionally, § 897.12 requires a manufacturer to be responsible only for the removal of the items it owns. The agency does not expect manufacturers to remove items owned by another manufacturer, but encourages manufacturers to inform another manufacturer and FDA if another manufacturer's items violate the requirements in part 897. However, the agency advises manufacturers who know or have reason to know that a distributor or retailer is misbranding that manufacturer's products, or causing its products to violate these regulations or the act, to take action, such as discontinuing sales, incentives, and supplies, to halt the violation. Manufacturers might be held liable for subsequent violations by the distributor or retailer, if the manufacturer knew or should have known about the violation and continued to supply its product to such parties.

Liability, both criminal and civil, under the act is very broad. Section 301 of the act (21 U.S.C. 331) prohibits certain acts "and the causing thereof." *United States v. Dotterweich*, 320 U.S. 277 (1943), and *United States v. Park*, 421 U.S. 658 (1975) elaborate on the meaning of "causing" in section 301 of the act (see *Park*, 421 U.S. at 673). These cases stand for the proposition that a corporate official can be held criminally liable as having caused the corporation's violations of the act of which he had no knowledge, so long as he stood in a "responsible relationship" to the violations (*Id.* at 672).

Under the act, "all who * * * have * * * a responsible share in the furtherance of the transaction which the statute outlaws" have caused the violation and are subject to civil and criminal liability (*Dotterweich*, 320 U.S. at 284). Indeed, a corporate employee and the corporation itself can have a responsible share in the furtherance of a violation of the act committed by another corporation or a person who is not an employee of the corporation. (See, e.g., *United States v. Parfait Powder Puff Co.*, 163 F.2d 1008, 1009-10 (7th Cir. 1947) (holding defendant corporation criminally liable for violations committed without its

knowledge by second corporation that defendant had contracted with to manufacture, package, and distribute its cosmetic product), *cert. denied*, 332 U.S. 851 (1948); *United States v. Articles of Drug*, 601 F. Supp. 392 (D. Neb. 1984) (enjoining drug distributor that induced its customers to pass off its drugs as controlled substances), *aff'd* in part, *rev'd* in part on other grounds, 825 F.2d 1238 (8th Cir. 1987); *cf. Inwood Lab., Inc. v. Ives Lab., Inc.*, 456 U.S. 844, 853-54 (1982) (manufacturer or distributor who "intentionally induces another" to violate trademark law or who "continues to supply its product to one whom it knows or has reason to know" will violate trademark law is itself responsible for violation).) And it is a "settled doctrine[] of criminal law" (*Park*, 421 U.S. at 669) that a person who knows or has reason to know that goods that he sells will be used unlawfully may be criminally liable as aider and abettor under 18 U.S.C. 2; *Bacon v. United States*, 127 F.2d 985, 987 (10th Cir. 1942) (discussing former 18 U.S.C. 550, precursor to 18 U.S.C. 2(a)).

For example, a manufacturer or distributor that continues to supply its product to a retailer whom it knows or has reason to know sells cigarettes or smokeless tobacco to young people (or who breaks open packages and sells single cigarettes) might be liable for subsequent violations by that retailer. Likewise, a manufacturer who paid a retailer a fee for the retailer to use an illegal self-service display in a store might be liable for the retailer's violation.

These examples are, however, only by way of illustration because, as the Supreme Court stated in *Dotterweich*, "[t]o attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress * * * would be mischievous futility" (320 U.S. at 285). It added that, "[i]n such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted" (*Id.*).

(29) One comment challenged FDA's authority to require manufacturers to remove items that fail to comply with the regulations. The comment explained that FDA, rather than manufacturers, is responsible for compliance activities and a manufacturer's representative is not deputized or authorized to act on the agency's behalf. The comment added that sales representatives are not trained to perform investigative or law enforcement functions and, unlike

Government employees, would not enjoy the same legal protections accorded to the agency's inspectors. The comment also argued that FDA lacks authority to require manufacturers, or any other party, to remove any materials that would violate the regulations. The comment asserted that the agency has no general recall authority and that the recall authority in the act for devices requires the agency to find that a reasonable probability of serious adverse health consequences or death exists and, when exercising that recall authority, to provide an opportunity for a hearing. Thus, according to the comment, the 1995 proposed rule is deficient because it makes no findings and fails to provide for a hearing.

The agency believes that the comment misinterprets the provision. Section 897.12 would not "deputize" manufacturers' representatives nor confer any official responsibility on them. FDA intends to enforce the act and regulations itself and, where appropriate, will consider commissioning State officials, under its authority in section 702(a) of the act, to perform specific functions on FDA's behalf. Section 702(a) of the act does not extend to commissioning private parties, and the agency has no intention of commissioning manufacturers' representatives.

FDA also disagrees with the comment's claim that FDA has no authority to require manufacturers to remove materials that violate FDA regulations. FDA is issuing this provision, as well as part 897 generally, under its authority under section 520(e) of the act, which expressly declares, in part, that the agency may, by regulation, require that a device be restricted to sale, distribution, or use "upon such other conditions as the Secretary may prescribe in such regulation." Section 897.12, as amended, is a logical and necessary complement to the restrictions on the devices' sale, distribution, and use because it requires the manufacturer to assume responsibility for removing items that it owns that do not comply with the restrictions. Furthermore, as the Supreme Court stated in *United States v. Park*, 421 U.S. 658, 672 (1975), "the act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur."

The comment's argument with respect to the agency's recall authority is also misplaced. Section 897.12 applies in situations where a manufacturer knows,

either acting on its own or on the basis of information supplied to it, that one of its items does not comply with the regulations. Knowing that the item does not comply with the requirements in part 897, the manufacturer is then obligated to remove the violative item. Notice of an opportunity for a hearing or other due process considerations associated with recalls under section 518 of the act (21 U.S.C. 360h) are inapplicable because the manufacturer, rather than the government, would be the principal party during this process, using information it has to act on its own items. In any case, section 518 of the act applies to the recall of a device, not its advertising.

FDA fully expects manufacturers to comply with § 897.12. For example, if the manufacturer provided advertising that used colors and photographs, contrary to § 897.32, which requires black and white text only, the manufacturer is deemed to know that the advertising does not comply with § 897.32 and should remove that advertising. In this situation, where the manufacturer's advertising clearly does not comply with the regulations, requiring FDA to provide notice and an opportunity for a hearing (as the comment would apparently require) would simply waste FDA's and the manufacturer's resources.

FDA will take regulatory action against manufacturers who fail to comply with this provision or any other applicable provision. The nature of the regulatory action will depend, in large part, on the violation, but could range from issuance of a warning letter, to an injunction under section 302 of the act (21 U.S.C. 332), the imposition of civil penalties, criminal fines, and/or imprisonment under section 303 of the act (21 U.S.C. 333), and seizures under section 304 of the act (21 U.S.C. 334).

2. Visual Inspections by a Manufacturer's Representative at Each Point of Sale

Proposed § 897.12(b) would have required a manufacturer's representatives to visually inspect each point of sale that they visit during the normal course of business to ensure that cigarettes and smokeless tobacco are "labeled, advertised, and distributed in accordance with this part." The preamble to the 1995 proposed rule indicated that manufacturers keep extremely detailed records about each retailer and that some records noted whether the retailer should be visited weekly, biweekly, etc. and noted the types of displays in the retailer's

establishment (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also stated that this provision would not impose a new responsibility or burden on companies that did not visit retailers as part of their ordinary business practice and, for those manufacturers that would be expected to comply, estimated that these visual inspections would take no more than 2 to 3 minutes per visit (60 FR 41314 at 41323 and 41365). Based on the comments received in response to this proposal, the agency has deleted § 897.12(b) from the final rule.

(30) Several comments opposed proposed § 897.12(b). One comment argued that proposed § 897.12(b) is unconstitutional because it would hold manufacturers vicariously liable for the acts of others in violation of the Due Process Clause, and would violate Article I, Section 8 of the Constitution, which implicitly reserves to States the authority to raise militias. One comment asserted that the number of manufacturers' representatives varies among manufacturers and that there are too many retail establishments for those representatives to inspect. The comment added that any inspection would require more than 3 minutes to be effective, so that conducting inspections at each retailer would be labor intensive and costly. Another comment, notwithstanding the statement in the preamble to the 1995 proposed rule that the provision applied only to those firms that visit retailers in the ordinary course of business, asserted that its entire staff would be too small to visit all the retailers that it services. A small number of comments added that such responsibilities would, in effect, constitute a hidden "tax" on manufacturers.

Other comments, many submitted by sales representatives, objected to proposed § 897.12(b), stating that the representatives have no power over a retailer's actions and cannot take any adverse action, such as discontinuing supplies, to retailers who sell cigarettes and smokeless tobacco to young people. Some comments explained that, even if a sales representative could ask a distributor to stop supplying certain retailers, the retailer could simply switch distributors and continue to obtain products. Other comments argued that the responsibility to prevent sales to young people rests solely with the retailer.

In contrast, several comments supported proposed § 897.12(b) because sales representatives frequently visit retailers or because manufacturers

deliver materials, such as self-service displays and promotional materials, to retailers. One comment even suggested amending the rule to require manufacturers to enter into contracts with retailers and distributors to comply with FDA regulations and to state that failure to comply would result in termination of the retailer's or distributor's ability to obtain the manufacturer's cigarettes or smokeless tobacco.

After consideration of the comments, the agency has removed § 897.12(b). FDA intends to examine this matter further and to develop a guidance describing how manufacturers may be able to assist retailers to comply with this subpart. Possible options might include methods suggested by the comments, such as contractual agreements between retailers and manufacturers including provisions on compliance and the consequences of noncompliance.

D. Additional Responsibilities of Retailers (§ 897.14)

Proposed § 897.14 would have established additional responsibilities for retailers, stating that "[i]n addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes and smokeless tobacco to any person (other than a distributor or retailer)" comply with specific, listed requirements.

FDA, on its own initiative, has amended § 897.14 to delete the parenthetical text referring to a distributor or retailer because the evidence does not establish that retailers sell these products to such parties, and if a retailer did sell these products to a distributor or retailer, the retailer would be acting as a "distributor" as defined in § 897.3(c).

FDA, also on its own initiative, has amended § 897.14 to add a new paragraph (a) stating that, as one of the listed requirements, "[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age" and has renumbered proposed § 897.14(a) through (c) accordingly. The new paragraph codifies a concept that was present throughout the 1995 proposed rule, namely that retailers are not to sell cigarettes or smokeless tobacco to young people under 18 years of age.

1. Use of Photographic Identification to Verify Age

Under proposed § 897.14(a) (now renumbered as § 897.14(b)), each retailer, or an employee of the retailer,

would have been required to verify, by means of photographic identification containing the bearer's date of birth, that no person purchasing or intending to purchase cigarettes or smokeless tobacco is younger than 18 years of age.

The preamble to the 1995 proposed rule explained that studies indicate that young people who purchase cigarettes and smokeless tobacco from stores are often not asked to verify their age. For example, one study found that 67 percent of young people, whose mean age was 15 years, were asked no questions when they attempted to purchase cigarettes. In some cases, retail clerks even encouraged purchases by young people, suggesting less expensive brands or offering to make up the difference if he or she lacked sufficient funds (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also noted that requiring proof of age to purchase cigarettes and smokeless tobacco could reduce cigarette and smokeless tobacco use among young people (60 FR 41314 at 41323). Consequently, the 1995 proposed rule would have required retailers to verify that persons who intend to purchase cigarettes or smokeless tobacco are legally entitled to do so.

The preamble to the 1995 proposed rule also indicated that a driver's license or college identification card would be acceptable forms of photographic identification, but the agency invited comment on whether the final rule should contain more specific requirements on the types of identification (60 FR 41314 at 41323).

FDA received many comments supporting a proof of age requirement. These comments came from law enforcement entities, drug abuse prevention groups, health care professionals, medical societies, public health organizations, and even some adult smokers who agreed that a proof of age requirement will reduce young people's access to cigarettes and smokeless tobacco. One comment from a coalition of State attorneys general said there "are many teenagers who look much older than they are, who can obtain tobacco products quite easily. When they are required to show age verification, they will not be mistaken for an older age. Therefore, they will not be permitted to acquire tobacco products." Another comment from a State public health department reported that, based on data analyzed from the State's own experience, illegal tobacco purchases occur less than 5 percent of the time when the retailer checks a photographic identification card to

verify age, as opposed to a 95 percent illegal sales rate when no photographic identification card is checked.

In response to comments and changes to § 897.16 regarding mail order and vending machine sales and self-service displays in facilities that are inaccessible to children and adolescents, the final rule excepts the proof of age requirement under these limited circumstances.

(31) Several comments objected to making retailers responsible for their employees' actions. These comments asserted that an employee's failure to verify a potential purchaser's age or an employee's error should not subject the retailer to any regulatory action. A few comments faulted the 1995 proposed rule for not holding sales clerks responsible or argued that the rule would be ineffective because it would not alter a sales clerk's behavior.

In contrast, many comments supported the requirements that hold retailers responsible for preventing illegal sales. Indeed, one comment suggested that there should be "significant penalt[ies] for sales to persons under 18, including the loss of the opportunity to sell tobacco * * *." Another comment stated that the rule should contain penalties for illegal tobacco sales.

The agency declines to amend the rule to relieve retailers from responsibility. Retailers, in general, are responsible for the acts of their employees. (See *United States v. Park*, 421 U.S. 658, 672 (1975).) Relieving retailers from responsibility for their employees' actions would only invite abuse because retailers could continue to sell products to young people and, if caught making such sales, could blame their employees without suffering any adverse consequences themselves. To reflect its position that retailers are generally responsible for their employees' actions, FDA has amended § 897.14 to remove all references to "an employee of the retailer." Thus, § 897.14 now refers to a "retailer" and makes no distinction for the retailer's employees.

As for the comment claiming the rule contains no penalties for illegal tobacco sales, the agency believes that the comment misunderstands how the rule will operate. In general, FDA regulations implement and interpret the agency's statutory obligations under the act, including various criminal and civil penalties. Thus, a regulation need not specify what penalties are attached to a violation because the act provides this information.

FDA has, however, amended proposed § 897.14(a) (now renumbered as § 897.14(b)) to state that, "[e]xcept as otherwise provided in § 897.16(c)(2)(i) and in paragraph (a)(2) of this section," a retailer shall ensure compliance with the prohibition against sales to persons under 18 by verifying the purchaser's age. FDA made this amendment to correspond with the prohibition, in § 897.14(a), against sales to persons under 18 and because, as discussed in greater detail below, the final rule permits sales from vending machines and self-service merchandisers that are inaccessible to young people and permits mail-order sales. These modes of sale are either secure from access by young people (by requiring age verification upon entrance to the facility) or not used by them. The exception for paragraph (a)(2) complements another change to § 897.14 (discussed in greater detail below) to not require proof of age from persons over the age of 26.

FDA has also amended § 897.14(b) to delete the words "intending to purchase." The requirement that retailers verify the age of persons "purchasing the product" sufficiently accomplishes the provision's goal of reducing illegal sales.

(32) Several comments supported the use of identification cards to verify the purchaser's age. Some comments, responding to a question in the preamble to the 1995 proposed rule asking whether the rule should specify the types of identification that would comply with a proof-of-age requirement, advocated using identification cards, passports, or other official documents establishing the bearer's age issued by States, the Federal Government, or foreign governments. One comment recommended that States develop a uniform coding system for identification cards to permit retailers to read or to scan identification cards quickly to verify a purchaser's age. Other comments advised against the use of college or school identification cards; the comments noted that colleges and schools have little incentive to design their identification cards to be sufficiently tamper-proof.

In contrast, one comment stated that the agency should not ask for comment on the type of identification card to require, arguing that the "degree of micromanagement implied by the Agency's invitation for such comment underscores the inappropriateness of federal action in this area."

FDA recognizes the comments' concern. However, the final rule does

not require a uniform coding system or a Federal, State, or local government identification card.

(33) FDA received several comments that addressed when a retailer should inspect a purchaser's photographic identification card. One comment interpreted the provision as requiring retailers to inspect visually the photographic identification card of every purchaser, and said that this would be unreasonable. The same comment contended that retailers and their employees should be required to demand proof of age only from prospective purchasers who do not appear to be over 18; this was the standard employed in Everett, WA, which was cited in the preamble to the 1995 proposed rule.

In contrast, other comments supported age verification for all tobacco sales. Some comments from retailers indicated that some retailers check identification cards for all tobacco sales, while many comments submitted by retailers stated that they check identification cards to verify the age of purchasers who appear to be "underage." Other comments suggested that the regulation require visual inspection of photographic identification cards for purchasers who appear to be younger than 21, 25, 26, or 30 years of age. Such a requirement appeared to be independently selected to ensure that the purchaser met the age requirement in the particular jurisdiction.

Contrary to the comment that interpreted the rule as requiring proof of age in all transactions, the 1995 proposed rule would have given retailers some flexibility in deciding when to demand proof of age. The preamble to the 1995 proposed rule cited studies and reports demonstrating that few retailers request proof of age from young people attempting to purchase cigarettes or smokeless tobacco (60 FR 41314 at 41323). Consequently, proposed § 897.14(a) (now renumbered as § 897.14(b)) would have required retailers to verify that prospective purchasers are of legal age, and the preamble to the 1995 proposed rule suggested that retailers request proof of age from anyone who does not appear to be at least 26 years old (60 FR 41314 at 41323). This suggestion was similar to a recommendation made in a report by 26 State attorneys general. The agency anticipated, for example, that requiring proof of age from a senior citizen would be unnecessary, but strongly recommended requiring proof

of age from an individual who appears youthful.

However, due to concerns that, despite the language in the preamble to the 1995 proposed rule, the rule would require age verification in all cases, the agency has amended the rule to except from the age verification requirement individuals who are over 26 years old. The agency declines to amend the rule to require age verification if the purchaser appears to be 21, 25, 26, or 30 years old. Determining a person's age by his or her physical appearance alone is a subjective determination, and so requiring age verification if a person "looked" like he or she was a particular age would be difficult to administer and to enforce. By requiring age verification if a purchaser is 26 years old or younger, regardless of his or her appearance, the retailer foregoes age verification at its own risk.

The agency notes that using the higher age of 26 as the threshold for requiring proof of age should increase the likelihood that illegal sales to young people will not occur. Using a lower age, such as 18 (which is used in some States) or 21, as the threshold for requiring proof of age may enable some young people to purchase cigarettes and smokeless tobacco, and, as a result, cause a retailer to be in violation of this subpart.

(34) Many comments, particularly comments from retailers, supported the requirement for age verification but added that the requirement should be voluntary. Others said that State law or regulations requiring age verification are adequate, and that, as a result, FDA regulation is unnecessary. Other comments claimed FDA regulation would add "red tape and paperwork" that would not reduce young people's access to cigarettes and smokeless tobacco and would instead "come at great cost to taxpayers."

On the other hand, State attorneys general and other State and local enforcement authorities commented that the Federal regulations requiring age verification by inspection of photographic identification card will complement and enhance their enforcement abilities.

FDA declines to delete an age verification requirement from the rule. The preamble to the 1995 proposed rule cited studies and reports to show that young people are often able to purchase cigarettes and smokeless tobacco without showing proof of age (60 FR 41314 at 41323). In one case, the young people were able to purchase cigarettes even when they admitted that they were

under the legal age (60 FR 41314 at 41323). These studies and reports suggest that the final rule must require retailers to demand proof of age because voluntary efforts are ineffective.

As for deferring to State laws and regulations, FDA believes that State efforts to require proof of age, and retailer compliance with such efforts, should increase and become more effective due to section 1926 of the PHS Act. This provision requires States to enact and to enforce laws prohibiting manufacturers, retailers, or distributors of tobacco products from selling or distributing such products to persons under age 18 in order to receive substance abuse prevention and treatment block grants. However, State laws may differ, and so the final rule requires retailers to verify the age of purchasers. This will establish a uniform, national requirement regarding proof of age and is consistent with the assertion of Federal authority over these products under the act.

(35) Many comments pointed out that there is no penalty for parents who allow underage children to smoke.

FDA believes that the vast majority of adults and parents do not purchase tobacco products for young people. Parental actions are also beyond the scope of FDA's authority. However, it should be noted that parental consent to a young person's purchase of cigarettes and smokeless tobacco cannot override the requirements in § 897.14(a) prohibiting sales to anyone under 18 and in § 897.14(b) that each purchase is subject to age verification. Thus, under this rule, a retailer must refuse to sell cigarettes or smokeless tobacco to any young person who claims that he or she has "permission" to purchase such products for himself or herself or for an adult.

(36) One comment contended that the photographic identification card requirement is invalid because it exceeds FDA's authority under section 520(e) of the act because it does not purport to provide reasonable assurance of the safety and effectiveness of cigarettes.

FDA disagrees with the comment. Section 520(e) of the act authorizes the agency to establish, by regulation, conditions restricting the sale, distribution, or use of a device if, because of the device's potentiality for harmful effect or the collateral measures necessary to its use, the agency determines that there cannot be a reasonable assurance of the device's safety or effectiveness. A photographic identification card requirement is a

condition of sale for these products and a collateral measure that is necessary to the requirement that the products are not sold to anyone under the age of 18.

(37) One comment contended that proposed § 897.14(a) (now renumbered as § 897.14(b)) is precluded by section 1926 of the PHS Act. The comment stated that this law established Congress' intent to allow States to enact necessary programs to keep tobacco products out of the hands of young people as a condition for receiving block grant funding. According to the comment, there is no single best approach, and the FDA proposal prevents States from emulating the successful approach used in Woodridge, IL. The comment stated that FDA may not preempt State laws without making a showing of clear and manifest congressional intent to authorize its preemption of those State laws.

The agency disagrees with the comment. The preemption issues related to this rule (as well as the rule's relationship to the regulations issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) implementing section 1926 of the PHS Act regarding the sale and distribution of tobacco products to individuals under the age of 18 (the SAMHSA rule) are discussed in great detail in section X. of this document.

2. Minimum Age

Proposed § 897.14(a) (now renumbered as § 897.14(b)), would have required retailers to verify that persons buying cigarettes or smokeless tobacco were not younger than 18 years of age. FDA received many comments supporting a Federal minimum age to purchase cigarettes and smokeless tobacco. Some comments suggested that enforcement of this provision would be as effective as advertising limitations in controlling underage smoking. In supporting the proposal, comments noted that while most teenage smokers do not plan to be smokers 5 years after they begin smoking, less than 10 percent of teenagers are able to quit within 5 years of starting. Moreover, like their adult counterparts, 70 percent of high school seniors who smoke would like to stop smoking completely. Some comments noted that the average age at which teenage smokers first tried their first cigarette is 13 or 14 years, and by age 18, many teens are smoking daily and smoking at a rate very near the adult rate. Health-care professionals (nurses, physicians, dentists, public health officials, etc.) as a group were very

supportive of a Federal minimum age limit of at least 18.

(38) A major American medical association suggested amending § 897.14(a) (now renumbered as § 897.14(b)) to raise the minimum age of sale to 21. It noted that one State, Pennsylvania, has set 21 as the minimum age for the purchase of cigarettes, and argued that prior to enactment of the national standard of age 21 for alcohol purchase, many States had laws that allowed purchase at age 18, but subsequently changed to 21 without hardship.

Other comments advocated raising the minimum age to 19 years. Several comments explained that many high school students are 18 years old; thus, if FDA increased the minimum age to 19 years, it would be less likely that an underage high school student would be able to purchase or obtain cigarettes or smokeless tobacco, because raising the age to 19 would eliminate from the high school environment peers who are legally able to obtain nicotine-containing tobacco products. In addition, the agency received a considerable number of comments from students, teachers, and even adult smokers, urging the agency to raise the legal age to purchase cigarettes to 21, to be consistent with the legal age to purchase alcohol. Indeed, many comments assumed that the legal age was already 21 and urged the agency to retain this age limit.

In contrast, other comments supporting 18 as the minimum age for purchasing cigarettes and smokeless tobacco argued that, because most States already established 18 as the minimum age, FDA regulations did not need to establish a minimum age. A few comments, mostly from young people, asked FDA to lower the legal age for purchasing cigarettes to below 18 years of age.

In order to make its decision on the appropriate minimum age, the agency weighed a variety of factors including evidence on the onset of nicotine addiction and the history underlying the age of majority. FDA's goal is to prevent underage use of tobacco in order to preclude as many new cases of nicotine addiction as possible. The agency considered minimum ages from 18 to 21, because individuals are generally viewed as reaching adulthood in this age range. The agency faced the question: At which age in this range are most individuals able to make an informed decision to begin using a product that the overwhelming majority of individuals will not be able to stop

using, even though using the product is likely to lead to severe disability and premature death?

The agency began by reviewing key data sources on the onset and course of nicotine addiction. The National Household Surveys on Drug Abuse sought to determine the age when individuals first tried a cigarette and the age when individuals first started smoking daily—an important measure of the progression toward addiction. The survey asked questions of 30 to 39 year olds who had ever smoked daily. The average age of first trying a cigarette was 14.5 years.⁴¹ Eighty-two percent had tried a cigarette before 18, 89 percent before 19, 91 percent before 20, and 98 percent before 25.⁴² Daily smoking began slightly later. Fifty-three percent began smoking daily before 18, 71 percent before 19, 77 percent before 20, and 95 percent before 25.⁴³

The agency reviewed the history underlying the theory of majority and the concept of adults making informed choices. Majority is defined in Black's Law Dictionary as "the age at which, by law, a person is capable of being legally responsible for all his or her acts * * *, and is entitled to the management of his or her own affairs and to the enjoyment of civic rights. * * *" ⁴⁴ The 26th Amendment to the United States Constitution provides those 18 years and above with the right to vote. Prior to the adoption of the 26th Amendment in 1971, the age of majority in almost every State was 21. Each State has the power to set its own age of majority and since enactment of the 26th Amendment most States have lowered the age of majority from 21 to 18.

The agency reviewed the reasons why Congress chose 18 as the appropriate age to vote. According to a Senate report on lowering the voter age, the 21 year age was believed to be derived by historical accident. Eighteen-year olds bore many adult citizens' responsibilities such as the ability to marry and raise a family, and serve in the military. A lower voting age was seen as benefiting society by bringing into the American political system the idealism, concern, and energy of young people. (See "Lowering the Voting Age to 18," S. Rept. 92-96, 92d Cong., 1st sess., p. 5, March 8, 1971.)

While the justifications do not necessarily support establishing a minimum age of 18 for tobacco

⁴¹ 1994 SGR, p. 67.

⁴² *Id.*, p. 65.

⁴³ *Id.*

⁴⁴ *Black's Law Dictionary*, edited by M. A. Black, West Publishing Co., St. Paul, MN, p. 955, 1990.

products, the agency declines to raise the minimum age for several reasons. First, as stated in the preamble to the 1995 proposed rule, all States prohibit the sale of tobacco products to persons under the age of 18; currently only four States prohibit cigarette sales to persons over 18 (60 FR 41314 at 41315). Consequently, setting a national minimum age of 18 is consistent with most States. Second, selecting 18 as the minimum age is consistent with the age Congress established under section 1926 of the PHS Act, which conditions a State's receipt of substance abuse grants on State laws to prohibit any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under the age of 18.

FDA also declines to amend the rule to eliminate a Federal minimum age and instead rely on existing State laws. Establishing 18 as the national minimum age will strengthen State and local enforcement, as discussed earlier.

FDA also declines to amend the rule to reduce the minimum age. Reducing the minimum age would undermine existing State laws and the rule's effectiveness because it would, in essence, circumvent statutory and regulatory protections by letting more young people purchase these products. Reducing the minimum age would also be contrary to the evidence cited in the preamble to the 1995 proposed rule, which shows that half of adults start smoking daily before age 18.

FDA does plan to monitor closely the incidence of new cases of nicotine addiction. If the evidence indicates that the number of new cases of nicotine addiction does not significantly decline, consistent with the agency's stated goal of a 50 percent reduction, but rather are merely delayed a year or two, FDA will consider whether increasing the minimum age for purchase of nicotine-containing tobacco products would further the goal of the rule.

3. Restrictions Against "Impersonal" Modes of Sale

Proposed § 897.14(b) (now renumbered as § 897.14(c)) would have required the retailer or an employee of the retailer to provide cigarettes or smokeless tobacco to a purchaser "without the assistance of any electronic or mechanical device (such as a vending machine or remote-operated machine)." The preamble to the 1995 proposed rule stated that this provision would have the practical effect of making access to cigarettes and smokeless tobacco more difficult for

young people (60 FR 41314 at 41324). In response to comments, the agency has amended § 897.14(c) to allow for the use of certain impersonal modes of sale, such as vending machines and self service displays (merchandisers only), in facilities which are inaccessible to individuals under the age of 18 at any time. Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to "an employee of the retailer" because retailers are generally responsible for their employees' actions and has revised the text to correspond more closely with § 897.16(c).

(39) Several comments objected to proposed § 897.14(b). One comment asserted that proposed § 897.14(b) (now renumbered as § 897.14(c)) was unjustified, and arbitrary and capricious because it would apply to locations where young people are not permitted to enter and, in places where they can enter, would be unnecessary if retailers required proof of age from prospective cigarette and smokeless tobacco purchasers. The comment stated that less restrictive alternatives, such as increased supervision over self-service displays, exist. The comment further argued that FDA lacked support for this provision, stating that, regardless of how tobacco products are sold over-the-counter, the key party in the transaction is the cashier. According to the comment, requiring retail clerks to comply with applicable minimum age laws should be sufficient to prevent illegal sales to young people, thereby making the proposed provision unnecessary. The comment, therefore, stated that the evidence did not support a rule that would preclude State and local governments from relying on "less drastic controls."

In contrast, many comments agreed that this provision would reduce a young person's access to cigarettes and smokeless tobacco because it would require potential purchasers to interact with retailers or would discourage young people from purchasing these products because they would have to interact with a retailer and provide proof of age. One comment stated that the regulations establish a code of conduct for merchants, ensuring that they take practical steps to prevent illegal sales of tobacco products to young people. One comment stated that face-to-face transactions are the only way to assure that identification of under-age customers is checked.

FDA disagrees, in part, with the comments that oppose this provision. FDA declines to amend the rule to rely

on alternative measures such as increased supervision of displays or proof of age alone. The preamble to the 1995 proposed rule cited reports and studies showing that young people can easily use impersonal modes of sale despite restrictions on their placement or the installation of devices to prevent illegal sales. For example, for self-service displays, the Institute of Medicine (IOM) Report *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youths* (1994) referred to surveys in two communities that found over 40 percent of daily smokers in grade school shoplifted cigarettes (60 FR 41314 at 41325). For vending machines, the preamble to the 1995 proposed rule cited several studies and reports showing that young people were able to purchase cigarettes—despite laws restricting the placement of those machines, or requiring the machines to have a locking device to prevent sales to young people (60 FR 41314 at 41324 through 41325).

FDA also found that relying solely on retailers to verify the purchaser's age had limited effect on reducing young people's access to cigarettes and smokeless tobacco; retail clerks rarely asked young people to verify their age or even assisted in completing a purchase. Some retail sectors also suffered from high employee turnover rates that undermined the effectiveness of retailer programs to prevent illegal sales (60 FR 41314 at 41323). Consequently, the agency believes that the most effective approach towards reducing young people's access to cigarettes and smokeless tobacco is a sufficiently comprehensive set of access restrictions to prohibit most impersonal modes of sale, require retailers to verify the consumer's age, and make young people's access to these products more difficult.

The agency also reminds parties that these products are restricted devices because of their potentiality for harmful effect. The final rule contains restrictions that the agency believes are necessary in order to reduce the number of children and adolescents who use and become addicted to these products. Relying solely on retail clerks to verify age, increasing supervision over displays, or deferring to other less restrictive alternatives would not, in comparison to the rule's comprehensive approach, be sufficient to achieve that goal.

With respect to locations that are entirely inaccessible to young people, however, the agency has amended

§ 897.16 to permit certain modes of sale, such as vending machines and self-service displays (merchandisers only), in facilities where young people are not present, or permitted to enter, at any time. These modes of sale do not involve hand-to-hand transactions between the retailer and the purchaser. Consequently, FDA has made a corresponding amendment to § 897.14(c) to require retailers to personally provide cigarettes or smokeless tobacco to purchasers "[e]xcept as otherwise provided in § 897.16(c)(2)(ii) and revised the text to correspond more closely with the language in § 897.16(c)(1)." The amendments to § 897.16 are discussed in greater detail below.

(40) A few comments questioned the need for proposed § 897.14(b) (now renumbered as § 897.14(c)). These comments said that the rule would not prompt retailers to verify a prospective purchaser's age because retailers who sell cigarettes and smokeless tobacco to minors are already in violation of State laws.

FDA disagrees with the comments' assertion. FDA's enforcement authority and the range of sanctions under the act should give retailers additional incentives to verify proof of age. Hence, FDA believes that the weight of Federal law and these regulations will prompt retailers to pay more attention to the consumer's age. By way of analogy, the United States enjoys a very high rate of compliance with prescription drug restrictions in part because a violation of the prescription requirement is actionable under Federal law. Similarly, section 1926 of the PHS Act gives States, as a condition for receiving a block grant for the prevention and treatment of substance abuse, further incentive to ensure that illegal tobacco sales to young people do not occur and that the illegal sales rate steadily decreases from 50 percent in fiscal year 1994 (or fiscal year 1995 for some States) to 20 percent 4 years later. States must also conduct annually a reasonable number of random, unannounced inspections to ensure compliance with State law (see 61 FR 1492 at 1508, January 19, 1996). Section 1926 of the PHS Act and its implementing regulations should also prompt States to devote more attention to compliance efforts to prevent illegal sales to young people and, through the requirement for random, unannounced inspections, make retailers more aware of the need to verify the consumer's age.

4. Restrictions Against the Sale of Individual Cigarettes

Proposed § 897.14(c) (now renumbered as § 897.14(d)) would have prohibited the retailer or an employee of the retailer from breaking or otherwise opening any cigarette package or smokeless tobacco product to sell or distribute individual cigarettes or any quantity of cigarette tobacco or of a smokeless tobacco that is smaller than the quantity in the unopened product. In response to comments and for other reasons discussed below, the agency has amended § 897.14(d) to prohibit retailers from breaking or otherwise opening "any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use." Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to "an employee of the retailer" because the retailer is generally responsible for its employee's actions.

(41) Several comments opposed proposed § 897.14(c) (now renumbered as § 897.14(d)) in conjunction with proposed § 897.10 (which would establish general responsibilities for manufacturers, distributors, and retailers). The comments said it would be unreasonable to expect retailers to inspect all packages to assure compliance with minimum package requirement, as well as other requirements, and yet retailers would face significant penalties if they failed to comply. Other comments asked whether retailers would be held liable for opening shipping packages consisting of individual cigarette packages or cartons and selling the individual packages or cartons.

The comments misinterpreted the proposed provision. Section 897.14(d) does not require retailers to police minimum package requirements, but rather expressly states that the retailer shall not break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or number of cigarettes or any quantity of cigarettes or smokeless tobacco that is smaller than the quantity in the unopened package. The confusion may have stemmed from the definition of "package." Section 897.3(f) defines "package" as a "pack, box, carton, or other container * * * in which

cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers." The provision, therefore, focuses on two distinct actions: (1) The retailer breaks or opens a cigarette package or smokeless tobacco product; and (2) the retailer sells or distributes a portion of the cigarette package or smokeless tobacco product to a consumer.

A literal reading of proposed §§ 897.3(f) and 897.14(d) together would prohibit a retailer from opening a carton of cigarettes to sell a single package of 20 cigarettes. The agency did not intend to prohibit retailers from opening shipped quantities or bundles of cigarette packages or cartons or smokeless tobacco in order to break that shipment down into ordinary packages, cartons, or other standard product units. The agency has amended § 897.14(d), to eliminate this unintended effect. The new language clarifies that retailers may open shipping boxes or cigarette cartons to sell a pack of cigarettes or a smokeless tobacco package. Additionally, FDA has modified the introduction to § 897.14(d), changing "the retailer shall not" break or open any cigarette or smokeless tobacco package to "no retailer may" break or open any package. This change is intended to simplify the text and does not alter a retailer's obligations under § 897.14(d).

(42) One comment from a company opposed a restriction on the sale of single cigarettes because it had made a substantial investment developing a vending machine that would sell single cigarettes that complied with applicable labeling and tax laws. The comment added that its machines are located in areas that are frequented by or limited to adults and that there is a market for adults who wish to smoke only occasionally.

The restriction against the sale of single cigarettes pertained to single cigarettes that are removed from cigarette packages or cartons and sold on an individual basis. Thus, the product described by the comment, a prepackaged single cigarette that complies with all applicable labeling and tax laws, does not appear to correspond to what is commonly known as a "loosie." As for selling a packaged single cigarette in a vending machine, the final rule permits vending machines to be used in certain locations that are entirely inaccessible to young people. This comment, and corresponding amendments to the rule, are discussed in greater detail in section IV.E.4.a. of this document.

(43) A small number of comments opposed any restriction on the sale of single cigarettes, stating that such a restriction would make purchases by adults more difficult or could actually work to the detriment of adults who are trying to reduce their cigarette consumption by purchasing single cigarettes.

Most comments, however, supported a prohibition against the sale of single cigarettes. In general, they agreed that eliminating single cigarettes would make cigarette purchases more expensive for young people and, as a result, less likely. A number of State attorneys general stated that this provision, in conjunction with others, would assist States in enforcing compliance with State laws. A few comments noted reports of single cigarette sales occurring within their State or jurisdiction; one stated that "the problem of loosies is a very old story within the inner city," while another even claimed seeing young people wait in line for free samples of single cigarettes.

The agency declines to amend the rule to exclude single cigarettes. The preamble to the 1995 proposed rule cited evidence that a significant number of retailers are willing to sell single cigarettes to young people and are sometimes more inclined to sell single cigarettes to young people than to adults (60 FR 41314 at 41324). The comments supporting the rule reinforce the notion that single cigarettes appeal to young people.

While FDA is sensitive to the fact that adults who wish to quit smoking may wish to purchase single cigarettes to reduce smoking, on balance, the agency believes that the benefits of eliminating single cigarette sales to young people outweighs any possible detriment to adults.

5. Additional Comments

(44) Several comments suggested that FDA license retailers and impose fines or other sanctions on retailers who sell cigarettes and smokeless tobacco to young people.

The agency declines to amend the rule to create a licensing system. FDA notes that SAMHSA confronted similar comments when it proposed rules to implement section 1926 of the PHS Act and elected not to require a licensing system (61 FR 1492 at 1495). The preamble to the SAMHSA rule indicated that States could use a licensing system to identify retail outlets and enforce State laws, with licensure fees and civil penalties funding the States' random,

unannounced inspections and covering administrative and enforcement costs (61 FR 1492 at 1495). FDA concurs with the SAMHSA analysis and, because licensure would be a State matter, will refrain from establishing a licensing system for retailers.

As for fines and other sanctions, no amendment to the rule is necessary. The act already establishes fines and other sanctions for parties who violate the act. For example, any restricted device that is sold, distributed, or used in violation of regulations for that restricted device is misbranded under section 502(q) of the act (21 U.S.C. 352(q)), and section 301(a) of the act prohibits the introduction or delivery for introduction into interstate commerce of a misbranded device. (Section 709 of the act creates a presumption that all devices are in interstate commerce and section 304 allows seizure of adulterated or misbranded devices even in the absence of interstate commerce.) Among other things, section 301(b) of the act prohibits the misbranding of a device in interstate commerce, while section 301(c) of the act prohibits the receipt in interstate commerce of any misbranded device. Additionally, any person who violates section 301 of the act is subject to injunctions under section 302 of the act and civil penalties, fines and imprisonment under section 303 of the act, while section 304 of the act authorizes seizure actions against misbranded devices themselves without any need for proof of interstate commerce.

(45) One comment argued that retailers should be required to keep cigarette products from public view.

FDA declines to amend the rule as suggested by the comment. The agency believes that concealing these products from view would not significantly enhance the restrictions against access by young people and would instead unduly impair an adult's ability to determine what products and brands a retailer is selling as well as the retailer's ability to sell those products.

(46) One comment stated that § 897.14 can only be enforced by routine compliance checks using underage agents. The comment suggested that FDA negotiate with States to receive information on violations of State laws and to use that information against retailers who fail to comply with § 897.14.

FDA intends to cooperate with State governments to curtail illegal sales of cigarettes and smokeless tobacco to young people. Additionally, as stated earlier in this document, FDA is

authorized to commission State officials to perform certain functions on behalf of the agency. FDA may consider commissioning State officials, where appropriate, if commissioned State officials would help ensure compliance with these regulations.

(47) One comment would amend § 897.14 to refer to "purchasing" and "obtaining" cigarettes or smokeless tobacco. The comment said this would prevent young people from attempting to obtain cigarettes or smokeless tobacco from retailers by claiming to act with a parent's permission or on behalf of a parent or adult.

The agency declines to amend the rule as suggested by the comment. As written, § 897.14 prohibits retailers from selling cigarettes or smokeless tobacco to anyone under 18 and also requires retailers to verify the purchaser's age. These provisions do not make any distinction or exception as to whether the person purchasing the products claims to be purchasing the products for an adult. In other words, even if a young person claimed to have a parent's permission or to be purchasing these products for an adult, § 897.14(a) still prohibits retailers from selling cigarettes or smokeless tobacco to that young person, and § 897.14(b) requires the retailer to verify the purchaser's age.

(48) As mentioned earlier in the discussion for § 897.10, FDA has amended the final rule to create a new § 897.14(e) to require each retailer to remove or bring into compliance all self-service displays, advertising, labeling, and other items at the retailer's establishment if those items do not comply with the requirements under this part. This amendment became necessary because comments from manufacturers and retailers claimed that retailers owned the self-service displays or that, once the manufacturer's representative gives an item to a retailer, the item becomes the retailer's property. Consequently, § 897.14(e) requires retailers to remove or otherwise bring into compliance items at the retailer's establishment if those items do not comply with this subpart. This provision essentially gives retailers three options with respect to an item that violates the requirements in this rule: (1) If the item belongs to a manufacturer, the retailer could ask the manufacturer to remove the item, consistent with the manufacturer's obligations under § 897.12; (2) the retailer could convert the item to another use or alter the item to make it comply with the regulations; or (3) the retailer could remove the item.

*E. Conditions of Manufacture, Sale, and Distribution (§ 897.16)***1. Restrictions on Nontobacco Trade Names on Tobacco Products**

Proposed § 897.16 would have established several important restrictions or conditions on the sale of cigarettes and smokeless tobacco. Proposed § 897.16(a) would have prohibited the use of a trade or brand name for a nontobacco product as the trade or brand name for a tobacco product “except for tobacco products on which a trade or brand name of nontobacco product was in use on January 1, 1995.” For example, Harley Davidson cigarettes would be “grandfathered” under this provision. The preamble to the 1995 proposed rule stated that the provision would be necessary to prevent the industry from circumventing the purpose behind the rule (60 FR 41314 at 41324) by benefitting from the promotion of the nontobacco items in ways that appeal to young people. FDA noted, however, that several cigarette brands already used trade names that are normally associated with nontobacco products and would exempt those brands from § 897.16. The final regulation remains essentially the same, but clarifies the agency’s intent by amending the language to limit the exception to those product names “whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.”

(49) FDA received few comments on this provision. The comments asserted that the 1995 proposed rule would effect takings compensable under the Fifth Amendment.

The agency disagrees with these comments. The final rule does not violate the Fifth Amendment. This issue is discussed in greater detail in section XI. of this document.

(50) Several comments on the use of nontobacco trade names on tobacco products would delete proposed § 897.16(a), arguing that the provision will have no effect on cigarette or smokeless tobacco use by young people, and that businesses should be free to decide how to advertise or sell their products. One comment challenged the agency’s authority to regulate nontobacco trade names, stating that the act only permits the agency to take action against names that are false and misleading. According to this comment, a nontobacco trade name that appeals to young people does not become subject to the act. The comment further charged

that FDA has no evidence to support a conclusion that a tobacco product bearing a nontobacco trade name would be especially appealing to young people; the comment explained that the brands mentioned by FDA in the preamble to the 1995 proposed rule—Harley-Davidson, Cartier, and Yves St. Laurent’s Ritz cigarettes—either have very small market shares or are not sold in the United States.

In contrast, one comment said § 897.16(a) is “essential to avoid the same problems that occur with ‘image’ advertising.” The comment explained that tobacco manufacturers have used nontobacco trade names on tobacco products to give the tobacco products an “instant image.”

The point of this provision, like the restrictions on advertising, is to ensure that the restrictions on sale and distribution to children and adolescents are not undermined by how the product is presented to the public. As detailed in subpart D of part 897, FDA is restricting the way cigarette and smokeless tobacco are advertised in order to eliminate those elements that resonate most strongly with the needs of those under 18 to establish an appropriate image and to create a sense of acceptance and belonging. The use of nontobacco trade names has particular appeal in the former regard. If a firm could use a popular nontobacco product trade name and put it on a tobacco product, the firm could attempt to exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco appeal to young people.

For example, young people might purchase a particular nontobacco product that they perceive as symbolizing the adult sophistication or sex appeal of its users; they might also be inclined to purchase cigarettes bearing the same trade name if they perceive that the cigarettes will enhance their lifestyles in the same manner. Section 897.16(a), therefore, eliminates a potential loophole in the advertising and labeling provisions.

FDA also disagrees with the comment challenging FDA’s authority. Section 897.16(a) is authorized under section 520(e) of the act which permits FDA to restrict, by regulation, the sale, distribution, or use of certain devices. Prohibiting firms from adopting nontobacco product names that appeal to young people is a restriction on the product’s “sale.” The comment’s suggestion that FDA cannot rely on section 502(a) of the act reveals a misunderstanding of FDA’s position.

FDA predicated its action on section 520(e) of the act and therefore it is not necessary to address the relevance of section 502(a).

FDA is not persuaded that small market shares for cigarette products bearing nontobacco trade names undermines the need for § 897.16(a). The preamble to the 1995 proposed rule demonstrated that young people use the most heavily advertised brands and that they can purchase cigarettes and smokeless tobacco easily (60 FR 41314 at 41323 through 41326, and 41332). The brands cited in the preamble, Harley-Davidson, Cartier, and Yves St. Laurent’s Ritz, are not among the most heavily advertised brands, and, according to the comment, two (Cartier and Ritz) are not sold in the United States. Thus, there is no reason to expect these brands to be especially appealing to or purchased by young people in the United States today. However, if the other provisions in this rule are effective, some manufacturers might try altering their advertising or marketing strategy in order to generate product appeal; § 897.16(a) thus eliminates this potentially significant avenue for making a product appeal to young people.

(51) A few comments noted that the provision did not elaborate on what constitutes a “trade or brand name for a nontobacco product.” One comment interpreted the terms as including any nontobacco product trade name used anywhere in the world and, as a result, argued that the provision would impose an impossible burden on manufacturers to conduct trademark searches. The comment added that manufacturers would not be able to conduct trade or brand names searches with certainty (because the 1995 proposed rule did not confine itself to registered trademarks) and manufacturers would be subject to regulatory action even if they unknowingly used a trade or brand name for a nontobacco product.

In contrast, another comment noted that a brand name directory published by the Tobacco Merchants Association of the United States lists numerous brand names for both nontobacco and tobacco products. The comment suggested that there are a greater number of cigarette products whose brand names were the same as brand names for nontobacco products than the three brands that FDA identified in the preamble to the 1995 proposed rule. The comment suggested that FDA amend the rule to limit eligible brand name “tie-ins” to those relating to both tobacco products and to nontobacco products

sold in the United States as of January 1, 1995.

FDA agrees, in part, with the comments. It would be unreasonable for the regulation to encompass all possible nontobacco product trade names, regardless of their nationality or whether the trade name was a registered trademark. Neither FDA nor manufacturers would be able to ensure that a name was not used elsewhere. FDA intended that proposed § 897.16(a) would apply to trade names in use in the United States, and that the exception for nontobacco product trade names would apply only to product trade names that were in use on both tobacco and nontobacco products as of January 1, 1995. Consequently, to clarify the rule, FDA has amended § 897.16(a) to restrict manufacturers to use of those product names that were used on both nontobacco and tobacco products in the United States as of January 1, 1995.

(52) One comment would amend § 897.16(a) to state that, in addition to being on the market as of January 1, 1995, the cigarette brand had to have generated sales of at least 500 million cigarettes or 500 million grams of cigarette or smokeless tobacco in 1994. The comment explained that this amendment would eliminate a "loophole" because a product with "nominal sales volume could open up large marketing holes for all sorts of product names."

FDA declines to amend the provision as suggested by the comment. The final rule, as amended, prohibits manufacturers from using a nontobacco product trade or brand name as the trade or brand name for a cigarette or smokeless tobacco product. The sole exception is for tobacco products whose trade or brand name was on both nontobacco and tobacco products sold in the United States as of January 1, 1995. FDA will construe this exception narrowly such that the trade or brand name on the nontobacco product must be the same. For example, if the trade name for a nontobacco product was "Old Time Country Store," a cigarette product called "Old Time" would not qualify for the exception because the name is not identical to that for the nontobacco product.

(53) FDA, on its own initiative, has amended § 897.16(a) to replace the word "may" with "shall." This amendment is intended to reinforce the notion that, except as otherwise provided in § 897.16(a), manufacturers are prohibited from using a trade or brand name of a nontobacco product as the

trade or brand name for a cigarette or smokeless tobacco product.

2. Minimum Package Size

Proposed § 897.16(b) would have made 20 cigarettes the minimum package size for cigarettes. The preamble to the 1995 proposed rule explained that FDA selected 20 as the minimum number of cigarettes because most cigarette packs in the United States contain 20 cigarettes and that establishing a minimum package size would preclude firms from manufacturing so-called "kiddie packs." The preamble to the 1995 proposed rule explained that "kiddie packs" usually contain a small number of cigarettes, are easier to conceal, and are less expensive than full-sized packs. The preamble to the 1995 proposed rule also noted that, based on studies or reports in other countries, significant numbers of children purchase "kiddie packs" (60 FR 41314 at 41324). Thus, by establishing a minimum package size, the 1995 proposed rule would have essentially eliminated the manufacture, distribution, and sale of "kiddie packs." The final rule provides a narrow exception to the minimum package size in response to a comment on vending machines that sell certain packaged, single cigarettes.

(54) Several comments opposed creating any minimum package size. A minority disputed that the rule would be effective, stating that young people will get cigarettes anyway or will simply begin purchasing full-sized packs. One comment, submitted on behalf of specialty tobacco companies, suggested exempting specialty tobacco products from the rule. The comment explained that many specialty tobacco products are produced in package sizes smaller than 20 cigarettes, ranging from 8 to 18 cigarettes, but that young people do not purchase specialty tobacco products. Consequently, the comment sought an exemption for specialty tobacco products or for products with a very small market share. One comment asserted that small package sizes reduce smoking by adults while another comment would amend the rule to lower the minimum size to 10 cigarettes; neither comment offered any evidence to support their assertions.

In contrast, many comments supported proposed § 897.16(b). The comments indicated that eliminating "kiddie packs" is "essential to protect youth" and described "kiddie packs" as an "obvious come-on that would appeal to kids." Other comments said the provision would reduce underage

purchases because children would not be able to afford full-sized packs as easily or as quickly as they might afford "kiddie packs."

The final rule retains 20 cigarettes as the minimum package size. The agency disagrees that this provision will be ineffective. The provisions in this subpart are designed to: (1) Make young people's access to cigarettes and smokeless tobacco more difficult by restricting specific modes of access to these products that young people use, and (2) make purchases by young people more difficult (by requiring proof of age, and other methods) and more expensive (by eliminating free samples and "kiddie packs").

Additionally, while some tobacco products, specifically the specialty tobacco products, may have been sold in smaller sizes, the benefits of eliminating "kiddie packs," namely eliminating a product size that is relatively inexpensive and appealing to young people, outweigh any inconvenience to adults.

FDA also declines to create an exemption based on market share or claims that young people do not use a particular type of cigarette; such exemptions would not treat manufacturers equally, would depart from FDA's traditional approach of regulating devices as a class (see section IV.B. of this document), and would be impractical because a firm's compliance with the rule could vary depending on fluctuations in market share and use by young people. Moreover, even a small percentage of a market, such as 1 or 2 percent, could translate into a large number of Americans; for example, 2 percent of the approximately 50 million Americans who smoke would represent 1 million people. Two percent of the approximately 3 million children under age 18 who are regular smokers would represent 60,000 young people.

Furthermore, FDA declines to make 10 cigarettes the minimum package size. The comment did not offer any justification for the lower figure, and the agency believes that a smaller package size would be counterproductive because a 10-cigarette minimum size would be tantamount to making a "kiddie pack" the minimum package size for cigarettes.

(55) One comment supported the provision, but suggested that FDA amend the rule to prevent the development of "mini" cigarettes or "short smokes." The comment said such products contain less tobacco so that they can be sold at a lower price.

The agency declines to amend the rule as suggested by the comment. Section 897.3(a) define a cigarette, in part, as any product that consists of any roll of tobacco; it does not establish a minimum quantity of tobacco. Thus, while manufacturers can develop such a product, it would still be a cigarette under this rule and subject to all restrictions for cigarettes.

(56) Two comments would amend the minimum package size by increasing it to 200 cigarettes or a carton of cigarettes. The comments explained that making cartons the minimum package size would further reduce access to cigarettes by young people because cartons would be more expensive than single packs and would be harder to shoplift. The comment said that adults would not be adversely affected by such a change because adults generally buy cartons.

The agency declines to make 200 cigarettes or one carton the minimum "package" size. Eliminating cigarette packages would unduly affect those adults who prefer to purchase cigarette packs rather than cartons due to limited funds or other reasons, and would unduly affect manufacturers, distributors, and retailers because, at the very least, they would need to revise manufacturing practices or machines and/or revise or reconfigure product storage practices and units to accommodate only cartons. It is even possible that some adults might consume more cigarettes if the minimum package size were increased to 200 cigarettes.

(57) One comment challenged the agency's authority for proposed § 897.16(b). The comment argued that requiring a minimum package size exceeds FDA's authority under the act because it does not purport to provide reasonable assurance of the product's safety and effectiveness to potential users.

FDA disagrees with the comment. Section 520(e) of the act authorizes the agency to impose restrictions on the sale, distribution, and use of a device. Establishing a minimum package size is a restriction on the sale and distribution of these devices and is reasonably related to assuring the product's safety for those persons, namely young people, whom this rule protects. Cigarettes and smokeless tobacco either cause or are associated with serious adverse health effects, and the evidence suggests that "kiddie packs" appeal to young people. Hence, establishing a minimum package size that is larger than a "kiddie pack" should help reduce young people's

access to these products and, as a result, protect them from those potential adverse health effects.

(58) One comment stated that the agency lacks factual support for a minimum package size, claiming that there is no evidence that young people buy such products or that "kiddie packs" are especially popular with young people. The comment claimed that the studies cited by FDA in the preamble to the 1995 proposed rule are flawed due to small sample size. The comment disputed the results of those studies, arguing that the studies did not show whether young people favored small package sizes because they are easily concealed—a reason identified by FDA in the preamble to the 1995 proposed rule—or because they are less expensive. The comment added that FDA's rationale is further undermined by the fact that FDA has claimed both that young people are price sensitive and that they do not purchase inexpensive brands. According to the comment, it is not possible to have it both ways.

Specifically, the comment questioned the validity of the 1987 Australian study by Wilson.⁴⁵ The comment argued that the authors could not assure that the subject population of 14- and 15-year olds was representative and, because selection criteria for the adult subjects differed, the results from the adult population could not be compared to the results from the 14- to 15-year old subjects. The comment disputed the study's finding that young Australians favored smaller cigarette packages because the small packs were more "concealable," stating that the study did not explain whether a pack containing 15 cigarettes was significantly smaller than a pack containing 20 cigarettes. The comment also criticized the study for being unclear as to whether the researchers surveyed youth smokers alone or young smokers and other youths to determine why young people purchased the 15-cigarette package, and it criticized FDA for not mentioning that the third most popular reason for purchasing 15-cigarette packs was "reducing smoking."

FDA is not persuaded that the studies are unreliable. The comment's criticisms of the Wilson study do not acknowledge that the study's authors compensated for the lack of a

population-based probability sample by using a sample size that exceeded the required size for a simple random sample. The authors used a cross-sectional sample of 649 young people between the ages of 14 and 15. This number exceeded the 363 persons required for a simple random sample, based on an estimate that 40 percent of the 25,000 South Australian children aged 14 to 15 years old would be smokers and using 95 percent confidence intervals of 35 to 45 percent, and exceeded the 567 person sample size that would be obtained when the random sample size is multiplied by a factor of 1.3 to allow for a clustered design and increased 20 percent to allow for persons dropping out of the survey.

Additionally, while the study did say that the sample of 14- and 15-year old children was a "sample of convenience," that, alone, does not make the study unreliable. Many studies use a sample of convenience rather than a representative sample, and the application of a study's results or findings to a broader population depends on the study's methodology.

The comment's criticism of the different selection methods lacks merit because it neglects to consider the context for the selection method. The authors selected schools in order to obtain underage subjects; this selection method precluded getting a representative sample of adults (because they would not be in schools). For the adult subjects, selection was based on a probability-based method of selection instead of school affiliation. Both selection methods were scientifically valid.

Moreover, two well-conducted studies provide a reasonable basis for comparison, even between different populations. This is especially true for the Wilson study because both the adolescent and adult studies were performed under the auspices of the South Australian Health Commission and were drawn from the same geographical area within 2 weeks of each other. Thus, one can reasonably assume that the studies were well conducted and that comparisons between the adolescent and adult groups were appropriate.

Finally, the comment's criticism of Wilson's findings is also misplaced. Contrary to the comment's assertion, the issue is not whether 15-cigarette packs are smaller or more easily concealed than full-sized packs. Nor is the issue whether underage smokers, as opposed to underage smokers and other young

⁴⁵ Wilson, D. H., et al., "15's: They Fit in Everywhere—Especially the School Bag: A Survey of Purchases of Packets of 15 Cigarettes by 14 and 15 Year Olds in South Australia," Supplement to Community Health Studies XI (1), pp. 16s–20s, 1987.

people, prefer 15-cigarette packs. Instead, the issue is whether young people, for whatever reason, favor and purchase smaller packs. The study indicated that over 90 percent of the young people surveyed preferred 15-cigarette packs because they considered them to be less expensive, easier to conceal, or helpful to reduce smoking. This led the authors to state that, "if adolescents did not have available to them these cheaper brands, or the price was raised considerably, or packaging in a way that is more appealing to adolescent budgets was prohibited then the current popularity of 15's would be reduced considerably."⁴⁶

(59) The same comment challenged a study by Hill.⁴⁷ The preamble to the 1995 proposed rule cited this study to show that younger children (12-year olds in the study) preferred 15-cigarette packages more than older children (17-year olds) and that older children preferred packages containing 25 cigarettes. However, the comment interpreted the Hill study in a much different manner, noting that, according to the study, the youngest age group experienced the greatest decline in smoking prevalence in the period following the introduction of the 15-cigarette package. Thus, the comment asserted that, "[t]his fact suggests that smaller packages are associated with less youth smoking, rather than more." The comment further stated that the researchers' opinion that price and "concealability" make smaller packages appealing to young people is contradicted by the findings that children in all age groups preferred 25- and 30-cigarette packages.

FDA believes that the comment misinterprets the study. While the study did indicate that the proportion of Australian students, aged 12 to 17 years, who smoked weekly declined from 1984 to 1987 (with the greatest declines in the youngest age groups), the study did not attribute the decline to the introduction of a smaller cigarette package. Instead, the study attributed the decline to "the health education and promotional campaigns that were established in Australia during the period between the surveys."⁴⁸

Similarly, a closer examination of the study does not support the comment's assertion that the popularity of larger cigarette packages among Australian

schoolchildren refutes FDA's statement that the price and "concealability" of smaller packages appeal to young people. The study found that 42 percent of the children surveyed smoked cigarettes from 25-cigarette packages, with the next most popular size being 30-cigarette packages. Nearly 20 percent smoked cigarettes from 15-cigarette packages, and "preference for packets of this size showed a marked inverse relationship with age, decreasing from 30% of 12-year-old school children to 11% of 17-year-old school children."⁴⁹ The study did not attribute the popularity of the smaller package size to lower price or concealability but merely cited the Wilson study to say that young people "presumably" prefer the smaller packages for those reasons. Yet, regardless of the reason, the Hill study illustrates that a significant percentage of young people prefer smaller package sizes and that the percentage increases in the younger age groups.

(60) The same comment also criticized the Nova Scotia study.⁵⁰ FDA cited this study to show that 49 percent of tobacco users in the sixth grade purchased 15-cigarette packages. The comment criticized the Nova Scotia study for the "absurdly small size of this population sample (37 students)." The comment also criticized the Nova Scotia study's assertion that price and concealability motivate young people to purchase small cigarette packages. The Nova Scotia study indicated that only 3 percent of the sixth grade students surveyed (or one out of the 37 students) purchased single cigarettes compared to 11 percent of the twelfth grade students (or 12 students out of the 123 surveyed). The comment argued that the Nova Scotia study showed that twelfth grade students "were four times as likely as the sixth-graders to purchase *single* cigarettes" and that, "[i]f price and 'concealability' were the key factors for young people, those in the youngest age group would surely be purchasing single cigarettes, not 15's".

The comment misconstrues the importance of the study. FDA cited this study to show that 49 percent of tobacco users in the sixth grade purchased 15-cigarette packages, but the agency did not rely solely on the Nova Scotia study as evidence that young people prefer small cigarette packages. Instead, the agency cited the Nova Scotia study and the Hill study that surveyed 19,166 Australian schoolchildren to show that

the youngest children prefer smaller cigarette packages. So, even if the Nova Scotia study used a small sample size, the study's findings are consistent with the Australian study that surveyed 19,166 children.

The agency also disagrees with the comment's claim that the Nova Scotia study contradicts FDA's view that young people purchase "kiddie packs" due to their low price and small size. The study did not examine specific reasons for purchasing single cigarettes as opposed to 15-, 20-, or 25-cigarette packages, and so it would be inappropriate to draw any conclusions based on different purchase rates alone. In other words, the percentage of students who purchase a particular package size may offer little or no insight as to the reasons why a student selected a particular package size.

Other factors might also explain the low rate of single cigarette sales relative to cigarette packages. Low price and concealability might be important factors in purchasing behavior, but they may not be the controlling or sole factors behind a purchase. For example, the preamble to the 1995 proposed rule stated, among other things, that single cigarettes make children more willing to experiment with tobacco products (60 FR 41314 at 41324), and stated that young people see or use tobacco products as a badge or method of conveying or creating a certain image for themselves (60 FR 41314 at 41329). A single cigarette, sold without a package, is an ineffective "badge" compared to the more conspicuous cigarette pack. Additionally, very young children may not opt for single cigarettes because such products are typically purchased from retailers that may question the children's age. (See 60 FR 41314 at 41325 (very young children rely on vending machines more often than older children).) The Nova Scotia study, however, did not examine reasons for purchasing single cigarettes as opposed to purchasing 15-cigarette packages, and so the agency declines to draw any conclusions solely from different sales rates for single cigarettes compared to those for cigarette packages.

(61) One comment suggested amending § 897.16(b) to prohibit manufacturers, distributors, and retailers from selling or causing to be sold, distributing or causing to be distributed, "cigarettes unless contained in packages of at least 20 cigarettes." The comment said that the rule did not prevent anyone other than retailers from selling individual cigarettes.

⁴⁶ *Id.*, p. 19s.

⁴⁷ Hill, D. J., et al., "Tobacco and Alcohol Use Among Australian Secondary Schoolchildren in 1987," *Medical Journal of Australia*, vol. 152, pp. 124-130, 1990.

⁴⁸ *Id.*, p. 128.

⁴⁹ *Id.*, p. 126.

⁵⁰ "Students and Tobacco," The Nova Scotia Council on Smoking and Health Survey, Final Report, March 1991.

FDA believes the comment misinterpreted the rule. Section 897.3 defines a "retailer" as any person who sells cigarettes or smokeless tobacco to individuals for personal consumption. Thus, a manufacturer or distributor who attempted to sell single cigarettes to a consumer would, under the final rule, be considered a "retailer" for purposes of that transaction and would be in violation of the individual cigarette restriction in § 897.14.

(62) One comment suggested amending the rule to create a minimum package size for smokeless tobacco. The comment would make the minimum package size for smokeless tobacco equivalent to 20 doses of nicotine, but it did not state what a dose would be.

The agency agrees that a minimum package size for smokeless tobacco may be helpful, but lacks sufficient information to determine what that size should be for the various forms of smokeless tobacco on the market. Unlike cigarettes, which are generally sold in packages of 20, smokeless tobacco comes in various forms and sizes, and, with the possible exception of prepackaged forms, can be used in quantities determined by the user. One individual, for example, might place more chewing tobacco in his or her mouth than another individual. Consequently, absent more information, the agency is unable to establish a minimum package size for smokeless tobacco.

(63) The agency, on its own initiative, has amended § 897.16(b) (minimum cigarette package size) to add the introductory phrase, "Except as otherwise provided under this section." This amendment became necessary because, as discussed in greater detail in section IV.E.4.a. of this document, the agency has concluded that vending machine sales should be permitted in facilities that are inaccessible to young people, and FDA is aware of at least one type of vending machine that sells packaged, single cigarettes. The agency is aware of vending machines that dispense cartons, packages, and now packaged, single cigarettes and has made an exception for packaged, single cigarettes due to their unique nature (relatively high price compared to "loosies," packaging in compliance with labeling and tax requirements, and sale only in adult locations). Additionally, FDA, on its own initiative, has revised the rule to state that no manufacturer, distributor, or retailer "may" sell (rather than "shall" sell) cigarette packages containing less than 20 cigarettes.

3. Maximum Package Size

The preamble to the 1995 proposed rule also invited comment as to whether a maximum package size should be established. The preamble to the 1995 proposed rule cited one study that found that older Australian children favored cigarette packs containing 25 cigarettes (60 FR 41314 at 41324).

(64) Several comments offered suggestions regarding a maximum package size. One comment noted that packages containing 10 and 25 cigarettes have been sold in the United States and suggested that, when considering a maximum package size, FDA should consider the attractiveness of the pack and whether a larger pack would encourage increased consumption. The comment added that one option would be to limit sales to 200 units (or one carton). Another comment would make 20 cigarettes the maximum package size, but conceded that there is insufficient evidence to make a strong recommendation.

In contrast, one comment stated that the agency has no authority or evidence to justify creating a minimum package size and so it lacks authority and evidence to create a maximum package size.

Based on the comments, there is insufficient evidence to establish a maximum package size for cigarettes. There is little experience in the United States with package sizes greater than 20 cigarettes. As a result, the final rule does not establish a maximum package size for cigarettes.

4. Impersonal Modes of Sale

Proposed § 897.16(c) would have permitted cigarettes and smokeless tobacco to be sold only in a direct, face-to-face exchange between the retailer, or the retailer's employees, and the consumer. Thus, the proposal would have prohibited the use of vending machines, self-service displays, mail-order sales, and mail-order redemption of coupons. Implicit in this provision, and in subpart B of part 897, is the notion that transactions involving restricted devices should involve a sense of "formality" or gravity that conveys to both the seller and the buyer the seriousness of the transaction and of the products themselves. FDA has amended this provision in response to comments. As discussed in section IV.E.4.c. of this document, certain mail-order sales are now exempted from this requirement, as are vending machines and self-service merchandisers in facilities not admitting individuals under the age of 18.

a. *Vending machines.* The preamble to the 1995 proposed rule cited numerous studies and surveys showing that significant percentages of young people are able to purchase cigarettes from vending machines, even in jurisdictions that have laws restricting the placement of those machines or requiring the use of locking devices. In some cases, young people successfully bought cigarettes from vending machines 100 percent of the time (60 FR 41314 at 41324 through 41325). Consequently, the agency elected to prohibit the use of vending machines rather than restrict their placement or require locking devices.

FDA's proposal to eliminate the use of vending machines (§ 897.16(c)) generated more comments than any other provision aimed at reducing children's and adolescents' access to tobacco products; the agency received thousands of comments on this provision. While agreeing that children and adolescents should not use tobacco products, comments submitted by adult smokers, the tobacco industry, and vending machine owners and operators, strenuously objected to the provision. Nearly all of the comments in opposition stated that the provision would be unnecessary if State and local jurisdictions enforced existing laws prohibiting the sale of tobacco products to children and adolescents under the age of 18.

By contrast, concerned adults, parents, educators, State and local public health agencies, and medical professionals overwhelmingly supported the provision. In addition, tens of thousands of school children wrote letters asking that vending machines be eliminated. Nearly all comments in favor of the provision pointed to the serious health risks that a lifetime of nicotine addiction poses to children and adolescents who begin to smoke, arguing that vending machines offer children and adolescents who choose to begin to smoke easy access to cigarettes.

(65) Several comments asserted that the proposed restriction pertaining to vending machines would effect takings compensable under the Fifth Amendment.

The agency disagrees with the comments. As discussed in greater detail in the paragraph below, FDA has amended the final rule to permit vending machines in facilities that are inaccessible to young people at all times. Additionally, given the character of this regulation and the lack of reasonable investment-backed expectations in personal property, its

economic impact, while potentially significant for some persons, is not such as to effect a taking. The agency addresses Fifth Amendment issues in greater detail in section XI. of this document.

(66) Most comments submitted by adult smokers and nearly all of the comments submitted by the cigarette and vending machine industries stated that the provision would not effectively reduce children's and adolescents' access to cigarettes. The comments argued that the proposed elimination of vending machines is not supported by the evidence in the record, either because the studies cited by FDA do not measure children's and adolescents' actual purchasing habits, or because the percentage of children and adolescents who reportedly buy cigarettes from vending machines is not significant. Finally, many adult smokers and some parents argued that determined teenagers will find a way to obtain cigarettes whether or not vending machines are eliminated.

On the other hand, almost all of the children, parents, adults who do not smoke, medical professionals, and public interest groups commented that the provision would effectively reduce children's access to cigarettes. These comments generally cited personal experience in concluding that vending machines provide an easy source of cigarettes for many children who smoke. For example, the executive director of a public health education program wrote: "It is outrageous that we allow tobacco, a most addictive drug, to be sold through vending machines where anyone can purchase it!" Comments overwhelmingly concluded that the elimination of vending machines, coupled with the other proposed access and advertising restrictions and the proposed education campaign, would effectively reduce the availability of cigarettes to children.

Several comments analyzed currently available studies and concluded that "easy access to vending machines * * * enable[s] young people to obtain cigarettes, and that high proportions of vending machine users are people under 18." Moreover, several comments in support of the provision cited their own studies indicating the ease with which children and adolescents obtain cigarettes from vending machines. For example, a coalition dedicated to preventing and reducing tobacco use submitted its 1994 annual report, which included an article describing an undercover buying survey, the largest of its kind, conducted in Spring, 1994. One

hundred and seven teenagers participated in the 12-county survey by entering stores under the supervision of an adult and attempting to purchase cigarettes, and:

[k]ids were more successful attempting to buy cigarettes through vending machines [than through retail outlets], without any adults trying to stop them. Teens made 21 of 24 successful attempts to purchase cigarettes through vending machines, an 88 percent success rate.

Similarly, the manager of a youth tobacco prevention program in Washington State's Department of Health commented that "[a] recent survey in one Washington county found that youth can still purchase tobacco from vending machines at a 75 percent success rate." The comment recommended that all tobacco vending machines be eliminated.

Finally, comments submitted by children, parents, and nonsmoking adults indicate that these groups believe tobacco vending machines are easily accessible to children and adolescents. One comment, typical of those submitted by children, stated: "I especially agree with getting rid of vending machines. That, I think, is probably the most common way that children get their cigarettes." The director of a public health center in California submitted the results of a poll indicating that 75 percent of Californians support banning cigarette vending machines.

Vending machines certainly represent one of the major ways that children currently obtain cigarettes. In addition to studies depicting how easily children and adolescents could purchase cigarettes from vending machines, the 1995 proposed rule cited surveys of children's actual purchasing behavior (60 FR 41314 at 41324 through 41325). Relying on both types of evidence, the agency concluded that the provision would eliminate one of the primary sources of cigarettes for at least 2 percent of 17-year-old smokers and 22 percent of 13- to 17-year-old smokers. Moreover, the agency finds that the number of children and adolescents in these two groups is substantial.

While the agency agrees that some children and adolescents who are determined to smoke may find or create new ways of obtaining cigarettes, the removal of vending machines from sites accessible to young people will eliminate what is currently a popular and easy means of access to tobacco, especially for younger children. In addition, if other access restrictions are imposed, such as requiring customers to provide proof of age, without also

eliminating vending machines, use of vending machines among children between the ages of 13 and 17 years would likely increase (60 FR 41314 at 41325). Therefore, the agency has concluded that the provision is an important part of the overall scheme to reduce children's and adolescents' access to cigarettes.

(67) The agency received many comments regarding the location of vending machines. A trade association representing the cigarette industry stated that most vending machines are currently inaccessible to children and adolescents because they are located either in areas that are off-limits to young people, such as nightclubs or casinos, or in areas that young people rarely frequent, such as industrial plants and private offices. Thus, the comment concluded, eliminating vending machines will not discourage youth smoking.

The vending machine industry and establishments that currently have vending machines unanimously opposed the provision. Some comments suggested that the agency specifically allow vending machines in locations where young people are not present. One vending machine operator commented, "[m]any cigarette machine vendors are small businessmen like myself; 95 percent of our locations are in taverns and lounges, where no one under 21 years old is allowed in." Other comments argued that, even if retail purchases become increasingly difficult, vending machines in establishments that are not open to the public should not be eliminated because children and adolescents cannot enter these places.

Both the cigarette and vending machine industries argued that FDA's conclusion, that children and adolescents can easily purchase cigarettes from vending machines even in "adult" locations, was based on flawed studies. Comments argued that the sting operations, on which these studies were based, do not demonstrate where teenagers actually or usually go. One comment, submitted by an association representing 1,700 vending machine companies, argued that: "it is highly questionable if minors might have alone and without encouragement entered taverns or bars in restaurants just to purchase cigarettes without exemption from the district attorney's office." Moreover, these comments argued, local sting operations do not establish the national cigarette purchasing habits of children and adolescents.

In contrast, a national public health organization concluded that available studies indicate that restricting the location of vending machines is an ineffective method of controlling sales of tobacco to young people. Another comment opposed to weakening the provision characterized as unreliable the number of machines currently in "adult" locations. The comment attacked as statistically unsound a vending machine industry survey that concluded that 77 percent of all vending machines are in "adult locations."

FDA has determined that cigarettes should not be dispensed to consumers from vending machines that are accessible to children and adolescents. While young people's actual current purchasing habits provide irrefutable evidence of accessibility, available evidence demonstrates that cigarette vending machines also are accessible to children and adolescents even in locations that are not often or currently frequented by young people. FDA has determined that cigarette vending machines should be eliminated from locations that are accessible to children and adolescents, whether or not children and adolescents currently use them.

While the IOM recommended that vending machines be eliminated altogether, it cautioned that, if partial bans were to be enacted, the definition of "adult" location must be narrowly drawn.

Youths do not now report "adult" locations as major sources of tobacco, but there is evidence that minors can often easily enter "adult" locations, and once inside, can easily buy tobacco products * * *. If partial vending machine bans are to be effective, the statutes must define "adult" locations carefully and narrowly. For example, the bar area of a restaurant is not sufficiently inaccessible to minors to deter their purchases. * * * Many bars only restrict access to alcohol; they do not restrict entrance by age. Accordingly, if vending machine are permitted at all, they should be permitted only in locations to which minors may not be admitted.⁵¹

Based on comments, FDA has determined that some "adult" locations can be made sufficiently secure to prevent young people's access and that vending machines should remain available to adults in these locations. For example, some establishments, such as nightclubs or casinos, require that patrons present proof of age before they are permitted to enter or post a guard at the door to prohibit underage access. In 1994, CDC analyzed 15 recent studies of children's access to tobacco and noted

that "[s]ome inspections of private clubs and bars were not carried out because access to the outlet was blocked by a doorman or security guard."⁵² FDA finds that those establishments where people under the age of 18 are legally prohibited from entering and where a system exists to ensure that children are prevented from entering, can, in fact, be sufficiently inaccessible to children that the goals of the rule would not be significantly advanced by prohibiting vending machines in those limited locations.

Other "adult" establishments prohibit children and adolescents from entering, as a matter of establishment policy. For example, some private clubs do not grant membership to persons under the age of 18 and require that members provide proof of membership before entering the club. Similarly, for example, some industrial or manufacturing facilities not open to the public may, for safety reasons, prohibit the hiring of persons under the age of 18, and require that employees present proof of employment upon entering the facility. FDA finds that these establishments, like some nightclubs or casinos, can be similarly inaccessible to children and, if so, should be permitted to make cigarette vending machines available to their adult members or employees.

Furthermore, an exemption for vending machines located in areas where no person under 18 is present or permitted to enter is consistent with the "Prohibition of Cigarette Sales to Minors in Federal Buildings and Lands Act" (Pub. L. 104-52, sec. 636). This particular statute, which became law on November 19, 1995, prohibits the sale of tobacco products in vending machines located "in or around any Federal building," but the statute authorizes the Administrator of the General Services Administration (GSA) or the head of an agency to exempt areas that prohibit the "presence of minors" (whom the statute defines as individuals under age 18). See also 41 CFR 101-20.109(d) (Administrator of the GSA or agency head may designate areas where vending machine sales of tobacco products may occur "if the area prohibits minors"); 61 FR 2121, January 25, 1996.

Consequently, § 897.16(c) exempts vending machines located in establishments that are totally inaccessible to persons under 18. The

owner of the facility must ensure, by means of photographic identification or some other means, that no one under 18 enters the facility. Thus, the rule would permit a vending machine in an establishment only where persons under 18 are not present, or permitted to enter, at any time. FDA emphasizes that this narrowly drawn exemption accommodates adults only in locations where young people, in fact, have no access at any time. For example, a vending machine might be permitted in a facility that employs only adults and where guards prevent any person under 18 from entering. A vending machine would not be permitted in a facility that employs only adults but also permits employees to bring children to work. The agency further emphasizes that it is the exempt establishment's responsibility to ensure that no one under 18 is present, or permitted to enter the premises, at any time.

In addition, under § 897.16(c), a vending machine in an exempt establishment must be entirely inaccessible to children. Thus, an establishment must place the machine entirely inside the premises, beyond the point where persons are required to present proof of age, membership, or employment. Vending machines are prohibited from any public area in or around the establishment, including, for example, lobbies, parking lots, and entrances.

FDA emphasizes that the final rule exempts only establishments that are, in fact, inaccessible to young people at all times. FDA will monitor young people's access to cigarettes from vending machines in exempt establishments, and, after 2 years, will assess whether the vending machine exemption has been effective. At that time, the agency finds that vending machines continue to be accessible to young people, FDA will propose further restrictions.

(68) Several comments suggested that, rather than eliminate vending machines or restrict their location, FDA require that they be supervised. These comments would allow vending machines to be placed anywhere, even in locations frequented by children and adolescents, as long as the machines were supervised.

FDA disagrees that supervising vending machines would prevent illegal sales to children and adolescents. Comments opposed to the provision offered no evidence that supervision of vending machines would sufficiently impede a young person's access to cigarettes. In fact, studies indicate that young people are able to purchase

⁵² "Design of Inspection Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors," Battelle, prepared for the CDC, OSH, p. 17, April 1994.

⁵¹ IOM Report, p. 214.

cigarettes even from vending machines under the immediate vicinity and control of employees.

One study conducted in a State requiring that vending machines be supervised demonstrated that youths were able to purchase from 72 percent of vending machines, in bars and taverns, within clear view of an employee.⁵³ Another report examining vending machine sales in New York City demonstrated that 11- and 12-year-olds successfully purchased cigarettes from supposedly supervised vending machines in bars and taverns 100 percent of the time. The study found that children and adolescents "had no more difficulty buying cigarettes from vending machines in bars than they had buying cigarettes from restaurants, pizza parlors, or video arcades. In all instances, the barman and/or patrons watched but did not intervene."⁵⁴

In other studies, employees helped children and adolescents to illegally purchase cigarettes by providing change for the cigarette vending machine⁵⁵ or suggesting that the children and adolescents go next door where cigarettes were cheaper.⁵⁶

Additionally, each provision in subpart B of part 897 is intended to eliminate a popular source of cigarettes and smokeless tobacco for children. The vending machine restriction is intended to complement, and be reinforced by, the other restrictions.

The preamble to the 1995 proposed rule cited studies indicating that the use of vending machines by adolescents is greater in jurisdictions that have stronger access restrictions (60 FR 41314 at 41325). Based on those studies and comments that it received, FDA concludes that decreasing the supply of tobacco products to children and adolescents by one means of access, such as restricting self-service displays, would cause an increased demand by another means of access, such as cigarette vending machines. FDA remains persuaded that, without eliminating cigarette vending machines accessible to children and adolescents,

other access restrictions would cause an increase in illegal vending machine sales.

(69) Most comments submitted by the tobacco and vending machine industries recommended that, rather than eliminate vending machines, FDA should require that they be equipped with electronic locking devices (devices that render the machine inoperable until activated by an employee) or token mechanisms (which require consumers to purchase tokens from an employee in order to use a vending machine). Either method would require a face-to-face transaction between the purchaser and the retailer.

The cigarette and vending machine industries commented that studies do not support FDA's conclusion that locking devices are ineffective. Comments asserted that the studies failed to include vending machines fitted with locking devices in traditionally adult locations or to account for the lack of enforcement in the jurisdiction in which the study was conducted. In addition, several comments pointed out that the tobacco sales ordinance in Woodridge, IL, where illegal tobacco sales were reduced from 70 percent to less than 5 percent 2 years later, included a locking device requirement rather than a ban on cigarette vending machines.

On the other hand, one comment from a public interest group strongly supported FDA's proposal to eliminate vending machines altogether and urged that FDA not permit the use of locking devices. The comment cited a survey, conducted by an association of public health officials in New Jersey, in which young people successfully purchased cigarettes from supposedly locked vending machines in 11 of 15 attempts. The comment noted that "[i]n some instances, the remote control device to operate the machine was sitting on top of the machine to save store personnel the bother of having to press the switch."

FDA acknowledges that properly installed locking devices require that vending machine purchasers engage in a face-to-face transaction, increasing the likelihood that children would be prevented from purchasing cigarettes. However, as explained in the preamble to the 1995 proposed rule, available evidence indicates that the industry is slow to install the locking devices, and that, after a short period, the locking devices are often disabled (60 FR 41314 at 41324 through 41325).

FDA agrees that the Woodridge, IL, community was able to dramatically

reduce illegal tobacco sales while permitting the use of locking devices on cigarette vending machines. However, FDA notes that when the community implemented its tobacco ordinance in May, 1989, the community had only six vending machines, and when the study was completed December, 1990, the number of vending machines had dropped to two. Moreover, despite the requirement of locking devices and persistent compliance checks by law enforcement, a child was able to purchase cigarettes from one of the two remaining vending machines in December, 1990.⁵⁷

Similarly, in 1990, Minnesota enacted a law eliminating vending machines in public areas unless the machines were only operable by activation of an electronic switch or token and were under the direct supervision of a responsible employee. One year after the law was passed, a study conducted in four cities found many machines had not been fitted with the required devices and, of those fitted with the devices, there was no significant reduction in purchase success.⁵⁸

IOM reviewed the available evidence and determined that locking devices do not effectively prevent youth access to cigarette vending machines. IOM noted that "although fewer cigarettes are sold to youths than where vending machines are completely unrestricted, businesses that installed locking devices on vending machines were still more likely to sell cigarettes to young people than businesses that used over-the-counter sales."⁵⁹

Finally, the Inspector General reported that Utah experienced limited success with locking devices:

Reportedly, clerks would simply activate the machine without checking the age of the purchaser. Since the locking devices require employee participation, they are often not as effective in busy places, such as bars or restaurants, where employees are more likely to simply activate the machine.⁶⁰

FDA has not been persuaded that vending machines equipped with locking devices sufficiently guard

⁵³ Cismoski, J., and M. Sheridan, "Availability of Cigarettes to Under-age Youth in Fond du Lac, Wisconsin," *Wisconsin Medical Journal*, vol. 92, No. 11, pp. 626-630, 1993.

⁵⁴ "Cigarette Vending Machines Sell Cigarettes to Children, 11-15 Years Old, 100% of the Time," Smokefree Educational Services, Inc., October 1990. "Critics Target Vending Machines," *The Christian Science Monitor*, p. 6, April 1990.

⁵⁵ Mead, R., "Teen Access to Cigarettes in Green Bay, Wisconsin," *Wisconsin Medical Journal*, pp. 23-24, January, 1993.

⁵⁶ "Springfield Teen Tobacco Purchase Survey," Stop Teenage Addiction to Tobacco (STAT), 1993.

⁵⁷ Jason, L. A., P. Y. Ji, M. D. Aneo, and S. H. Birkhead, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," *JAMA*, vol. 266, No. 22, pp. 3159-3161, December 11, 1991.

⁵⁸ Kotz, K., "An Evaluation of the Minnesota Law to Restrict Youth Access to Tobacco," presented to the American Public Health Association (APHA) 121st Annual Meeting, San Francisco, CA, October 24-28, 1993.

⁵⁹ IOM Report, p. 213.

⁶⁰ "Youth Access to Cigarettes," Department of Health and Human Services (DHHS), Office of the Inspector General, Pub. No. OEI-02-90-02310, p. 9, May 1990.

against children's access to tobacco products. Comments provided no evidence, and FDA is not aware of any studies, on whether law enforcement efforts affect children's ability to access tobacco products through locked vending machines. However, one study examined the effect of law enforcement efforts on illegal vending machine sales in three comparable communities that did not require locking devices. Despite the fact that merchants in one of the three communities received a letter describing the State law and warning them of the city's intention to enforce the law, there was no significant difference in the rate of illegal vending machine sales among the communities.⁶¹

Comments also provided no evidence that restricting the location of cigarette vending machines equipped with a locking device renders the machines less accessible to children and adolescents. FDA notes that, if locking devices were effective, the location of the machine would be of no consequence. Yet, as discussed in the preceding paragraphs, FDA is persuaded that some establishments are entirely inaccessible to young people. Accordingly, the final rule allows the use of vending machines in those establishments without requiring that the machines be equipped with a locking device.

FDA declines to grant an exception for tokens in the absence of evidence that machines operated only by tokens prevent children from obtaining cigarettes. Several comments suggested, rather than eliminate vending machines, that FDA require either locking devices or tokens. These comments focused on locking devices, without offering any evidence of the number of vending machines currently operating with tokens, the extent to which tokens have been tested in the marketplace, or whether the technology prevents children and adolescents from obtaining cigarettes from vending machines. FDA is aware that three States whose laws restrict the use of vending machines permit the use of locking devices or tokens. However, FDA is not aware of any evidence indicating that the use of tokens prevents young people's access to cigarettes from vending machines that are otherwise accessible to children.

(70) The most common concern raised by adult smokers was that the elimination of vending machines would

inconvenience them. Most adult smokers stated that vending machines are closer than retail outlets to their homes or places of work. Some adult smokers stated that they would be unable to purchase cigarettes late at night if vending machines were eliminated. Others indicated that vending machines provide the only means of obtaining their brand, or of obtaining cigarettes altogether.

In contrast, while acknowledging that adult smokers would be somewhat inconvenienced, comments in support of eliminating vending machines pointed out that adult smokers would still be able to purchase their products in retail transactions. Nearly all comments in support of the provision, including comments from grade school students, parents, and health professionals, said that the significant reduction in children's access to cigarettes would outweigh any inconvenience experienced by adult smokers.

The agency is persuaded that the provision would not unduly burden adult smokers, who could continue to purchase cigarettes in retail transactions, and that the inconvenience some smokers would experience is a small burden when compared to the significant public health benefit of reducing children's and adolescents' access to tobacco.

(71) A few comments questioned the propriety of using young people in "sting" operations to determine the level of compliance with existing laws restricting the sale of tobacco products to children. One comment suggested that these operations taught children how and where to purchase cigarettes, concluding that the operations "have done more to increase smoking in our youth than any tobacco company or advertisement could have."

FDA relied on several types of evidence in proposing these regulations, including teen surveys and peer-reviewed studies. Compliance testing involves sending underage children and adolescents into tobacco outlets to attempt to purchase cigarettes or smokeless tobacco. This type of study provides reliable evidence of children's ability to illegally obtain tobacco products.

A 1994 review⁶² of the design of recent studies indicates children who participated in these studies received specific instructions about the method

and purpose of the study and were escorted by at least one adult. Some adults waited outside the outlet for the young person while others went inside to observe the child attempt the purchase. In response to comments on the final rule on substance abuse prevention and treatment block grants (suggesting that participating in sting operations could be detrimental to children and adolescents), DHHS explained that "proper training and adult supervision can reduce any potential risk of negative consequences toward youth" (61 FR 1492 at 1494, January 19, 1996). In addition, DHHS offered States assistance in developing compliance testing procedures.

FDA is not persuaded that participating in compliance testing entices children to smoke. The agency believes that, with proper training and adult supervision, children and adolescents who participate in compliance testing will understand that their role in this testing is to help reduce teenage smoking by identifying places that illegally sell tobacco products to children, and that, after identification and publicity or enforcement action, these places will stop illegal sales.

(72) Several adult smokers commented that the provision, either alone or in conjunction with other provisions, would cause a decrease in tobacco consumption. To compensate for this loss, they argue, tobacco companies will raise their prices and governments will increase taxes. Overwhelmingly, adult smokers commented that the price of a package of cigarettes is already unfairly high.

The agency has narrowly tailored the final regulations to prevent only young people's use of cigarettes and smokeless tobacco. Because sales to children account for a small percentage of total tobacco sales, industry revenues will be significantly diminished only after many years have passed. Moreover, the long-term effect on product prices is difficult to forecast because reduced product demand could easily result in price decreases.

(73) In contrast, one comment cited a 1995 survey in which three-quarters or more of those Californians polled supported increasing the tobacco tax by 25 cents. Another comment suggested that an additional portion of excise taxes be allocated to smoking cessation programs and to prenatal care, especially antismoking messages targeted to pregnant women. Other comments noted that increased prices

⁶¹ Forster, J. L., M. Hourigan, and P. McGovern, "Availability of Cigarettes to Underage Youth in Three Communities," *Preventive Medicine*, vol. 21, No. 3, pp. 320-328, May 1992.

⁶² "Design of Inspections Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors," Battelle, prepared for CDC, OSH, p. 14, April 1994.

could serve to deter some children and adolescents from purchasing cigarettes.

The agency cannot act on these comments as it lacks the authority to levy taxes or mandate prices.

(74) One comment submitted by cigarette manufacturers characterized as misleading FDA's claim that its proposal to eliminate vending machines is consistent with recommendations from IOM, PHS, a working group of State attorneys general, and the Inspector General of DHHS (60 FR 41314 at 41325). FDA disagrees. IOM and PHS specifically recommended that vending machines be eliminated. IOM advocated that less restrictive measures be adopted only if shown to be effective,⁶³ while PHS cautioned that alternatives be examined carefully.⁶⁴ Moreover, PHS specifically noted that Utah found disabling devices to be "ineffectual in practice."⁶⁵

The State attorneys general determined that "very young children rely heavily on vending machines as a major source of tobacco products," and that "their use of these machines is difficult to police."⁶⁶ Consequently, the group recommended that retail stores "remove cigarette vending machines from their premises and sell tobacco products only from the controlled settings recommended above."⁶⁷ The referenced controlled settings included the use of electronic price scanners to prompt retail clerks to check a customer's identification and to display the last acceptable date of birth, using price scanner systems with tobacco "locks," and requiring tobacco products to be kept behind sales counters. The State attorneys general did acknowledge that, "at a minimum," vending machines should be modified to require tokens that could be purchased only from a store manager or be programmed to operate only if a cashier activates a remote switch, but their principal recommendation was the removal of vending machines.

While the Inspector General made no recommendation, his report noted that 42 percent of State health department

officials believe that total bans are the only way to prevent teens from using cigarettes.⁶⁸

FDA believes the provision on vending machines is consistent with the positions taken by the IOM, PHS, State attorneys general, and the Inspector General of DHHS.

(75) One comment suggested that the rule define "vending machine" to avoid regulating machines that dispense cigarettes to salespersons rather than customers. The comment described a machine designed to limit theft and to control the inventory of cigarettes and other similarly packaged items in retail stores, principally supermarkets. The machine requires that a computer command be entered before it dispenses a package of cigarettes. The comment asserted that among the machine's benefits is its ability to exclude customer access to cigarettes.

FDA did not contemplate the type of inventory machine described by the comment, and the provision, as drafted, would not include this type of machine. Section 897.16(c) is intended, in part, to eliminate mechanical devices that dispense cigarettes or smokeless tobacco to purchasers in locations that are accessible to children. FDA declines at this time to define "vending machine" so as to exclude from the rule mechanical devices developed in the future, including those intended to aid in preventing theft.

(76) One comment opposed to the provision interpreted it as prohibiting a vending machine that dispenses single cigarettes, packaged separately in tubes, each bearing the Surgeon General's warning and in compliance with tax laws. The comment explained that in some adult locations, such as cocktail lounges and casinos, many adults would like to purchase a single cigarette, and that the person submitting the comment developed the machine to fill this perceived gap in the marketplace.

The proposal did not contemplate the type of machine described by the comment. Accordingly, § 897.16(c) has been amended to permit the sale of a packaged, single cigarette in locations inaccessible to persons under the age of 18. This exception is restricted to packaged, single cigarettes that comply with other applicable laws and regulations.

b. *Self-service displays.* Proposed § 897.16(c) also would have prohibited the use of self-service displays. The preamble to the 1995 proposed rule

explained that self-service displays enable young people to quickly, easily, and independently obtain cigarettes and smokeless tobacco. FDA cited one report that reviewed surveys of grade school students; the report found that over 40 percent of the students who smoked daily shoplifted cigarettes from self-service displays (60 FR 41314 at 41325). The agency also cited one study showing that tobacco sales to young people dropped 40 to 80 percent after enactment of ordinances prohibiting self-service displays and requiring vendor-assisted sales (60 FR 41314 at 41325). The proposed provision, therefore, was intended to prevent young people from helping themselves to these products and to increase the amount of interaction between the sales clerk and the underage customer.

The preamble to the 1995 proposed rule also referred to the IOM Report which stated that placing products out of reach "reinforces the message that tobacco products are not in the same class as candy or potato chips."⁶⁹

In response to the comments, the agency has amended this section to except certain self-service displays (merchandisers) in facilities inaccessible to persons under the age of 18.

(77) Several comments asserted that the proposed restriction pertaining to self-service displays would effect takings compensable under the Fifth Amendment.

The agency disagrees with the comments. Given the character of the section, as modified in this final rule, and the lack of reasonable investment-backed expectations in personal property, its economic impact, while potentially significant for some parties, is not such as to effect a taking. The agency addresses Fifth Amendment issues in greater detail in section XI.A. of this document.

(78) Several comments challenged FDA's basis and authority for prohibiting self-service displays. The comments focused, in part, on the studies and reports cited by the agency. They argued that active enforcement of laws, rather than elimination of self-service displays, led to decreases in young people's access to cigarettes and smokeless tobacco. Other comments disputed whether significant shoplifting occurs from self-service displays. According to these comments, FDA did not provide any evidence to suggest that eliminating self-service displays is necessary to prevent shoplifting.

⁶³ IOM Report, p. 214.

⁶⁴ "Model Sale to Tobacco Products to Minors Control Act, A Model Law Recommended for Adoption by States of Localities to Prevent the Sale of Tobacco Products to Minors," DHHS, p. 2, May 24, 1990.

⁶⁵ *Id.*, p. 5.

⁶⁶ "No Sale: Youth Tobacco and Responsible Retailing Developing Responsible Retail Sales Practices and Legislation to Reduce Illegal Tobacco Sales to Minors, Findings and Recommendations of a Working Group of State Attorneys General," pp. 31-32, December 1994.

⁶⁷ *Id.*, p. 32.

⁶⁸ "Youth Access to Cigarettes," DHHS, Office of the Inspector General, Pub. No. OEI-02-90-02310, pp. 8-9, May 1990.

⁶⁹ IOM Report, p. 215.

One comment examined studies that FDA did not cite in the 1995 proposed rule and found one study estimating that less than 5 percent of the adolescents surveyed had shoplifted cigarettes. Also, a number of comments stated that, if shoplifting were truly a significant problem, retailers would have a financial interest in reducing their losses and would remove self-service displays themselves. The comments implied that shoplifting is not a significant problem, and several claimed FDA's rationale was inconsistent because, if young people could purchase cigarettes and smokeless tobacco easily from retailers, they would not have to steal them from self-service displays.

In contrast, several comments supported the prohibition on self-service displays, reiterating FDA's position that displays encourage shoplifting, and their absence increases the likelihood of age verification. For example, a drug addiction counselor commented that teens do not want to go to the counter and ask for cigarettes since there is a greater likelihood that they will be asked to show their identification and they might be embarrassed. One comment also asserted that retailers get products for displays at a discount, and such discounts are, in effect, a subsidy for shoplifting. Another comment alleged that, in one area of the country, low-priced brands are put in displays and that retailers are compensated for any shoplifting losses.

Comments from other areas of the country agreed that shoplifting occurs, sometimes at significant rates. One comment stated that a 1993 survey of 9th-grade students in one county revealed that 51 percent had shoplifted cigarettes. Another comment, reflecting on experiences conducting retailer compliance checks in three small towns, stated that its teenage volunteers "commented on the ease with which they could have lifted cigarettes from free-standing displays." A comment describing practices in a rural part of the country stated that theft was one method of acquiring smokeless tobacco, and that young people often began using such products at the age of 10, 11, or 12.

Other comments suggested an additional reason for eliminating self-service displays. These comments indicated that young people can easily pick up products from displays, leave their money at the cashier's desk, and leave the premises without being challenged by a retailer or before the retailer can request proof of age.

FDA believes there is ample evidence to support a restriction on self-service displays. The preamble to the 1995 proposed rule cited surveys suggesting that a significant percentage of children and adolescents (40 percent in the two areas surveyed) shoplift cigarettes (60 FR 41314 at 41325), and at least one comment reported an even higher percentage (50 percent). Although one comment from cigarette manufacturers suggested the shoplifting rate to be only 5 percent, FDA emphasizes that, even if one accepts the 5 percent figure, the numbers of young people engaging in shoplifting can be very large. For example, 5 percent of the estimated 3 million young people who smoke cigarettes daily equals 150,000 children and adolescents. Five percent of the estimated 3 million smokeless tobacco product users under the age of 21 also equals 150,000 people.

These numbers may even be artificially low because they exclude the number of young people who do not smoke or use smokeless tobacco daily, and these numbers may be extremely low if the 40 or 50 percent shoplifting rates identified by the agency or by other comments prove to be more accurate than the 5 percent rate cited by the cigarette manufacturers.

FDA also disagrees with those comments claiming that shoplifting is not a significant problem. Generally, such comments asserted that the problem is not significant because, if it were, retailers would move self-service displays, and most have not done so. Such comments, however, misconstrue the significance of the problem. The agency did not, and does not, claim that individual retailers are suffering significant shoplifting losses (although FDA did receive one comment containing information showing that shoplifting losses at two stores amounted to several thousands of dollars worth of cigarettes annually). Instead, FDA is stating that significant numbers of young people shoplift these products. The distinction is critical. To illustrate, if 1,000 retailers each lose 1 cigarette package to shoplifting, each retailer might feel that the shoplifting rate, from its perspective, is insignificant. However, if 1,000 young people acquire cigarettes by shoplifting, the shoplifting problem, from a public health perspective, then becomes much more significant.

(79) Several comments argued that the studies cited by the agency, having been conducted at only two locations in the United States (Erie County, NY, and Fond du Lac, WI), cannot be used to

justify a nationwide prohibition against self-service displays.

The agency disagrees with these comments. The comments offered no evidence to show that these communities are so distinct or unique from the remainder of the United States to require FDA to discount or to ignore their findings. To the contrary, FDA received other comments from various parts of the nation supporting the rule, and these comments often agreed that young people shoplift these products from displays.

FDA also notes that it does not require clinical investigations for product approvals to be conducted on a national scale. One important aspect of any study, whether it is submitted as part of an investigational product exemption, marketing application, or rulemaking, is whether the study is conducted and analyzed in a scientifically valid way that permits the results to be extrapolated to a broader population. In other words, the methodology and analysis are more important than where the study was conducted. If the agency could only act after nationwide studies had been conducted, it would be unable to act or to respond promptly, even in response to significant public health problems or emergencies.

(80) Several comments questioned the evidence supporting the proposed restriction on self-service displays. The comments stated that FDA had no evidence to support the assertion that removing self-service displays will increase the likelihood of retail clerks requesting proof of age. One comment stated that the one document cited by FDA (which compared smoking practices in five California counties before and after the institution of ordinances prohibiting self-service merchandising)⁷⁰ cannot be used to justify a rule with nationwide application because the document, which the comment correctly identified as a "position paper" rather than a study, did not: (a) Indicate whether the ordinances contained other provisions that would have led to enhanced compliance with minimum age laws; and (b) disclose whether retailers were told of the compliance testing operation before or after the fact, such that, had the retailers known, they would have been more vigilant in ensuring

⁷⁰ Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales," Stop Tobacco Access for Minors Project (STAMP), North Bay Health Resources Center, November 3, 1994.

compliance regardless of how their products were displayed. This comment further asserted that the act of adopting the ordinances, and the penalties they contained, may have made retailers more vigilant in ensuring compliance with minimum age laws than the restrictions in the ordinances themselves. Finally, the comment stated that the document was not a controlled study and that there was no indication that it was not biased, was subjected to peer review, or was even published in a scientific journal. The comment stated that the document would not be acceptable to FDA if it had been submitted as proof of a product's effectiveness.

Another comment echoed criticism of the document, stating that factors besides the restriction on self-service displays could have reduced tobacco use by young people and so the document does not support a prohibition against self-service displays.

FDA acknowledges that the document omitted details regarding the author's methodology and the ordinances in the 5 California counties and the 24 cities covered in the document. The agency disagrees, however, with the comments' assertion that factors other than the restriction on self-service displays or other features of the ordinances may have been principally responsible for decreasing tobacco use among young people. Such comments overlook the document's statement that the ordinances were to "prohibit self-service merchandising (display and sale) of tobacco products and point-of-sale tobacco promotional products and require only vendor-assisted sales of tobacco products and point-of-sale tobacco promotional products in retail stores."⁷¹ This statement suggests that the ordinances focused on restricting self-service displays (or merchandisers) and point-of-sale promotional products rather than other activities.

Other criticisms of the document are inappropriate as well. For example, the comment claimed that other provisions in the ordinances or other factors may have contributed to the decline in tobacco use in young people so that a restriction on self-service displays, alone, may not have been a significant factor in reducing tobacco use among young people. This criticism, however, overlooks the fact that the rule's restriction on self-service displays is also complemented by other provisions (such as requiring retailers to verify age and prohibiting distribution of free

samples) that will, both individually and collectively, reduce young people's access to cigarettes and smokeless tobacco.

Similarly, FDA does not agree that the document is flawed because retailers were not informed of the compliance testing operation before it was conducted. Alerting a retailer to an upcoming compliance test would bias any results because the retailer would alter its behavior in order to "pass" the test.

Additionally, in drafting the 1995 proposed rule, FDA used the best evidence available to it. The comments did not provide any studies to contradict the cited document, and while some criticisms of the document may be valid, such criticisms do not require the agency to revoke the provision entirely. The document was not FDA's sole basis for proposing to restrict self-service displays. The preamble to the 1995 proposed rule indicated that such a restriction would also reduce shoplifting, eliminate the "message" that displays send to young people, and increase interaction between retailers and their customers. These other justifications, and the comments pertaining to them, are discussed in greater detail in this document.

(81) Other comments objected to a prohibition on self-service displays because, according to these comments, the rule did not impose any sanctions on young people or contain any provisions that would modify a young person's behavior so that he or she would not shoplift. Some comments suggested that, instead of restricting the use of self-service displays, shoplifters should be prosecuted, but these same comments also declared that State or local government authorities usually decline to prosecute young shoplifters.

As stated earlier, it would be inappropriate for FDA to amend the rule to impose penalties on young people who purchase or possess cigarettes or smokeless tobacco. The main focus of the act is on the introduction, shipment, holding and sale of goods in interstate commerce. Thus, whether young people should be prosecuted for shoplifting, and the penalty for shoplifting are appropriately matters for State or local law.

(82) Several comments challenged the statement in the preamble to the 1995 proposed rule that removing self-service displays would reinforce the message to children that tobacco products are not as acceptable as candy or potato chips. The comments said that young people

know that tobacco products are not like candy or potato chips and that there is no evidence to show that the statement is true. A small number of comments added that FDA's rationale would force retailers to remove other "unhealthy" products (such as products containing fat or cholesterol) from displays.

In contrast, a few comments agreed that self-service displays for cigarettes and smokeless tobacco convey an implied message that these products are acceptable. One comment from a local government reported that young people often see tobacco products as being socially acceptable (or less harmful to health) because they are openly displayed. The comment noted that the local jurisdiction had restricted displays to being within 20 feet of the checkout counter and in a direct line of sight, but expressed regret that it had not eliminated displays altogether. Other comments noted that many retailers display cigarettes next to candy, baseball cards, and other items that appeal to children and adolescents. These comments concluded that it is necessary to eliminate self-service displays so that young children do not associate cigarettes with other products that they find amusing or that adults give to children and adolescents as treats.

The IOM Report advanced the theory that young people see self-service displays as an implied message regarding the acceptability or safety of cigarettes and smokeless tobacco. The IOM report represents the informed decisions, opinions, and recommendations of a body of experts, and so, with respect to this issue, the agency disagrees with those comments that would have FDA dismiss the IOM's opinion.

FDA also disagrees with those comments arguing that the agency would have to eliminate self-service displays for potato chips, candy, and other supposedly "unhealthy" products. These food products do not present the same range or magnitude of adverse health effects or effects on the body to warrant tighter restrictions on their sale, distribution, or use.

(83) Several comments challenged FDA's claim that removing self-service displays would increase direct interaction between sales clerks and underage consumers. The comments asserted that removing self-service displays will not prompt sales clerks to check for proof of age and that FDA had no evidence to support this proposition. Other comments opposed any restriction on self-service displays

⁷¹ *Id.*, p. 3.

because, they claimed, retail clerks, rather than self-service displays, are responsible for sales to young people. If retail clerks consistently demanded proof of age, these comments would permit self-service displays to be used.

Other comments asserted that FDA has no reasonable basis to assume that clerks will check for proof of age when clerks already ignore State laws.

In contrast, a few comments agreed that eliminating self-service displays would increase interaction between clerks and underage consumers or deter young people from attempting to purchase cigarettes or smokeless tobacco. One comment from a local board of health stated that it eliminated self-service displays because its evidence indicated that young people in the locality are less likely to purchase cigarettes if they have to request them from retail clerks. Another comment reflected on the author's own experience as a child when she would purchase cigarettes and said it is easy to grab a cigarette package, leave money on the counter, and simply leave a store before the sales clerk can react.

Section 897.14(b)(1) requires retailers to verify that persons purchasing cigarettes or smokeless tobacco are not under the age of 18. This provision, in conjunction with the prohibition against sales to anyone under 18 in § 897.14(a), the restriction on self-service displays in § 897.16(c), the sanctions that are available under the act, and the likelihood that State agencies will devote more attention to illegal sales to young people as a result of section 1926 of the PHS Act should increase the probability that retailers will verify the age of prospective purchasers.

Yet logically, removing self-service displays should increase interaction between retailers and potential consumers because the retailer, under this rule, must physically hand the product to the consumer. While this action probably will take little time (the preamble to the 1995 proposed rule and to this final rule estimate that the elimination of self-service displays would require 10 seconds of additional labor time for many retail transactions), nevertheless it increases the interaction between the retailer and potential customers. Furthermore, by restricting self-service displays, the rule eliminates a young person's ability to take a package of cigarettes or smokeless tobacco, leave money on the counter, and leave the retailer's premises without having to provide proof of age.

(84) Many comments opposed any restriction on self-service displays

because they said eliminating self-service displays would adversely affect adult consumers or would be "inconvenient" because adults would not be able to purchase products quickly; see, handle, or choose products; or obtain information about a product or a special promotion. A few comments asserted, without any supporting evidence, that self-service displays are not or cannot be used by young people, and, therefore, should not be regulated.

Conversely, one comment supporting the provision recommended that FDA clarify or modify the term "self-service displays" to distinguish self-service sales or merchandisers from advertising displays.

The comments opposing the rule misinterpreted how it would apply. The final rule prohibits self-service displays from being in facilities that are accessible to young people. Eliminating self-service displays from such facilities simply means that a consumer will not be able to take physical possession of a product without the retailer's assistance. Any inconvenience to an adult should be slight. For example, it is extremely unlikely that adults will suffer undue hardship or wait an unreasonable amount of time if they must ask a retail clerk to hand a product to them. Moreover, the provision does not prevent adults from seeing or choosing a product or from seeing or receiving information about a product; products would remain visible, but they would be behind a counter or in an area accessible only to the retailer.

Deleting self-service displays from the rule because adults wish to avoid contact with clerks would be inappropriate as well. As a practical matter, adults who use self-service displays would not be able to avoid all contact with a retailer because they presumably still interact with the retailer when they pay for the product. An important component of these regulations is to eliminate those modes of sale used by young people that do not require them to show proof of age or otherwise do not challenge a young person to show that he or she is legally entitled to purchase the product.

FDA does agree, however, that the rule should be clarified so that the reference to displays in § 897.16(c) is understood to cover self-service sales or merchandisers rather than advertising displays that contain no products and has amended the rule accordingly. However, advertising displays are restricted under the advertising provisions in this rule.

(85) The preamble to the 1995 proposed rule expressed a belief that retailers, in order to comply with a prohibition on self-service displays, could move displays behind a retail counter or create an area that would be accessed only by the retailer's employees.

Many comments rejected this notion, claiming that, due to space constraints, many retailers would be unable to move displays behind a counter and would be obliged to build areas where access would be controlled. The comments said such construction and remodeling could be expensive and could force some retailers to scale back their tobacco sales or abandon them completely; such actions would lead to decreased sales by the retailer and trigger reductions in staff and in State or local Government tax revenues.

One comment estimated that, for convenience stores, the average remodeling cost would be as high as \$7,000 per store and noted that tobacco purchases account for 28 percent of convenience store sales. So, instead of eliminating self-service displays, some comments advocated alternative approaches. The alternatives included attaching electronic article surveillance tags to products (although the comment suggesting this alternative conceded that new technology or assistance at the manufacturer's level would be needed); "source tagging," where random packages contain an electronic tag so that would-be shoplifters would not know which packages were tagged and, as a result, would be less inclined to shoplift products; and requiring displays to be within a certain distance of a cash register or the cashier's line of sight, supplemented by posting signs against underage sales and by training sales clerks. "Source tagging" would require manufacturers, rather than retailers, to insert tags into packages.

The alternatives identified by the comments appear to be less effective or less practical than removing self-service displays from places that are accessible to young people. For example, surveillance tags and, to a lesser extent, "source tagging" might deter shoplifting, but this would require all manufacturers to agree to place such tags in their products and would require retailers to install machines or gates to detect those tags. More importantly, comments from manufacturers did not address the creation or use of such tags. A "line-of-sight" or restricted-placement alternative (requiring a display to be within a certain distance of a retail employee) would require no changes by

manufacturers and few changes by retailers, yet the preamble to the 1995 proposed rule cited studies where similar requirements for vending machines failed to prevent illegal sales to young people (60 FR 41314 at 41325). Employees might also be distracted or blocked from seeing the displays, thereby reducing the effectiveness of any "line-of-sight" or restricted placement alternative. Furthermore, the alternatives would fail to eliminate the implied message that self-service displays send regarding the acceptability or safety of these products. Because FDA is unaware of any effective alternative, the agency declines to amend the rule as suggested by the comments.

FDA has, however, amended the rule to permit self-service displays (merchandisers only) in facilities that are inaccessible to people under 18 at all times. The agency made this change in response to comments stating that some facilities are inaccessible to young people and so certain requirements, such as restrictions against vending machines and self-service displays, should not apply. This exception is subject to the same restrictions as the exception on vending machine sales.

(86) Many comments, particularly from retailers, opposed eliminating self-service displays, stating that they derive a significant portion of their revenue from displays and slotting fees provided by manufacturers. Several cited figures that were in the hundreds of thousands of dollars. The comments generally stated that eliminating self-service displays would decrease or eliminate a significant portion of their revenue and, according to some, lead to layoffs or prevent them from hiring young people.

Similarly, FDA received a few comments from firms that manufacture or sell displays. These comments stated that the firms would lose significant amounts of revenue or would be forced out of business if self-service displays were eliminated.

A few comments, however, disputed whether retailers would lose slotting fees. One comment explained that manufacturers would continue to pay fees to ensure that their products would be placed in strategic locations behind the counter, while another comment noted that many retailers in a northern California region where self-service displays were eliminated did not lose slotting fees.

The agency declines to amend the rule because of the possible loss of slotting fees or other revenue from manufacturers. The theoretical loss of

fees that are, at best, tangential to the sale of these products is an inappropriate basis for determining whether this provision denies young people's access to these products effectively. Furthermore, FDA appreciates that such fees may be important to certain retailers, but, as stated earlier, the agency has no reason to conclude that all manufacturers will discontinue those fees because of this rule. The preamble to the 1995 proposed rule (see 60 FR 41314 at 41369) and one comment cited experience in California to show that retailers might not suffer significant economic losses if self-service displays are removed.

FDA reiterates that removing self-service displays from places that are accessible to young people does not mean that cigarettes and smokeless tobacco must be hidden from public view. It simply means that retailers will be required to hand these products to consumers. Presumably, if the products are moved behind the counter, manufacturers still have an incentive to ensure that their products are strategically placed in order to attract adult consumers.

(87) Several comments objected to a restriction on self-service displays, claiming that retailers have a "right" to advertise and sell products in their own establishments in any manner they select.

As mentioned in section IV.B. of this document earlier, section 520(e) of the act states, in part, that the agency may issue regulations to establish conditions on the sale, distribution, or use of a restricted device. Restrictions on cigarette and smokeless tobacco sales are appropriate given the potential adverse health effects caused by or associated with the use of these products and their accessibility and appeal to young people.

(88) A few comments said that eliminating self-service displays will make it difficult or impossible for marginal brands of cigarettes or smokeless tobacco to compete against established brands.

FDA reiterates that eliminating self-service displays from places that are accessible to young people does not mean that the products must be hidden from view; it simply means that consumers will not be able to take physical possession of the product without the retailer's assistance. Consequently, all products will face the same constraints, insofar as retailer space is concerned.

(89) Many comments would delete a prohibition against self service displays

because, according to these comments, the prohibition would be ineffective. These comments stated that self-service displays do not entice young people to smoke, do not increase consumption of tobacco products, or are only used where retailers check the consumer's age. Others stated that young people would get the products anyway, so there was no need to prohibit the use of self-service displays.

The preamble to the 1995 proposed rule stated, among other things, that young people shoplift products from displays (60 FR 41314 at 41325). Additionally, the preamble to the 1995 proposed rule indicated that young people will adjust or shift their purchasing behavior as certain avenues of obtaining these products are eliminated. (See 60 FR 41314 at 41325 (citing different vending machine use rates depending on the access restrictions used in the jurisdiction).) Given this evidence, it is reasonable to assume that, as young people are precluded from purchasing these products, they may be inclined to acquire them by theft and other means. Thus, when properly framed, the issue is not whether displays entice young people to smoke or to use smokeless tobacco (which FDA did not advance as the principal justification for the rule), but whether the agency should eliminate self-service displays as an avenue that young people use to obtain these products. The agency concludes that self service displays must be eliminated from places that are accessible to young people as part of the general restriction against impersonal modes of sale.

(90) Several comments opposed elimination of self-service displays because they claimed that retailers would be forced to hire additional staff. These comments contrasted sharply with the majority of comments from retailers who predicted that the loss of self-service displays would compel them to lay off staff. One comment explained that a self-service display frees the retailer's staff to perform other tasks. The other asserted that the rule would compel retailers to hire additional staff in order to sell these products and that this would result in an "unfunded mandate" in violation of the Unfunded Mandates Reform Act.

The preambles to the 1995 proposed rule and to this final rule estimate that eliminating self-service displays would require 10 seconds of additional labor time for many retail transactions involving cigarette cartons (60 FR 41314 at 41367). The "Analysis of Impacts"

discussion in section XV. of this document places the labor cost for this time at approximately 2.6 cents per carton. Thus, for a retailer to be compelled to hire additional staff to compensate for the loss of self-service displays, cigarette and smokeless tobacco product purchases would have to account for a substantial number of transactions. Some retailers may indeed feel that they need to hire additional staff, but the agency believes that the rule's benefits—reducing young people's access to cigarettes and smokeless tobacco nationwide—outweigh the hiring and accompanying economic burdens that might be imposed on some retailers. Moreover, because the final rule permits self-service displays (merchandisers only) in facilities that are inaccessible to under 18 people at all times, the final rule's impact on some retailers may be reduced.

FDA also disagrees with the comment claiming that the agency violated the Unfunded Mandates Reform Act. The preamble to the 1995 proposed rule contained a discussion of the Unfunded Mandates Reform Act as well as the estimated added labor costs in the "Analysis of Impacts" (60 FR 41314 at 41367 and 41359 through 41372).

(91) One comment disputed FDA's estimate that eliminating self-service would result in 10 seconds of additional labor time for most retail transactions. The comment, however, did not provide any estimate of the time that would be required.

The agency did not receive any data to suggest that the additional labor time would be greater or less than 10 seconds. While some transactions may take more than 10 seconds, the agency believes that the additional labor time will be so negligible that it will not be a significant burden on the retailer.

c. Mail-order sales and mail-order redemption of coupons.—i. *Mail-order sales.* Proposed § 897.16(c) would also have prohibited the use of mail-order sales and mail-order redemption of coupons. The preamble to the 1995 proposed rule stated that mail-order sales and mail-order redemption of coupons do not involve a face-to-face transaction that would enable verification of the consumer's age.

The agency received thousands of comments on the proposed restriction against the mail-order sale of cigarettes and smokeless tobacco. Comments supporting the proposed restriction noted that it would make cigarettes and smokeless tobacco more difficult for young people to obtain. Specifically,

comments stated that "mail-order sales should be prohibited since the seller has obvious difficulties verifying the age of the purchaser in selling where there is no face-to-face encounter." A comment from 26 State attorneys general stated that "ending distribution of tobacco by mail-order * * * will greatly assist our efforts to enforce compliance with our state laws." As a result of some comments discussed in detail below, however, the final rule permits mail-order sales, except for redemption of coupons and free samples.

(92) The agency received hundreds of comments opposing the proposed restriction against mail-order sales. Many comments were submitted by older smokers (senior citizens, retirees on fixed incomes, etc.) who identified themselves as pipe tobacco smokers who purchased tobacco products through the mail; most individuals appeared to be clients from one tobacco product supply house in Tennessee. These comments stated that young people do not smoke pipe tobacco and added that they would like to continue to purchase their pipe tobacco through the mail.

The agency believes that the comments misinterpreted the 1995 proposed rule. The preamble to the 1995 proposed rule stated that the rule did not apply to pipe tobacco or to cigars because FDA has no evidence demonstrating that pipe tobacco and cigars are drug delivery devices under the act or that young people use such products to any significant degree (60 FR 41314 at 41322).

(93) One comment asserted that the proposed mail-order provision is unauthorized and contrary to law. According to the comment, neither section 520 of the act nor any other provision of the act gives FDA the authority to declare matter unmailable. The comment explained that, under the Prescription Drug Marketing Act (PDMA), prescription drug samples may be sent through the mail to those authorized by law to obtain them. Furthermore, the comment argued, Congress has specifically determined and legislated what products should not be sent through the mail (39 U.S.C. 3001(f) and (g) (Federal statute on "nonmailable matter")).

The agency disagrees with the comment. Section 520(e) of the act expressly authorizes the agency to issue regulations pertaining to the sale, distribution, or use of a restricted device. Restrictions on the sale or distribution of such a device through

the mail are clearly within the scope of FDA's authority under that section.

Additionally, FDA does not agree that the PDMA or 39 U.S.C. 3001 prevents the agency from acting on mail-orders. The PDMA's mail-order restrictions represented a congressional response to a specific problem, namely the diversion of adulterated prescription drug products (including drug samples) into illegal markets. Here, the products in question are devices rather than prescription drugs, and the rule does not purport to address the diversion of adulterated cigarettes or smokeless tobacco or samples of those products.

Similarly, the Postal Service provision (39 U.S.C. 3001) on "nonmailable matter" does not preclude FDA from issuing regulations pertaining to the distribution of a regulated device. The provision simply states that certain items or types of items are nonmailable and directs the United States Postal Service (USPS), in certain situations, to issue regulations (such as regulations pertaining to fragrance advertising samples). FDA interprets 39 U.S.C. 3001, therefore, as establishing certain "nonmailable" items for USPS purposes rather than precluding FDA from regulating the sale and distribution of a device pursuant to its device authority. Nevertheless, as discussed in comment 94 below, FDA has amended the rule to permit mail order sales, so the issue of the USPS restrictions on nonmailable matter is moot.

(94) The agency received many comments from individuals who contended that the proposed mail-order restriction is unwarranted because the agency cited no studies to demonstrate that young people actually use the mail to obtain cigarettes. One comment noted that IOM acknowledges that "the extent of mail-order purchase of tobacco products by minors is not known." According to the comment, the mail-order restriction must be based on actual evidence that a substantial number of young people use the mail to purchase cigarettes and not based on "theoretical purchasability."

Other comments stated that young people do not obtain cigarettes through the mail because they do not possess checks or credit cards to effectuate mail-order purchases. In addition, the comments questioned whether young people are patient enough to wait several weeks to obtain tobacco products. A few comments, including a comment from a mail-order firm, contended that mail-order purchases would be too expensive for young people, either because of the cost or the

minimum order sizes (which, according to one comment, usually consists of several pounds of tobacco). These comments opposed the proposed mail-order restriction on the basis that it would not effectively reduce young people's access to tobacco products and would instead eliminate an adult's access to entirely legal tobacco products.

Other comments from firms with a significant mail-order business stated that the elimination of mail-order sales would force the firms to terminate staff or go out of business.

The agency also received many comments from adults opposing the proposed mail-order restriction. These comments stated that because mail-order sales are highly preferable to purchases in retail stores the products sold through the mail are unavailable in stores or are less expensive than those sold in stores. Other comments (including one from a prison inmate) said that because mail-order sales serve those in rural or isolated areas, eliminating mail-order sales would eliminate the principal or sole source of tobacco for those adults.

After carefully reviewing the comments, the agency has decided to delete mail-order sales from § 897.16. The restriction was intended to preclude young people from having easy access to cigarettes and smokeless tobacco. However, there is inadequate evidence demonstrating that young people use mail-order sales to any significant degree. This lack of evidence may indicate that it is not relatively easy for young people to purchase cigarettes and smokeless tobacco through the mail.

FDA also considered the impact of the proposed mail-order restriction on adults. The agency does not intend to unreasonably interfere with an adult's ability to obtain legally his or her preferred tobacco products.

Consequently, FDA has amended § 897.16(c) to allow mail-order sales of cigarettes and smokeless tobacco. The agency emphasizes, however, that the final rule retains the restrictions against the redemption of coupons and distribution of free samples through the mail. This amendment is consistent with the IOM Report which recommended a suitably limited Federal ban on the distribution of tobacco products through the mail as part of a long-term access strategy and, at a minimum, restrictions against the mail-order redemption of coupons and the

distribution of free samples through the mail.⁷²

FDA remains concerned, however, that young people may turn to mail-order sales as the rule's restrictions against other forms of access (such as vending machines and retail stores) become effective. Accordingly, FDA strongly advises mail-order firms to take appropriate steps to prevent sales to young people and reminds mail-order firms that § 897.14(a) prohibits the sale of cigarettes and smokeless tobacco to anyone under age 18. The agency will monitor the sales of mail-order tobacco products, and if FDA determines that young people are obtaining cigarettes or smokeless tobacco through the mail, the agency will take appropriate action to address the situation.

(95) Several comments criticized the agency for failing to consider less restrictive alternatives. The comments noted that tobacco mail-order houses require payment by check or credit card. Other comments would amend the rule to require firms to maintain records evidencing compliance with proof of age requirements. Another comment suggested a requirement for photocopies of photographic identification cards, such as an identification with a drivers license number, for mail-order transactions.

As stated previously, FDA has amended the final rule to permit mail-order sales, but will monitor such sales to ensure that young people do not obtain cigarettes or smokeless tobacco through the mail. The agency, therefore, strongly advises firms to take appropriate measures to prevent sales to young people.

(96) Several comments expressed concern about the financial well being of the USPS. These comments predicted that the USPS would lose income if tobacco products could no longer be sent by mail. The comments predicted that the USPS would be forced to raise postal rates to compensate, thus affecting product users and nonusers alike.

As stated previously, the agency has amended the rule to permit mail-order sales to continue. However, FDA notes that speculative or theoretical impacts on the USPS are not an appropriate basis for determining how or whether to regulate a restricted device under the act.

(97) One comment representing the concerns of specialty tobacco products noted that 90 percent of its manufacturer-distributor-retailer

distribution system uses the mail or other commercial carriers. This comment requested that FDA clarify that the proposed restriction on mail-order sales pertained to mail-order sales to the ultimate user rather than to inter-company transfers.

Proposed § 897.16(c) was intended to address sales and distributions to consumers. Transactions and shipments between manufacturers, distributors, and retailers, therefore, are not subject to the restrictions on mail-order sales of cigarettes and smokeless tobacco. However, because the final rule permits mail-order sales, there is no need to amend the rule to clarify this point.

(98) One comment supported the restriction against mail-order sales in part because, the comment claimed, such sales permit the purchaser to avoid taxes on these products (by purchasing the products from firms in States with lower taxes). The comment also stated that eliminating these sales would help Canadians because American mail-order firms are not subject to high Canadian taxes and can sell comparatively lower-cost cigarettes in Canada. The comment said this practice increases cigarette consumption in Canada and undermines the health benefits resulting from high Canadian taxes.

The issues raised by the comments are beyond the scope of this rule and FDA's authority.

ii. *Mail-order redemption of coupons.* Proposed § 897.16(c) would have prohibited mail-order redemption of coupons. The preamble to the 1995 proposed rule addressed mail-order redemption of coupons in conjunction with mail-order sales, and the restriction against mail-order redemption of coupons was meant to apply only to coupons that a prospective purchaser would send through the mail (regardless of whether the prospective purchaser used the USPS or a private carrier) to a firm to obtain cigarettes or smokeless tobacco.

(99) Most comments on this issue mistakenly assumed that FDA was proposing to ban all direct mail coupons. These comments contended that direct mail coupons are redeemed during face-to-face transactions at larger retail establishments such as grocery stores. For the most part, these comments suggested that young people do not routinely use coupons to purchase tobacco products, noting that the smaller, convenience stores where young people frequently obtain cigarettes and smokeless tobacco often do not accept coupons.

⁷² IOM Report, pp. 108, 225-226.

In contrast, FDA also received several comments supporting the proposal to eliminate mail-order redemption of cigarette and smokeless tobacco coupons. For example, the attorney general for a populous northeastern State commented that “[i]n another operation conducted by my office earlier this year, 30 minors mailed in coupons to obtain free samples of smokeless tobacco products from United States Tobacco Company. Virtually all of the minors were provided with such free samples.”

Proposed § 897.16(c)’s reference to mail-order redemption of coupons was directed at the redemption of coupons through the mail. The provision was not intended to prevent adults from redeeming coupons at a point of sale or from receiving coupons through the mail. FDA based this provision on the IOM Report which, among other things, noted that value added promotions, including coupons, constituted the largest market expenditure by the tobacco industry in 1991, that coupons are accessible to young people through direct mail campaigns, and that price-sensitive young people are attracted to such schemes or may be increasingly attracted to such schemes as their other sources of tobacco products are restricted.⁷³

Comments supporting this provision confirmed the need for prohibiting mail-order redemption of coupons. These comments reported incidents where one or more young people obtained several packages of cigarettes or smokeless tobacco by sending in coupons (usually for free samples). Consequently, the final rule retains the restriction against mail-order redemption of coupons. FDA adds that, for purposes of this subpart, “mail” is not confined to USPS delivery but includes items shipped through private carriers.

d. *Free samples.* Proposed § 897.16(d) would have prohibited manufacturers, distributors, and retailers from distributing or causing to be distributed any free samples of cigarettes or smokeless tobacco. The agency proposed this restriction because free samples are often distributed at “mass intercept locations,” such as street corners and shopping malls, and at events such as festivals, concerts, and games. The preamble to the 1995 proposed rule stated that free samples represent a “risk-free and cost-free” way for young people to obtain and possibly use cigarettes or smokeless tobacco and that, when free samples are distributed

at cultural or social events, peer pressure may lead some young people to accept and to use the free samples (60 FR 41314 at 41326).

The preamble to the 1995 proposed rule also cited surveys and reports demonstrating that young people, including elementary school children, can obtain free samples easily. Young people were able to obtain free samples despite industry-developed, voluntary codes that supposedly restrict distribution of free samples to underage persons. The agency cited the IOM Report which suggested that distribution of free samples to young people occurs because the samplers are often placed in crowded places and operating under time constraints that may limit their ability to request proof of age. The IOM Report added that the samplers are usually young themselves and, as a result, “may lack the psychological wherewithal to request proof of age and refuse solicitations from those in their own peer group” (60 FR 41314 at 41326).

(100) FDA received a few comments that opposed any restrictions on free samples, claiming that eliminating free samples would violate the “rights” of adult consumers, reduce choices for adults, or deprive adults of the opportunity to save money.

In contrast, many comments supported proposed § 897.16(d), including several that opposed the remainder of the rule but expressly supported a prohibition on the distribution of free samples. Several comments stated that young people can easily obtain free samples; a few comments, including two from 12-year old students, mentioned that their classmates were able to receive free samples or reported that young people were able to receive free samples without being asked to show proof of age. One comment even reported that a young person was able to receive 4 cigarette packages through the mail as free samples, while another claimed to have seen 12 cans of smokeless tobacco being given to teenagers.

Another comment supported the provision, based on the author’s own experience when he was 15 years old; a neighborhood grocer gave him and his friends free cigarettes “until we were hooked” and then the grocer “had steady paying customers.” Other comments supported this provision for the same reason that they supported eliminating single-cigarette sales and establishing a minimum package size: Such items encourage young people to experiment with cigarettes or they

represent, as a consortium of State attorneys general said, “sales and marketing practices that provide young people with the easiest access to tobacco.”

The agency agrees that § 897.16(d) will affect adults by effectively requiring them to purchase cigarettes and smokeless tobacco rather than receive them free of charge. However, the comments opposing the elimination of free samples did not offer any suggestions as to how to prevent free samples from reaching young people. In view of the evidence showing that young people obtain free samples despite any industry-imposed restrictions or (in the case of at least one comment) that they obtain free cigarettes from a retailer, the agency concludes that the benefits of eliminating free samples as a source for young people outweigh the inconvenience to adults.

FDA also disagrees with the comments asserting that eliminating free samples adversely affects an adult’s ability to choose products or otherwise violates adult “rights.” The final rule does not alter an adult’s ability to select or purchase cigarettes and smokeless tobacco.

(101) Several comments submitted by manufacturers or their representatives opposed the prohibition against the distribution of free samples, stating that manufacturers use free samples to introduce new products, to encourage adult consumers to switch brands, or to thank their adult consumers for their patronage. Others comments added that free samples do not encourage young people to smoke or to use smokeless tobacco or that eliminating free samples would not reduce cigarette or smokeless tobacco use by young people.

The agency is eliminating free samples because they are an inexpensive and easily accessible source of these products to young people and, when distributed at cultural or social events, may increase social pressure on young people to accept and use free samples (60 FR 41314 at 41326). The preamble to the 1995 proposed rule cited studies and reports to support the agency’s views; those documents contradict the comments’ claim that free samples do not encourage young people to use these products or affect use by young people.

As for the rule’s impact on manufacturers’ practices, the public health benefits from eliminating free samples as an avenue that young people use to obtain cigarettes and smokeless tobacco outweigh any inconvenience to

⁷³ *Id.*

manufacturers who will be obliged to devise new ways to introduce new products, to get adults to switch brands, or to thank adult consumers. FDA believes that manufacturers will be able to devise new approaches to promote new brands or to attract new adult customers that comply with these regulations.

(102) One comment expressed strong opposition to proposed § 897.16(d). The comment argued that FDA lacked authority to ban free samples, especially when the agency would permit sales to adults, and that the agency had no evidence to support a ban on free samples. The comment added that the act did not extend to device samples and argued that Congress knows how to give FDA authority over samples, as evidenced by sampling provisions in the PDMA. The comment further stated that the term "sample" was over-broad because it was not limited to products distributed in public settings for promotional purposes; thus, the comment continued, any complimentary gift could be a "sample" under proposed § 897.16(d).

FDA disagrees with the comment. Section 520(e) of the act states that the agency may "require that a device be restricted to sale, distribution, or use * * * upon such other conditions as the Secretary may prescribe by * * * regulation." Restricting free samples is clearly a restriction on the product's distribution.

As for the PDMA, the comment's claim that the PDMA's sampling restrictions shows that Congress has not authorized FDA to regulate device samples (due to the absence of express language on device samples) fails to take into account the fact that FDA's restricted device authority is broader than its prescription drug authority. Also, the comment fails to take into account the reasons behind enactment of PDMA. PDMA was enacted not to give FDA new authority over prescription drug samples, but to curtail the illegal diversion of drugs, including samples, into the market. (See S. Rept. 100-303, 100th Cong., 2d sess. 2-3 (1988).) Before PDMA was enacted, FDA regulated prescription drug samples in the same manner as prescription drug products. Thus, PDMA is not intended to give FDA new authority over samples; instead, it reflects a congressional decision to give FDA a comprehensive and explicit set of new authority to prevent illegal diversions of prescription drug products, including the diversion of prescription drug samples to illegal markets.

FDA also declines to amend the rule to allow "gifts." Allowing "gifts" would enable parties to declare that their free samples were now "gifts" and therefore outside the rule and could lead to disputes as to whether an item was a prohibited "sample" or an allowable "gift." However, the agency will exercise discretion in interpreting and enforcing this rule. For example, a manufacturer's employee who sends cigarettes or smokeless tobacco to an adult relative to celebrate a birthday would not be subject to regulatory action under the free sample restriction in § 897.16(c).

(103) One comment stated that, notwithstanding the preamble to the 1995 proposed rule, FDA has no evidence to support a restriction on the distribution of free samples. The comment stated that the rule overestimated the prevalence of sample activities and that cigarette sampling accounted for only 0.7 percent of the total spent on cigarette advertising and promotion in 1993. The comment also said that FDA relied on an outdated version of the cigarette manufacturers' voluntary code. According to the comment, the outdated code prohibited distribution of cigarette samples within two blocks of any "center of youth activities" and "required samplers to demand proof of age in doubtful cases." The revised code adds that "[s]ampling shall not be conducted in or on public streets, sidewalks or parks, except in places that are open only to persons to whom cigarettes lawfully may be sold."

In contrast, two comments cautioned FDA against deferring to a voluntary code or relying on the industry. One comment stated that, in Maine, the industry agreed to submit reports on sampling activities to the State in place of legislation that would have curtailed sampling activities, but the industry discontinued these reports as soon as State authorities stopped sending reminders that the reports were due. Another comment stated that, in Massachusetts, a lawsuit over sampling practices by a smokeless tobacco firm ended in a settlement whereby the firm would require photocopies of identification cards for all mail-in requests for samples. The comment said that the settlement represented an improvement over requiring no proof of age at all, but noted that the firm refused to apply this practice outside the State and that the restriction did not apply to other smokeless tobacco firms. The comment also claimed that firms often agree to restrict sampling activities only after adverse publicity or agree to

restrict sampling activities without setting any measurable performance goals.

FDA disagrees with the comment asserting that the agency has no evidence to support a restriction on free samples. The preamble to the 1995 proposed rule cited several reports and surveys showing that young people, including elementary school children, obtain free samples easily (60 FR 41314 at 41326). The agency also has no assurance that the revised cigarette industry code will be any more effective than earlier versions. Moreover, as mentioned earlier in this document, FDA received comments stating that young people continue to receive free samples of cigarettes and smokeless tobacco. The comments refute the claim that voluntary industry restrictions on sampling preclude the need for FDA regulation of free samples.

Additionally, the rule offers several important advantages over voluntary codes. The rule creates enforceable obligations which, if violated, may subject the manufacturer, distributor, or retailer to sanctions under the act. These sanctions, in turn, create an incentive for regulated parties to adhere to the act and its implementing regulations. A voluntary code also applies only to the parties that accept the code or fall within the same industry; for example, a voluntary manufacturers' code might not extend to distributors or to retailers, or, as the comment recognized, a voluntary cigarette manufacturers' code might differ from a voluntary smokeless tobacco manufacturers' code.

Furthermore, a regulation creates uniform standards and policies for the same product. Those standards apply regardless of whether a firm is a member of a voluntary organization.

Finally, the agency notes that, while the comment said that "only 0.7 percent of the total spent on cigarette advertising and promotion" in 1993 went to cigarette sampling activities, this percentage still translates into a large sum. Cigarette advertising and promotion expenditures, according to the same FTC report cited by the comment, were approximately \$6 billion in 1993. Thus, the seemingly small percentage devoted to cigarette sampling activities, when translated into dollars, represents \$42 million.

(104) Several comments supported the prohibition against the distribution of free samples, but suggested that FDA amend the rule to prevent distribution of cigarettes and smokeless tobacco at prices below their fair market value. One comment would define a product's

fair market value as the average retail price in the region. Another comment would amend § 897.16(d) to prohibit sales or distribution of cigarettes and smokeless tobacco "in return for nominal consideration."

The agency declines to amend the rule as suggested by comments. While the comments have merit, FDA usually has no role in the prices charged for an FDA-regulated product. Additionally, it would be difficult for FDA to monitor fair market values for various products, and disputes would inevitably arise as to whether the "market" should cover a broader or narrower geographic area, the data used to determine the fair market value, and how compliance actions would be affected by fluctuations in the fair market value. Similar disputes would arise regarding "nominal consideration." Furthermore, regardless of the price at which the product is sold, other provisions in this subpart should deter or reduce access by young people.

e. Restrictions on labeling and advertising. The agency on its own initiative has added § 897.16(e) as a point of clarification to the final rule. This provision states that "no manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with the restrictions in Subparts C and D * * *." The restrictions on labels, advertising, and labeling in subparts C and D of part 897 are authorized, in part, under section 520(e) of the act and are considered conditions of sale, distribution, and use. Therefore, § 897.16(e) clarifies the statutory obligations of manufacturers, distributors, or retailers under this rule.

V. Label

In the 1995 proposed rule (60 FR 41314, August 11, 1995), subpart C of part 897 was entitled "Labels and Educational Programs," and contained two provisions. Proposed § 897.24, would have required cigarette or smokeless tobacco packages to contain the appropriate "established name" of the product; the final rule retains that provision and does not make any substantive changes to it. Proposed § 897.29 would have required manufacturers to establish and maintain a national educational program to discourage children from using cigarettes and smokeless tobacco. Based on issues raised by comments, proposed § 897.29 has been deleted from the final rule, and instead, the Food and Drug Administration (FDA) has determined

that issuing notification orders under section 518 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) would be the most practicable and appropriate means of requiring tobacco manufacturers to inform young people of the unreasonable health risks. Discussion of the comments received regarding this education provision is included in section VII. of this document.

A. Established Name (§ 897.24)

Proposed § 897.24 would have required that each cigarette or smokeless tobacco product package, carton, box, or container of any kind that is offered for sale, sold, or otherwise distributed bear whichever of the following established names is appropriate: "Cigarettes," "Cigarette Tobacco," "Loose Leaf Chewing Tobacco," "Plug Chewing Tobacco," "Twist Chewing Tobacco," "Moist Snuff," or "Dry Snuff."

The preamble to the 1995 proposed rule explained that this provision was intended to implement section 502(e)(2) of the act (21 U.S.C. 352(e)(2)), which states that a device shall be deemed misbranded if its label fails to display the established name for the device. Section 502(e)(4) of the act, in turn, explains that the "established name" for a device is the applicable official name of the device designated under section 508 of the act (21 U.S.C. 358), the official title in a compendium if the device is recognized in an official compendium but has no official name, or "any common or usual name of such device." In this case, no official names have been designated under section 508 of the act, and no compendium provides an established name for these products. Consequently, § 897.24 proposed designating "cigarettes," "cigarette tobacco," and the common or usual names for smokeless tobacco (such as "moist snuff" or "loose leaf chewing tobacco") as established names for these products.

(1) The agency received few comments on proposed § 897.24. One comment that opposed the provision stated that it was unnecessary and would produce anomalous results. The comment stated that, because cigarettes are already required to be labeled "cigarettes" under regulations adopted by the Bureau of Alcohol, Tobacco and Firearms (BATF) under the Internal Revenue Code (27 CFR 270.215 (1995)), "Cigarettes" is already the common and usual name and, therefore, there is no need to designate an "established name."

The agency has concluded that the BATF requirement does not conflict with the act's requirement that the label bear the established name of these products. The agency recognizes that BATF regulations currently require cigarette packages to include the word "cigarettes" on the package or on a label securely affixed to the package (27 CFR 270.215). For smokeless tobacco and chewing tobacco, BATF regulations require the packages to include the words "snuff" or "chewing tobacco," or alternatively, "Tax Class M" or "Tax Class C," respectively (27 CFR 270.216). These terms also describe the established name, as required in section 502(e) of the act.

Many of the labeling provisions of the act, including section 502(e)(2), are intended to provide important basic information to consumers and others coming in contact with a regulated product. In this case, the act requires that the established or common name be placed on the product's label in a clear way so that it is easily seen and consumers can readily identify the product. Congress provided an exception only for cases where compliance with this provision is "impracticable." If a manufacturer believes that it cannot comply with this provision of the rule, the manufacturer should consult with the agency to determine if it qualifies for an impracticability exception under section 502(e)(2) of the act.

(2) One comment that supported the provision on established name recommended that, in addition to the established names set forth in the 1995 proposed rule, little cigars and tobacco sticks should also be listed as separate products with their own specific established names, "little cigars" and "tobacco sticks" "in keeping with the manner and style of the established names to be used for smokeless tobacco products."

One comment that opposed the provision stated that since proposed § 897.3(a) would define "cigarettes" to include little cigars, the same package of little cigars that must be labeled "small cigars" or "little cigars" (under current BATF regulations, 27 CFR 270.214(c) (1995)), would also have to carry the established name of "cigarettes" under the proposed FDA regulation. The comment argued that such a conflicting labeling requirement is absurd, and would create confusion where none now exists.

The agency has modified the definition of "cigarette" found in proposed § 897.3(a) to exclude little

cigars from the final rule. The agency also advises that, to the best of its knowledge, tobacco sticks currently are not sold in the United States. If tobacco sticks were to be marketed in this country, the agency advises that such products would be subject to premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807, and could be included under the established name of "cigarette tobacco," and therefore do not need to be listed as separate products at this time.

B. Package Design

(3) Several comments noted that the 1995 proposed rule did not include any action to eliminate the use of the tobacco product package itself to influence children. A few comments cited a March 1995 Canadian study, which found that package designs affect the ability of teens to associate lifestyle and personality imagery to specific brands and detract from the health message.⁷⁴ Another study found that the "badge" value of cigarette packages for youths was decreased when the packages were stripped of their unique characteristics.⁷⁵ The comment suggested that the provisions of proposed § 897.30, requiring text only with black text on a white background, should be extended to cigarette packages. One comment pointed out that FDA has the authority to require plain packaging without violating the Federal Cigarette Labeling and Advertising Act (the Cigarette Act), 15 U.S.C. 1334(a), which prohibits additional statements related to smoking and health on cigarette packages.

The agency agrees with the comments that cigarette package design and imagery are powerful tools that increase the appeal of the product, especially to young people. In the preamble to the 1995 proposed rule the agency cited several studies demonstrating that "[i]magery ties the products to a positive visual image" (60 FR 41314 at 41335). Another study showed that "children and adolescents react more positively to advertising with pictures and other depictions than to advertising (or packaging) that contains only print or text" (60 FR 41314 at 41335).

The agency has considered extending the requirements of § 897.30 (text only, black on white background) to the package itself, but believes at this time these measures are not necessary considering the comprehensive nature of the regulatory scheme contained in this rule. Therefore, the agency is not extending the requirements applicable to advertising and labeling to the package itself.

C. Ingredient Labeling

The agency specifically requested comments on whether it should implement recommendations from the Ad Hoc Committee of the President's Cancer Panel, which recommended, among other things, that the range of tar, nicotine, and carbon monoxide delivered by each product be communicated to consumers. In addition, the Ad Hoc Committee recommended that smokers be informed of "other hazardous smoke constituents."

(4) The agency received several comments suggesting that tar and nicotine delivery or yield information should be disclosed on product packages in order to assist consumers in making more informed decisions about the use of cigarettes. Some of these comments also suggested that labels list the toxins present in, or delivered from, cigarettes and state their effect, e.g., "known carcinogen."

One comment stated that it cannot be claimed that the ingredients are trade secret information and, therefore, cannot be disclosed, because the tobacco companies voluntarily released a list of ingredients to the public in 1995. The comment noted that, under current case law, only items kept confidential qualify as trade secrets. (See *Kewanee Oil v. Bicron Corp.*, 416 U.S. 470 (1974); *Avtect Systems v. Peiffer*, 21 F.3d 568 (4th. Cir. 1994).) The comment noted further that because companies can and do perform reverse engineering on another company's products, the ingredients are not trade secret. The comment proposed that, at a minimum, FDA should designate a partial list of previously disclosed ingredients and require that the list be included on package labels. Another comment stated that only a reasonable number of ingredients should be listed on the label or in a package insert.

One comment stated that ingredient listing is not barred by the Cigarette Act or by the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Act). (See 15 U.S.C. 1331 *et seq.* and 15 U.S.C. 4401 *et seq.*) These

statutes require the current Surgeon General's warnings on tobacco products and preempt any additional statements relating to smoking or health from being required on cigarette or smokeless tobacco packages. The comment asserted that a list of ingredients is not a statement, and cannot be reasonably construed as a statement relating to smoking and health, because a statement expresses a point of view, whereas an ingredient list does not.

One comment noted that the Cigarette and Smokeless Acts require manufacturers to submit annually to the Department of Health and Human Services (DHHS) a list of ingredients added to tobacco products, and the statutes further require that the lists be treated as confidential commercial or trade secret information. (See 15 U.S.C. 1335(a) and 15 U.S.C. 4403.) The comment stated that the confidentiality provisions in both statutes bind the Secretary of DHHS with respect to trade secrets, but do not restrict FDA's authority to require ingredient listing.

FDA agrees that accurate information about the tar, nicotine, and carbon monoxide delivery from a cigarette to the user would be useful information. FDA is aware of the Federal Trade Commission's (FTC's) recent efforts to develop a system to measure, more accurately than the current test, the tar, nicotine, and carbon monoxide delivered by cigarettes. FTC has announced that it will issue a report of its findings regarding a new test method in the near future. FDA believes that it would be premature to require manufacturers to put any of this information on tobacco product labels before FTC has issued its report and made recommendations on accurately measuring the delivery of tar, nicotine, and carbon monoxide to product users.

With regard to ingredients other than tar, nicotine, and carbon monoxide, the agency agrees that it has authority under the act to require labeling or listing of other substances present or delivered by cigarettes. (See section 502(r) of the act.) The agency notes that there are hundreds of ingredients added to or delivered by cigarettes and smokeless tobacco. Even if the agency were to require listing of only a "reasonable number," current methodologies are not adequate to accurately identify and quantify the added ingredients or the constituents delivered by these products. Moreover, at this time there is not enough data to enable the agency to determine what a "reasonable" number of ingredients would be or to determine which ingredients should be listed and

⁷⁴ "When Packages Can Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products," Health Minister of Canada, March 1995.

⁷⁵ Rootman, I., B. R. Flay, and D. Flay, "A Study on Youth Smoking, Plain Packaging Health Warnings, Event Marketing and Price Reductions, Key Findings," A Joint Research Project by University of Toronto, University of Illinois, York University, Ontario Tobacco Research Unit, Addiction Research Foundation, p. 7, 1995.

which should not. Therefore, the agency is not requiring the listing of ingredients in the rule.

As discussed in the preamble to the 1995 proposed rule, cigarettes and smokeless tobacco are subject to various pre-existing requirements in the statute and the regulations. The preamble stated that such "regulations include the general labeling requirements for devices at part 801 (21 CFR part 801) (excluding § 801.62)" (60 FR 41314 at 41352). The parenthetical reference was a typographical error because the 1995 proposed rule would have exempted such products from § 801.61, not § 801.62 (60 FR 41314 at 41342). Section 801.62 states the requirements for "Declaration of net quantity of contents." This provision requires that the label of an over-the-counter device bear a declaration of the net quantity and weight of the contents, e.g., "20 cigarettes." The agency fully expects manufacturers to comply with this provision and, as discussed below, also expects manufacturers to comply with § 801.61.

D. Labeling for Intended Use

(5) The agency received comments suggesting that FDA require intended use information on the package label of cigarettes and smokeless tobacco. Proposed § 801.61(d) would have exempted cigarettes and smokeless tobacco from the statement of identity and labeling for intended use requirements of § 801.61. The comments stated that such information informs the public about the product's intended use. One comment supported proposed § 801.61(d).

Based on the comments received, the agency has reconsidered the matter and concluded that it is appropriate to require that this information appear on the label. Consequently, the agency has deleted § 801.61(d) from the final rule.

All over-the-counter devices are required to comply with § 801.61 and bear the "common name of the device followed by an accurate statement of the principal intended action(s) of the device" on the principal display panel of the package. (See § 801.61.) As over-the-counter devices, cigarettes and smokeless tobacco are legally required to comply with this provision.

In the 1995 proposed rule, the agency proposed to exempt these products because "section 801.61 stems, in part, from the Fair Packaging and Labeling Act (FPLA), and [t]obacco products are exempt from the statute's requirements" (60 FR 41314 at 41342). Further evaluation revealed that the

requirements in § 801.61 are also based on FDA labeling authorities including, but not limited to, section 502(a), (c), (e), (f), and (q) of the act, and not the FPLA.

Furthermore, section 1460 of the FPLA contains "Savings provisions" (15 U.S.C. 1460). The provisions state that "Nothing contained in this Act [15 U.S.C. 1451 et. seq.] shall be construed to repeal, invalidate, or supersede * * * (b) the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et. seq.] * * *." Thus, because FDA's assertion of jurisdiction over these products is under its statutory authority under the act, any conflict between the two statutes shall be resolved in favor of the act. (See *Jones v. Rath Packing*, 430 U.S. 519 (1977).) Consequently, section 1459 of the FPLA, which removes tobacco from the definition of "consumer commodity," and thus, removes it from jurisdiction under the FPLA, is superseded by FDA's coverage of these products under the act.

As stated in the preamble to the 1995 proposed rule, manufacturers of cigarette and smokeless tobacco are expected to comply with the general labeling requirements in part 801 (60 FR 41314 at 41352). For purposes of § 801.61, the "common name of the device" is the established name as set forth in § 897.24.

To more accurately reflect the permitted intended use of these products, the agency has modified the statement of intended use set forth in the proposal. The agency proposed that the intended use of these products be described as a "nicotine delivery device." Under this rule, these products may be intended for use only by persons 18 years of age and older. Thus, a more accurate statement of the permitted intended use of these products is "Nicotine Delivery Device For Persons 18 or Older."

Further authority for this requirement stems from section 520(e)(2) of the act (21 U.S.C. 360j(e)(2)). This provision states that: "The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe." The statement of intended use, in essence, incorporates the statement of one of the principal restrictions FDA is imposing on these products.

Accordingly, a provision has been added to § 897.25 that codifies this intended use statement and statement of restrictions for purposes of § 801.61.

E. Adequate Directions for Use and Warnings Against Use (Section 502(f) of the act)

(6) A few comments stated that FDA failed to discuss or provide for adequate directions for use, as required in section 502(f) of the act. The comments stated that FDA's silence on this issue is a tacit acknowledgment that the agency cannot have jurisdiction over these products because adequate directions for use cannot be prepared for them.

The agency disagrees with these comments. It does not logically follow that because the agency was silent on this issue, it does not have jurisdiction over tobacco products. In fact, in the preamble to the 1995 proposed rule, the agency cited one of the authorities for the labeling requirements for these products as section 502 of the act.

According to section 502(f) of the act, a device shall be deemed misbranded:

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

For devices, "adequate directions for use" means "directions under which the layman can use a device safely and for the purposes for which it is intended" (§ 801.5). These regulations outline the type of information which, if missing, may lead to a product being deemed to be misbranded. Such information includes conditions, purposes, and uses for which the device is intended; quantity of dose; frequency, duration, time, route or method of administration; or preparation for use (§ 801.5).

The agency acknowledges that it is very difficult to establish adequate directions for use for cigarettes and smokeless tobacco, primarily because of the inherent nature of the products, their addictiveness, the numerous hazards associated with their use, and because the behavior of each user (e.g., the depth of inhalation, the duration of puff, whether the filter holes are covered, and length of time in mouth) determines the amount of tar and nicotine delivered to the user from the device.

Section 502(f) of the act provides for an exemption for adequate directions for use if they are "not necessary for the

protection of the public health.” For example, the agency has established exemptions from adequate directions for use where adequate directions for common uses of certain devices are known to the ordinary individual. (See § 801.116.) Tobacco products have a very long history of use in this country, and they are one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge. FDA believes that the public health would not be advanced by requiring adequate directions for use. Accordingly, the agency has added a provision to the final rule exempting cigarette and smokeless tobacco from the requirement of having adequate directions for use. Section 801.126, states, “Cigarette and smokeless tobacco as defined in part 897 of this chapter are exempt from section 502(f)(1) of the Federal, Food, Drug, and Cosmetic Act.”

The agency has considered the requirement in section 502(f)(2) of the act that the labeling of a medical device must provide “adequate warnings against use * * * by children where its use may be dangerous to health.” In the agency’s view, the warnings mandated by the Cigarette Act (15 U.S.C. 1333) and the Smokeless Act (15 U.S.C. 4402) satisfy this requirement. Additionally, the Surgeon General’s warnings provide information warning against use in persons with certain conditions, i.e., pregnant women. Consequently, cigarettes and smokeless tobacco are not exempt from the statutory requirements under section 502(f)(2) of the act.

F. Package Inserts

(7) Several comments stated that FDA should require cigarette and smokeless tobacco packages to contain package inserts that contain health information and information about the chemicals added to cigarettes and smokeless tobacco. One comment stated that FDA has statutory authority to require package inserts under sections 502(a) and (q) and 520(e) of the act. Another comment stated that the agency is not preempted from requiring package inserts because sections 1334(a) and 4406 of the Cigarette Act and the Smokeless Act, respectively, preempt statements related to health “on any package,” not *in* any package.

FDA agrees with the comments that it has statutory authority under the act to require package inserts for these products. Under section 502(a) of the act, a device is misbranded if its labeling is false or misleading in any

particular. Section 201 of the act (21 U.S.C. 321), the “Definitions” section of the act, describes the concept of “misleading” in the context of labeling and advertising. Section 201(n) of the act explicitly provides that, in determining whether the labeling of a device is misleading, there shall be taken into account not only representations or suggestions made in the labeling, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to the consequences that may result from use of the device under the conditions for use stated in the labeling or under customary or usual conditions of use.

These statutory provisions, combined with section 701(a) of the act (21 U.S.C. 371(a)), authorize FDA to issue a regulation designed to ensure that persons using a medical device will receive information that is material with respect to the consequences that may result from use of the device under its labeled conditions. In the prescription drug context, this interpretation of the act and the agency’s authority to require patient labeling for prescription drug products have been upheld. (See *Pharmaceutical Manufacturers Assn. v. FDA*, 484 F.Supp. 1179 (D. Del. 1980) *aff’d per curiam*, 634 F.2d 106 (3rd Cir. 1980).)

Additionally, on several occasions, the agency has required patient package inserts for devices, and has specified either the express language for the patient package insert or the type of information to be included in the patient package insert. These devices include hearing aids (§ 801.420), intrauterine devices (§ 801.427), and menstrual tampons (§ 801.430).

The agency also agrees with the comment that it is not prohibited from requiring patient package inserts due to the preemption clauses in the Cigarette Act and the Smokeless Act. Each of the clauses in these statutes specifically prohibits requirements that statements relating to smoking and health be placed on the package. Package inserts, by nature, are typically found in the package.

Although the agency believes that package inserts for these products are authorized under the act and would provide useful information to users, further evaluation would be needed to determine what specific information a package insert would contain. Therefore, the agency is not requiring them as part of this rule.

VI. Advertising

A. Subpart D—Restrictions on Advertising and Labeling of Tobacco Products

Subpart D in part 897 contains the restrictions for advertising and labeling of cigarettes and smokeless tobacco. Subpart D of part 897 in the Food and Drug Administration’s (FDA’s) August 11, 1995, proposed rule (60 FR 41314) (the 1995 proposed rule) provoked some of the strongest and most passionate comments from both supporters and opponents of the proposed restrictions. Many comments from the tobacco industry, the advertising industry, public interest groups, and individuals expressed major concerns about the legality, constitutionality, and wisdom of the advertising restrictions in general and about the underlying support for individual sections of the 1995 proposed rule. Comments from the largest organization of psychologists in the world, public interest and health groups, individual advertisers, and individuals expressed strong support for the legality and constitutionality of the proposal, provided information supporting various provisions of the proposal, and emphasized the necessity for comprehensive advertising regulations.

The purpose of the advertising regulations is to decrease young people’s use of tobacco products by ensuring that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people. (See *Central Hudson Gas and Electric Corp. v. Public Serv. Comm’n of N.Y.*, 447 U.S. 557, 569 (1980).) Proposed subpart D of part 897 included a range of restrictions that attempted to preserve the informational components of advertising and labeling which can provide useful product information for adult smokers, while eliminating the imagery and color that make advertising appealing and compelling to children and adolescents under 18 years of age.

Briefly, the 1995 proposed rule included four provisions. Section 897.30 would have defined those media in which labeling and advertising for cigarettes or smokeless tobacco may appear. In addition, it would prohibit outdoor advertising within 1,000 feet of elementary and secondary schools and playgrounds. Proposed § 897.32 would limit all advertising to black text on a white background. Advertising in any publication that is read primarily by adults would be permitted to continue to use imagery and color. Further, all

cigarette and smokeless tobacco product advertisements would be required to include the product's established name and intended use, e.g., "Cigarettes—A Nicotine Delivery Device," and cigarette advertisements would be required to include a brief statement, such as "About one out of three kids who become smokers will die from their smoking." Proposed § 897.34 would prohibit the sale and distribution of nontobacco items, contests and games of chance, and sponsored events using any indicia of product identification (e.g., brand name, logo, recognizable pattern of color). Finally, proposed § 897.36 outlined those conditions under which the agency would find the advertising or labeling of any cigarette or smokeless tobacco product to be false or misleading.

In response to comments filed, FDA has modified the proposed regulations. Briefly, some of the more substantive changes include: The definition of adult-oriented publications remains unchanged, but the preamble makes clear that the responsibility will be assigned specifically to the manufacturer, distributor, or retailer of tobacco products that wishes to place advertisements to gather and retain competent and reliable evidence that the readership of the publication meets the criteria for an adult-oriented publication. Moreover, unrestricted advertising, i.e., with color and imagery, may be displayed at facilities described in § 897.16(c)(2)(ii) that may sell tobacco from vending machines and self-service provided that the advertising, e.g., posters and signs, must be displayed so that they are not visible from outside the facility and are affixed to a wall or fixture in the facility.

The revised intended use statement is "Nicotine Delivery Device for Persons 18 or Older," and the agency will not require a brief statement other than the Surgeon General's warnings.

As provided in the 1995 proposed rule, the final rule states that any event sponsored by a manufacturer, distributor, or retailer of tobacco products is to be sponsored only in the corporate name. Teams and entries also may be sponsored but only in the corporate name. The regulation includes a ban on all brand-identified nontobacco items, including those transactions based upon proofs-of-purchase. However, the proposed ban on contests and games has been deleted. Finally, the agency has decided to delete the definition of false or misleading advertising and labeling from this final rule because it is duplicative and

unnecessary in light of the underlying requirements in sections 201(n), 502(a), and 502(q) (21 U.S.C. 321(n), 352(a), and 352(q)) of the Federal Food, Drug, and Cosmetic Act (the act).

Section VI.B. of this document provides a general discussion of the rationale for including significant advertising restrictions in the final regulation, including a discussion in response to comments concerning the theory of advertising and the importance of color and imagery to advertising's appeal, especially for young people. This section also provides a discussion of the effects of advertising on young people, including expert opinion and research evidence provided by the American Psychological Association.

Section VI.C. of this document provides responses to questions raised about the constitutionality of the regulations. Section VI.D. of this document includes a discussion of the evidence that cigarettes and smokeless tobacco advertising plays a direct and material role in young people's decisions to purchase and use these products. This part also explains why restricting tobacco advertising will advance the Federal Government's interest in preventing the use of tobacco products by young people, and provides responses to comments about the evidence. Finally, section VI.E. of this document responds to comments concerning the factual evidence provided by FDA in support of its proposed regulation in a section-by-section format, as well as to comments claiming that each of these sections was not narrowly tailored to minimize the burden on commercial speech.⁷⁶

B. The Need for Advertising Restrictions

In the preamble to the proposed 1995 rule, FDA tentatively asserted that a preponderance of the quantitative and qualitative studies of cigarette advertising suggested: (1) A causal

⁷⁶ For the purposes of section VI. of this document, the agency will refer to advertising and labeling merely as "advertising." As the agency pointed out in the preamble to the 1995 proposed rule, advertising and labeling often perform the same function: to convey information about the product; to promote consumer awareness, interest, and desire; to change or shape consumer attitudes and images about the product; and/or to promote good will for the product (60 FR 41314 at 41328). Moreover, most court cases involving advertising do not distinguish between the forms of advertising that FDA calls labeling and those referred to as advertising. When there is a need to distinguish between the two forms of promotion, for example, when labeling and advertising are subject to different statutory requirements, this document will make clear what is being discussed.

relationship between tobacco advertising and tobacco use by young people, and (2) a positive effect of stringent advertising measures on smoking rates and on youth tobacco use. In arriving at this tentative finding, FDA relied heavily on the National Academy of Sciences Institute of Medicine's (IOM's) Report entitled *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youths*, Washington, DC 1994 (the IOM Report) and the Department of Health and Human Services' (DHHS') Center for Disease Control and Prevention's (CDC's) Report entitled *Preventing Tobacco Use Among Young People, A Report of the Surgeon General* (1994) (1994 SGR). Both indicated that advertising was an important factor in young people's tobacco use, and that restrictions on advertising must be part of any meaningful approach to reducing smoking and smokeless tobacco use among young people. In addition, FDA was careful to note that industry statements and actions and examples of youth oriented advertising and marketing campaigns lent support to the agency's findings.

FDA's review and consideration of the comments received has led the agency to conclude that advertising plays a material role in the decision by those under 18 to use tobacco products.

1. Advertising and Young People

(1) Comments from the tobacco industry argued that FDA had simply assumed that young people found cigarette and smokeless tobacco advertising to be appealing, and that there was no empirical evidence of how young people actually perceived the imagery displayed in cigarette and smokeless tobacco advertisements. The comments argued that the research cited by the agency relates primarily to the role of imagery in brand choice decisions. In addition, several comments disputed FDA's evidence that young people are particularly vulnerable to image-oriented advertisements. To respond to these comments, it is necessary to describe the function of advertising and how it affects young people.

a. *Function of advertising.* Advertisers use a mix of advertising and promotional vehicles to call attention to the product they are selling—to describe its properties, to convey its superiority over other products, and in some cases to give it an allure above and beyond the qualities of the product itself. (A red convertible can be a mode of transportation; it can also tell people a

lot about who you are, or who you think you are or want to be.)

Advertising creates a matrix of attributes for a product or product category and beliefs about the product and its possessor. It can serve to convey images that are recalled later when an event prompts the consumer to think about a purchase. Consumers, as a general rule, overestimate the effect that advertising has on the market in general, but they routinely underestimate its effect upon them and their own purchasing choices.⁷⁷

As discussed in sections VI.B.1.b. and VI.B.1.c. of this document, advertising that is diverse, image-laden, and colorful can be particularly effective in attracting attention in a cluttered advertising environment. Further, advertising that is repeated frequently and in as many different media as possible is most likely to ensure that its message is received by the maximum number of consumers. This trend toward the use of many media in a coordinated effort to communicate an advertising message supports the need for a comprehensive approach to mitigating the effects of tobacco advertising.⁷⁸

Every presentation can add to and build upon the imagery and appeal created for a product category or a particular brand. Print advertising, direct mail, and outdoor advertising help to create an image of the brand (and sometimes an image of the brand's user) and provide information about price, taste, relative safety, and product developments for current or prospective users. William Campbell, Chief Executive Officer of Philip Morris, explained the importance of linking the brand imagery in various media in relationship to the success in marketing its Marlboro product:

[W]e've managed to take what was originally tunnel vision advertising and positioning * * * into every kind of avenue * * *. For example, our auto racing activities are just another way to express the Marlboro positioning. Some would say the Marlboro Cup is different from Marlboro Country, but it is absolutely consistent.⁷⁹

⁷⁷ Gunther, A. C., and E. Thorson, "Perceived Persuasive Effects of Product Commercials and Public Service Announcements: Third Person Effects in New Domains," *Communication Research*, vol. 19, pp. 574-575, 1992.

⁷⁸ Flynn, B. S., J. K. Worden, R. H. Secker-Walker, G. J. Badger, B. M. Geller, and M. C. Costanza, "Prevention of Cigarette Smoking Through Mass Media Intervention and School Programs," *American Journal of Public Health*, vol. 82, pp. 827-834, 1992.

⁷⁹ "Philip Morris Keeps Smoking—Campbell Sees Growth for Tobacco Unit in Declining Industry," *Advertising Age*, p. 20, Nov. 19, 1990.

The use of many different media is also important in advertising directed to children. An example of a successful multimedia approach directed to children is the cigarette smoking prevention program conducted by Flynn et al., in Vermont, New York, and Montana, and cited in the preamble to the 1995 proposed rule.⁸⁰ This effort combined school cigarette smoking prevention programs with a mass media intervention featuring more than 50 different television and radio spots over a 4-year period. Some communities received the school cigarette smoking prevention programs alone, and others received the school program in combination with the mass media intervention. By the final year of the program, students exposed to both school and mass media interventions were 35 percent less likely to have smoked during the past week than students exposed only to the school program. Further, this preventive effect persisted for at least 2 years following the completion of the program.⁸¹ The researchers attributed the effectiveness of their program in part to the fact that their intervention used a wide variety of messages and message styles over a significant period of time.

Thus, all media collectively along with the amount of exposure time to young people, can increase the effectiveness of the advertiser's message. For example, billboards near schools or playgrounds expose children to unavoidable advertising messages for a more prolonged period of time than billboards they pass on the highway. Further, sponsored events that typically last for 2 to 3 hours ensure that those attending the event or viewing it at home on television are exposed for a sustained period of time.

b. *Color contributes.* Color is an important component of advertising. It can be used to promote a "feeling" and a message—blue is cool, red is hot, green is menthol. Studies have shown that four-color advertisements significantly increase attention and recall relative to two color or black- and white- advertisements.⁸² Moreover, the

⁸⁰ Flynn, B. S., J. K. Worden, R. H. Secker-Walker, G. J. Badger, B. M. Geller, and M. C. Costanza, "Prevention of Cigarette Smoking Through Mass Media Intervention and School Programs," *American Journal of Public Health*, vol. 82, pp. 827-834, 1992.

⁸¹ Flynn, B. S., J. K. Worden, R. H. Secker-Walker, P. L. Pirie, G. J. Badger, and B. M. Geller, "Mass Media Interventions for and School Interventions for Cigarette Smoking Prevention: Effects Two Years After Completion," *American Journal of Public Health*, vol. 84, pp. 1148-1150, 1994.

⁸² Hanssens, D., and B. Weitz, "The Effectiveness of Industrial Print Advertisements Across Product

importance of color in advertising becomes more salient when it is considered that most consumer behavior occurs in conditions of "low involvement."⁸³ Low involvement conditions are those that occur when a reader skims a magazine advertisement rather than carefully searching for an advertisement for information about price, taste, relative "safety" of the product, or product improvement.

A recent article in *The European*⁸⁴ described the importance of color:

[S]ecuring a brand colour is more important than ever, particularly for companies chasing a youth market. The main reason is the increasing use of fast and furious graphics in advertising and marketing communications generally. "This makes owning a colour more and more important. You can keep changing the graphics, but the colour remains constant in the consumer's mind." Owning a colour also helps when sponsoring a sports event, for instance, "All Pepsi now has to do is put up lots of blue," said Brant.⁸⁵

c. *The importance of imagery.* Imagery also enhances the ability of advertising to communicate more quickly in low involvement situations and in quick exposure contexts. Pictorial information is remembered much better than verbal information, as pictures perform a function of "organizing" the qualities of the product as depicted with an image. Generally, as the pictures or images in an advertisement increase (both in number and the proportion of the advertisement occupied by the image), the advertisement is more likely to be recognized, and the brand name more likely to be remembered. In most cases, pictorial or image advertising is a more robust and flexible communications medium and can be used to communicate with the functionally illiterate or the young person in a hurry.⁸⁶

Categories," *Journal of Marketing Research*, vol. 17, pp. 294-306, 1980.

⁸³ MacInnis, D. J., and L. L. Price, "The Role of Imagery in Information Processing: Review and Extensions," *Journal of Consumer Research*, vol. 13, pp. 473-491, 1987.

⁸⁴ Short, D., "The Colour of Money," *The European*, p. 21, April 10, 1996.

⁸⁵ Id. Brant was commenting on Pepsi's decision to change its brand color to blue.

⁸⁶ Lutz, K. A., and R. J. Lutz, "Effects of Interactive Imagery on Learning: Applications to Advertising," *Journal of Applied Psychology*, vol. 62, pp. 493-498, 1977; Hendon, D. W., "How Mechanical Factors Affect Ad Perception," *Journal of Advertising Research*, vol. 13, pp. 39-45, 1973; See also Holbrook, M. B., and D. R. Lehmann, "Form Versus Content in Predicting Starch Scores," *Journal of Advertising Research*, vol. 20, pp. 53-62, 1980; Twedt, D. W., "A Multiple Factor Analysis of

An executive from Griffin Bacal, one of the largest advertising agencies in New York, explained how visual imagery scored with young people:

Pictures sell. Visuals count * * * even those visuals that seemingly have nothing to do with the product sale. * * * [including locations, sets, props, wardrobe, colors, numbers, sexes and ages of people in the ads] * * * Kids want to be like each other. Group acceptance, and living the life of the gang, is critical. * * * Similarly, kids define themselves by the product choices they make and share. Be sure your advertising makes the "world" accessible and "invites" the viewer to join.⁸⁷

Evidence from social psychology and marketing research shows image-based advertising, such as that employed by the cigarette and smokeless tobacco industry, is particularly effective with young people, and that the information conveyed by imagery is likely to be more significant to young people than information conveyed by other means in the advertisement.

According to the "elaboration-likelihood model of persuasion," persuasive communications, such as advertisements, can persuade people either: (1) By the "central route," or (2) by the "peripheral route."⁸⁸ The central route refers to the process by which a person reads the messages or information contained in the advertisement and thinks carefully about it and is influenced by the strength of its arguments. The peripheral route is a process in which individuals, particularly young people, are more likely to pay attention and be persuaded by peripheral cues such as attractive models, color and scenery, which are unrelated to the primary parts of the message. Therefore, a young person, or anyone who is unmotivated or unable to carefully consider the arguments in a message, is likely to be persuaded via the peripheral route.

In markets where most brands in a product category are similar (as is the case with cigarettes and smokeless tobacco products), most advertising provides little, if any, new information. Thus, peripheral cues (such as color and imagery) take on added significance. Moreover, according to the model, for children, the motivation and ability to "elaborate" upon the arguments (pay

attention to and think about the factual information) contained in cigarette and smokeless tobacco advertising are relatively low, making young people more susceptible to influence from peripheral cues such as color and imagery.

Finally, according to the comment from the nation's largest psychological association, children generally have less information-processing ability than adults, and they are less able or less willing to pay attention to the factual information in the advertisements. This comment stated that because any possible negative health consequences associated with using tobacco products are relatively far in the future for them, children are less motivated than adults to carefully consider information such as tar and nicotine content or the Surgeon General's warnings, which are contained in cigarette and smokeless tobacco advertising. Thus, the comment concludes, color and imagery in advertisements are important components for young people.⁸⁹

A communications researcher who provided comments on FDA's 1995 proposed rule for the consolidated comment of the cigarette industry asserted that the elaboration likelihood model was relevant to the way children respond to tobacco advertising, but took a somewhat different view than that expressed above. Specifically, the comment stated that children are most likely to use the central route when they are ego-involved in the subject of persuasion, and that "ego-involvement generally comes from those subjects which are salient to the groups with which one is aligned - e.g. peers." However, the comment also stated that because children would have no real experiences surrounding the initiation of cigarette smoking, they would be likely to engage in peripheral processing, and would rely on credible sources, such as peers. The comment contended,

The reason the elaboration likelihood model is relevant here is that the decision to begin smoking cigarettes does not come out of a set of fixed or habituated experiences personal to the decision maker. For that reason *this decision is likely to be one on which a person is particularly susceptible to the influence of others*, and therefore source credibility becomes key. [Emphasis added].

The agency is not convinced by the comment. This explanation does not address children's responses to tobacco

advertisements—it essentially assumes that children are influenced by advertising only insofar as it is filtered through the experience of their peers. This reasoning is both circular and illogical. However, the agency does concur with the comment's view that children typically process tobacco advertising via the peripheral route, that children are particularly susceptible to the influence of others regarding the decision to start smoking or to use smokeless tobacco, and that perceived source credibility plays an important role. FDA maintains that the "source" of the persuasive message in tobacco advertising is frequently conveyed by the imagery presented in the advertisement. The same comment expressed this sentiment, stating "[s]ince the media consumer often does not know the writer or broadcaster personally, the consumer or receiver may attribute source credibility to the media themselves." To the extent that characters featured in tobacco advertising, such as Joe Camel, the Marlboro Man or the attractive models or race car heroes typically portrayed in such advertising appear credible and appealing, they are perceived as credible sources, and could influence children regarding the decision to smoke or to use smokeless tobacco products.

2. Advertising and Adults

(2) Several comments from the tobacco industry and the advertising industry stated that cigarette and smokeless tobacco advertising plays an important economic role in tobacco marketing. A comment from the tobacco industry stated that FDA proposed restrictions would: (1) Substantially impair advertising of tobacco to adults; (2) deprive adults of useful information about products and services such as availability, price, and quality; (3) reduce the incentive and ability to market improved products; and (4) deprive adult smokers of the benefits of competition to provide a broad range of choices and to assure that tobacco products are provided at the lowest possible cost. Consequently, the comment said that the 1995 proposed rule would have a far greater adverse impact on advertising to adults than on advertising seen by young people.

One comment from an advertising agency argued that restrictions on the advertising of tobacco products would "significantly erode the progress made over the past 15 years in increasing the quantity and variety of information readily available to the public." This

Advertising Readership," *Journal of Applied Psychology*, vol. 36, pp. 207-215, 1952.

⁸⁷ Kurnit, P., "10 Tips From the Top Agency-Exec Explains How Griffin Bacal Scores with Kids," *Advertising Age Supplement*, pp. 19-20, February 10, 1992.

⁸⁸ Petty, R. E., and J. T. Cacioppo, *Communication and Persuasion: Central and Peripheral Routes to Attitude Change*, Springer-Verlag, New York, p. 3, 1986.

⁸⁹ See also, Huang, D. P., D. Burton, H. L'Howe, and D. M. Sosin, "Black-White Differences in Appeal of Cigarette Advertisements Among Adolescents," *Tobacco Control*, vol. 1, pp. 249-255, 1992.

progress, the comment reiterated, has benefited and continues to benefit the public.

Further, several comments argued that unfettered advertising is consistent with our Nation's belief in providing the broadest possible range of information to individuals, so that they can exercise informed judgment in their daily lives. For these reasons, the comment stated, further restrictions on the advertising of legal products would not be in the public interest and should be opposed.

FDA recognizes, as these comments maintained, that imagery and color make advertising appealing to adults, as well as to children, and that advertisers consistently use these elements to make advertisements compelling and attention getting. Moreover, removal of color and imagery will make advertising's role in presenting information to adults more difficult. However, as stated more fully in the preamble to the 1995 proposed rule, FDA has attempted to tailor its advertising restrictions as narrowly as possible consistent with its purpose of reducing young people's attraction to and use of tobacco. Thus, rather than banning all advertising, the proposed regulations retain the informational function of advertising by permitting text-only advertising while removing color and imagery from those advertisements to which young people are unavoidably exposed.

FDA does not believe that these restrictions should dramatically increase search costs for adult smokers and smokeless tobacco users who are actively looking for information on price and new product innovations. Text-only advertising requires a high involvement on the part of the consumer but can realistically be expected to provide sufficient information to carry the message and also provide sufficient appeal to attract current smokers and smokeless tobacco users. Some advertising for low-tar products relies on text-only or text with few pictures.

If the information about product type is important and desired by adult tobacco users, it can and will be provided by text-only advertisements if the industry desires to make the information available. As noted above, advertising for low-tar cigarettes is generally high-involvement advertising at the present and therefore can be expected to survive in a text-only environment. Nonetheless, the agency recognizes that it may be more difficult for advertising, without imagery and color, to attract the attention of current tobacco users. However, the agency has

decided that the public health benefits of reducing advertising's ability to create appeal for young people greatly outweighs the tobacco companies' interest in unrestricted advertising to adults.

The position argued by these comments is essentially that industry has the right to communicate freely with its intended audience regardless of the impact its advertising has on the illegal and vulnerable audience of children and adolescents. Other comments counter this comment asserting that it is the Government's obligation to protect children because of their special vulnerabilities, their lack of experience and knowledge, and their limited ability to make appropriate decisions regarding behavior that will have lifelong health consequences. FDA believes its obligation with respect to tobacco products is to safeguard the health and safety of young people to ensure that they do not begin a potentially lifelong addiction to products that cause so much disease and premature death.

C. The Regulations Under the First Amendment

1. Introduction

Under section 520(e) of the act (21 U.S.C. 360j(e)), FDA included a number of proposed conditions in the 1995 proposed rule on how cigarettes and smokeless tobacco could be advertised as part of its proposed restrictions on the sale of these products. The agency tentatively found that these conditions are necessary to reduce the advertising's ability to create demand for these products—that is, the desire to purchase them—among children and adolescents under 18, for whom these products are not safe (60 FR 41314 at 41350). In addition, FDA tentatively found that it was necessary to include an industry-financed education program among these conditions.

In proposing these measures, FDA recognized that they would have to pass muster under the protections of communication extended by the First Amendment to the United States Constitution, in particular, under the protections extended to commercial speech (60 FR 41314 at 41353). Before addressing the commercial speech analysis, however, this section responds to several comments which registered more fundamental complaints under the First Amendment about FDA's proposed approach.

(3) Several comments, which were from the tobacco and advertising industries, found in statements made by FDA evidence of an intent not merely to

protect the health of young persons but to “delegitimize” lawful adult conduct, to engage in “viewpoint discrimination,” and to run “roughshod” over the rights of cigarette and smokeless tobacco companies. One comment said that it is outside the realm of permissible exercise of governmental power to suppress speech for the purpose of instilling values that the Federal Government believes are appropriate. This comment also said that the purpose of FDA's rulemaking is to eliminate speech that conflicts with Government messages on smoking and health. The comment noted that FDA's goal is to bring about the demise of smoking as a social custom. However, a comment from a consumer group disagreed, saying instead that FDA's 1995 proposed rule was limited to covering only those activities designed to promote the sale of the product to young people and thus covered only commercial speech.

FDA has carefully considered these comments and has taken the concerns that they expressed into account as it developed this final rule. The agency recognizes that its authority is limited by the act and the Constitution. Thus, it has scrutinized each of the conditions on advertising that it proposed in light of whether the condition advances the purposes of section 520(e) of the act or some other section of the act, and whether the condition is consistent with the First Amendment.

FDA's primary concern is the public health. Because of the potentiality for harmful effects on individuals under 18 from use of cigarettes and smokeless tobacco, FDA is adopting restrictions on advertising among other restrictions on the sale, distribution, and use of these products. These restrictions will mean that it should be more difficult to sell these products to people under age 18, who currently purchase these products in significant numbers.

The agency acknowledges that insofar as these restrictions help reduce the sale of tobacco products to young people, the restrictions will have an adverse effect on the cigarette and smokeless tobacco companies. However, this fact does not mean that FDA is trying to bring about the demise of the tobacco industry. The restrictions that FDA is adopting have been tailored to help reduce tobacco advertising's ability to create an underage market for these products, while leaving open ample avenues for cigarette and smokeless tobacco companies to communicate to current users 18 years of age or older about their products. As explained in detail in

section VI.E. of this document, this is all that the First Amendment requires.

(4) Several comments argued that, in the 1995 proposed rule, FDA had understated the protection that commercial speech is afforded under the First Amendment. These comments pointed out that advertisers and consumers have powerful First Amendment rights to send and receive commercial messages. To support this point, one comment pointed out that the Supreme Court has recognized that the free flow of commercial information is "indispensable to proper allocation of resources in a free enterprise system." (See *Virginia State Bd. of Pharmacy v. Virginia Citizens' Consumer Council, Inc.*, 425 U.S. 748, 765 (1976).) The comment also pointed out that the Court went on to say that a "particular consumer's interest in the free flow of commercial information * * * may be as keen, if not keener by far, than his interest in the day's most urgent political debate" (*Id.* at 763).

Another comment, however, citing *Ohrlik v. Ohio State Bar Ass'n.*, 436 U.S. 447 (1978), stated that there are dangers inherent in a free-for-all marketplace, and that, at times, vigilant Government action is needed to protect the public from false, deceptive, or overbearing sales campaigns.

In addition to the comments, the agency has considered the Supreme Court's recent decision in *44 Liquormart, Inc. v. Rhode Island*, 116 S.Ct. 1495 (1996), which was handed down after the rulemaking record was closed. The Court ruled unanimously that Rhode Island's ban on all dissemination of price advertising for alcoholic beverages was violative of the First Amendment. No rationale for this judgment commanded a majority of the Court, however. Nonetheless, FDA considered each part of the principal opinion, as well as the concurring opinions, in arriving at the decisions that are set forth in this final rule.

FDA in no way underestimates the protection extended to commercial speech by the First Amendment. FDA recognizes the important societal interests served by this type of speech and has given full consideration to those interests in developing this final rule. Nonetheless, it is also true, as the agency stated in the 1995 proposed rule (60 FR 41314 at 41353 to 41354), that the measure of protection that commercial speech receives is commensurate with its subordinate position in the scale of First Amendment values, and it is subject to modes of regulation that might be

impermissible in the realm of noncommercial expression. (See *Florida Bar v. Went For It, Inc.*, 115 S.Ct. 2371, 2375 (1995).)

However, in *44 Liquormart, Inc.*, three Justices stated:

[w]hen a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands. (116 S.Ct. at 1507)

This statement has no application to the restrictions that FDA is imposing for two reasons. First, FDA is not entirely prohibiting the dissemination of commercial messages about cigarettes and smokeless tobacco. As explained in section VI.E. of this document, it is adopting carefully tailored restrictions on the time, place, and manner in which such messages may be conveyed so that they are not used to undermine the restrictions on access by minors. Second, the restrictions are related to the bargaining process. As explained in section II.C.3. of this document in the discussion of section 520(e) of the act, the access restrictions, and the concomitant restrictions on promotion of these products, derive from the fact that, at least as a matter of law, minors are not competent to use these products.

"The protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation." (See *Central Hudson*, 447 U.S. at 563.) FDA has weighed these factors in deciding what restrictions on cigarette and smokeless tobacco advertising can appropriately be included in this final rule.

2. The *Central Hudson* Test

The comments were unanimous in agreeing that any restrictions the agency adopts on commercial speech will be assessed under the test first articulated by the Supreme Court in *Central Hudson*, 447 U.S. at 563–64. This test was originally set out as a four-step analysis in *Central Hudson*; however, in one recent case, *Florida Bar v. Went For It, Inc.*, the Supreme Court described the test as having three prongs after a preliminary determination is made, although the matters to be considered remain unchanged:

Under *Central Hudson*, the government may freely regulate commercial speech that concerns unlawful activity or is misleading* * *. Commercial speech that falls into neither of these categories, * * * may be regulated if the government satisfies a test consisting of three related prongs: first, the government

must assert a substantial interest in support of its regulation; second, the government must demonstrate that the restriction on commercial speech directly and materially advances that interest; and third, the regulation must be "narrowly drawn" * * *. (115 S.Ct. at 2376 (citations omitted))

FDA explained in the preamble to the 1995 proposed rule why the restrictions on advertising that it was proposing met each requirement of the *Central Hudson* test (60 FR 41314 at 41354 and 41356). The agency received a number of comments on its analysis—mostly from the tobacco industry, newspaper or magazine associations, and advertisers. These comments argued that FDA's proposed restrictions failed under one or more elements of the *Central Hudson* test. The agency also received comments from a public interest group, which has the protection of commercial speech as one of its interests, and from a coalition of major national health organizations. Both of these comments argued that, in virtually all respects, FDA's proposed restrictions satisfy the *Central Hudson* test.

In the sections that follow, for each of the restrictions on advertising that the agency proposed, FDA will analyze the case law that elucidates the applicable standard, the information presented in comments, and all other available evidence and decide whether that standard is met. However, before the agency does so, it must first consider the preliminary inquiry under *Went For It* and decide whether the First Amendment provides any protection to the advertising that is restricted by this final rule.

3. Is Cigarette and Smokeless Tobacco Advertising Misleading, or Does It Relate to Unlawful Activity?

As stated earlier, the preliminary inquiry under the *Went for It* case is whether the commercial speech is misleading or relates to unlawful activity. FDA did not specifically address this aspect of the *Central Hudson* analysis in its proposal (60 FR 41314 at 41354). Nonetheless, several comments did.

Many of the comments asserted that the targeted speech concerns lawful conduct, and that, therefore, this aspect of the *Central Hudson* analysis is satisfied. One comment noted FDA's silence on this matter and said that there is thus no suggestion that cigarette advertisements propose an illegal transaction or urge youths to begin smoking before it is lawful for them to do so.

Some comments argued, however, that cigarette and smokeless tobacco

advertising is not entitled to First Amendment protection because it is misleading, and it concerns unlawful activity. These comments pointed out that it is unlawful in all 50 States to sell tobacco products to children under the age of 18. The comments said the evidence that FDA assembled in its 1995 proposal suggested that manufacturers of tobacco products are aware that their advertising campaigns induce minors to experiment with tobacco products (citing 60 FR 41314 at 41330–41331), and that much of the promotional efforts of the tobacco industry are geared toward an illegal end—inducing minors to try to break the law by obtaining cigarettes and smokeless tobacco that may not legally be sold or otherwise provided to them.

The comments also argued that governmental entities are entitled to broad discretion when regulating the promotion of legal products or activities that pose dangers to society (citing, e.g., *United States v. Edge Broadcasting Co.*, 509 U.S. 418 (1993)). The comments argued that cigarette advertising is designed to persuade minors that any concerns about health hazards are misplaced or overstated, and that their peers are having fun because they smoke.

Contrary positions were taken by several comments. One argued that the fact that the sale of tobacco to minors is illegal under State law does not remove the constitutional protection for advertising to adults an otherwise lawful product (citing *Dunagin v. City of Oxford*, 718 F.2d 738, 743 (5th Cir. 1983) (en banc), cert. denied, 467 U.S. 1259 (1984).) A second comment cited the conclusion of a respected researcher that: “the suggestion that advertising messages are somehow working subliminally to twist children’s minds before they are old enough to know better is a complete invention, for which there is no evidence whatever” (citing McDonald, C., “Children, Smoking and Advertising: What Does the Research Really Tell Us?,” 12 *International Journal Of Advertising* 286 (1993)). These comments also argued that given the warnings that must appear in all tobacco advertising, it could not be maintained that tobacco advertising is misleading.

FDA has carefully considered these comments. They raise the fundamental question of whether tobacco advertising is protected by the First Amendment. This question cannot be disposed of based simply on the question of whether such advertising explicitly urges young people to begin purchasing or using

tobacco products before it is lawful for them to do so.⁹⁰

The Supreme Court has repeatedly said that commercial speech “related to” unlawful activity is not entitled to First Amendment protection. (See *44 Liquormart, Inc.*, 116 S.Ct. at 1505 n.7 (“By contrast, the First Amendment does not protect commercial speech about unlawful activities.”); *Florida Bar v. Went For It*, 115 S.Ct. 2376 (“Under *Central Hudson*, the government may freely regulate commercial speech that concerns unlawful activity or is misleading”); *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 69 (1983) (“The State may also prohibit commercial speech related to illegal behavior.”); *Central Hudson*, 447 U.S. at 563–564 (“The government may ban * * * commercial speech related to illegal activity.” (citations omitted)).) Tobacco advertising is “related to illegal activity” in two significant respects and thus, in fact, might not be protected speech.

First, tobacco ads, at least as a legal matter, propose a commercial transaction (see *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976); *Pittsburgh Press Co. v. Human Relations Com’n*, 413 U.S. 376, 389 (1973)), that is, to sell cigarettes and smokeless tobacco. In proposing these transactions, the advertisers do not differentiate between adult and minor purchasers. Because sales to minors are unlawful in every State,⁹¹ the undifferentiated offer to sell constitutes, at least in part, an unlawful offer to sell. At the very least, these advertisements are clearly perceived by minors as offers or inducements to buy and use these products. Millions of American children and adolescents act on these perceived offers. It is estimated that each year children and adolescents consume between 516 million and 947 million cigarette packages and 26 million containers of smokeless tobacco (60 FR 41314 at 41315). Thus, in a practical sense, cigarette and smokeless tobacco advertising is proposing transactions that are illegal (see *Virginia State Board of Pharmacy v. Virginia Citizens Council, Inc.*, 425 U.S. at 772), whether

or not that is the advertiser’s intent. As such, the protections of the First Amendment might not attach to such advertising because it proposes an illegal transaction. (See *Pittsburgh Press Co.*, 413 U.S. at 389; *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 638 (1985) (“The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading, * * *, or that proposes an illegal transaction * * *” (citations omitted)).)

Second, even if it is assumed, *arguendo*, that cigarette and smokeless tobacco ads are not, for constitutional purposes, literal offers to sell to minors, they nonetheless are “related to” an unlawful activity. Whether it is the advertiser’s intent or not, as explained in sections VI.D.3. through VI.D.6. of this preamble, cigarette and smokeless tobacco advertising has a powerful appeal to children and adolescents under the age of 18 and through this appeal, by means of the image that it projects, it has an effect on a young person’s decision to use, and thus to attempt to purchase, tobacco products. Yet, as stated above, sale of tobacco products to minors is unlawful in all 50 States, and the purchase, possession, or use of tobacco products by minors is unlawful in a majority of States.⁹² Thus, the appeal of tobacco advertising to minors is such that this type of advertising can appropriately be viewed as encouraging, and thus being “related to”, illegal activity. As a result, it is arguable that, without more, FDA would be able to freely restrict such advertising.

Nevertheless, the advertising also relates to lawful activity—the sale of tobacco products to adults. Consequently, FDA may not have unlimited discretion to regulate tobacco advertising. (See *Dunagin v. City of Oxford*, 718 F.2d at 743.) At the very least, however, FDA should be afforded discretion to do what it has tried to do in these regulations; that is, to distinguish advertising that “relates to” commercial activity that, in substantial respects, is unlawful, the sale of tobacco products to children, from advertising that does not.

Significantly, the Supreme Court was confronted with a situation similar to this in *United States v. Edge Broadcasting*. In *Edge*, the Supreme Court upheld a Federal statute that prohibited advertising that “related to” unlawful activity (broadcast of lottery advertising by a broadcaster licensed to

⁹⁰ As explained more fully below, FDA finds unpersuasive the quote from McDonald because it does not address the means by which cigarette and smokeless tobacco product advertising influences minors’ decisions on whether to purchase and use these products. Therefore, the agency turns to the legal issue raised by the comments.

⁹¹ “State Laws on Tobacco Control—United States, 1995,” *Morbidity and Mortality Weekly Report (MMWR)*, CDC, DHHS, vol. 44, No. ss–6, pp. 16–17, November 3, 1995.

⁹² *Id.*

a State that does not allow lotteries), but not advertising that did not relate to unlawful activity (broadcasting of lottery advertising by a broadcaster licensed to a State that allowed a lottery.)

Edge was recently cited with approval by the plurality opinion in *44 Liquormart Inc.*, 116 S.Ct. at 1511. Justice Stevens (joined by Justices Thomas, Kennedy, and Ginsburg) reasoned that the statute in *Edge* “was designed to regulate advertising about an activity that had been deemed illegal in the jurisdiction in which the broadcaster was located.” He contrasted the statute in *Edge* to the statute in *44 Liquormart* which “targets information about entirely lawful behavior” (*Id.*). Thus, the Supreme Court has countenanced distinctions in how speech is regulated that are based on whether the underlying conduct to which the speech relates is *entirely lawful* or not. That is exactly the type of distinction that FDA is drawing here.

Thus, a credible argument can be made that advertising of cigarettes and smokeless tobacco, at least to the extent that it is related to sale of these products to children under 18, is not speech protected by the First Amendment, and thus that the regulations that FDA is adopting restricting such advertising are subject only to review under an arbitrary or capricious standard. (See *Florida Bar v. Went For it, Inc.*, 115 S.Ct. at 2376.) However, FDA is not relying solely on this analysis. Alternatively, FDA has assumed that a *Central Hudson* test, such as that applied in *Edge*—for products that relate to both lawful and unlawful transactions—would be appropriate here. Therefore, a full analysis of these restrictions under *Central Hudson* follows.

Before proceeding to the *Central Hudson* analysis and considering the comments that bear on it, FDA wants to emphasize that, even if the First Amendment applies to tobacco advertising, the restrictions that the agency is adopting have very limited impact on those attributes of commercial speech that are protected by the First Amendment. In *44 Liquormart, Inc.*, a plurality of the Supreme Court reemphasized that commercial speech is protected solely because of the informational value:

Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made

through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

116 S.Ct. at 1505 (emphasis added), quoting *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council*.

The restrictions that FDA is adopting have virtually no effect on the core informational function of commercial speech as described in *44 Liquormart, Inc.* and *Virginia Board of Pharmacy*. Except for billboards within 1,000 feet of schools and playgrounds, which, as explained below, present special circumstances, FDA is not restricting the ability of a manufacturer, distributor, or retailer to inform the public about what they are selling, why they are selling it, or the price of their products or, for that matter, about the characteristics of their products or about any other aspect of what they sell. FDA’s concerns are about the ability of manufacturers to use images, color, and peripheral presentations (such as sponsorship) in their advertising and promotion of their products to create particular appeal for children and adolescents under 18. Thus, FDA has designed the restrictions that it is adopting to ensure that adults can continue to be informed by the information in tobacco advertising while restricting the noninformative aspects of advertising that appeal to children and adolescents under the age of 18. The agency will explain how it has achieved this end in the discussion that follows.

4. Is the Asserted Government Interest Substantial?

Assuming that the *Central Hudson* test applies, “[t]he State must assert a substantial interest to be achieved by restrictions on commercial speech.” (See *Central Hudson*, 447 U.S. at 564.) In the 1995 proposed rule, FDA stated that this prong of the *Central Hudson* test was satisfied because the proposed regulations serve the substantial Government interest of protecting the public health. FDA stated that the advertising restrictions will help to reduce the use of cigarettes and smokeless tobacco by those who are “the most vulnerable to addiction and, perhaps, the least capable of deciding whether to use the products. Decreased use of these products will reduce the risk of tobacco-related illnesses and deaths” (60 FR 41314 at 41354).

Most of the comments that FDA received on this issue, even some from those who otherwise opposed the

agency’s proposed restrictions, agreed with the agency that it has a substantial interest in protecting the health of individuals under 18 years of age.

(5) Two comments, however, said that the interest asserted by FDA is insufficient to justify the proposed restrictions on speech. One of those comments said that smoking is a legal and widespread activity, and that there is no congressional policy against smoking. One comment said that while the Government has a substantial interest in ensuring that tobacco products are used by adults only, FDA is not empowered to protect that interest.

FDA strongly disagrees with the latter comments. The Government’s interest in the public health, and particularly in the well-being of minors, is well-established. (See *Action for Children’s Television v. FCC*, 58 F.3d 654, 661 (D.C. Cir. 1995) and 60 FR 41314 at 41354.) In fact, the Supreme Court has found that there is a compelling, not merely a substantial, interest in protecting the physical and psychological well-being of children, *New York v. Ferber*, 458 U.S. 747, 756–57 (1982), and that the Government’s interest in the well-being of youth and in parents’ claim to authority in their own household can justify the regulation of otherwise protected expression, *FCC v. Pacifica Foundation*, 438 U.S. 726, 749 (1978). (See also *Denver Area Educational Telecommunications Consortium v. FCC*, 64 U.S.L.W. 4706 (in press) (June 28, 1996).)

As the agency has explained in section II.B. and in the 1996 Jurisdictional Determination annexed hereto, cigarettes and smokeless tobacco are drug delivery devices that are subject to regulation as devices under the act. Their use by children and adolescents under 18 presents serious risk to the health of this segment of the population. For example, studies show that the age one begins smoking influences the amount of smoking one will engage in as an adult and will ultimately influence the smoker’s risk of tobacco related morbidity and mortality (60 FR 41314 at 41317). In addition, the risk of oral cancer increases with increased exposure to smokeless tobacco products (60 FR 41314 at 41319). Thus, the health of children and adolescents is related to their use of cigarettes and smokeless tobacco.

FDA’s compelling interest in the health and well-being of minors supports restrictions on cigarette and smokeless tobacco advertising to ensure

that advertising does not undermine FDA's restrictions on the sale of these products.

One comment said that while FDA's articulated interest in protecting minors from harm clearly is substantial, this interest is not served by FDA's regulations. According to the comment, the only goal served directly by the proposed regulations is that of delegitimizing smoking. Two comments said that under the guise of protecting adolescents and children, FDA is trying to "'save' all Americans from the 'evils' of smoking." Two comments said that the agency is trying to prevent cigarette advertising from presenting smoking in a positive light. One comment, citing *Carey v. Population Services International*, 431 U.S. 678 (1977), said that the Government cannot restrict cigarette advertising because it legitimizes or favorably influences a young person's views toward tobacco products.

FDA finds no merit in these comments. Advertisements for cigarette and smokeless tobacco are not banned by the restrictions that FDA is adopting. For example, the companies are free to use advertising in almost all media that communicates to adults about the price, taste, or joys of using their product, as long as they do so using black-and-white, text-only advertisements, or using imagery and color in publications read primarily by adults. Thus, it is simply not true that manufacturers will be prevented from presenting tobacco use in a positive light or that they will be prevented from conveying truthful, nonmisleading information in almost all media.

These regulations are intended, however, as explained in section VI.E. of this document, to prevent manufacturers from advertising their tobacco products in a way that encourages underage individuals to purchase these products. They are authorized by sections 520(e) and 502(q) of the act and are in no way inconsistent with *Carey v. Population Services International*.

Carey involved a challenge to a law that banned all advertisement of contraceptives. The Government argued that advertising contraceptives would legitimize sexual activity of young children. The Supreme Court said that this basis was not a justification for validating suppression of expression protected by the First Amendment (431 U.S. at 701).

Carey is distinguishable from the present situation in several ways. The advertisements in that case stated the

availability of products and services that were not only entirely legal but were constitutionally protected because they involved the exercise of a fundamental right (*Id.*). (The Court also struck down other provisions of the law that prohibited distribution of contraceptives to anyone under the age of 16 and by anyone other than a licensed pharmacist.) Cigarettes and smokeless tobacco are neither lawful for all people nor constitutionally protected. The sale of these products to individuals under 18 is unlawful in every State (see also, 42 U.S.C. 300x-26), and possession, purchase, or use of at least some tobacco products by this segment of the population is unlawful in a majority of States.⁹³ Moreover, there was no credible suggestion in any of these comments that the restrictions on the sale of these products infringe on the exercise of a fundamental right.

The Supreme Court in *Carey* made clear the limited coverage of its holding. (See 431 U.S. at 702, n. 29 ("We do not have before us, and therefore express no views on, state regulation of the time, place, or manner of such commercial advertising based on these or other state interests.")) Thus, given the significant differences in the two situations, *Carey* does not limit FDA's ability to adopt conditions on advertising that are designed to ensure that restrictions on sale to minors are not undermined.

(6) Finally, a group of comments on this first prong of the *Central Hudson* test attacked FDA for being paternalistic. These comments said that a principal theme of commercial speech doctrine is a societal intolerance for Government-enforced ignorance designed to "help" consumers who are not trusted by bureaucrats to evaluate advertising for themselves. One comment said that how to balance short-term gratification against long-term risk is a uniquely personal analysis that is best left to individual autonomy rather than Government censorship. The comment said that people must be trusted to perceive their own best interests without Government intervention in the information flow. These comments take on a particular significance in light of the plurality's statement in *44 Liquormart, Inc. v. Rhode Island*, 116 S.Ct. at 1508, that "[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."

⁹³ *Id.*

FDA has no disagreement with these comments with respect to individuals and, in fact, finds these regulations cannot fairly be characterized as paternalistic with respect to that population group. These regulations do not prohibit the inclusion of any information in advertising. They also do not impose the type of ban on accurate commercial information that has characterized the limitations on commercial speech that the Supreme Court has branded as paternalistic. (See, e.g., *44 Liquormart, Inc.*, 116 S.Ct. at 1510; *Virginia Bd of Pharmacy*, 425 U.S. at 769-770.)

The agency acknowledges, however, that in another respect, these regulations are paternalistic. These regulations are specifically aimed at protecting children and adolescents under the age of 18 from the appeal of tobacco advertising. The agency finds however, that for it to be paternalistic with respect to children and adolescents in no way offends the First Amendment or Supreme Court precedent. (See *Denver Area Communications Consortium, Inc. v. FCC*, No. 95-124 (U.S. June 28, 1996) *slip op.* at 25.) Nothing in *44 Liquormart, Inc.*, for example, suggests in any way that government may not be paternalistic with respect to children and adolescents under the age of 18.

In fact, the Supreme Court has stated: "* * * [T]he law has generally regarded minors as having a lesser capability for making important decisions." (See *Carey v. Population Services International*, 431 U.S. at 693, n. 15.) Given these facts—that most cigarette smokers smoke their first cigarette before 18, that children and adolescents who use tobacco products quickly become addicted to them before they reach the age of 18, that among smokers aged 12 to 17 years, 70 percent regret their decision to smoke, and 66 percent state that they want to quit (60 FR 41314)—the decision to smoke is among the most important that an individual will make. Significantly, all 50 States have prohibited sales of cigarettes to people under 18 years of age. These regulations have been tailored to help ensure that individuals do not make a decision on whether to smoke before they are 18 and have a greater capacity to understand the consequences of their actions, and that they are not influenced to make this decision before that time by advertising. At the same time, FDA has sought to ensure that the restrictions do not burden any more speech than is necessary to accomplish this goal. Thus, FDA's purpose is not inconsistent with law, commercial speech doctrine, or the

country's precepts of individual autonomy.

D. Evidence Supporting FDA's Advertising Restrictions

1. Introduction

Having considered the preliminary inquiry and the first prong of the *Central Hudson* analysis, the agency turns to the heart of this analysis, whether the restrictions on cigarette and smokeless tobacco advertising that FDA is imposing are in proportion to the interest that it is seeking to advance. To meet its burden on this issue, FDA first must show that tobacco advertising plays a concrete role in the decision of minors to smoke, and that each specific restriction on this advertising that it is adopting will contribute to limiting its effects and thus to protecting the health of children and adolescents under the age of 18. The extensive evidence in this proceeding fully supports these judgments.

2. Do the Regulations Directly Advance the Governmental Interest Asserted?

In *Central Hudson*, the Supreme Court said that any limitation on commercial speech that the State imposes "must be designed carefully to achieve the State's goal" (447 U.S. at 564). " * * * [T]he restriction must directly advance the State interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose" (*Id.*).

The Supreme Court elaborated on what this aspect of the *Central Hudson* test requires in *Edenfield v. Fane*, 507 U.S. 761, 770-771 (1993);

It is well-established that "[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it." * * * This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree * * *. Without this requirement, a state could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.

In *Edenfield*, the Court struck down a Florida ban on in-person solicitation by Certified Public Accountants (CPA's) because the State board failed to demonstrate that the harm it recited was real.

It presents no studies that suggest personal solicitation of prospective business clients by CPAs creates the dangers of fraud, overreaching, or compromised independence that the Board claims to fear. The record does

not disclose any anecdotal evidence, either from Florida or another State, that validates the Board's suppositions.

(*Id.*)

In *Rubin v. Coors*, the Court struck down a section of the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) that prohibited beer labels from displaying alcohol content because the Government failed to demonstrate that this restriction would alleviate the recited harm to a material degree. (See 115 S.Ct. at 1592.) The Court characterized the Government's regulatory scheme as "irrational" (*Id.*). See also, Justice Stevens' opinion in *44 Liquormart*, 116 S.Ct. at 1509, 1510. (In striking down Rhode Island's ban on price advertising for failure to demonstrate that the restrictions would advance the State's interest, Stevens, joined by Justices Kennedy, Ginsburg, and Souter, found that while the record "suggests that the price advertising ban may have some impact on the purchasing patterns of temperate drinkers of modest means * * * no evidence [has been presented] to suggest that its speech prohibition will significantly reduce market-wide consumption." Therefore, Stevens stated that "[s]uch speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends.")

Thus, under the applicable case law, to adopt the proposed restrictions on cigarette and smokeless tobacco advertising, FDA must find that it can conclude from the available evidence that: (1) Advertising plays a material role in the process by which children and adolescents decide to begin or to continue to use these products; and (2) Limitations on advertising will contribute in a direct and material way to FDA's efforts to ensure that the restrictions it is adopting on the sale and use of tobacco products to minors are not undermined.

Contrary to what some comments asserted, it is not necessary for FDA to establish by empirical evidence that advertising actually causes underage individuals to smoke, or that the restrictions on advertising will directly result in individuals that are under 18 ceasing to use cigarettes or smokeless tobacco. It is not necessary in satisfying this prong of *Central Hudson* for the agency to prove conclusively that the correlation in fact (empirically) exists, or that the steps undertaken will completely solve the problem. (See *United States v. Edge Broadcasting Co.*, 509 U.S. 418, 434-35.) Rather, the agency must show that the available

evidence, expert opinion, surveys and studies provide sufficient support for the inference that advertising does play a material role in children's tobacco use.

In the 1995 proposed rule, FDA suggested that its judgment as to whether the governmental interest involved was directly advanced by its actions was entitled to some deference. "The Supreme Court has stated that, when determining whether an action advances the governmental interest, it is willing to defer to the 'common sense judgments' of the regulatory agency as long as they are not unreasonable" (citing, *Metromedia Inc. v. City of San Diego*, 453 U.S. 490, 509 (1981) (60 FR 41314 at 41354)).

Several comments took issue with this suggestion. One comment said that FDA had mischaracterized Supreme Court jurisprudence, and two comments said that courts will defer only to common sense judgments of legislatures.

FDA disagrees with those comments. In *Florida Bar v. Went For It, Inc.*, the Supreme Court said that it had permitted "litigants," which it did not limit to State legislatures, to justify speech restrictions by "studies and anecdotes pertaining to different locales altogether, * * * or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense * * *'" (115 S.Ct. at 2378). Thus, FDA's reliance on common sense (which, as made clear in section VI.D.3. through VI.D.6. of this document, provides only part of the basis for FDA's findings) is justified.

(7) One comment said that, rather than giving FDA deference, courts review with special care any regulations that suppress commercial speech to pursue a nonspeech-related policy.

FDA disagrees with this comment for two reasons. First, these regulations do not suppress commercial speech. While they limit such speech, they leave open significant means of communication about these products. Second, this comment derives specifically from footnote 9 of *Central Hudson*, 447 U.S. at 566 ("We review with special care regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy."). In that case, the Supreme Court found that control of demand for electricity was a speech-related policy (see 447 U.S. at 569). Similarly, the policy that FDA seeks to advance here, control of demand for cigarettes and smokeless tobacco by minors, is a speech-related policy.

(8) Finally, one comment said that FDA claimed deference for its common sense judgments to deflect attention from the lack of a factual basis for the 1995 proposed rule. Two comments, however, stated that FDA has compiled a record on the problem that is more extensive than any that existed in any of the cases in which the Supreme Court upheld restrictions on commercial speech.

In the discussion that follows, FDA reviews the evidence on whether cigarette and smokeless tobacco advertising affects the decision by minors to use these products, and whether the restrictions on advertising that it is imposing will limit the effect to a material degree. This review demonstrates that FDA's judgment on these issues is supported not only by common sense but by studies, anecdotes, history, expert consensus documents, and empirical data. All of this evidence provides support that restrictions on the advertising of these products will directly advance the Government's interest in protecting the health of children and adolescents under 18 years of age.

3. Is There Harm? Does Advertising Affect the Decision by Young People to Use Tobacco Products?

a. *In general.* In the preamble to the 1995 proposed rule, FDA stated that perhaps the most compelling piece of evidence supporting restrictions was that these products were among the most heavily advertised and widely promoted products in America. The agency cited the most recent Federal Trade Commission (FTC) figures of overall expenditures for 1993, that indicated that over \$6.1 billion had been spent by the cigarette and smokeless tobacco industries to promote their products in diverse media. These include magazines, newspapers, outdoor advertising, point of purchase, direct mail, in-store, dissemination of nontobacco items with brand identification, and sponsorship of cultural and sporting events.

(9) Several comments from the tobacco industry and the advertising industry criticized FDA's reliance on the immensity of advertising expenditures that show that tobacco products are heavily advertised. The comments claimed that the size of the industry advertising budget is not evidence that it is effective in causing young people to smoke. Conversely, one comment concluded that:

[h]ighly repetitious ad exposure likely leads to judgment biases in both risk and

social perceptions, such as assessments of smoking prevalence and the social acceptance experienced by smokers.

The largest psychological association, in its comments, agreed and stated that research indicates that young people are indeed exposed to substantial and unavoidable advertising and promotion,⁹⁴ even though they have been banned from radio and television. Referencing numerous studies, this comment stated further that:

there is considerable evidence that young people are exposed to tobacco ads, that those who smoke are especially likely to be aware of cigarette advertising, and that liking of cigarette advertising among young people is predictive of smoking behavior * * *.

The comment continued that increasing one's exposure to advertising and promotions creates persuasion, and that reducing that exposure will impede that process.⁹⁵ One study⁹⁶ found that even brief exposure to tobacco advertising can cause some young people to have more favorable beliefs about smokers.⁹⁷

FDA did not cite the industry's expenditures to indicate that the size of the industry's advertising budget was, in and of itself, a problem, but rather to show that the very size of the campaign, and the resultant ubiquity and unavoidability of the advertising in all media, created a climate that influences young people's decisions about tobacco use. The ubiquity creates what FDA referred to in the preamble to the proposed rule (60 FR 41314 at 41343), as "friendly familiarity" that makes smoking and smokeless tobacco use seem respectable to young people. In its comments, the advertising agency that coined this phrase in the 1960's has

⁹⁴ Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 years: Mickey Mouse and Old Joe Camel," *Journal of the American Medical Association (JAMA)*, vol. 266, pp. 3145-3148, 1991; Mizerski, R., K. Straughn, and J. Feldman, "The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children," presented at Marketing and Public Policy Conference, 1994.

⁹⁵ For example, Lavidge, R. J., and G. A. Steiner, "A Model for Predictive Measurements of Advertising Effectiveness," *Journal of Marketing*, vol. 25, pp. 59-62, 1961; McGuire, W. J., "Persistence of the Resistance to Persuasion Induced by Various Types of Prior Belief Defenses," *Journal of Abnormal and Social Psychology*, vol. 64, pp. 241-248, 1962.

⁹⁶ Pechmann, C., and S. Ratneshwar, "The Effects of Antismoking and Cigarette Advertising on Young Adolescents' Perceptions of Peers who Smoke," *Journal of Consumer Research*, vol. 21, pp. 236-251, 1994.

⁹⁷ See also, Hock, J., P. Gendall, and M. Stockdale, "Some Effects of Tobacco Sponsorship Advertisements on Young Males," *International Journal of Advertising*, vol. 12, pp. 25-35, 1993.

protested that FDA used the phrase improperly. However, regardless of the firm's protest, the agency finds that this phrase "friendly familiarity" accurately describes the effect of massive marketing that uses a variety of media and saturates potential consumers with information and imagery. Researchers have found that "the ubiquitous display of messages promoting tobacco use clearly fosters an environment in which experimentation by youth is expected, if not implicitly encouraged."⁹⁸

b. *Evidence regarding young people's exposure to, recall of, approval of, and response to advertising.* Many studies have demonstrated that young people are aware of, respond favorably to, and are influenced by cigarette advertising. In the preamble to the 1995 proposed rule, FDA presented a number of studies examining young people's exposure to, recall of, approval of, and response to cigarette advertising.⁹⁹ Collectively, these studies showed that children who smoke are more likely to correctly identify cigarette advertisements and slogans in which the product names or parts of the slogans have been removed than are children who do not smoke, and that exposure to and approval of cigarette advertising were positively

⁹⁸ Bonnie, R. J., and B. S. Lynch, "Time to Up the Ante in the War on Smoking," *Issues in Science and Technology*, vol. 11, pp. 33-37, 1994.

⁹⁹ Chapman, S., and B. Fitzgerald, "Brand Preference and Advertising Recall in Adolescent Smokers: Some Implications for Health Promotion," *American Journal of Public Health*, vol. 72, pp. 491-494, 1982; Aitken, P. P., and D. R. Eadie, "Reinforcing Effects of Cigarette Advertising on Under-Age Smoking," *British Journal of Addiction*, vol. 85, pp. 399-412, 1990; Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, "Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements," *Journal of Pediatrics*, vol. 110, pp. 488-491, 1987; Botvin, G. L., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, "Smoking Behavior of Adolescents Exposed to Cigarette Advertising," *Public Health Reports*, vol. 108, pp. 217-224, 1993; Klitzner, M., P. J. Gruenewald, and E. Bamberger, "Cigarette Advertising and Adolescent Experimentation With Smoking," *British Journal of Addiction*, vol. 86, pp. 287-298, 1991; Aitken, P. P., D. R. Eadie, G. B. Hastings, and A. J. Haywood, "Predisposing Effects of Cigarette Advertising on Children's Intentions to Smoke When Older," *British Journal of Addiction*, vol. 86, pp. 383-390, 1991; O'Connell, D. L., H. M. Alexander, A. J. Dobson, D. M. Lloyd, G. R. Harde, H. J. Springthorpe, and S. R. Leeder, "Cigarette Smoking and Drug Use in Schoolchildren: II. Factors Associated With Smoking," *International Journal of Epidemiology*, vol. 10, pp. 223-231, 1981; Alexander, H. M., R. Calcott, A. J. Dobson, G. R. Harde, D. M. Lloyd, D. L. O'Connell, et al., "Cigarette Smoking and Drug Use in Schoolchildren: IV. Factors Associated With Changes in Smoking Behaviour," *International Journal of Epidemiology*, vol. 12, pp. 59-66, 1983.

related to smoking behavior and intentions to smoke.

(10) Several comments from the tobacco industry and advertising groups were critical of these studies. The comments argued that none of the studies demonstrated that recognition of, exposure to, or approval of, cigarette advertising caused the initiation of cigarette smoking; that smoking in fact engendered increased exposure to, approval of and recognition of cigarette advertising; and that the samples were inappropriate and not generalizable. One comment took issue with the way in which smoking transition was defined in the Aitken study cited by the agency.¹⁰⁰ In addition, the same comment questioned the use of self-reported measures of cigarette advertising exposure in several of the studies.

FDA agrees that none of these studies individually is sufficient to: (1) Establish that advertising has an effect of directly causing minors to use tobacco products; (2) determine directionality—that is, did advertising cause the observed effect, or are smokers more observant of advertising (the Klitzner, Aitken, et al., and Alexander studies attempted to control for this effect); or (3) define terms or disprove the influence of peer pressure in smoking behavior.

However, none of these defects is sufficient to render it inappropriate for FDA to use the studies as evidence. The studies, in fact, present useful insight into how advertising affects smoking behavior and when considered with other studies provide sufficient support for the agency's conclusions. For example, one study¹⁰¹ stated that the results show that part of the process of becoming a smoker is to adopt a preferred brand, which the advertising and tobacco industries concede is affected by advertising. Moreover, these studies clearly indicate that, at a minimum, advertising plays an important role in developing an appealing and memorable image for brands. Finally, FDA recognizes that advertising may not be the most important factor in a child's decision to smoke; however, the studies cited by the agency establish that it is a substantial,

contributing, and therefore material, factor.

c. *Evidence concerning overestimation of smoking prevalence.* In the preamble to the 1995 proposed rule, FDA cited numerous studies finding that children's misperceptions about the prevalence of smoking are related to smoking initiation and the progression to regular smoking.¹⁰² Further, the evidence indicated that cigarette advertising plays a role in leading young people to overestimate the prevalence of smoking.

(11) Several comments criticized the overestimation of smoking prevalence studies presented by FDA in its 1995 proposed rule. The most common criticism was that the cited studies did not demonstrate a causal relationship between either exposure to advertising or overestimation of smoking prevalence and intentions to smoke. One comment noted that some of the cited studies did not necessarily measure "overestimation," but instead simply measured respondents' perceptions of smoking levels among their peers and adults. Another comment argued that FDA ignored other variables (such as whether or not one's friends smoked) that were predictive of smoking status or intentions to smoke.

It is true that some of the cited studies did not measure "overestimation" in the most literal sense but instead measured respondents' perceptions of smoking levels among peers and adults. However, the perceived levels were still uniformly higher among those who smoked than among those who did not. The importance of these studies is the fact that they established differences in perception between smoking and

nonsmoking young people about the prevalence, and therefore the acceptability, of smoking.

d. *The effects of selected advertising campaigns that were effective with children.* In the preamble to the 1995 proposed rule, FDA presented evidence about two campaigns that appear to have been particularly effective with children, and a historical analysis of trends in U.S. smoking initiation among 10- to 20-year-olds from 1944 to 1980.¹⁰³

FDA presented several studies finding that the "Joe Camel" campaign had a significant impact on underage smoking in the United States,¹⁰⁴ and that a humorous character for Embassy Regal cigarettes named "Reg" was appealing to children in the United Kingdom.¹⁰⁵

FDA also cited a recent study that used data from the National Health Interview Survey to study trends in smoking initiation among 10 to 20 year olds from 1944 through 1980.¹⁰⁶ The study concluded that tobacco marketing campaigns that targeted women resulted in increased smoking uptake in young women and girls, but not in adults generally.¹⁰⁷

The Joe Camel Campaign—In the preamble to the 1995 proposed rule,

¹⁰³ Pierce, J. P., E. Gilpin, D. M. Burns, E. Whalen, B. Rosbrook, D. Shopland, and M. Johnson, "Does Tobacco Advertising Target Young People to Start Smoking?" *JAMA*, vol. 266, pp. 3154–3158, 1991; Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe Camel," *JAMA*, vol. 266, pp. 3145–3148, 1991; Hastings, G. B., H. Ryan, P. Teer, and A. M. MacKintosh, "Cigarette Advertising and Children's Smoking: Why Reg was Withdrawn," *British Medical Journal*, vol. 309, pp. 933–937, 1994; Pierce, J. P., L. Lee, and E. A. Gilpin, "Smoking Initiation by Adolescent Girls, 1944 through 1988: An Association with Targeted Advertising," *JAMA*, vol. 271, pp. 608–611, 1991.

¹⁰⁴ Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe Camel," *JAMA*, vol. 266, pp. 3145–3148, 1991; Pierce, J. P., E. Gilpin, D. M. Burns, E. Whalen, E. Rosbrook, D. R. Shopland, and M. Johnson, "Does Tobacco Advertising Target Young People to Start Smoking?", *JAMA*, vol. 266, pp. 3154–3158, 1991.

¹⁰⁵ Hastings, G. B., H. Ryan, P. Teer, and A. M. MacKintosh, "Cigarette Advertising and Children's Smoking: Why Reg was Withdrawn," *British Medical Journal*, vol. 309, pp. 933–937, 1994.

¹⁰⁶ Pierce, J. P., L. Lee, and E. A. Gilpin, "Smoking Initiation by Adolescent Girls, 1944 through 1988: An Association with Targeted Advertising," *JAMA*, vol. 271, pp. 608–611, 1994.

¹⁰⁷ *Id.*; See also Pierce, J. P., and E. A. Gilpin, "A Historical Analysis of Tobacco Marketing and Uptake of Smoking by Youth in the United States: 1890–1977," *Health Psychology*, vol. 14, pp. 500–508, 1995. Burns, D. M., L. Lee, J. W. Vaughn, Y. K. Chiu, and D. R. Shopland, "Rates of Smoking Initiation Among Adolescents and Young Adults, 1907–1981," *Tobacco Control*, vol. 4, suppl. 1, pp. 52–58, 1995.

¹⁰⁰ Aitken, P. P., D. R. Eadie, G. B. Hastings, and A. J. Haywood, "Predisposing Effects of Cigarette Advertising on Children's Intentions to Smoke When Older," *British Journal of Addiction*, vol. 86, pp. 383–390, 1991.

¹⁰¹ Chapman, S., and B. Fitzgerald, "Brand Preference and Advertising Recall in Adolescent Smokers: Some Implications for Health Promotion," *American Journal of Public Health*, vol. 72, pp. 491–494, 1982.

¹⁰² Chassin, L., C. C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, "Predicting the Onset of Cigarette Smoking in Adolescents: A Longitudinal Study," *Journal of Applied Social Psychology*, vol. 14, pp. 224–243, 1984; Collins, L. M., S. Sussman, J. Mestel Rauch, C. W. Dent, C. A. Johnson, W. B. Hansen, and B. R. Flay, "Psychosocial Predictors of Young Adolescent Cigarette Smoking: A Sixteen-Month, Three-Wave Longitudinal Study," *Journal of Applied Social Psychology*, vol. 17, pp. 554–573, 1987; Sussman, S., C. W. Dent, J. Mestel-Rauch, C. A. Johnson, W. B. Hansen, and B. R. Flay, "Adolescent Nonsmokers, Triers, and Regular Smokers' Estimates of Cigarette Smoking Prevalence: When do Overestimations Occur and by Whom?", *Journal of Applied Social Psychology*, vol. 18, pp. 537–551, 1988; 1994 SGR, p. 192–195, citing Burton, et al., The L.A./Finland Study; Sherman, S. J., C. C. Presson, L. Chassin, E. Corty, and R. Olshavsky, "The False Consensus Effect in Estimates of Smoking Prevalence: Underlying Mechanisms," *Personality and Social Psychology Bulletin*, vol. 9, pp. 197–207, 1983; Botvin, G. J., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, "Smoking Behavior of Adolescents Exposed to Cigarette Advertising," *Public Health Reports*, vol. 108, pp. 217–224, 1993.

FDA described R. J. Reynolds' (RJR) use of the cartoon Joe Camel as the centerpiece of a very successful campaign that sought to revitalize Camel cigarettes. The preamble to the 1995 proposed rule described two sets of studies. One set indicated that the campaign was so pervasive and juvenile that children as young as 3 to 6 years old, recognized the Joe Camel character and knew that he sold cigarettes. The other set of studies provided evidence that the campaign had resulted in Camel's share of the adolescent youth market rising from below 4 percent of underage smokers to between 13 and 16 percent in a short period of time (60 FR 41314 at 41333).

This description of the Camel campaign produced over 200 comments from the advertising, tobacco, legal and publications industries, members of legislative bodies, State and local government officials and agencies, health providers and organizations, academics, and the general public. The latter included many anecdotal references to children's positive reactions to the campaign, including comments from parents, teachers, and children themselves. One comment, from a State attorney general, stated that "in 1993, after reviewing research documenting the extremely powerful effect R. J. Reynolds' 'Cool Joe Camel' ads have on children, I joined with 26 other State Attorneys General in calling" for a ban on that campaign.

(12) The comments differed radically in assessing the accuracy of FDA's use of Joe Camel as evidence of the effect of a youth-oriented campaign. A number of comments stated that the Joe Camel campaign was neither directed toward children nor effective at reaching them, and that FDA's evidence did not support the agency's position. The comments criticized the studies cited by FDA and referred to other studies that they believed supported their contention that the Joe Camel campaign was not directed toward children. For example, one comment argued there was no evidence to suggest that brand recognition had any influence on smoking initiation. This same comment also complained that the studies relied on by FDA were ungeneralizable and were from medical journals, not marketing journals. Another comment argued that the Pierce study cited by the agency had demonstrated only that Camel and Marlboro were thought to be

the most advertised brands across all respondent age groups.¹⁰⁸

Several comments argued that the finding in the Fischer and Mizerski studies that children recognize Joe Camel did not necessarily indicate that they liked Joe Camel, let alone that they would be more likely to take up cigarette smoking.¹⁰⁹ For example, some comments from the tobacco industry discussed the Mizerski study funded by RJR and criticized FDA's use of it. FDA, as noted above, had cited this study in the 1995 proposed rule to show that 72 percent of 6 year olds and 52 percent of children between the ages of 3 and 6 could identify Joe Camel.¹¹⁰ This exceeded the recognition rates for Ronald McDonald, a character frequently advertised on television. The comments, however, stated that the results of the study indicated that while recognition of the cartoon trade characters and liking of the associated product each tended to increase with age, for Joe Camel, at every age, children who recognized Joe Camel were more likely to report disliking cigarettes than did children who did not recognize Joe Camel.

Several comments also cited another study by Henke (the Henke Study),¹¹¹ which found results suggesting that even though recognition of brand advertising symbols increases with age, recognition does not necessarily indicate favorable attitudes about a product. Although the children in the study were generally able to recognize Joe Camel, 97 percent of the respondents reported that cigarettes were "bad for you," and all but one of the minors stated that cigarettes were for adults. Several comments also mentioned a November 1993 Roper survey of over 1,000 young people

between ages 10 and 17.¹¹² This survey found that 97 percent of those youths who recognized "Joe Camel" had negative opinions about smoking.

Finally, these comments also stated that the Joe Camel campaign did not increase the smoking rates of minors. The comments cited to data from CDC's Office of Smoking and Health's (OSH's) study "1993 Teenage Attitudes and Practices Survey, Public Use Data Tape" (TAPS II)¹¹³ that show that, contrary to FDA's assertion and citation to data from Monitoring the Future,¹¹⁴ there has not been an increase in youth smoking rates as a result of the Joe Camel campaign.

Conversely, several comments from professional associations and many from private citizens supported FDA's tentative conclusion that some tobacco advertising campaigns—particularly Joe Camel—are very effective with children. Some comments referred to the same research evidence cited by FDA in the 1995 proposed rule.

It is not the agency's position that the recognition studies provide evidence of the effect of this campaign upon the smoking habits of children. The Henke study found that children age 6 and younger do not smoke and uniformly report that they dislike smoking.¹¹⁵ However, although young children usually dislike smoking, many of them later do smoke. FDA's point in using the recognition studies was that advertising for Camel cigarettes was so pervasive and appealing to young people that children saw the advertisements and assimilated them even though they were too young to even think about smoking. These studies provide important evidence of the pervasiveness of tobacco advertising.

The Henke study (cited by comments opposed to the 1995 proposed rule), which reported that although recognition of brand advertising symbols increases with age, recognition does not necessarily indicate favorable attitudes toward a product—is subject to

¹⁰⁸ Pierce, J., et al., "Does Tobacco Advertising Target Young People to Start Smoking? Evidence from California," *JAMA*, vol. 266, No. 22, p. 3154–3158, 1991.

¹⁰⁹ Fischer, P. M., et al., "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel," vol. 266, pp. 3145–3148, 1991; Mizerski, R., "The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children," presented at "Marketing and Public Policy Conference," May 13–14, 1994.

¹¹⁰ Independent research by Fischer found that 91 percent of 6 year-olds and 30 percent of 3 year-olds recognized Joe Camel. Fischer, P. M., J. W. Schwartz, A. O. Goldstein, and T. H. Rojas, "Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel," *JAMA*, vol. 266, pp. 3145–3148, 1991.

¹¹¹ Henke, L., "Young Children's Perceptions of Cigarette Brand Advertising Symbols: Awareness, Affect and Target Market Identification," *Journal of Advertising*, in press.

¹¹² Roper Starch, "Advertising Character and Slogan Survey," pp. 16–17, November 1993 (conducted for R. J. Reynolds Tobacco Co.).

¹¹³ "1993 Teenage Attitudes and Practices Survey, Public Use Data Tape," CDC, OSH, p. 3, 1993 (unpublished data).

¹¹⁴ Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Survey, 1975–1993: vol. I: Secondary School Students*, Rockville, MD, DHHS, Public Health Service (PHS), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), NIH Pub. No. 94–3809, 1994.

¹¹⁵ Henke, L., "Young Children's Perceptions of Cigarette Brand Advertising Symbols: Awareness, Affect and Target Market Identification," *Journal of Advertising*, in press.

many of the same criticisms as those leveled by the tobacco industry at studies cited by FDA, and in fact contains more serious flaws that suggest that its results should be interpreted with a great deal of caution.

First, the sample employed in this study was both inadequate to test the author's hypotheses, and is nongeneralizable to other populations. There were only 83 participants in the study; this sample is too small to allow for adequate power to test the author's fine-grained hypotheses concerning age. In fact, the inadequate sample size led the author to collapse the participants into three age groups for many analyses, which meant that 3-year olds were placed into the same group as children who were 5-and-a-half years old. In addition, participants all were recruited from middle class neighborhoods in the same "small coastal town" in Maine. Racial breakdowns were not presented, but it is likely, given the demographics of upstate Maine, that whites were overrepresented and African-Americans underrepresented. In addition, males were overrepresented. At best, the sample represents the population of 3- to 8-year-old children in that small town in Maine, but it is not even clear that this is the case.

Second, the interview process used to collect data in the study, and even the nature of the interviewers themselves, greatly limit the conclusions that may be drawn from the study. The study used six different interviewers, five of whom were college undergraduates, and one of whom was a child care professional. Each interviewer participated in but a single training session before collecting data. Further, not all of the interviewers were blind to the hypotheses of the study. This is a great concern, considering the very subjective nature of the interview. It was not reported whether who the interviewer was had significant effects on the results of the study (and indeed the sample size is probably too small to permit such an analysis), but it is unlikely that all six interviewers conducted the interviews in precisely the same way or elicited the same types of responses from the participants.

The interview process itself appeared to be highly biased and subjective in nature. It is not surprising that the children overwhelmingly reported that cigarettes were "bad for you" and were meant for adults, given that they were being interviewed face-to-face by adult strangers. Any potential differences attributable to recognition of cigarette advertising were probably masked by

the intimidating presence of the interviewer. Further, the answers to questions such as "Do you like this product or not like this product?" and "Is this product good for you or bad for you?" can depend to a great extent on the manner in which they are asked.

Overall, the small, nonrepresentative sample, the excessive number of questionable interviewers, and the interview process itself all cast serious doubt on the value of this study. Finally, as noted in the previous paragraph, children almost uniformly report that smoking is bad, but many of them will smoke in the future in part due to the appeal created for the product by advertising.

Additional studies—Two additional studies on this issue of recognition were submitted to the docket. The first, an article by Joel S. Dubow,¹¹⁶ merely commented on several general studies on recall of advertising. The result was that children and especially adolescents remember more about advertising than adults. (FDA agrees with the point that advertising is more memorable to children.) Further, all the advertisements tested, and those that children and adolescents remembered so well, were either on television or presented in a movie theater setting.

Children and adolescents are more visually oriented than adults; they remember what they see on television. However, as noted, commercials for cigarettes are not on television and so the high recognition rates of Joe Camel cannot be accounted for on that basis. Thus, the study begs the same question that is raised by the Mizerski study: Where did those 3 to 6 year olds see the cigarette advertisements they found so memorable?

The answer may be provided by the second recognition study submitted by RJR. One study was conducted by Roper Starch in November 1993 for RJR and tested young people's recognition of advertising characters. The results of that study show that Joe Camel was recognized by 86 percent of all 10 to 17 year olds, in both aided and unaided recall. The characters with greater recognition were all televised characters: the Energizer Bunny, Ronald McDonald, the Keebler Elves, etc. Recognition scores for those characters were in the 97 percent to 100 percent range. Of more interest, 95 percent of those who recognized Joe Camel knew that he sold cigarettes, similar to the

product familiarity rates for the other characters.¹¹⁷

But perhaps the most interesting answers were those provided by the children who responded that they knew that Joe Camel sold cigarettes. In response to the question, "[p]lease tell me the ways that you might have seen or heard about this character," 51 percent said the information came from a billboard advertisement, 45 percent said from an advertisement in a magazine, 32 percent said from an advertisement in the store, and 22 percent said on a tee shirt. A sizable group said they had seen him on television (42 percent). On the other hand, all the other characters were identified as having been on television (88 percent to 100 percent). Recognition based upon billboard exposure for these other characters was between 6 percent and 13 percent. Most were not recognized as having been on tee shirts.

Clearly, cigarettes are marketed differently than most consumer products; nonetheless, whatever the marketing mix used by the tobacco industry, cigarette advertisements are clearly being seen and assimilated by those too young to be interested in or to have started smoking.

A second type of study, provided evidence of the effect of this campaign on adolescent smoking rates. As noted, one comment disputed that there was a rise in young people's smoking rates that corresponded to the introduction of the Joe Camel campaign. The significance of this argument is that if smoking rates after the introduction of the Joe Camel advertising campaign did not rise, there is little reason to believe that the campaign caused young people to take up smoking. This comment referred to its own analysis of smoking trends, which it stated were derived from TAPS II¹¹⁸ data and not from the data in Monitoring the Future used by FDA.¹¹⁹

FDA has provided a more detailed answer to this comment above. As explained there, the agency finds this comment to be without merit. The Monitoring the Future study is the most consistent source of data available on youth smoking rates. RJR's expert, Dr. J.

¹¹⁷ "Advertising Character and Slogan Survey," pp. 10, 12, 22–23.

¹¹⁸ "Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993," *MMWR*, CDC, vol. 43, pp. 577–581, Aug 19, 1994.

¹¹⁹ Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Study, 1975–1993: Vol. I; Secondary School Students*, DHHS, PHS, NIH, NIDA, NIH Pub. No. 94–3809, 1994.

¹¹⁶ Dubow, J. S., "Advertising Recognition and Recall by Age-Including Teens," *Journal of Advertising Research*, pp. 55–60, Sept/Oct 1995.

Howard Beales, III, has referred to it as "[t]he most consistent data available" to track the incidence of teen smoking over time.¹²⁰ Moreover, Dr. Beales noted that other Government studies are "sporadic" and, by implication, cannot be relied upon to give an accurate picture of overall smoking trends.

The Monitoring the Future Study indicates that from 1987 to 1993, the 30-day smoking rates and daily smoking rates for male high school seniors increased steadily, although with variations in some years.¹²¹ During that same period, Camel's share of the youth market rose from below 4 percent to around 13 percent (60 FR 41314 at 41330).

These data do not absolutely prove that Camel advertising "caused" a rise in youth smoking. However, they do provide further evidence that the Joe Camel campaign had an effect on youth smoking rates.

(13) Comments from the tobacco industry maintained that FTC's investigation, which failed to produce "evidence to support" FTC action against RJR for the Joe Camel campaign, should have been dispositive of the issue. Therefore, the comments argued, it is inappropriate for FDA to use the campaign as evidence that advertising causes children to start to smoke. The comments maintained that the FTC review included the same studies relied upon by FDA to condemn the Joe Camel campaign.

Comments stated further that Congress has vested jurisdiction in FTC to prosecute unfair and deceptive advertising of tobacco products, and that it has sole jurisdiction in this area. (See Federal Trade Commission Act (the FTC Act) (15 U.S.C. 41).) These comments noted further that FTC has shown its ability to fulfill its responsibilities in this area, citing two recent consent agreements secured by FTC. One was against RJR for advertising that disputed some of the health risks of smoking. (See *In the matter of R. J. Reynolds Tobacco Company*, 113 FTC 344 (1990).) The other was against American Tobacco Company for allegedly misleading statements about tar and nicotine ratings. (See *In the matter of The American Tobacco Company*, Dkt. No.

C-3547 (Consent Order, January 31, 1995).)

On the other hand, comments from two national health organizations alleged that the fact FTC concluded it was unable to take action against Joe Camel demonstrates that the FTC Act, as it is currently being interpreted by the Commission, is not sufficient to protect American youth from inappropriate tobacco advertising and that FDA, therefore, needs to take action under its authority.

The industry comments misapprehend FDA's citation to the Joe Camel campaign. As noted above, FDA cited to numerous studies that had been performed by independent researchers on children's recognition of the main character of a youth oriented advertising campaign (60 FR 41314 at 41333). The agency also cited to several documents that it had obtained that indicated that RJR may have intended for its Joe Camel campaign to appeal to and attract young people (60 FR 41314 at 41330). FDA's discussion of the marketing success of the Joe Camel campaign is not intended to suggest that FDA had found or concluded that the Joe Camel campaign violated any law, but that FDA had found in that success—tripling Camel's share of the youth market—support for restricting such activities in the future through rulemaking.

Moreover, FTC did not disagree with FDA's use of the campaign. In its comment to FDA on the 1995 proposed rule, FTC stated, "This decision [by FTC to close the RJR investigation without issuing a complaint] does not contradict FDA's conclusion." FTC continued that its failure to initiate legal action did not "mean that cigarette and smokeless tobacco advertising, in the aggregate, is not one of a number of factors that 'play[s] an important role in a youth's decision to use tobacco.'" ¹²²

(14) The other citation to the Joe Camel campaign (60 FR 41314 at 41330) utilized RJR's documents to illustrate the youth focus of one advertising campaign through use of the company's own documents. Some comments received from the tobacco industry (including one from RJR), trade associations, and some individuals disagreed with this use and stated that the Camel campaign was designed to, and did in fact, attract the attention of

young adult smokers, aged 18 to 24. These comments stated that the Joe Camel campaign was directed to adult smokers, specifically existing male Marlboro smokers aged 18 to 24. The comments stated that the illustrated character Joe Camel was developed to reposition the brand by stressing images and characteristics, such as the "Smooth Moves" image, which appeal to the young adult, particularly male, Marlboro smoker.

Industry comments further stated that the company conducted no market research on nonsmokers, and that the campaign reached adult smokers aged 18 to 24 years. One comment postulated that it is merely the cartoon form of Joe Camel that causes people to mistakenly believe that Joe Camel is child-oriented. It stated further that many adult products are advertised using illustrated characters, such as the Pink Panther for fiberglass insulation, Garfield the Cat for a hotel chain, Mr. Clean for household products, and the Peanuts characters for life insurance. Moreover, RJR stated that it made efforts to ensure that the ad copy and promotional activity for Joe Camel would not appeal to minors. It said that a skateboard promotion proposed by an advertising agency was rejected by the company because it was assumed that skateboarding is disproportionately engaged in by children and adolescents. Similarly, marketing research included 25 to 34 year olds "to serve as a safety check to make sure that the concept appeal did not skew too young."

These comments further stated that Joe Camel advertisements were directed to, and reached, the intended market. Examples of publications in which the Joe Camel advertisements were placed are *Cycle World*, *Penthouse*, *Gentleman's Quarterly*, and *Road and Track*. Joe Camel's share of 18 to 24 year olds increased by 6.9 percentage points, from 3.2 in 1986, the year before Joe Camel's inception, to 10.1 by the end of 1994. The comment stated that Camel's and Marlboro's growth came at the expense of other brands. These comments are consistent with the industry's assertion that this is the whole point of cigarette advertising: to encourage current smokers to buy the advertised brand either by switching brands or remaining loyal to their existing brands. (This comment states that because there is no evidence that smoking rates have risen among adolescents, there cannot be a reason to believe that Camel's success among adolescents came from new, as opposed to existing, smokers. See section III.B. of

¹²⁰ Beales, J. H., "Teenage Smoking: Fact and Fiction," *The American Enterprise*, vol. 21, March/April 1994.

¹²¹ Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Study, 1975-1994, Vol. I: Secondary School Students*, DHHS, PHS, NIH, NIDA, NIH Pub. No. 94-3809, 1995.

¹²² FTC analyzed the complaint recommendation before it under its unfairness jurisdiction. An action is unfair if it causes substantial consumer injury, without offsetting benefits to consumers or competition, which consumers cannot reasonably avoid. (*International Harvester*, 194 FTC 949, 1070, 1984.)

this document for a refutation of the industry assertion that smoking rates among adolescents are static.)

In contrast, comments from health organizations and concerned citizens stated that Joe Camel has been successful in attracting underage smokers. These comments further stated the belief that the campaign was intended to attract children, citing the methods of advertising and promotion employed as evidence of its intention to appeal to children. For example, one comment stated: “* * * T-shirts and caps, like those marketed with ‘Joe Camel’ are found in disproportionate numbers of children.”

FDA continues to believe that RJR documents do illustrate the creation of and execution of a decidedly youth-oriented campaign.

FDA finds that previously confidential RJR documents provide convincing evidence of the company’s intention to attract young smokers and so-called presmokers to its Camel brand. These documents, identified as RJR marketing documents and submitted during the comment period, reflect a company policy that in order to grow and ensure a profitable future, the company must develop new brands that would appeal to and capture a share of the youth market. These young people were described as “presmokers” and “learners” in RJR marketing language and were identified as being 14 to 18 year olds.

While the documents concerning the Camel campaign (focus group reports, etc.) submitted by RJR to the rulemaking docket do not identify the under-18 group as the company’s target, the implication arises from the company-submitted documents that the Camel campaign was the logical outgrowth of the planning and forecasting contained in the heretofore confidential marketing documents.

In a 1972 memo entitled “Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein,” the author, Claude Teague Jr., Assistant Director of Research and Development, wrote:

[I]t may be well to consider another aspect of our business; that * * * the factors which induce a presmoker or nonsmoker to become a habituated smoker. * * * He does not start smoking to obtain undefined physiological gratifications or reliefs, and certainly he does not start to smoke to satisfy a nonexistent craving for nicotine. Rather, he appears to start to smoke for purely psychological reasons—to emulate a valued image, to conform, to experiment, to defy, to be daring, to have something to do with his hands, and the like. Only after experiencing smoking for

some period of time do the physiological “satisfactions” and habituation become apparent and needed. Indeed, the first smoking experiences are often unpleasant until a tolerance for nicotine has been developed. * * * [I]f we are to attract the nonsmoker or presmoker, there is nothing in this type of product that he would currently understand or desire. We have deliberately played down the role of nicotine, hence the nonsmoker has little or no knowledge of what satisfactions it may offer him and no desire to try it. Instead, we somehow must convince him with wholly irrational reasons that he should try smoking, in the hope that he will for himself then discover the real “satisfactions” obtainable.¹²³

In 1973, the same author reported in another memo, “Research Planning Memorandum on Some Thought about New Brands of Cigarettes for the Youth Market,” his thoughts on how to acquire a portion of the important youth market:

[W]e should simply recognize that many or most of the “21 and under” group will inevitably become smokers, and offer them an opportunity to use our brands. Realistically, if our Company is to survive and prosper, over the long-term we must get our share of the youth market. In my opinion this will require new brands tailored to the youth market; I believe it unrealistic to expect that existing brands identified with an over-thirty ‘establishment’ market can ever become the ‘in’ products with the youth group. Thus we need new brands designed to be particularly attractive to the young smoker, while ideally at the same time being appealing to all smokers.¹²⁴

Mr. Teague then described the factors he thought must be taken into account in designing a brand that would attract young people:

Several things will go to make up any such new “youth” brands, the most important of which may be the image and quality—which are, of course, interrelated. The questions then are: What image? and What quality? Perhaps these questions may best be approached by consideration of factors influencing pre-smokers to try smoking, learn to smoke and become confirmed smokers. * * * For the pre-smoker and “learner” the physical effects of smoking are largely unknown, unneeded, or actually quite unpleasant or awkward. The expected or derived psychological effects are largely responsible for influencing the pre-smoker to try smoking, and provide sufficient motivation during the “learning” period to keep the “learner” period going, despite the physical unpleasantness and awkwardness of the period. * * *¹²⁵

Mr. Teague continues with some reasons why young people smoke and

then gives advice on the type of advertising campaign that would appeal to the presmoker group based on these reasons:

A. Group Identification—Pre-smokers learn to smoke to identify with and participate in shared experiences of a group of associates. If the majority of one’s closest associates smoke cigarettes, then there is strong psychological pressure, particularly on the young person, to identify with the group, follow the crowd, and avoid being out of phase with the group’s value system even though, paradoxically the group value system may esteem individuality. This provides a large incentive to begin smoking.

* * * * *

[The brand’s] promotion should emphasize togetherness, belonging and group acceptance, while at the same time emphasizing individuality and “doing ones own thing.”

B. Stress and Boredom Relief—The teens and early twenties are periods of intense psychological stress, restlessness and boredom. Many socially awkward situations are encountered. [the documents mentions smoking gives you something to do with your hands—find an ashtray etc.]

C. Self-Image Enhancement—The fragile, developing self-image of the young person needs all of the support and enhancement it can get. Smoking may appear to enhance that self-image in a variety of ways. [Values mentioned in the document include adventurousness, adult image.] If one values certain characteristics in specific individuals or types and those persons or types smoke, then if one also smokes he is psychologically a little more like the valued image. This self-image enhancement effect has traditionally been a strong promotional theme for cigarette brands and should continue to be emphasized.

D. Experimentation—There is a strong drive in most people, particularly the young, to try new things and experiences. This drive no doubt leads many presmokers to experiment with smoking, simply because it is there and they want to know more about it. A new brand offering something novel and different is likely to attract experimenters, young and old, and if it offers an advantage it is likely to retain those users.¹²⁶ In March 1976 R. J. Reynolds’ Research Department created a memo entitled, “Planning Assumptions and Forecast for the Period 19*–1986 for R. J. Reynolds Tobacco Company.” Under a heading, The Tobacco Industry and R. J. Reynolds Tobacco Company—subheading E. Products—the memo states:

The present large number of people in the 18–35 year old age group represents the greatest opportunity for long-term cigarette sales growth. Young people will continue to become smokers at or above the present rates during the projection period. The brands which these beginning smokers accept and

¹²³ Teague, C., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, pp. 4–5, 1972.

¹²⁴ Teague, C., *Research Planning Memorandum on Some Thought About New Brands for Cigarettes for the Youth Market*, p. 1, 1973.

¹²⁵ *Id.*, pp. 1–2.

¹²⁶ *Id.*, pp. 6–7.

use will become the dominant brands in future years. Evidence now available * * * indicate[s] that the 14 to 18 year old group is an increasing segment of the smoking population. RJR must soon establish a successful new brand in this market if our position in the industry is to be maintained over the long term.

(Emphasis omitted.)¹²⁷

By the mid to late 1980's, RJR was marketing its newly revitalized Camel brand to "young adults" 18 to 20 years old. According to an internal memo cited in the *Wall Street Journal*,¹²⁸ the business plan for 1990 had a single-minded focus on getting young adults, especially the 18 to 20 year olds, to smoke Camels. The brand was to be refocused on young adult smokers, aged 18 to 24 with a strong emphasis on males 18 to 20.¹²⁹

¹²⁷ An RJR spokesperson referred to these documents and did not dispute their validity. (See Levy, D., "RJR Memo Targeted Teen Market," *USA Today*, p. 1D, October 6, 1995; "Report: Teen Cigarettes Eyed," *AP Online*, October 4, 1995.); *Planning Assumptions and Forecast for the Period 197*-1986 for R.J. Reynolds Tobacco Company*, Research Department, 1976.

¹²⁸ Freedman, A. M., and S. L. Huang, "Reynolds Marketing Strategy Sought to Get Young Adults to Smoke Camels," *Wall Street Journal*, p. B10, col. 3, November 2, 1995.

¹²⁹ A 1984 strategic research document, authored by Diane Burrows of R. J. Reynolds and entitled "Younger Adult Smokers: Strategies and Opportunities," came to FDA's attention as a result of its inclusion as an exhibit attached to a brief filed by the State of Minnesota and Blue Cross in Ramsey County District Court in litigation involving the seven tobacco companies. The document was also described in numerous press accounts of the event (e.g., Phelps, D., and J. Hodges, "Suit: Kids were focus of Reynolds strategy. Documents filed in state's lawsuit against the tobacco industry show how R. J. Reynolds targeted young smokers as critical to the industry's future," *Star Tribune*, 1A, July 11, 1996; Worklan, P., "R. J. Reynolds Secret Report Targets Young Adult Market," *Chicago Tribune*, N19, July 11, 1996.) Although the agency has not relied on this memo as part of the justification for this rule, FDA is citing to it here because it is relevant to the issues discussed.

The memo indicates that by 1984, R. J. Reynolds was beginning to conduct research on the concepts detailed above that were developed during the 1970's. The memo describes the problem facing Reynolds at that time of declining market share and then proposed a solution: "RJR's consistent policy is that smoking is a matter of free, informed, adult choice which the Company does not seek to influence. However, in order to plan our business, we must consider the effects those choices may have on the future of the Industry. Furthermore, if we are to compete effectively, we must recognize the imperative to know and meet the wants of those who are 18 and have already elected to smoke, as well as those of older smokers (emphasis added)."

The memo recognizes several important facts: "The renewal of the market stems almost entirely from 18-year-old smokers. No more than 5% of smokers start after age 24." Moreover, the memo also recognizes that: "[t]he brand loyalty of 18-year-old smokers far outweighs any tendency to switch with age. Thus, the annual influx of 18-year-old smokers provides an effortless, momentum to successful 'first brands'."

Documents submitted by RJR in its comment detail its plans for developing and promoting Joe Camel as the spokesperson for the brand. In language reminiscent of the 1973 Teague memo, RJR reemphasized the importance of the young adult smokers (which RJR nicknamed the "YAS")—noting that only 5 percent of smokers start after age 24.¹³⁰ The paper noted that 40 percent of the "virile" segment have made a brand choice at age 18—a brand to which they will be loyal for years or throughout their smoking career. Thus, although this document describes the YAS as 18 to 24 year olds, the company's interest appears to have been with those younger than 18 who are in the process of selecting their first brand, the 14 to 18 year olds described by Teague.

In addition, the problem, the White Paper emphasized, was that Camel needed a facelift to make it relevant to this YAS group. Research, they noted, indicates that YAS see advertising as "younger adult oriented" when it is speaking directly to them. Therefore, advertising needed to be developed to speak to the target audience, to appeal to the "hot buttons" of young people such as to "escape into imagination." "Fantasy to these smokers can mean imagining a place to escape to or an image of yourself that is better than reality."

These "first brands" were identified as those which appeal to the 18-year-old smoker rather than switchers ages 19–24.

The memo identifies additional factors that had to be considered in this calculus: (1) Although 18- to 24-year-olds account for a very small part of market share, this age group represents the future of a brand. Those young, brand loyal smokers who now consume very few cigarettes, will consume more cigarettes with age and generally remain loyal to this first brand, its brand family or to the company; (2) Although young smokers are easier to switch than older smokers, a brand can not rely exclusively on switching younger smokers to produce a lasting brand equity—the major and most important share advantage available to a company is to have a cigarette brand relevant to young people and accepted by them as their "first brand."

The reports's recommendation was to research and capitalize on the factors and strategies which have been successful with youth brands of the past. This would require devoting substantial resources to identifying and tracking values, wants, and media effectiveness relevant to younger people. Because of the sensitivity of this young market, the memo continued: "brand development/management should encompass all aspects of the marketing mix and maintain a long term, single-minded focus to all elements-product, advertising, name, packaging, media, promotion and distribution. (Emphasis omitted)"

This must include, the memo stated, a careful emphasis on the "imagery and product positives" relevant to "younger adults."

¹³⁰ "White Paper," Camel Advertising Development, p. 1, undated.

The YAS group also relates to excitement and fun, noted the White Paper: "Younger adults center their lives on having fun in every way possible and at every time possible. Their definition of success is 'enjoying today' which differentiates them from older smokers. Advertising which incorporates an 'exciting', 'fun', 'humorous' theme provides a way for these smokers to 'feel good' about the message."

By 1988 RJR was testing its new ideas about Camel. It described the results in a *Marketing Research Report*, entitled *Camel "Big Idea" Focus Groups—Round II* dated September 21, 1988, and written by M. R. Bolger. The group was composed of male Marlboro smokers ages 18 to 34. Two groups were men 18 to 20, two groups were 21 to 24, and one group was age 25 to 34 to serve as a "safety check" to make sure the concept did not skew too young. Various themes were tested and one, "Smooth Moves," was received best by the younger portion of the target—those that had fewer responsibilities, are single, and go to parties. The focus groups also showed that premiums (nontobacco items) performed best among the younger portion of the group. Older smokers were more discerning and saw the items as being of little value to them.¹³¹

What resulted from this research was the Joe Camel campaign, an unusually successful effort, particularly with the group that RJR research documents discussed—the 14 to 18 year olds. Thus, RJR appears to have used its research on 18 to 20 year olds to its advantage with the 14 to 18 year old group—a group who shares many of the same interests and "hot" buttons of the older group. These internal documents complement those cited in the preamble to the 1995 proposed rule. In the preamble to the 1995 proposed rule, FDA described two letters from RJR sales managers about the placement of YAS [Camel] merchandise. Both letters stated that high school neighborhoods were a likely location for YAS. RJR, in its comments to the proposed rule, stated that those two letters were mistakes. However, these latest documents rebut RJR's comment. The mistake made by the two sales representatives was in speaking too clearly of the company's intention.

"Reg"—The second campaign reviewed by FDA was the "Reg" campaign used in the United Kingdom. One comment took issue with FDA's claim that the "Reg" campaign was

¹³¹ Bolger, M. R., "Camel 'Big Idea' Focus Groups—Round II," *Marketing Research Report*, September 21, 1988.

particularly effective with British adolescents and argued that the study that FDA relied on was based on unreliable evidence and is not applicable to American adolescents. The comment contended that there was no evidence to show that liking the "Reg" character caused children to smoke and argued instead that children who smoked came to like "Reg." The comment also argued that the recognition task, described in the study, was too suggestive and biased, and suggested that the young people were primed and pressured to say they had seen the advertisements during "games" that they say took place before the recognition task.

First, this comment is wrong. Games were played during another portion of the study, not the one referenced. The comment confused the quantitative survey with the qualitative. Second, evidence from England about youth smoking habits is no less probative than evidence from the United States, as it provides insights into children's smoking behavior.

Smoking Trends—A few comments were critical of the study of trends in the smoking initiation study, which found a temporal relationship between advertising targeted at women and rising initiation rates among girls and young women.¹³² The principal criticisms were that the authors failed to examine the actual advertising campaigns in question, that FDA failed to consider alternative explanations for the study's findings, and that the study's measures were subjective and unreliable.

In response, the agency reiterates that it did not cite to this study, or any one study, as "proof" that advertising during this period "caused" a rise in smoking initiation. The study was provided as one example of targeted marketing being "associated" with increases in cigarette consumption among young people.¹³³ A logical inference to be drawn from the cumulative effect of such studies is that advertising does play a role in young people's smoking behavior.

e. Evidence that youth brand choices are related to advertising. Virtually all

of the comments from the tobacco industry claimed that cigarette and smokeless tobacco manufacturers market their products solely to adults. They disputed the findings of studies, cited by FDA in the preamble to the 1995 proposed rule, examining advertising campaigns that had been particularly effective with children. In addition, while the comments acknowledged that younger smokers are the intended targets for some cigarette advertising, they argued that only younger smokers of legal age were targeted.

In the preamble to the 1995 proposed rule, FDA presented a number of studies showing that youth cigarette brand choices are related to advertising.¹³⁴ These studies showed that young people smoke many fewer brands than adults, and that their choices are directly related to the amount and kind of advertising. While 86 percent of youths who smoke choose the three most advertised brands,¹³⁵ the most commonly smoked cigarettes (39 percent) among adult smokers are brandless (i.e., private label, generics, or plain packaged products).¹³⁶ Another study found that children who smoke as few as one cigarette per week can identify a preferred brand.¹³⁷

One comment argued that the CDC study that found that most children smoke the three most advertised brands showed only a correlation between advertising expenditures and brand preferences, and that the data did not even support this correlation consistently. The comment noted that the data on which these findings were based included 18 year olds, who are of legal age to smoke. The comment also contended that the data did not allow a determination of what came first: Changes in advertising expenditures or changes in brand preference (directionality).

¹³⁴ "Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993," *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994; Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, "Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements," *Journal of Pediatrics*, vol. 110, pp. 488–491, 1987.

¹³⁵ "Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993," *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994.

¹³⁶ Teinowitz, I., "Add RJR to List of Cig Price Cuts," *Advertising Age*, pp. 3 and 46, April 26, 1993.

¹³⁷ Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, "Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements," *Journal of Pediatrics*, vol. 110, pp. 488–491, 1987.

The same comment also criticized the study indicating that children who smoke as few as one cigarette per week can identify a preferred brand. In addition to pointing out that the study did not demonstrate a causal relationship and that the sample was not generalizable, the comment argued that:

* * * other research has found that adolescents smoke a smaller number of different brands than do adults, [the researchers] tested only the correlation between adolescent smoking and advertising recognition. [The researcher] did not know which brands the adolescents in this study smoked. [emphasis in original]

Contrary to the comment, these studies are evidence that, when considered together, form a coherent pattern that establishes the role that advertising plays in young people's smoking behavior.

The CDC study¹³⁸ provides evidence of young people's smoking choices. Neither the fact that the data included 18-year-olds nor the question of directionality is sufficient to invalidate the study's utility. While the data available for the study contained 18-year-old use, there is little difference between 17- and 18-year-old cigarette use; certainly not enough to invalidate the general finding that underage and 18-year-old smokers choose the three most heavily advertised brands. The issue of directionality of the results is no more important. The results showed that young people chose cigarettes that are heavily advertised, not ones that are cheap or low tar, etc. The CDC study, as noted, did not prove causality—it was not intended to and it did not.

The comment's criticism of the study, which involved children who smoke as few as one cigarette a week, is not correct. The researchers did know the brands that the adolescents in the study smoked. "Fifty-two percent of all students who had used cigarettes identified a single preferred brand * * *. One brand of cigarettes (Marlboro) accounted for 76% of all preferred brands." The study's finding is consistent with every other study of adolescent brand preference: Marlboro is the number one brand choice.

The effect of advertising on brand choice by young people is important. It shows that young people choose the imagery of the two or three most highly advertised brands to smoke, brands that provide specific definitions of a user.

¹³⁸ "Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993," *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994.

¹³² Pierce, J. P., L. Lee, and E. A. Gilpin, "Smoking Initiation by Adolescent Girls, 1944 through 1988, An Association with Targeted Advertising," *JAMA*, vol. 271, pp. 608–611, 1994.

¹³³ A more sophisticated example of this type of time series analysis was published by the FTC to show that health claims in food advertising could have a beneficial effect upon people's consumption of high fiber breakfast cereals. (Ippolito, P., and A. Mathios, *Health Claims in Advertising and Labeling, A Study of the Cereal Market*, Bureau of Economics Staff Report, FTC, August 1989.)

The choice permits the user to adopt the image created by the brand.

f. *The Canada advertising case.* A series of comments raises new issues not considered in the preamble to the 1995 proposed rule.

The September 1995 decision of the Supreme Court of Canada on the Canadian Tobacco Products Control Act (TPCA),¹³⁹ enacted to regulate tobacco advertising and promotion in Canada, prompted several comments, primarily from the tobacco industry. The TPCA banned all tobacco advertising, restricted the promotion of tobacco products and required packaging to display prominent unattributed health messages and toxic constituent information. As soon as the TPCA was enacted in 1988, the tobacco companies challenged the act as unconstitutional. On September 21, 1995, the Supreme Court of Canada found that Parliament had the criminal law power to legislate regarding the advertising and promotion of tobacco products, but that, based on the record developed in the court below, the restrictions on advertising and promotion violated the tobacco companies' freedom of expression guaranteed to all Canadians. Several of the key sections of the TPCA were struck down by the Canadian Supreme Court. The Canadian court ruled that the government had failed to demonstrate that the restraints regarding advertising, promotion, and labeling were reasonable and justified restrictions on freedom of expression.

The Canadian court also found that the government had failed to demonstrate that less intrusive measures, falling short of a complete restriction on advertising and promotion, would be less effective in protecting young people from inducements to use tobacco products. Further, the Canadian court found that the government had failed to show that unattributed health messages were required to achieve its objective of reducing tobacco consumption. Finally, the Canadian court decided that there was no rational connection between prohibiting a tobacco product trademark on a nontobacco product and the objective of the TPCA. The decision left the advertising and promotion of tobacco products substantially unregulated in Canada.

Because of some similarities between the Canadian federal tobacco control strategy and FDA's proposed regulation, some comments suggested that the

opinions of the Canadian court are a basis for rejecting actions and laws targeting lawful tobacco advertising, particularly FDA proposed regulations. Moreover, the comments said that the Canadian court concluded that the proposed prohibition on tobacco advertising could not be sustained because it "failed the rational connection test" in that there was no causal connection "whether based on direct evidence or logic and reason" justifying the law (100 C.C.C. 3d. 449, Charter of Rights).

In contrast, one comment suggested that the ruling on this case is consistent with FDA's emphasis on reducing image advertising directed towards young people. The comment stated that FDA's focus fits the Canadian court's decision and had the Canadian government restricted image advertising rather than banning all advertising, it would have upheld the regulation.

FDA does not find the decision of the Canadian court to be contrary to its findings. The Canadian court did recognize that image or lifestyle advertising can affect overall consumption. Moreover, contrary to the comment's suggestion, the court specifically recognized that: "measures * * * to prohibit advertising aimed at children and adolescents * * * would be a reasonable impairment of the right to free expression, given the important objective and the legislative context" (100 C.C.C. 3d. 449).

Finally, FDA has considered a much larger quantity of evidence than that which was before the Canadian court, including the evidence concerning nontobacco item ownership by young people and the materials received during the comment period. The latter included the heretofore confidential or secret documents from RJR's marketing department and also those concerning the results of RJR's focus groups, which showed that interest in nontobacco items was highest among the young. Thus, FDA considered a much fuller record than that before the Canadian court. Moreover, the comment period provided the agency with additional evidence concerning various proposed provisions. FDA's final rule is thus based on a very complete and full record and its decisions are well justified.

g. *Roberts and Samuelson.*

Concerning the effect of advertising on consumption patterns, one study not considered by the court in Canada, but cited by FDA in the preamble to the 1995 proposed rule, was an econometric analysis employed by Roberts and

Samuelson¹⁴⁰ to show that advertising can increase the market demand for tobacco products. The study measured the effect on brand share and market size of advertising for low and high-tar cigarettes. The results indicated that advertising for low tar cigarettes did increase overall market size.

The study looked at the question of the effect of advertising not from the viewpoint of the consumer, but from the producer's perspective—how much should a firm invest in advertising in order to maximize its profits. A predicate assumption is that a manufacturer would not invest in advertising if the cost did not produce a return. This study also was conducted by independent economists and appeared in a peer reviewed journal.

Several comments criticized the study as an "ambitious failure." The industry comments criticized the study on the following grounds: The study inappropriately measures the level of advertising in messages and not in expenditures, and the study had inadequacies in some assumptions and in the data and these flaws thus call into question the study's results. Moreover, the comments alleged that misallocation of advertising expenditures may have biased the results. The results of the study show that advertising for low tar cigarettes had a beneficial effect on the overall level of consumption, but that the same effect did not occur for high tar cigarette advertising. The comments noted that young people do not consume low tar cigarettes, and therefore the results are irrelevant to a discussion of youth smoking. Moreover, the comments said that the results are not generalizable to all cigarette advertising. Finally, the comments said that population growth may have accounted for the finding of a relationship between advertising and consumption.

The agency disagrees with the criticisms of this study and finds instead that it is persuasive evidence of the effects of tobacco advertising for low-tar cigarettes on the overall market. In answer to the first criticism, the study used messages instead of expenditures as a measure of advertising in order to increase the accuracy of the analysis. It is the messages actually seen by a consumer, and not the amount spent by the company on advertising, that is more relevant in assessing the effect of advertising. If the cost of advertising

¹³⁹ *RJR-MacDonald, Inc. v. Canada (Attorney General)*, S.Ct. of Canada, 100 C.C.C. 3d 449, Sept. 21, 1995.

¹⁴⁰ Roberts, M. J., and L. Samuelson, "An Empirical Analysis of Dynamic, Nonprice Competition in an Oligopolistic Industry," *Rand Journal of Economics*, vol. 19, pp. 200-220, 1988.

were to go up, and thus firms would have to pay more for fewer messages, we would not expect to find a greater effect on consumers, which was the effect shown by the study.

The second issue, that there were flaws in the study, is similarly not fatal. As noted in section VI.D.4.d. of this document, each study utilizes the best data and methods available at the time. This may not be the perfect study, but its flaws are minor and do not affect its usefulness. Moreover, one major criticism was with the advertising variable and as noted more fully in section VI.D.6.a. of this document data on advertising expenditures are generally considered trade secrets by the companies. Thus, independent researchers have to use whatever data are available, even if they are not perfect. If the industry wanted to ensure more complete studies, it could release old data relevant to advertising expenditures.

Third, the comments complain that the focus of the study, low-tar advertising, limits the applicability of the results. However, the fact that this study found that advertising for low-tar cigarettes increased the market is not a limitation that restricts the results to that one example. The importance of the results is that the study shows that advertising in this oligopolistic industry can affect the market size. The purpose of dividing the market into high- and low-tar advertising was an attempt to isolate the effect of advertising for each of the product classes.

Fourth, the comments expressed concern about the possibility of population growth as an intervening factor. Population growth should not have affected the results as growth would have affected the high-tar market as well as the low-tar market, a consequence that did not occur.

FDA concludes that this study presents excellent evidence of the effect of advertising on consumption patterns and, that it would have provided quite supportive evidence before the Canada court for advertising restrictions.

h. *The African-American youth market.* Referring to the declining African American youth tobacco market, several comments argued that FDA's tentative finding in the preamble to the 1995 proposed rule on the relationship between outdoor cigarette advertising and tobacco consumption by young people is incorrect. Comments said that if cigarette advertising increases the prevalence of smoking among young people, the percentage of African-American young people who smoke

should be equivalent to that of whites, because African-American young people see as much or more cigarette advertising than do whites. However, smoking rates for young African-Americans are much lower than for white young people. One comment further indicated that African-American young people's decision to smoke may be more responsive to peer influence and parental and community advice than cigarette advertising.

It is unclear why African-American young people do not use tobacco at the same rate as white young people. It is surely not that their parents smoke less; the smoking rate among African-American adults is 26 percent, almost the same rate as for white adults.¹⁴¹ Whatever may be the reason (and it is unknown) for the lower smoking rates among youth among that segment of the population, it does not provide sufficient evidence against advertising restrictions when other evidence shows that advertising does affect children's decisions to use tobacco products.

i. *The evidence relating to smokeless tobacco.* A couple of comments argued that FDA had presented insufficient evidence regarding the effect of advertising on the decision to use smokeless tobacco. One joint comment from the smokeless tobacco manufacturers stated:

The studies cited by the agency regarding cigarette advertisements and smoking are all either highly flawed, biased, or simply do not support the agency's hypothesis. * * * Even more troubling—and from the standpoint of sustaining its legal obligation, a fatal flaw—is the agency's audacity to propose a virtual ban on advertising for smokeless tobacco products without even deigning to build a case.

The comment is correct that there is less evidence available regarding smokeless tobacco advertising practices and smokeless tobacco use. Nevertheless, the record contains sufficient evidence to provide a basis for applying the advertising restrictions in the 1995 proposed rule to smokeless products. In the preamble to the 1995 proposed rule (60 FR 41314 at 41331), reference was made to the remarkably successful regeneration of the smokeless tobacco market by U.S. Tobacco (UST), the leading smokeless tobacco company, in the 1980's. In the 1970's, the segment of the population with the highest use of these products was over age 50, and young men were among the lowest. Fifteen years later, there had been a tenfold increase in the use of smokeless

tobacco by young men, whose use became double that of men over 50. The preamble to the 1995 proposed rule attributed that increase to the concerted advertising and marketing efforts of UST.

As detailed more fully in the preamble to the 1995 proposed rule (60 FR 41313 at 41331), officials at UST held a marketing meeting in 1968 where, according to the *Wall Street Journal*, the vice-president for marketing said, "We must sell the use of tobacco in the mouth and appeal to young people *** we hope to start a fad." Another official attending the same meeting was quoted as saying, "We were looking for new users—younger people who, by reputation, wouldn't try the old products."

Later, Louis Bantle, the chairman of the board of UST, described the reason that so many young males use smokeless tobacco, "I think there are a lot of reasons, with one of them being that it is very 'macho;'" UST's advertising utilized the themes that play well with 'macho' boys—rugged masculine images—and utilized heroes to this group—professional athletes. Bantle described the success of this program thus: "In Texas today, a kid wouldn't dare to go to school, even if he doesn't use the product, without a can in his Levis."

The UST program also utilized a promotional program that it called "graduation strategy":

UST distributes free samples of low nicotine-delivery brands of moist snuff and instructs its representatives not to distribute free samples of higher nicotine-delivery brands. The low nicotine-delivery brands also have a disproportionate share of advertising relative to their market share. For example, in 1983, Skoal Bandits, a starter brand, accounted for 47 percent of UST's advertising dollars, but accounted for only 2 percent of the market share by weight. In contrast, Copenhagen, the highest nicotine-delivery brand, had only 1 percent of the advertising expenditures, but 50 percent of the market share. This advertising focus is indicative of UST's "graduation process" of starting new smokeless tobacco product users on low nicotine-delivery brands and having them graduate to higher nicotine-delivery brands as a method of recruiting new, younger users.

(60 FR 41314 at 41331)

Therefore, the agency disagrees with the assertion that it has presented no evidence to support restricting smokeless tobacco advertising. In fact, it finds the graduation strategy to be strong evidence of the effectiveness of advertising in targeting young people to become new users and consistent with and supported by the general

¹⁴¹ "Cigarette Smoking Among Adults—United States—, 1993," *MMWR*, CDC, vol. 43, pp. 925–930, 1994.

discussion, see sections VI.B. and VI.D. of this document.

4. Why Young People Use Tobacco and the Role of Advertising in That Process

(15) Regardless of the evidence cited in section VI.D.3. of this document, many comments argued that children start to smoke and use smokeless tobacco because of influences on them other than advertising, primarily the influence of their friends and peers.

a. *Why young people use tobacco.* One comment cited studies showing that young people who were most likely to be smokers were those who were particularly rebellious or prone to deviant behavior,¹⁴² and said that it was counterintuitive that young people fitting these profiles would want to conform to what advertising portrayed as desirable.

Conversely, many comments said that cigarette advertising, like all advertising portrays highly attractive images. One comment stated that when young people's peers are also smoking, this can serve to personalize the images and make them relevant for their own lives, and cause them to have favorable impressions about their friends who smoke.¹⁴³

One comment argued further that children smoke because they hope to convey a positive self-image.¹⁴⁴ Hence, young people may be particularly vulnerable to being influenced by the attractive images presented in cigarette and smokeless tobacco advertising.¹⁴⁵

Specifically, the same comment cited numerous studies that indicate that many young people smoke because they

hope to convey a positive image.¹⁴⁶ Based on these studies, the comment stated: "Image or impression management (Schlenker, 1980) has great utility for young people as they struggle for social acceptance and autonomy (citations omitted)."

Finally, the comment described the developmental aspects of adolescents that are relevant to this issue:

With respect to developmental aspects of adolescence, there are two related factors that make adolescents especially vulnerable to being influenced by tobacco advertising. First, adolescents are typically beginning to focus on peer group interactions more than on family interactions (e.g., Brown et al., 1986), which they may likewise value to a far greater extent. Second, tobacco use constitutes a "temporal trap" (Messick and McClelland, 1983) in the sense that the peer group benefits of tobacco use are immediate, while the negative consequences in terms of health outcomes are so far into the future that many adolescents, who often see themselves as invulnerable even in the present, would consider them to be irrelevant. Furthermore, the negative social consequences of tobacco use in adulthood (i.e., social stigmatization * *) are also unimportant to adolescents at the time they are making the decision to use tobacco products.¹⁴⁷

Stated differently, adolescence is a time of "identity formation." Young people use the attractive imagery of advertising as a "window into the adult world." They are "susceptible to the images of romance, success, sophistication, popularity, and

adventure * * *." ¹⁴⁸ By adolescence, clothes, possessions, and "badge products" such as cigarettes are used to define oneself and to control relations with others.¹⁴⁹

Support for this view of the role of tobacco advertising also comes from the tobacco industry:

FDA turns a blind eye to the fact that the personal display of products with commercial logo—through dress and other forms of expression—is a form of participation in American popular culture. It is a way to register a group identity to signal one's place in the social fabric. In addition to these comments, FDA has the words of RJR's research department in a 1973 memo, detailed in section VI.D.3.d. of this document, that chart a course for attracting the young smoker.¹⁵⁰

On the basis of the evidence cited and reviewed in section VI.D.3. of this document, the agency finds that the suggestion that it is impossible to advertise in a way that would appeal to rebellious nonconformist teenagers is

¹⁴⁸ Nichter, M., and E. Cartwright, "Saving the Children for the Tobacco Industry," *Medical Anthropology Quarterly*, vol. 5, pp. 236–256, 1991.

¹⁴⁹ Stacey, B. G., "Economic Socialization in the Pre-Adult Years," *British Journal of Social Psychology*, vol. 21, pp. 159–173, 1982.

¹⁵⁰ A July 3, 1974 memo, authored by D. W. Tredennick, of R. J. Reynolds' Marketing Research Department was submitted to the rulemaking docket by the Attorney General of Mississippi in response to the reopening of the rulemaking record (61 FR 11349, March 20, 1996). Although the agency has not relied on the memo as part of the justification for this rule, FDA is citing to it here because it is relevant to the issues discussed. The memo was also reported in the press, see Schwartz, J., "R. J. Reynolds Marketing Memo Discusses Young Smokers' Brand Image," *Washington Post*, A03, April 23, 1996. The memo asked and answered the question: "What causes smokers to select their first brand of cigarettes?" The answers developed by Mr. Tredennick echos the concepts discussed above. The memo hypothesized that: "[t]he causes of initial brand selection relate directly to the reasons a young person smokes. The more closely a brand meets the psychological 'support' needs (advertising or otherwise communicated brand or physiological needs (product characteristics), the more likely it is that a given brand will be selected. (Emphasis added)" One important characteristic was associated with the user "image" associated with a brand. "To some extent young smokers 'wear' their cigarette and it becomes an important part of the 'I' they wish to be, along with their clothing and the way they style their hair." The memo also recognized the importance of peer influence on a young person's decisions about smoking and noted that: "It must also be true that influential young smokers (perhaps relatively few) have made brand selections based on product characteristics or advertising and promotion communication. The fact that two brands, Marlboro and Kool, have such dominant shares among youths suggests the above hypothesis * * *." Tredennick noted further that both Marlboro and Kool project imagery that is psychologically important to adolescents—the need for support and strength.

¹⁴² Chassin, L., C. C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, "Predicting the Onset of Cigarette Smoking in Adolescents: A Longitudinal Study," *Journal of Applied Social Psychology*, vol. 14, pp. 224–243, 1984; Collins, L. M., S. Sussman, J. Mestel Rauch, C. W. Dent, C. J. Johnson, W. B. Hansen, and B. R. Flay, "Psychosocial Predictors of Young Adolescent Cigarette Smoking: A Sixteen-Month, Three-Wave Longitudinal Study," *Journal of Applied Social Psychology*, vol. 17, pp. 554–573, 1987.

¹⁴³ Pechmann, C., and S. J. Knight, "Cigarette Ads, Antismoking Ads and Peers: Why do Underage Youth Smoke Cigarettes?" *Advances in Consumer Research*, Association for Consumer Research, edited by Corfman, K. P., and J. G. Lynch, eds., Provo, UT, vol. 23, pp. 267–268, 1996.

¹⁴⁴ Chassin, L., C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, "Self-Images and Cigarette Smoking in Adolescence," *Personality and Social Psychology Bulletin*, vol. 7, pp. 670–676, 1981; Barton, J., L. Chassin, C. Presson, and S. J. Sherman, "Social Image Factors as Motivators of Smoking Initiation in Early and Middle Adolescence," *Child Development*, pp. 1499–1511, 1982.

¹⁴⁵ *Id.*

¹⁴⁶ Chassin, L., C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, "Self-Images and Cigarette Smoking in Adolescence," *Personality and Social Psychology Bulletin*, vol. 7, pp. 670–676, 1981; Barton, J., L. Chassin, C. C. Presson, and S. J. Sherman, "Social Image Factors as Motivators of Smoking Initiation in Early and Middle Adolescence," *Child Development*, pp. 1499–1511, 1982; Belk, R. W., "Possessions and the Extended Self," *Journal of Consumer Research*, vol. 15, pp. 139–168, 1988; Belk, R. W., R. Mayer, and A. Driscoll, "Children's Recognition of Consumption Symbolism in Children's Products," *Journal of Consumer Research*, vol. 10, pp. 386–397, 1984; Brown, B. B., M. J. Lohr, and E. L. McClenahan, "Early Adolescents' Perceptions of Peer Pressure," vol. 6, pp. 139–154, 1986; Messick, P. M., and C. C. McClelland, "Social Traps and Temporal Traps," *Personality and Social Psychology Bulletin*, vol. 9, pp. 105–110, 1983; Levy, S. J., "Meanings in Advertising Stimuli," *Advertising and Consumer Psychology*, Praeger, New York, pp. 214–226, 1986; Solomon, M. R., "The Role of Products as Social Stimuli: A Symbolic Interactionism Perspective," *Journal of Consumer Research*, vol. 10, pp. 319–329, 1983.

¹⁴⁷ Brown, B. B., M. J. Lohr, and E. L. McClenahan, "Early Adolescents' Perceptions of Peer Pressure," *Journal of Early Adolescence*, vol. 6, pp. 139–154, 1986; Messick, P. M., and C. C. McClelland, "Social Traps and Temporal Traps," *Personality and Social Psychology Bulletin*, vol. 9, pp. 105–110, 1983.

without merit. Tobacco advertising plays directly to the factors that are central to adolescents as they decide whether to use tobacco products. Thus, the available evidence clearly supports a finding that advertising plays an important role in young people's tobacco use.

b. *Determinants of smoking.* Several comments from the advertising and tobacco industries claimed that the econometric studies performed for them by experts found that peers, parents, and siblings have the greatest influence on young peoples' decision to start smoking.

Citing an econometric analysis performed for RJR by Dr. J. H. Beales, on data concerning its Joe Camel advertising campaign, one comment argued that "minors balance the risks and rewards of smoking to decide whether or not to smoke, just as they would any other consumption decision. The greater an individual minor perceives the net rewards of smoking, the more likely he or she will try smoking. Minors who perceive greater net rewards of smoking are also likely to smoke more intensively."

The comment further argued that an analysis based upon this theoretical model by Dr. Beales found that neither advertising nor advertising expenditures has an appreciable effect on young people's perceptions of the benefits of smoking and thus would have no indirect effect on teenage smoking decisions.¹⁵¹ More specifically, the comments stated that the Beales' studies show that advertising expenditures for the particular brands that most teenagers smoke, Marlboro and Camel, do not influence and are not associated with smoking decisions. Moreover, Dr. Beales reported that the results of his studies indicate further that advertising did not have an indirect effect on smoking behavior. Beales concluded that minors who had been exposed to more advertising did not identify the perceived rewards of smoking—"smoking helps when bored," "smoking helps relax," "smoking helps with stress," and "smoking helps in social situations," in a greater number than did those minors who reported less exposure. The comment concluded that the failure of the 1993 Beales study to find either direct or indirect effects from advertising on smoking behavior should be conclusive.

FDA does not agree. The 1993 Beales study presents only one analysis of

youthful smoking and that analysis is flawed.¹⁵² Dr. Beales appears to have performed tests using an ordered logistic regression model to test for: (1) The effect of advertising on smoking behavior, using advertising expenditures and young people's view of "most advertised brand" as measures; and (2) smoking behavior as a function of a number of psychosocial variables and determinants.

First, a logistic model is only as good as the variables used. Thus, if a variable is misspecified or imprecise, the model's predictive capacity will be severely compromised. The variable "most advertised brand" appears to be quite imprecise as a measure to capture the effect of advertising. The most that this variable would capture would be the ability of the campaign to be seen and remembered. It would not capture the appeal of the campaign, or the effect of the campaign on consumers, nor could it measure the ability of an advertising campaign to change or create consumer action. In addition, it would not be surprising to find that almost as many nonsmoking young people as young smokers found Camel (or Marlboro) to be the most advertised brands, since those advertising campaigns were quite ubiquitous at the time the data for this study were collected and were, in fact, the most advertised brands. A variable that cannot discriminate between users and nonusers, because all had seen and remembered the advertising, cannot be expected to produce useful predictive results in a regression analysis of why people, particularly young people, smoke.

Second, Dr. Beales attempted to determine whether differences in advertising expenditures would predict smoking behavior. It appears, however, that Dr. Beales did not look at this question longitudinally—that is, he did not look at whether smoking rates varied as a function of advertising expenditures for Camel cigarettes before the Joe Camel campaign and after the campaign started. Instead, he appears to have measured smoking rates as a function of the differences in regional advertising expenditures in California during one time period. It should not be surprising therefore that little if any effect on smoking rates was found: (1) There is no reason to expect to find significant changes in smoking behavior based on small regional variations within one State in advertising expenditures, and (2) optimum

expenditures for advertising outlays in any given region would have been determined in advance by an advertising agency and therefore would more likely reflect smoking patterns already in existence. Had he wanted to measure smoking behavior as a function of Camel's advertising, he should have modeled it longitudinally over time. Since the regional advertising expenditures must have been obtained from a RJR data base, Beales clearly had access to other sources of data within the company. He therefore should have been able to acquire advertising expenditures for the Camel brand before the introduction of Joe Camel and advertising expenditures for the period after Joe Camel's appearance. This would have been a better test.

Finally, Dr. Beales performed an analysis to determine the "true" determinants of smoking. Dr. Beales' regression analysis utilized a series of psychosocial characteristics and beliefs about smoking. He found that the only factor that failed to produce an association was advertising. First, as noted, there is no reason to believe that "most advertised brand" would perform as a useful surrogate for the effects of advertising. Therefore, regardless of the value of the study, it is not good evidence concerning the role of advertising in young people's smoking decision. Second, the analysis indicates what is already known: certain beliefs and life patterns can help predict who may become a smoker. However, it does not measure what effect advertising can have on a young person's perception or beliefs.

Additional concerns about the study are similar to those that the tobacco industry comments raised about studies cited by FDA. The first concern is that several variables used in the model measure the same impact. This redundancy could create a multicollinearity problem (i.e., two or more variables vary together but it is very difficult to determine which variable influences the other). Moreover, the redundancy may have caused irrelevant variables to be included in the regression equation. Both multicollinearity and the inclusion of irrelevant variables can affect the efficiency of the model's estimates. The second concern is that the model used in the study is questionable. The correct model could well have been a double hurdle model, i.e., modeling the decision to smoke first and then modeling the choice of what brand to smoke, second.

¹⁵¹ Dr. Beales used children's designation of a "most advertised brand" as a surrogate for the effect of advertising.

¹⁵² Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," p. 44, 1993.

Finally, there is concern that the data for the impact of advertising expenditures and smoking behavior were incompatible and, thus, may have failed to find a relationship that did in fact exist. The teen smoking prevalence data were from a behavioral study, and the measurement of advertising expenditures was from regional advertising expenditures, undoubtedly maintained by the company. The smoking decision for a teenager may very well not have been influenced by the amount of money spent but by the number of messages he/she receives. The aggregate expenditures for advertising cannot measure the number of messages actually received by an individual teen.

Given the multitude of problems with the design of the study and the choice of variables, the study has limited capability for producing results that can adequately describe advertising effects on smoking behavior. Moreover, this study is but one of many and, whatever its value, it does not overwhelm the evidence that FDA has relied on.

c. *Laugesen and Meads*. In contrast to the Beales' study, FDA had cited a study by Laugesen and Meads, entitled "Advertising, Price, Income and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets,"¹⁵³ which provided evidence that increases in advertising expenditures had an effect on youth smoking behavior including recruiting new smokers and increasing the market base.

One comment stated that data from supermarkets were unrepresentative, both because of the percentage of sales from supermarkets in New Zealand (presumably not large), and because it is not known what percentage of sales to young people are made at supermarkets. Moreover, many conditions were not accounted for, including possible different pricing structures between retail outlets.

The comments also criticized several major assumptions they claim were made in the study, for example, that young people purchase the less expensive, down market brand. Finally, the comment criticizes the failure to control for other variables (such as rotating health warnings and new advertising restrictions).

The authors themselves responded to some of the concerns expressed. For

example, they explained that they specifically chose to collect data from supermarkets because other "authors with access to full industry data¹⁵⁴ have recommended that the data interval [for supermarket sales] should reflect the inter-purchase time for cigarettes," which in New Zealand is a week or less. Moreover, the authors found that supermarket cigarette sales are more consistent than other points of sales. Hence there were fewer fluctuations in the demand data for cigarettes.

Moreover, in response to the second comment, the authors did not assume that young people purchase downmarket cigarettes at a higher rate than the general population, but that people with lower income, which includes young people, purchase these brands more often. But more importantly, the study found that it takes only 2 years of advertising of this downmarket brand to expand the teen market by 4 percent, and this fact was not disputed.

d. *Other comments*. Finally, several comments criticized the quality of the evidence cited by FDA in its preamble to the 1995 proposed rule. One comment stated that FDA has relied too heavily on studies conducted by physicians or others not familiar with the art and science of persuasion. Further, it asserted that most of the evidence cited in support of the regulations had been published in medical journals and not in peer reviewed marketing journals.

However, a review of the evidence presented belies that concern. First, FDA relied on the research and expert opinion of consumer psychologists, business and marketing experts, economists and social science researchers as well as medical experts. Moreover, FDA has relied on two outstanding reports issued in the past few years that specifically addressed the issue of young people's use of tobacco—the 1994 SGR and the IOM Report. Both commented extensively on the role that advertising plays in young people's smoking behavior and use of smokeless tobacco and both recommended strongly that a comprehensive plan to attack the problem of youth tobacco use include stringent advertising restrictions.

Moreover, of the 15 members of the IOM committee, 7 were expert in the fields of behavioral sciences, including psychology, psychiatry and public policy, anthropology, and economics. Similarly, the contributing authors to the 1994 SGR included experts in economics, social research, marketing, and business administration. Finally, the comments submitted include additional empirical evidence, the expert opinion of the American Psychological Association,¹⁵⁵ and the words of the tobacco industry itself, all of which are referred to in this document.

One comment criticized FDA's reliance on the IOM Report and the 1994 SGR as simply presenting "selective reviews" of much of the same "dubious literature" reviewed by FDA. Another comment stated that FDA had indiscriminately relied on studies cited in the 1994 SGR, none of which, the comment claimed, was capable of determining whether advertising influences children to initiate smoking.

Several comments appeared to place great importance on the fact that both reports acknowledge that the psychosocial and econometric research that they present do not prove that cigarette advertising causes young people to begin smoking or to use smokeless tobacco. The IOM Report stated that, because of the nature of the research, it is not known for certain whether youths already interested in smoking or smokeless tobacco become more attentive to advertisements for these products or whether these advertisements lead youths to become more interested in these products. One comment argued that the "IOM's recognition of this weakness fatally undermines its own and FDA's arguments on the impact of advertising on smoking behavior." Another comment claimed that the IOM Report acknowledges the lack of a causal relationship between advertising and smoking and acknowledges that the very econometric studies it cites are unreliable to determine whether advertising contributes to youth smoking behavior. The comment also stated that FDA misstates IOM's conclusion regarding evidence of a

¹⁵³ Laugesen, M., and C. Meads, "Advertising, Price, Income, and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets," *British Journal of Addiction*, vol. 86, pp. 83–89, 1991.

¹⁵⁴ The authors cited this study as an example of one having access to full industry data. Leeflang, P. S. H., and Reuiyl, "Advertising and Industry Sales: An Empirical Study of the West German Cigarette Market," *Journal of Marketing*, vol. 49, p. 97, 1985; Laugesen, M., and C. Meads, "Advertising, Price, Income, and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets," *British Journal of Addiction*, vol. 86, pp. 83–89, 1991.

¹⁵⁵ The American Psychological Association represents 132,000 members and affiliates and is the largest organization of psychologists in the world. Its comment represents the organization's "research-based recommendations" and reflects significant input from several relevant divisions including the Division of Personality and Social Psychology, the Division of Society for the Psychological Study of Social Issues, and the Division of Consumer Psychology.

causal relationship between advertising and smoking initiation. Further, several comments cited to a statement in the 1994 SGR that “no longitudinal study of the direct relationship of cigarette advertising to smoking initiation has been reported in the literature.”¹⁵⁶ However, these comments failed to include the sentence immediately preceding this quote: “Considered together, these studies offer a compelling argument for the mediated relationship of cigarette advertising and adolescent smoking.”

Another comment in support of advertising restrictions on tobacco products argued that the multidisciplinary studies cited in the 1994 SGR supported the conclusion that marketing and advertising tobacco products do play a role in tobacco use among young people. The comment suggested that this conclusion is consistent with the 1989 Surgeon General’s conclusion that “the collective empirical, experiential, and logical evidence makes it more likely than not that advertising and promotional activities do stimulate cigarette consumption.”¹⁵⁷ Additionally, the comment supported the findings of the 1994 SGR that “cigarette advertising appears to increase young people’s risk of smoking” by conveying the impression that smoking has social benefits and is far more common than it really is.¹⁵⁸ Moreover, this comment contended that the IOM’s conclusions supported FDA’s tentative view that image advertising of tobacco products is tremendously appealing to young people.

As noted more fully in section VI.B. of this document, FDA did rely heavily on the two reports, and continues to find the reports persuasive evidence. They represent mainstream scientific consensus and are appropriately entitled to a great deal of deference. The agency notes that, in a different but not entirely unrelated context, that of health claims for food, Congress has said that FDA would have to specifically justify any decision rejecting the conclusions of a report from an authoritative scientific body of the United States. (See section 403(r)(4)(C) of the act (21 U.S.C. 343(r)(4)(C)).) No justification for rejecting the IOM’s conclusions exists here.

Finally, the agency, like the 1994 SGR and IOM Report, finds that an adequate basis does exist to conclude that

advertising plays a “mediated relationship” to adolescent tobacco use.¹⁵⁹ The proper question is not, “Is advertising the most important cause of youth initiation?” but rather, “does FDA have a solid body of evidence establishing that advertising encourages young people’s tobacco use such that FDA could rationally restrict that advertising?” The answer to this question is “yes.”

5. Has the Agency Met Its Burden?

(16) Several comments from the tobacco and advertising industries criticized the agency for failing to present evidence that conclusively establishes a causal link between advertising and young people’s decisions to begin using cigarettes and smokeless tobacco.

FDA disagrees that its burden is to conclusively prove by rigorous empirical studies that advertising causes initial consumption of cigarettes and smokeless tobacco. No single study is capable of doing so. As one comment stated, it would in fact be practically and ethically impossible to conduct such a study. Certainly no study presented by industry or any other party demonstrated that advertising does *not* cause the initial consumption of cigarettes and smokeless tobacco. Indeed, it should be noted that not one study cited by FDA or submitted by industry could conclusively demonstrate that *any* factor actually *caused* children to begin smoking or to use smokeless tobacco. This includes family and peer influences, which the tobacco industry repeatedly cite as the major determinants of youth smoking and smokeless tobacco use. As was suggested by a comment, however, even when a young person’s decision to smoke is strongly influenced by a friend or parent, advertising reinforces the decision and makes the young person feel good about the decision and the “identity” thereby acquired.

It should also be noted that the apparent focus on the possible causal role of cigarette and smokeless tobacco advertising in young people’s *initial* decision to smoke or to use smokeless tobacco is overly narrow. Human behavior cannot be modeled so simplistically. In point of fact, tobacco advertising has an effect on young people’s tobacco use behavior if it affects initiation, maintenance, or attempts at quitting.

The evidence that FDA has gathered in this proceeding establishes that

cigarette and smokeless tobacco advertising does have such an effect. While not all the evidence in the record supports this conclusion, there is more than adequate evidence, that when considered together, supports a conclusion that advertising, with the knowledge of the industry, does affect the smoking behavior and tobacco use of people under the age of 18. This behavior includes the decision whether to start using cigarettes or smokeless tobacco, whether to continue using or to increase ones consumption, when and where it is proper to use tobacco, and whether to quit. This evidence includes:

Expert opinion—The American Psychological Association provided expert opinion, with specific citation to numerous studies, to show that tobacco advertising plays directly to the factors that are central to children and adolescents and thus plays an important role in their decision to use tobacco. (See section VI.D.4.a. of this document; and 60 FR 41314 at 41329.)

Advertising Theory—Basic advertising and consumer psychology theory, statements from advertising experts, and general consumer testing show that advertising that is multi-media, that uses color, and that employs more pictures, characters, or cartoons as opposed to text is more robust and can be better processed, understood and remembered by children and adolescents, who have less information processing ability than adults. (See section VI.B.1. and VI.B.2. of this document.)

Studies and Surveys—Studies show that children are exposed to substantial and unavoidable advertising, that exposure to tobacco advertising leads to favorable beliefs about tobacco use, that advertising plays a role in leading young people to overestimate the prevalence of tobacco use, and that these factors are related to young people’s tobacco initiation and use. (See sections VI.D.3.a., VI.D.3.b., and VI.D.3.c. of this document.)

Empirical Studies—Studies conducted on sales data have shown that advertising did increase one segment of the tobacco market (low tar cigarettes), that advertising in New Zealand had the effect of increasing tobacco sales to young people, and that a large multi-country survey showed that advertising tends to increase consumption of tobacco products. (See 60 FR 41314 at 41333 through 41334; sections VI.D.3.g., VI.D.4.c., and VI.D.6.a. of this document)

Anecdotal Evidence, and Various Advertising Campaigns Successful with

¹⁵⁶ 1994 SGR, p. 188.

¹⁵⁷ 1989 SGR, p. 157.

¹⁵⁸ 1994 SGR, p. 195.

¹⁵⁹ *Id.*, p. 188.

Young People—Studies show that the buying behavior of young people is influenced by advertising, that they smoke the most advertised brands, that children ages 3 to 6 can recognize a cartoon character associated with smoking at the same rate as they recognize Ronald McDonald, that various ad campaigns (Camel cigarettes, Reg cigarettes, products designed for women, and smokeless tobacco advertising aimed at new users) that appeared to be targeted to young people did have an effect upon young people's purchases and use of tobacco, and that young people report that they got their information about a tobacco brand from billboards, magazines, in store advertising and on teeshirts (60 FR 41314 at 41329 through 41334; and see sections VI.D.3.d., VI.D.3.e., and VI.D.3.i. of this document).

Industry Statements—Statements in documents created by R. J. Reynolds' researchers, by Philip Morris advertising people, by executives of US Tobacco and by people in and doing work for various Canadian tobacco companies indicate that young people are an important and often crucial segment of the tobacco market.

Consensus Reports—The IOM and 1994 SGR concluded on the basis of an exhaustive review of the evidence that advertising affects young people's perceptions of the pervasiveness, image, and function of smoking, that misperceptions in these areas constitute psychosocial risk factors for the initiation of tobacco use, and thus advertising appears to increase young people's risk of tobacco use.

Consequently, tobacco advertising works in a way that is roughly analogous to the way the Supreme Court described how deceptive advertising works (*FTC v. Colgate - Palmolive Co.*, 380 U.S. 374 (1965)). The Supreme Court described how sellers use deceptive practices to break down the resistance of the buying public (*Id.* at 389–90). Here, as the 1994 SGR, the IOM report, and the comment of the American Psychological Association demonstrate, cigarette and smokeless tobacco companies use image and other advertising techniques to appeal to adolescents' need to belong and to appear to be adult, and thereby to break down their resistance to tobacco use. The advertising helps the companies to overcome the fact, as documents for R. J. Reynolds show, that there is no natural craving for nicotine. While the advertising techniques used by the tobacco industry are quite different than those used by the company in the

referenced Supreme Court case, they ultimately have the same goal—to induce people, in this case young people, to purchase and use these products.

Thus, the evidence in this proceeding demonstrates that cigarette and smokeless tobacco advertising plays a material role in the decision of children and adolescents under the age of 18 to engage in tobacco use behavior. It therefore establishes that the harm from this advertising is real.

6. The Efficacy of the Restrictions; Empirical Evidence Concerning Advertising Restrictions

The final aspect of the analysis under the second prong of the *Central Hudson* test requires a showing by the agency that the restrictions that it seeks to impose will alleviate the harm to a material degree. FDA finds, based upon a review of all of the evidence and the comments received, that the restrictions will, in fact, meet this test.

(17) Nearly all comments in opposition to advertising restrictions argued that the preponderance of the empirical evidence supported a finding of no effect from advertising on young people. Some comments stated that, consequently, the advertising restrictions are “unwarranted, unjustified, unnecessary, [and] will not be effective in reducing underage smoking.” Several comments, representing a variety of interest groups, claimed that the “best available evidence” found that “peer pressure,” “peer and family smoking behaviors” and “young people's perceptions of the costs and benefits of smoking” are more important than advertising and promotion in encouraging young people to experiment with cigarettes and smokeless tobacco.¹⁶⁰ Still others claimed that “being a girl,” “living with a single parent,” “having relatively less negative views about smoking,” “having no intention to stay in full-time education after age 16,” and “thinking they might be a smoker in the future,” are key influencing factors for a young person to start smoking.¹⁶¹

The tobacco industry and the advertising industry stated that their advertising is not directed at children and adolescents but to adults who

already use tobacco, and thus it is not a proper subject for government regulation. The advertising agency for the largest cigarette brand stated, “[T]obacco advertising has as its intended audience existing smokers * * * it is not the company's desire that children start to smoke.”

However, one comment questioned this and asked how cigarette advertising that has an impact upon adults can be assumed to leave unaffected a young viewer, smoker or otherwise. The same comment also cited the words of one retired Marlboro ad man: “I don't know any way of doing this (advertising cigarettes) that doesn't tempt young people to smoke.”¹⁶²

Many comments from consumer groups, public health organizations and numerous private individuals were supportive of the agency's position that the 1995 proposed rule will reduce underage smoking and use of smokeless tobacco. The comments cited evidence from numerous sources such as government officials, university researchers, and antismoking advocates to demonstrate that restrictions on advertising would be effective.

For example, a comment from a leading psychological association stated that research, common sense, and its expert opinion support that, if image-oriented advertising and promotion are replaced with text-only advertising, it would reduce the advertiser's ability to suggest that tobacco users project a desirable image, e.g., glamour, sexiness or maturity.¹⁶³

FDA has concluded that restrictions on advertising and promotion are necessary to reduce the appeal of tobacco products to young people. Such restrictions will protect the access restrictions that the agency is adopting from being undermined and thereby the health of young people. To be effective,

¹⁶² Daniels, D., *Giants, Pygmies and Other Advertising People*, Crain, Chicago, p. 245, 1974.

¹⁶³ Cohen, J. B., “Reconceptualizing Alcohol Advertising Effects: A Consumer Psychology Perspective,” *The Effects of the Mass Media on the Use and Abuse of Alcohol*, Research Monograph, No. 28, Bethesda, MD, NIH, 1995; Goldberg, M. W., J. Madill-Marshall, G. J. Gorn, J. Liefeld, and H. Vredenburg, “Two Experiments Assessing the Visual and Semantic Images Associated with Current and Plain (Generic) Cigarette Packaging,” *Advances in Consumer Research*, edited by Corfman, K. P., and J. G. Lynch, Association for Consumer Research, Provo, UT, vol. 23, 1996; Pollay, R. W., and A. M. Lavack, “The Targeting of Youths by Cigarette Marketers: Archival Evidence on Trial,” *Advances in Consumer Research*, Association for Consumer Research, Provo, UT, vol. 20, pp. 266–271, 1993; Richins, M. L., “Social Comparison and the Idealized Images of Advertising,” *Journal of Consumer Research*, vol. 18, pp. 71–83, 1991.

¹⁶⁰ Beales, J. H., “Advertising and the Determinants of Teenage Smoking Behavior,” vol. 44, 1993.

¹⁶¹ McDonald, C., “Children, Smoking and Advertising: What Does the Research Really Tell Us?,” *International Journal of Advertising*, vol. 12, pp. 279–287, 1993; Goddard, E., “Why Children Start Smoking,” *British Journal of Addiction*, vol. 87, No. 1, pp. 17–25, 1992.

these restrictions must be comprehensive, that is, they must apply to the many types of media currently used in a coordinated way to advertise cigarettes and smokeless tobacco.

FDA finds support for the need for comprehensive regulation in the experiences of other countries which have enacted and put into place some form of restrictions on the advertising of tobacco. Some comments discussed the experience in other countries in which tobacco advertising has been banned. These comments indicated that in countries that have enacted restrictions on advertising that were not comprehensive, the industry was able to continue advertising and portraying attractive imagery in media left uncovered by regulations. For example, Canada, Finland, Great Britain, and Australia enacted regulations of tobacco advertising that did not completely ban or restrict all forms of advertising and promotion. In each of those instances, according to the comments, the tobacco industry was able to take advantage of loopholes in the system to continue to advertise to reach their target audience. Thus, in Canada the advertising ban, which did not ban nontobacco items, was accompanied by the increased use of nontobacco items that carried the tobacco brand name as a mechanism for continuing to advertise the tobacco brand and its prior image. In Great Britain, sophisticated colorful advertisements appeared when the use of human figures in tobacco advertising was banned; in Australia, loopholes in sports sponsorship provisions enabled the industry to continue sports advertising.

Another comment detailed numerous other examples of tobacco companies continuing to advertise effectively in spite of a ban or restrictions on advertising. For example, this comment noted that after France banned all cigarette advertising in magazines, Philip Morris set up a travel agency and advertised "Marlboro Country Travel" in French magazines (Thus, although there was no longer any "cigarette advertising," Philip Morris was able to continue using its western, cowboy theme in advertisements for a travel agency). The comment noted further that in Europe, advertising for cigarettes was replaced by advertisements, using the same imagery, for Camel and Marlboro sports watches and Camel boots. In Malaysia, cigarette companies set up travel agencies called Marlboro, Kent, and Peter Stuyvesant, clothing stores named Camel, jewelry stores named for Benson and Hedges, luxury

car dealerships named More, Salem record stores and Salem and More concert and movie promotions to advertise cigarettes in a country that has banned cigarette advertising. FDA finds that these comments provide strong support for the need for the advertising restrictions to be comprehensive and apply to all advertising media to be effective.

Two aspects of the evidence in this proceeding are particularly persuasive in evidencing that restrictions on advertising will directly advance the agency's goal of protecting the health of children and adolescents under 18. The experience of other countries that have adopted advertising restrictions shows that when those restrictions are enforced, they have resulted in reductions in the level of tobacco use. In addition, the courts themselves have generally found that, as a matter of common sense, reductions in advertising have produced a reduction in demand. While some comments tried to distinguish these cases, FDA finds that they are relevant.

A discussion of each of these aspects of the evidence follows:

a. *International and cross country studies.* FDA did not receive consistent comment on the international studies¹⁶⁴ that it cited in the preamble to the 1995 proposed rule on the relationship between advertising restrictions and consumption.

(18) Several comments stated that advertising restrictions have not affected tobacco product consumption, and further stated that, in fact, tobacco product consumption has increased in most countries with advertising and promotional restrictions.

In contrast, other comments supported the findings of the same studies and stated that the studies support the conclusion that advertising and promotional restrictions can be effective in curbing smoking initiation among young people.

Several comments opposing the 1995 proposed rule maintained that better surveys of the results of advertising restrictions abroad were done in conjunction with the World Health

Organization (WHO). The two WHO surveys on the health behavior of schoolchildren in four countries found that smoking among schoolchildren is related to peer smoking behaviors and to the number of smokers in the family.¹⁶⁵ More importantly, the comments said that the survey found "no systematic differences" between the smoking behavior of young people in countries where tobacco advertising is completely restricted and in countries where it is not. They asserted that the findings of the WHO survey completely repudiate FDA's assertion that advertising restrictions reduce tobacco consumption among young people. The comments further argued that a followup survey found that the prevalence of smoking among schoolchildren in countries with total tobacco advertising restrictions was actually higher than countries with fewer restrictions.¹⁶⁶

However, the two surveys cited by these comments did not compare the percentage of young people who smoked before and after the implementation of tobacco advertising restrictions within countries. In order to realistically measure the effect of advertising restrictions, each country must be looked at individually. For example, country A, with a high rate of smoking, cuts its smoking rate in half. This would be considered a major success for country A, but country A still may have a higher smoking rate than country B. Country B may not have instituted any advertising restrictions because its smoking rate has always been low. Thus, comparing the rates of countries A and B would be like comparing apples and oranges.

Studies that have looked at before and after data from individual countries have reported downward trends in smoking rates among young people following advertising restrictions.¹⁶⁷ For example, in Norway the percentage of 15-year old boys and the percentage of 15-year old girls who were daily smokers in 1975, before a restriction on all forms of tobacco advertising and promotion was put in place, was

¹⁶⁵ Aaro, L. E., B. Wold, L. Kannas, and M. Rimpela, "Health Behavior in Schoolchildren: A WHO Cross-National Survey," *Health Promotion*, vol. 1, pp. 17-33, May 1986.

¹⁶⁶ Van Reek, J., H. Adriaanse, and L. Aaro, "Smoking by Schoolchildren in Eleven European Countries," *Proceedings of the 7th World Conference on Tobacco and Health*, Duroton, B., and K. Jamrozik, vol. 301, pp. 301-302, 1991.

¹⁶⁷ Bjartveit, K., "The Effect of an Advertising Ban—Who has the Burden of Proof," National Health Screening Service, Norway, 1994; Rimpela, M., L. E. Aaro, and A. H. Rimpela, "The Effects of Tobacco Sales Promotion on Initiation of Smoking," *Scandinavian Journal of Social Medicine*, 1994.

¹⁶⁴ Smea, C., "Effect of Tobacco Advertising on Tobacco Consumption—A Discussion Document Reviewing the Evidence," Department of Health, Economics, and Operational Research Division, London, 1992; "Health or Tobacco—An End to Tobacco Advertising and Promotion," Toxic Substances Board (TSB), Wellington, New Zealand, May 1989; Laugesen, M., and C. Meads, "Tobacco Advertising Restriction Price, Income and Tobacco Consumption in OECD Countries, 1960-1986," *British Journal of Addiction*, vol. 86, pp. 1343-1354, 1991.

approximately 23 percent and 28 percent, respectively.¹⁶⁸ According to the WHO followup survey, the percentage of 15- to 16-year old boys and the percentage of 15- to 16-year old girls who were daily smokers in 1986–1987 was 16 percent and 17 percent, respectively.¹⁶⁹ This represents success not only with the group that was prohibited from purchasing cigarettes, those younger than 16, but also with a group that could legally purchase cigarettes. These results also appear to indicate that the restrictions did not simply move the onset of smoking to the first legal year of purchase.

Comments from the tobacco industry also relied upon research conducted by J. J. Boddewyn, which has found results contrary to those presented by FDA, to argue that tobacco advertising bans have not been a successful part of tobacco control policy.¹⁷⁰ Boddewyn's research is directly contrary to many of the studies cited by FDA in support of its 1995 proposed rule and is also inconsistent with the best available data on smoking rates from the countries studied.

Boddewyn has used selective data on the total number of cigarettes sold in a particular country as the basis for his analysis and has used it to justify a finding that, in those countries where advertising bans have been introduced, decreases in the total number of cigarettes sold have not followed. Relying solely on the number of cigarettes sold in a country to measure the effects of government restrictions fails to take into account the myriad of influences that can affect cigarette consumption and, thus, will not yield accurate results.

First, the overall number of cigarettes sold in a country may be influenced by factors other than the percentage of the population that smokes. For example, if the population of a country has risen, or if those who remained smokers were the heaviest smokers, the number of

cigarettes smoked may not fall even though the percentage of the population that smokes has decreased. Moreover, an analysis based on the number of cigarettes sold would not account for the success advertising restrictions might have had with those not yet addicted to tobacco. The preaddicted group, mostly composed of children, does not smoke as many cigarettes as do older addicted smokers. Therefore, any success in stemming initiation rates would not show up for many years if measured as fewer cigarettes consumed.

Finally, Boddewyn and others have claimed that the experience in Norway, Finland, and Sweden supports the view that advertising restrictions have been ineffective in reducing smoking rates. However, three reports¹⁷¹ presented at the World Conference of Tobacco and Health in Paris, France in October 1994 support the conclusion that advertising restrictions, if comprehensive and enforced, are effective in helping to reduce the percentage of people who smoke, particularly young people not yet addicted to tobacco.

Bjartveit's report presented the results of the Norwegian experience after the implementation of the 1975 Norway advertising ban. In 1975, Norway banned all advertising of tobacco products and prohibited the sale of tobacco to anyone under the age of 16. Norway also required warnings on packages, an educational program, and, in 1980, a larger excise tax. The results of Norway's actions belie Boddewyn's claims. First, the prevalence of smoking for boys and girls declined between 1975 and 1990. The percentage of daily smokers aged 13 to 15 declined from 15 percent to 9 percent for boys and from 17 percent to less than 10 percent for girls. Per-capita consumption for boys and girls also declined. Between 1975 and 1994, the overall sales of cigarettes and smoking tobacco per person among 15 year olds has declined from over 2,000 grams of tobacco to less than 1,800 grams.

In 1976, Finland banned some forms of tobacco advertising and promotion and increased expenditures for health education. While relatively little data are available on the smoking trends in Finland, one comment reported data

that showed the government's actions did have an impact, although the extent has been more uneven than in Norway. Before the advertising restrictions, cigarette consumption was increasing at the rate of 2.2 percent per year. In the decade since the 1975 Finland advertising ban, the rate of increase has been cut in half to a little over 1 percent per year—a meaningful change but not a decline. However, the greatest benefits have been for teenagers. In 1973, 26 percent of 16 to 18 year olds in secondary school smoked. By 1979, 2 years after restrictions went into place, this rate dropped to 14 percent. Since that time, the decrease has continued but has leveled off. In 1973, 19 percent of 14-year old children in Finland smoked. By 1979, 2 years after the ban, only 8 percent of 14-year old children in Finland smoked, a decrease of over 50 percent.

Moreover, a report by Rimpela¹⁷² provided a more complete explanation of the experience that Finland has had with its advertising restrictions. Although the 1978 Finnish Tobacco Act banned cigarette advertisements in youth magazines, it did not eliminate the advertising of product-families or the sponsorship of events. Consequently, the tobacco companies found new means of sales promotion through image advertising in these two venues. The author concluded that a promotional onslaught in these two forums undercut the so-called advertising ban, and the weak implementation of the legislation by health authorities caused the advertising restrictions to be less effective than they might have been with a total ban. The author contrasted these uneven results with the success of Norway's total ban.

The study presents strong evidence for the need for comprehensive advertising restrictions covering all forms of advertising and promotion in order to achieve the best results in reducing youth tobacco use. Finally, the restrictions imposed in Sweden have not been in effect long enough to measure accurately.

i. *The British Health Department Report.* Several comments from the tobacco industry criticized the findings of the British Health Department Report (Smee Report) that advertising increases consumption of tobacco products, and that restrictions on advertising decrease tobacco use beyond what would have occurred in the absence of

¹⁶⁸ Rimpela, M., L. E. Aaro, and A. H. Rimpela, "The Effects of Tobacco Sales Promotion on Initiation of Smoking," *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1–23, 1994.

¹⁶⁹ Van Reek, J., H. Adriaanse, and L. Aaro, "Smoking by Schoolchildren in Eleven European Countries," *Proceedings of the 7th World Conference on Tobacco and Health*, Duroton, B., and K. Jamrozik, vol. 301, pp. 301–302, 1991.

¹⁷⁰ Boddewyn, J. J., "Tobacco Advertising Bans and Consumption in 16 Countries," *International Advertising Association*, 1986; Boddewyn, J. J., "Why do Juveniles Start Smoking?" *Children's Research Unit of London (CRU) Study*, 1986; Boddewyn, J. J., "Cigarette Advertising Bans and Smoking: The Flawed Policy Connection," *International Journal of Advertising*, vol. 13, No. 4: pp. 311–332, 1994.

¹⁷¹ Bjartveit, K., "The Effect of an Advertising Ban—Who Has the Burden of Proof," *National Health Screening Service*, Oslo, Norway, October 1994; Lund, K., "Tobacco Advertising and How to Measure Its Effect on Smoking Behavior," *Tobacco and Health*, Slama, K., ed., Plenum Press, New York, pp. 199–204, 1995; Rimpela, M., L. E. Aaro, and A. H. Rimpela, "The Effects of Tobacco Sales Promotion on Initiation of Smoking," *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1–23, 1994.

¹⁷² Rimpela, M., L. E. Aaro, and A. H. Rimpela, "The Effects of Tobacco Sales Promotion on Initiation of Smoking," *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1–23, 1994.

regulation.¹⁷³ The Smee Report examined: (1) The relationship between cigarette advertising, (2) the effects of partial and complete advertising bans on tobacco consumption, and (3) the results of cross-national studies. The study focused on countries for which the most complete data exists—Norway, Finland, Canada, New Zealand, and the United Kingdom. One reported result of this analysis was that in all five countries, bans or restrictions on cigarette advertising resulted in an aggregate decrease in cigarette consumption.

(19) The comments argued that the WHO study contradicts the findings of this report regarding Norway, Finland, and Canada, stating that the findings do not indicate that advertising restrictions affect consumption. Several comments stated their belief that the author's (Smee's) "sweeping and unjustified" conclusions are based on "data collected over a short time period" and on a "limited and incomplete review of the available evidence". They also argued that Smee's reliance on existing studies linking advertising and consumption is misplaced. Furthermore, the comments specifically criticized the report's use of several of the reviewed studies, which, they claim, did not apply rigorous statistical analysis. Finally, the comments stated that the author's model made no allowances for the effect of externalities, such as health shocks (the Royal College of Physicians' Report on Smoking in 1962, the Report of the Surgeon General's Panel on Smoking and Lung Cancer in 1964, etc.). All the above comments maintained that the Smee Report should not be relied upon as evidence of the causal relationship between advertising restrictions and teen smoking behavior.

FDA disagrees with the comments' assessment and finds the Smee Report to be unbiased and useful as a comprehensive survey of the literature. Upon examining the specific concerns expressed by the comments in connection with specific country analyses, FDA has found that the criticisms are without merit. For example, the comments stated that the reduction in tobacco consumption found in Norway could be attributed to externalities, such as to enforcement of other provisions of the antitobacco legislation package, e.g., health

warnings, health education, and sales restrictions. However, Smee reported that the share of reduction in tobacco consumption attributable to the advertising ban "is likely to account for the great majority of the effect." Another comment expressed concern that Smee, in reporting on the Canadian experience, failed to include income as an independent variable. The comment stated that this could seriously bias the results because real income was falling in Canada at the time the advertising ban went into effect. However, in the initial Smee model, the income variable was included, and it did not explain the variation in tobacco consumption. In the final model, Smee did not include the income variable. However, removing the income variable did not significantly change the estimated coefficient and would not have biased the estimates from the model.

Finally, all econometric studies are subject to limitations. As noted in sections VI.D.4.d. and VI.D.5. of this document, it would require controlled studies to produce better results and it is neither practical nor ethical to conduct such studies. Empirical research is always subject to the criticism that some variables were omitted, or that alternative specifications would yield different results. However, Smee collected many studies, and hence his compilation includes many different specifications of tobacco demand. Thus, although it is difficult to evaluate the causes of variations in each study, an analysis of all the existing studies should yield more generalizable and robust results than those of a single study. The question here is not whether each of the studies has limitations, but to what extent those limitations impair the findings of the overall survey. Smee's study represents the best attempt to date to compile the numerous studies on the effects of advertising restrictions on tobacco use and to provide a coherent analysis. His conclusion was that restrictions on advertising did reduce tobacco use.

A comment in support of the findings of the Smee Report stated that this study was unbiased and performed by a credible organization. The comment argued that advertising restrictions produced the decline in the percentage of young people who smoke in the countries studied. In response to the tobacco industry's claim that the total number of cigarettes consumed continued to rise in several countries, the comment said that "it takes a number of years for the impact of the

fact that fewer people are starting to smoke to show up in overall tobacco consumption data."

ii. *New Zealand Toxic Substances Board Study.* Several comments gave considerable attention to the New Zealand Government Toxic Substances Board ("TSB") Study which reviewed the effect of advertising restrictions in 33 countries.¹⁷⁴ The study concluded that there was a correlation between the degree of restrictions imposed in each country and decline in tobacco use.

(20) Comments submitted by those opposing the proposed regulations argued that the study lacked objectivity because of methodological errors, particularly in the collection, sorting and selective use of data. The comments argued that these errors removed all probative value from the study. Moreover, the comments noted that FDA's use of the study illustrates its inconclusive nature. In addition, one comment asserted that the drop-offs in consumption and the number of smokers may be related to events other than legislated restrictions.

One comment argued that several studies cited by FDA in the preamble to the 1995 proposed rule, including Chetwynd and Harrison, do not support the claimed relationship between advertising expenditures and consumption because the studies have flawed data and fundamental methodological errors. For instance, the comment argued that, in the Laugesen study on tobacco consumption in 23 Organization for Economic Cooperation and Development (OECD) countries described below,¹⁷⁵ the qualitative variables used were not relevant to the regression model and biased the results. Additionally, the comment criticized the authors of the study for ignoring contradictory findings.

One comment suggested that the findings in several smaller studies cited by FDA¹⁷⁶ do not indicate that

¹⁷⁴ "Health or Tobacco—An End to Tobacco Advertising and Promotion," TSB, Wellington, New Zealand, May 1989.

¹⁷⁵ Laugesen, M., and C. Meads, "Tobacco Advertising Restrictions, Price, Income, and Tobacco Consumption in OECD Countries, 1960–1986," *British Journal of Addiction*, vol. 86, pp. 1343–1354, 1991.

¹⁷⁶ Chetwynd, J., P. Coope, R. J. Brodie, and E. Wells, "Impact of Cigarette Advertising on Aggregate Demand for Cigarettes in New Zealand," *British Journal of Addiction*, vol. 83, p. 409–414, 1988; Harrison, R., J. Chetwynd, and R. J. Brodie, "The Influence of Advertising on Tobacco Consumption: A Reply to Jackson and Ekelund," *British Journal of Addiction*, vol. 84, pp. 1251–1254, 1989; Raferty, J., "Advertising and Smoking—A Smoldering Debate?", *British Journal of Addiction*, vol. 84, pp. 1241–1246, 1989.

¹⁷³ Smee, C., "Effect of Tobacco Advertising on Tobacco Consumption—A Discussion Document Reviewing Evidence," Department of Health, Economics, and Operational Research Division, London, p. 18, 1992.

advertising affects consumption. The comment argued that one of the analyses failed to account for common trends resulting from the diffusion of information about health risks. The comment further stated that Chetwynd used a model in his study that was more likely to indicate correlation than causation. The comment also asserted that the model suffers from poor data and fails to take into account changing social mores. In addition, the comment argued that a comparable study (Boddewyn) has not shown a decrease in cigarette consumption in areas that restrict advertising.¹⁷⁷

Industry comments uniformly criticized the TSB study. This study was also criticized by the Canadian courts in the course of litigation over the validity of Canada's advertising restrictions, see section VI.D.3.f. of this document. In response, the TSB published a modification of the original study that recognized that mistakes had been made in the initial report. The reissued report was entitled "A Reply to Tobacco Industry Claims about Health or Tobacco," ISBN-0-477-04574-X (hereinafter referred to as the Reply). According to one comment from a public interest group:

The Reply re-analyzed the data of the impact of advertising in a number of countries based upon criticisms of the original report by the tobacco industry. Even after taking into account the criticisms of the tobacco industry, the New Zealand government found strong empirical evidence of the link between tobacco advertising and tobacco consumption.

In addition to the issuance of the Reply, Laugesen and Meads¹⁷⁸ retested the typology created by the TSB and applied it to 22 OECD countries for a 15-year period. In the preamble to the 1995 proposed rule, FDA referred to the Laugesen study as providing affirmation of the TSB's analysis and conclusions, that, as a group, countries prohibiting tobacco advertising in most or all media experienced more rapid percentage falls in consumption than the group of countries that permitted promotion (60 FR 41314 at 41334).

The industry comments' major criticism of the Laugesen study is that the scale developed by Laugesen is flawed. The comments criticized the amount of weight accorded to different

types of advertising restrictions (i.e., TV ban versus warning on package). However, the rating scale accurately reflects the level of restrictions in each country. The steps between the ratings in the scale may be smaller or larger than the comments believe were warranted, but the relative rankings would remain the same regardless.

Finally, several comments found fault with the smaller studies cited by FDA, including ones by Chetwynd and Harrison. Contrary to the comments' assertions, the studies do include the most relevant variables such as price, income and advertising expenditures. A major complaint of the industry regarding studies done abroad is that the advertising expenditures fail to be totally inclusive. However, the solution to that problem lies with the industry in most cases. Advertising expenditures are a closely guarded industry trade secret,¹⁷⁹ which the companies state cannot be released to the public because of their commercial sensitivity. However, the industry could release older relevant data that are no longer sensitive for the purposes of investigation and study. Moreover, researchers who have had access to industry data have not released their data sets for replication by other research groups.¹⁸⁰

The final study criticized by the industry, performed by Harrison, was written in response to earlier criticism by the industry about the Chetwynd study, and it therefore provided some answers to the comments' concerns. For example, the comments fault Chetwynd for failing to take into account changing social mores. Harrison stated that he retested Chetwynd's model and found that the model was structurally stable through time in the long term. He also found that the long run analyses indicated that the impact of cigarette advertising on consumption may be larger than was suggested in the original work.¹⁸¹

After reviewing the studies provided by the comments and reevaluating the studies relied upon in the preamble to the 1995 proposed rule, FDA reaffirms

that the statement that it made in the preamble is correct:

These studies provide insight into the effects of advertising on the general appeal of and demand for cigarettes and smokeless tobacco products. They also provide evidence confirming advertising's effect on consumption and the effectiveness of advertising restrictions on reducing youth smoking. (60 FR 41314 at 41333)

Based on the foregoing, FDA finds that the international experience provides empirical evidence that restrictions on tobacco advertising, when given appropriate scope and when fully implemented, will reduce cigarette and smokeless tobacco use among children and adolescents under the age of 18. This experience provides strong evidence that the restrictions that FDA is imposing will directly advance its interest in protecting the health of these young people.

b. *Case law considering the effect of advertising and advertising restrictions upon tobacco use by young people.* Virtually every court that has examined the issue has held that there is a direct connection between advertising and demand for the product advertised. For example, in *Central Hudson Gas and Electric*, 447 U.S. at 569, the Supreme Court stated: "[T]he State's interest in energy conservation is directly advanced by the Commission order at issue here. There is an immediate connection between advertising and demand for electricity." See also *Posadas de Puerto Rico v. Tourism Co. of Puerto Rico*, 478 U.S. at 341-342. In *United States v. Edge Broadcasting Co.*, the Supreme Court carried its position in *Central Hudson* one step further:

If there is an immediate connection between advertising and demand, and the federal regulation decreases advertising, it stands to reason that the policy of decreasing demand for gambling is correspondingly advanced. (509 U.S. 434)

Each circuit court that has considered the issue has also concluded that the regulation of advertising is reasonably aimed at reducing demand. (See, *Anheuser-Busch, Inc. v. Schmoke*, 63 F.3d 1305, 1314-15 (4th Cir 1995), *vacated and remanded* 64 U.S.L.W. 3333 (May 20, 1996); *Dunagin v. City of Oxford, Miss.*, 718 F.2d at 750 ("[W]e hold that sufficient reason exists to believe that advertising and consumption are linked to justify the ban, whether or not 'concrete scientific evidence' exists to that effect."); and *Oklahoma Telecasters Ass'n v. Crisp*, 699 F.2d 490, 501 (10th Cir. 1983), *rev'd* on other grounds sub.nom. *Capital*

¹⁷⁷ Boddewyn, J. J., "Tobacco Advertising Bans and Consumption in 16 Countries," International Advertising Association, 1986.

¹⁷⁸ Laugesen, M., and C. Meads, "Tobacco Advertising Restriction, Price, Income, and Tobacco Consumption in OECD Countries, 1960-1986," *British Journal of Addiction*, vol. 86, pp. 1343-1354, 1991.

¹⁷⁹ Even in the United States, only FTC has access to company expenditure data and it is prevented from disclosing information concerning advertising expenditures except at the industry-agglomerated level.

¹⁸⁰ Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," p. 44, 1993.

¹⁸¹ Harrison, R., J. Chetwynd, and R. J. Brodie, "The Influence of Advertising on Tobacco Consumption: A Reply to Jackson and Ekelund," *British Journal of Addiction*, vol. 84, pp. 1251-1254, 1989.

Cities Cable, Inc. v. Crisp, 467 U.S. 691 (1984)). In *Greater New Orleans Broadcasting Ass'n v. United States*, 69 F.3d 1296, 1301 (5th Cir. 1995), the court said:

They cannot seriously dispute that a prohibition of advertising of casino gambling directly advances the governmental interest in discouraging such gambling and fulfills the [second] *Central Hudson* prong. It is axiomatic that the purpose and effect of advertising is to increase consumer demand.

To counter the weight of this case law, comments that opposed FDA's advertising restrictions made two arguments. First, several comments from the tobacco and advertising industries argued that the agency cannot rely on the assumption of a link between advertising and demand that is embodied in these decisions and, citing the Court's more recent *Coors* decision, contended that the agency's evidentiary record will be held to a higher standard of proof.

However, as one comment correctly noted, the Court in *Coors* wrote:

It is assuredly a matter of 'common sense' that a restriction on the advertising of a product characteristic will decrease the extent to which consumers select a product on the basis of that trait. (115 S.Ct. at 1592) Moreover, in *44 Liquormart, Inc.*, Justice Stevens quoted with apparent approval *Central Hudson's* reliance on the "immediate connection" between "promotional advertising" and demand (116 S.Ct. at 1506, quoting *Central Hudson* 447 U.S. at 569). Thus, the Supreme Court continues to hold that there is a connection between advertising and demand, and FDA finds no merit to this contention in the contrary argument in the comments.

The second argument that these comments made is that because tobacco products constitute a "mature product" whose availability and qualities are widely known to consumers, the purpose and function of cigarette advertising is to build market share and to maintain brand loyalty, not to stimulate demand. FDA considers these comments in depth in the following section of this document.

c. *The function of advertising in the "mature" market.* Comments from the industry, advertisers, psychologists, and economists argued that although it may be true that advertising generally serves the function of increasing demand for a product category, that truism does not work for tobacco, which, they claim, is a mature market.

(21) The comments argued that because tobacco is a mature product, advertising serves to reinforce brand

loyalty and to induce current smokers to switch brands. They stated that because consumers are already aware of the tobacco category, advertising does not serve to inform potential consumers of the product and to entice them to become a user. One comment likened tobacco to other mature products such as soft drinks, deodorants, antiperspirants, and appliances. Moreover, this comment argued that "[b]ecause FDA lacks marketing expertise," it has been misled by the size of the industry's advertising expenditures and assumed, incorrectly, that this means that the industry is attempting to expand its overall market. Finally, several comments stated that there are no data that clearly prove that advertising and promotion increase demand in the tobacco market.

Other comments took the opposing view and agreed with FDA's assessment that tobacco advertisements make tobacco products more appealing to young people and affects tobacco use among young people. Several comments argued that the market for cigarettes and smokeless tobacco is not mature but is actually very dynamic. In addition to brand switching and brand loyalty, they argued that tobacco marketing generates market expansion. The comment noted that there is substantial movement at the margins with new customers entering the market, and many current customers trying to leave.

FDA agrees with those comments that expressed the view that labeling the tobacco market as a "mature market" is a simplistic denotation, which fails to recognize the movement into the market each day of new young smokers often motivated in part by advertising. Even "mature" markets must replenish their customer base as older consumers leave the market. In fact, approximately one million new young smokers enter the tobacco market each year. These new smokers are necessary to keep the mature market stable and to prevent decline. There is no evidence to suggest that these new smokers are predestined¹⁸² to enter the market. RJR acknowledged this in one marketing memo,

"[I]f we are to attract the nonsmoker or the presmoker, there is nothing in this type of product that he would currently understand or desire. * * * Instead, we somehow must convince him with wholly irrational reasons that he should try smoking."¹⁸³

¹⁸² Teague, C., *Research Planning Memorandum on Some Thought about New Brands of Cigarettes for the Youth Market*, 1973.

¹⁸³ Teague, C., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, 1972.

They must be influenced by peers, parents, and advertising, either to join the market or to decline to enter.

The agency finds that regardless of whether marketers and their advertising agencies intentionally target children and adolescents, young people are still affected by advertising. Children are not isolated from tobacco advertising's attractiveness or inducements. There is no "magic curtain around children and teenagers who seek to learn how to fit into the adult world," nor is there any evidence to support a claim that young people are immune from advertising's blandishments.¹⁸⁴

Comments asserting that tobacco advertising fails to increase consumption for the tobacco market run contrary to the views of one well-known advertising executive who stated:

I am always amused by the suggestion that advertising, a function that has been shown to increase consumption of virtually every other product, somehow miraculously fails to work for tobacco products.¹⁸⁵

Further, the view that advertising does not affect consumption is contradicted by industry experience, logic, and evidence. It does not appear credible that the industry spends more than \$6 billion annually merely to maintain brand share and to try to switch current smokers; this argument defies common sense. The economics of this argument are strained—five manufacturers control almost 100 percent of the market, and three of these have approximately 90 percent of the market.¹⁸⁶

The courts have also expressed skepticism about this argument. In *Dunagin v. City of Oxford, Miss.*, the advertiser's expert, a professor in sociology who specialized in alcoholism, testified that advertising merely affected brand loyalty and market share, rather than increasing overall consumption or consumption of individual consumers (718 F.2d at 748). The court rejected this argument:

It is beyond our ability to understand why huge sums of money would be devoted to the promotion of sales of liquor without expected

¹⁸⁴ Cohen, J. B., "Charting a Public Policy for Cigarettes," *Marketing and Advertising Regulation: The Federal Trade Commission in the 1990's*, edited by Murphy, P. E., and W. L. Wilkie, University of Notre Dame Press, Notre Dame, IN, pp. 234-254, 1990.

¹⁸⁵ Foote, E., "Advertising and Tobacco," *JAMA*, vol. 245, pp. 1667-1668, 1981.

¹⁸⁶ Weidner, D., "RJR Tobacco International Gets New Chief," *Winston-Salem Journal*, p. A1, Dec. 8, 1995. (Philip Morris, 45 percent, Reynolds 27 percent.); Antunes, S., "B & W Harassed Workers," *Evening Standard*, p. 47, Nov. 16, 1994. (After Brown & Williamson acquired American Tobacco, it had 18 percent of the market.)

results, or continue without realized results. No doubt competitors want to retain and expand their share of the market, but what businessperson stops short with competitive comparisons? It is total sales, profits, that pay the advertisers and dollars go into advertising only if they produce sales. Money talks: it talks to the young and the old about what counts in the marketplace of our society, and it talks here in support of Mississippi's concern.

(718 F.2d at 749)

The court concluded: "We simply do not believe that the liquor industry spends a billion dollars a year on advertising solely to acquire an added market share at the expense of competitors" (718 F.2d at 750). The same reasoning applies here.

(22) One comment discussed the results of a recent study that the comment said had been accepted for publication¹⁸⁷ which found that less than 10 percent of adult smokers switch brands each year, and that only 6.7 percent switch companies. The commentary suggests that this amount of "real" brand switching would not justify \$6.1 billion, an amount in annual advertising and promotional expenditures.

In addition to logic, there is empirical evidence that advertising can expand demand in a so-called mature market and in fact has done so in the cigarette market before. Smoking rates for teenage girls rose from 8.4 percent in 1968, when major promotional campaigns first targeted women, to 15.3 percent in 1974, by which time other tobacco companies had also begun marketing women's brands.¹⁸⁸ The same phenomenon was captured differently in a recent study¹⁸⁹ that tracked initiation rates for girls and women over a 40-year period. The study found that smoking initiation rates rose for girls under 18 during the period between 1967 and 1973 (women's targeting period), even though initiation rates did not rise for women 18 and older. Finally, as detailed more fully in the preamble to the 1995 proposed rule (60 FR 41314 at 41345), another study looked at the effect of variations in advertising expenditures for low tar

cigarettes. Although the advertising did not increase the advertiser's brand share, increased advertising for low tar cigarettes caused the entire market for cigarettes to increase.¹⁹⁰

The ability of advertising to expand total demand for a particular class of products through market segmentation has also been demonstrated in other markets when the breakfast cereal industry first began making health claims for their products, such as those regarding the cancer-prevention benefits of dietary fiber. The creation of a new segment of the cereal market—healthy cereal—through the use of advertising resulted in an increase in the overall adult cereal market. Advertising caused an increase in aggregate demand by giving consumers a "new" product that met their needs, wants, and desires.¹⁹¹

Thus, advertising can serve an important role in meeting and expanding desires in the marketplace. It identifies consumers' needs and desires and then matches them with the attributes of particular product categories and brands. Advertising can perform this function through its use of explicit claims or through imagery, code words, or psychosocial cues. And, in doing so, it can both shift demand across the entire product category and create new demand.

Moreover, the industry's mature market categorization assumes that the product category has no outside competitors, i.e., that there is no other product line that competes for the consumers' attentions and dollars. For example, soft drinks are a mature market, but more healthful drinks, such as milk, juices, or even water, can attempt to draw off part of the market. In addition, soft drinks can try to expand their own market share as Coca Cola and later Pepsi did a number of years ago¹⁹² when they promoted cola for breakfast.

Similarly, tobacco has competitors. New users or "presmokers," as one RJR employee refers to them,¹⁹³ are faced not only with tobacco imagery but also with antismoking health messages in commercial media and in schools.

Current smokers are faced with alternatives to smoking, including over-the-counter and prescription drug advertising for nicotine replacement products and stop-smoking cures. The tobacco market thus has to convince the presmoker or new smoker to switch from the nonuse category promoted by health professionals, public service announcements, and school messages, to tobacco use. Also, it must constantly convince the addicted smoker not to leave the market by use of a competing nicotine-delivery product, a nicotine replacement source, or by other voluntary means.

Finally, even the industry acknowledges that young people are a strategically important audience because brand loyalty often develops during this period of trying cigarettes and becoming a smoker. In 1973, RJR's research and development officer wrote "Realistically, if our Company is to survive and prosper over the long term, we must get our share of the youth market."¹⁹⁴ And, as noted in the preamble of the 1995 proposed rule, these words reflect those uttered by the Canadian sister company of the American tobacco company, Brown and Williamson Tobacco Corp.

If the last ten years have taught us anything, it is that the industry is dominated by the companies who respond most effectively to the needs of younger smokers.¹⁹⁵

FDA finds that there is no merit to the industry's claim that because the tobacco market is a mature market, advertising does not stimulate demand but only reallocates the existing market between companies. Not only is the industry's argument overly simplistic, but, as shown, advertising plays an important role in creating new customers, including young people. FDA shares the incredulity expressed by the court in *Dunagin*, 718 F.2d at 750, regarding this argument: "It is beyond our ability to understand" why an industry would spend billions a year merely to acquire market share at the expense of its competitors, when it has a much harder job of convincing young people to start a habit that is neither easy to acquire nor pleasant. Consequently, FDA finds that the second prong of *Central Hudson* is satisfied, i.e., the advertising restrictions directly and materially advance the substantial state interest.

¹⁸⁷ Siegel, M., et al., "The Extent of Cigarette Brand and Company Switching: Results from the Adult Use-of-Tobacco Survey," *American Journal of Preventive Medicine*, vol. 12, No. 1, pp. 14-16, 1996.

¹⁸⁸ Botvin, G. J., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, "Smoking Behavior of Adolescents Exposed to Cigarette Advertising," *Public Health Reports*, vol. 108, pp. 217, 222, 1993.

¹⁸⁹ Pierce J. P., L. Lee, and E. A. Gilpin, "Smoking Initiation by Adolescent Girls, 1944 through 1988," *Journal of the American Medical Association*, vol. 271, No. 8, pp. 608-611, 1994.

¹⁹⁰ Roberts, M. J., and L. Samuelson, "An Empirical Analysis of Dynamic, Nonprice Oligopolistic Industry," *Rand Journal of Economics*, vol. 19, pp. 200-220, 1988.

¹⁹¹ Ippolito, P., and A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, p. 32, 1989.

¹⁹² Dourado, P., "Breakfast Cola Takes on America's Coffee Giants," *The Independent*, p. 28, April 15, 1990.

¹⁹³ Teague, C., *Research Planning Memorandum on Some Thoughts about New Brands of Cigarettes for the Youth Market*, p. 1, 1973.

¹⁹⁴ *Id.*

¹⁹⁵ Overall Marketing Objectives-F88, 1988 Imperial Tobacco Ltd. Marketing Plan, p. 6; 60 FR 41314 at 41331.

E. Provisions of the Final Rule

FDA selected each of the restrictions that it included in the 1995 proposed rule based on its tentative view that the particular restriction is necessary to providing a comprehensive response to the appeal of tobacco advertising to young people. Each proposed restriction was intended to address an aspect of this advertising that contributes to its appeal. The agency tentatively concluded that, together, these restrictions will ensure that advertising is not used to undermine the access restrictions that FDA proposed and thus will help to protect the health of children and adolescents under the age of 18.

In this section of the document, FDA will respond to comments on each element of this comprehensive approach, including comments on whether the regulations are legally supportable. A key question about the agency's approach is whether there is a reasonable fit between the agency's interest and the means that it has chosen to accomplish it; that is, between the agency's interest and the specific restrictions that it proposed. This inquiry involves consideration of the restrictions under the third and final prong of *Central Hudson*.

FDA will first consider comments that raised general concerns about its approach under the third prong of *Central Hudson*. It will then consider comments that raised concerns about specific restrictions under this aspect of *Central Hudson* as part of its discussion of the comments on each restriction.

1. Are FDA's Regulations Narrowly Drawn?

In the preamble to the 1995 proposed rule, FDA stated that the regulations that it was proposing met the final prong of the *Central Hudson* test (60 FR 41314 at 41355). In *Central Hudson*, the Supreme Court stated that the First Amendment mandates that speech restrictions be "narrowly drawn." The Court continued:

The regulatory technique may extend only as far as the interest it serves. The State cannot regulate speech that poses no danger to the asserted State interest, * * * nor can it completely suppress information when narrower restrictions on expression would serve its interest as well.

(447 U.S. at 565, n.7) FDA pointed out, however, that: "The Supreme Court has made it clear that this prong does not require a 'least restrictive means test,' but rather that there be a 'reasonable fit' between the government's regulation and the substantial governmental

interest sought to be served" (*Board of Trustees of State University of New York v. Fox*, 492 U.S. 469, 480 (1989); (60 FR 41314 at 41355)).

(23) This statement by FDA provoked a significant amount of comment. Several comments said that FDA had mischaracterized its burden. These comments argued that *Fox* did not dilute the *Central Hudson* analysis, and that any restriction on commercial speech must be narrowly tailored. One comment pointed out that, in *Rubin v. Coors*, the Supreme Court made no mention of reasonable fit. The comment stated that in *Rubin v. Coors*, the Supreme Court said that *Central Hudson* requires that a valid restriction be no more extensive than necessary to serve the governmental interest (115 S.Ct. at 1591). Finally, one comment said that FDA was arguing that courts have applied a rational basis standard to restrictions on commercial speech, but the comment stated that FDA was wrong because courts have rejected this notion.

In response to these comments, FDA has carefully evaluated the relevant case law. The agency does not agree that it mischaracterized its burden in the 1995 proposed rule.

It is true that in *Rubin v. Coors* the Supreme Court found that the challenged statutory provision violated the First Amendment's protection of commercial speech, at least in part, because it was more extensive than necessary (115 S.Ct. at 1594). However, the Court also stated that its inquiry under the last two steps of *Central Hudson* involves "a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends" (*Id.* at 1391 (quoting *Posadas De Puerto Rico Associates v. Tourism Co. of Puerto Rico*, 478 U.S. at 341); (See also *44 Liquormart, Inc. v. Rhode Island*, 116 S.Ct. at 1510 ("As a result, even under the less than strict standard that generally applies in commercial speech cases, the state has failed to establish a reasonable fit between its abridgment of speech and its temperance goal."))).

Moreover, the Court's statement in *Rubin v. Coors* that a restriction on commercial speech must be no broader than necessary, which was cited by a comment, must be read in light of the Court's discussion of this requirement in *Board of Trustees of State University of New York v. Fox*, 492 U.S. at 476-481. In *Fox*, the Supreme Court concluded from its consideration of how this phrase has been used in its case law and in the related case law on time, place, and manner restrictions, that what is required, exactly as the agency

said in the 1995 proposed rule, is a fit between the Government's ends and the means chosen to accomplish those ends that is not necessarily perfect but reasonable (492 U.S. at 480). The Supreme Court reiterated this point in *Florida Bar v. Went For It, Inc.*, 115 S.Ct. at 2380 (citations omitted):

With respect to this prong, the differences between commercial speech and noncommercial speech are manifest. In *Fox*, we made clear that the "least restrictive means" test has no role in the commercial speech context * * * "What our decisions require," instead, "is a 'fit' between the legislature's ends and the means chosen to accomplish those ends," a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interest served' that employs not necessarily the least restrictive means but * * * a means narrowly tailored to achieve the desired objective.

Thus, FDA did not mischaracterize its burden in the 1995 proposed rule. Moreover, in any event, FDA has narrowly tailored its provisions.

Before turning to the question of whether there is a reasonable fit between FDA's interest in the health of children and the restrictions that FDA proposed on tobacco advertising, the agency wishes to make clear that, contrary to the claim of one comment, it recognizes that courts have not equated the reasonable fit test with rational basis review. (See, e.g., *Florida Bar v. Went For It, Inc.*) FDA recognizes that the reasonable fit test requires that the Government goal be substantial, and that the cost of achieving that goal be carefully calculated. (See *Board of Trustees of State University of New York v. Fox*, 492 U.S. at 480.) It also recognizes that this test requires that the agency consider whether there are less burdensome alternatives to restrictions on speech.

Having already established that its goal is substantial (see section VI.C.4. of this document), FDA will consider the issues of the costs of the restrictions and alternatives to these restrictions in its analysis of the comments that follows.

(24) Several comments argued that the restrictions on cigarette and smokeless tobacco advertising that FDA proposed are not narrowly tailored. One comment said that the premise of the narrow tailoring requirement is that commercial speech is valuable, and that it may only be restricted when it is necessary to do so. Other comments argued that restrictions on speech must attack only problem speech, and that FDA had failed to prove that this is what the proposed restrictions did. These

comments stated that FDA's proposed restrictions are more extensive than necessary to achieve the agency's asserted interest, particularly because the agency had failed to show that the advertising restrictions will have any effect on underage smoking. Some comments argued that the restrictions that FDA proposed were tantamount to a ban because they will prevent the advertiser's message from reaching consumers.

Other comments disagreed. These comments said that FDA's proposed action is narrowly tailored. They argued that FDA had steered clear of imposing a categorical ban on tobacco advertising, or even broad prophylactic rules. One comment said that tailored prohibitions, instead of all-out bans, are important signposts indicating a measured response.

FDA disagrees with the comments that claimed that the restrictions were not narrowly tailored. The agency recognizes, as the Supreme Court said in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985), that it has the burden of distinguishing the harmless from the harmful. FDA has met this burden.

The restrictions that FDA is adopting are not like those in *Central Hudson*, which, even though the Public Service Commission's interest was limited to energy conservation, reached all promotional advertising, regardless of the impact of the touted service on energy use. (See 447 U.S. at 570.) Rather, FDA's restrictions are carefully crafted to focus on those media and aspects of advertising that children are routinely exposed to and that the available evidence shows has the greatest effect on youngsters, while leaving the informational aspects of advertising largely untouched. FDA is not banning outdoor advertising; it is restricting it so that it does not unavoidably confront children when they play. It is not banning print advertising. It is restricting the use of images and color, which are particularly appealing to children, in publications that have a large number of young readers under the age of 18 and in other forms of advertising to which children are routinely exposed but permitting unrestricted advertising in adult publications and adult venues. It is restricting cigarette and smokeless tobacco companies' use of brand names and product identifications in sponsored events, but again in a way that reflects the agency's concern about children and adolescents under the age of 18. That is, it is permitting companies

to sponsor in the corporate name in order to engender good will, but preventing them from using the brand specific attractive imagery that is influential with young people. Finally, it is prohibiting the use of branded promotional items because it is the young who find particular value in these items. In each of these respects, the agency has gone no further than it has found, based on the evidence, is necessary to meet its ends. (See *Dunagin v. City of Oxford, Miss.*, 718 F.2d at 751.)

Under the restrictions that FDA is adopting, firms will remain free to disseminate advertising that performs all the informational functions that are protected by the First Amendment. They will be able to disseminate information on what they are selling, for what reason, and at what price. (See *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 765 (1976); *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977).) Thus, the situation here is analogous to that in *Friedman v. Rogers*, 440 U.S. 1 (1979), where the Supreme Court found that a restriction on the use of optometrical trade names had only an incidental effect on the content of commercial speech. The Court said that "the factual information associated with trade names may be communicated freely and explicitly to the public" (440 U.S. at 16). So, here, any information that firms wish to communicate to adults may still be communicated by use of words. Indeed, the tobacco industry has used text-only advertising successfully in the past.¹⁹⁶

It may be true, as some of the comments state and as the agency recognized above, that it will be more difficult for adult consumers to find cigarette and smokeless tobacco advertising without images and color, but willingness to search for information is one of the things that adults will do when they need information about price, quality, or product performance. Moreover, as discussed above, adult tobacco users are particularly interested in information on price, "safer" cigarettes, and new products, information that can be freely conveyed under FDA's regulations.

(25) The effect of the proposed restrictions on cigarette and smokeless tobacco product manufacturers' ability to communicate with adults was the subject of a number of comments. These comments argued that the proposed

restrictions would not only preclude speech that may be perceived by young people, it would preclude speech that would be received by adults. The restrictions, these comments asserted, would deprive adults, who are legally entitled to smoke, of their right to the free flow of relevant commercial information. Other comments, relying on several cases, said that the First Amendment does not countenance wholesale censorship of speech for adults under the guise of protecting children. Many comments, for example, quoted a statement from *Butler v. State of Michigan*, 352 U.S. 380, 383 (1957) ("Surely, this is to burn the house to roast the pig.") in support of this point. One comment said that FDA's purpose of reducing tobacco use by minors cannot support massive censorship between tobacco advertisers and adults.

One comment, however, argued that FDA's proposed restrictions are narrowly tailored to the specific types of advertising that are most effective with children. This comment said that these restrictions permit companies to continue marketing practices that do not appeal to children.

FDA has considered the concerns expressed in the comments. First, FDA does not agree that its interest is limited. As discussed above, the agency's interest is compelling. Nonetheless, the agency has tried very hard to tailor the restrictions on advertising in this final rule to focus them in order to limit the appeal of advertising to the young and ensure that the restrictions on access to cigarettes and smokeless tobacco will not be undermined, while at the same time, minimizing their effect on adults. Given this approach, FDA's restrictions differ significantly from those struck down in *Butler v. State of Michigan*, where the Court overturned conviction of a bookseller for selling a book to adults that contained some portions that might be objectionable to young people. In that case, the Supreme Court stated:

We have before us legislation not reasonably restricted to the evil with which it is said to deal. The incidence of this enactment is to reduce the adult population of Michigan to only what is fit for children. (352 U.S. at 383)

This statement clearly does not describe the situation under the restrictions FDA is adopting. Except for limits on images and colors, the restrictions that FDA is adopting do not limit what cigarette and smokeless tobacco manufacturers, distributors, or retailers may say. As stated above, they are free to put into words any nondeceptive message that they would have communicated by color or image.

¹⁹⁶ As discussed more fully elsewhere, advertising for low-tar products is generally more reliant on text than on imagery.

FDA's restrictions, as one comment stated, restrict only those advertising techniques that have the most appeal. Thus, contrary to the situation in *Butler v. Michigan*, these restrictions are reasonably restricted to the harms they are intended to address.

Nor are the restrictions that FDA is imposing like the one struck down in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), which was cited by several comments. In that case, a Federal statute prohibited the mailing of unsolicited advertisements for contraceptives. The Postal Service sought to justify this restriction as aiding parents' efforts to discuss birth control with their children. While the Court found this interest to be substantial, it found the restriction to be more extensive than the Constitution permits (463 U.S. at 73). The Supreme Court struck down the restrictions, stating: "The level of discourse reaching the mailbox simply cannot be limited to that which would be suitable for a sandbox" (*Id.* at 74). It is in this respect that FDA's restrictions differ from those in *Bolger*. While FDA may limit the type of color or imagery, or the use of noncommunicative media, i.e., hats, FDA's restrictions do not limit the types of information that can be disseminated, except within 1,000 feet of schools and playgrounds.

(26) Other comments cited *Sable Communications v. FCC*, 492 U.S. 115 (1989), in which the Supreme Court struck down an outright ban on indecent as well as obscene interstate commercial telephone messages. This case is not relevant here because FDA is not imposing an outright ban on cigarette and smokeless tobacco advertising,¹⁹⁷ and because in contrast to Congress's failure to make findings that would justify the ban in *Sable*, FDA is fully explaining the basis for each of the restrictions that it is adopting here.

Other comments cited *Erznoznik v. City of Jacksonville*, 422 U.S. 205 (1975), in which the Supreme Court struck down an ordinance that, to protect minors, made it illegal to exhibit a motion picture visible from public streets in which female buttocks and bare breasts were shown. In doing so,

the Supreme Court stated that: "Speech * * * cannot be suppressed solely to protect the young from ideas or images that a legislative body thinks unsuitable for them" (422 U.S. at 213).

Again, however, FDA is imposing restrictions on the manner and, to a limited extent, places in which cigarettes and smokeless tobacco are advertised, not content restrictions. Moreover, FDA is restricting commercial speech, which, as stated in section VI.C.1. of this document, is subject to a subordinate position in the scale of First Amendment values to the noncommercial expressions involved in *Erznoznik*. Thus, this case has no application here.

(27) Finally, a few comments cited *Project 80's, Inc. v. City of Pocatello*, 942 F.2d 635 (9th Cir. 1991), a case in which the U.S. Court of Appeals for the Ninth Circuit struck down ordinances that prohibited door-to-door solicitation because they restricted both wanted and unwanted solicitations. (See 942 F.2d at 638-639.) The municipalities sought to defend these ordinances on the grounds that they did not prohibit in-home sales. However, the court said that residents who wanted to receive unwanted solicitors had to post a "Solicitors Welcome" sign, and that the Government's imposition of affirmative obligations on the residents' First Amendment rights to receive speech is not permissible (*Id.* at 639).

Presumably, the comments cited this case as evidence that FDA's restrictions on tobacco advertising sweep too broadly because they affect the rights of both minors and adults to receive speech. Again, however, the case is distinguishable. Under FDA's restrictions, adults will be able to continue to receive tobacco advertising without any obligation to take any affirmative steps. They will have to look a little harder because, to advance FDA's interest in protecting the health of minors, advertisements will generally not have images or color, and such advertising will not be around schools or playgrounds. However, the advertising should otherwise continue to be available in newspapers, magazines, and billboards and appear unrestricted in adult publications and venues. There is no indication in *Project '80, Inc. v. City of Pocatello*, that the Ninth Circuit would find in such restrictions an undue burden under the First Amendment.

This review of the case law shows that FDA's effort to tailor the restrictions that it is adopting for cigarette and smokeless tobacco advertising that

clearly distinguishes them from the governmental efforts to protect minors that have been struck down as sweeping too broadly and as impinging on the rights of adults. Under FDA's restrictions, there will still be a free flow of information to adults and not massive censorship as some comments allege. Thus, these comments do not provide a basis to conclude that FDA's restrictions fail the third prong of the *Central Hudson* test.

(28) Several comments pointed out that the Supreme Court has stated on several occasions that regulations that disregard numerous and obvious less restrictive and more precise means of achieving the government's asserted objectives are not narrowly tailored. These comments suggested that there are several less restrictive alternatives to the restrictions on advertising that FDA had proposed. One alternative pointed to by the comments was better enforcement of laws prohibiting sales to minors. The comments pointed out that Congress passed legislation as part of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, that prohibits DHHS from providing block grants for the prevention and treatment of substance abuse unless the State prohibits the sale and distribution of tobacco products to persons under 18. The comments said that FDA should give this new law a chance to work before imposing restrictions on speech, particularly in light of the fact that DHHS itself said in its 1995 proposed rule to implement this new law that "[e]liminating virtually all sales [of tobacco products] to minors does not even present particularly difficult enforcement problems" (see 58 FR 45156 at 45165, August 26, 1993).

The other alternative, according to the comments, that exists to the restrictions is an educational campaign that is sponsored either by the Government or that is provided through voluntary counter speech by the tobacco industry.

The agency recognizes that the various opinions by the Justices in 44 *Liquormart* reiterate the need to consider nonspeech restrictions. Justice Stevens, speaking for himself and Justices Kennedy, Ginsburg, and Souter stated that the legislature "cannot satisfy the requirement that its restriction on speech be no more extensive than necessary," given that alternative forms of regulation, such as taxation or limits on purchases that did not involve restrictions on speech, could achieve the goal of promoting temperance as well as, or better, than,

¹⁹⁷ The Court specifically distinguished *FCC v. Pacifica Foundation*, 438 U.S. 726 (1978), because that case did not involve a total ban on broadcasting indecent material. The Court pointed out that the FCC rule in that case sought to channel the indecent material to times of the day when children most likely would not be exposed to it (*Sable Communications v. FCC*, 492 U.S. at 127). FDA's intention here is to impose a similar type of focused and tailored restriction on tobacco advertising to limit the appeal of such advertising to children.

its ban. Moreover, Justice O'Connor in a concurrence, joined by the Chief Justice, and Justices Souter and Breyer stated:

The availability of less burdensome alternatives to reach the stated goal signals that the fit between the legislature's ends and the means chosen to accomplish those ends may be too imprecise to withstand First Amendment scrutiny. (116 S.Ct. at 1521)

(29) One comment, however, argued that, for two reasons, there is no plausible claim that FDA has disregarded reasonable alternatives. First, the comment pointed out that the Federal Government has engaged in an incremental effort for 30 years to strike the appropriate balance in regulating the sale of tobacco products. This effort was successful in bringing down overall smoking rates, but youth smoking rates remained stable during the 1980's and have recently begun to rise. Because previous measures have failed, the comment said, it was now appropriate for FDA to take stricter action to reduce the use of tobacco products by minors. Second, the comment noted that a lack of narrow tailoring often manifests itself in a restraint that is either grossly underinclusive or overinclusive. The comment said that FDA had been neither here.

In *Florida Bar v. Went For It, Inc.*, 115 S.Ct. at 2380, the Supreme Court made clear that the question whether a restriction on commercial speech is reasonably well-tailored turns, at least in part, on the existence of "numerous and obvious less burdensome alternatives to restrictions on commercial speech * * *." (See 115 S.Ct. at 2380 (citing *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 418 n.13 (1993)).) FDA has considered the alternatives suggested by the comments and finds that none of them is an appropriate alternative to the restrictions that FDA is adopting.

First, the Government has engaged in a 30-year effort to eliminate young people's access to and use of tobacco products. The industry, through its voluntary code and various education programs, has professed to be part of the solution. However, tobacco can be easily obtained by young people (between 516 million and 947 million packs of cigarettes sold illegally per year to children (1992–1993) (60 FR 41314 at 41315)). Moreover, although adult smoking rates have declined dramatically since the publication of the first Surgeon General's Report in 1964 (from over 42.4 percent in 1965 to 25 percent in 1993) (60 FR 41314 at 41317), young people's smoking rates failed to decline during the decade of the 1980's

and began to rise in 1991. Between 1991 and 1995, the proportion of 8th and 10th graders who reported smoking in the 30 days before the survey had risen by one-third, to about 19 percent and 28 percent, respectively. Smoking among high school seniors had increased by more than one-fifth since 1992, with 33.5 percent saying that they had smoked in the 30 days before the survey.¹⁹⁸ Thus, past efforts involving age restrictions and warning messages on packages and advertising have not been sufficient to reduce the demand for tobacco by young people. The restrictions on advertising are designed to affect the demand.

Second, the agency proposed a sufficiently comprehensive set of regulatory restrictions to address the problem of tobacco use by young people, to wit: (1) Provisions that restrict and prevent sales of tobacco products to young people; (2) provisions that reduce the appeal of tobacco products for young people that is created by advertising and promotions; and (3) a program to provide educational messages for young people to help them resist tobacco use. Thus, the agency has not relied solely on regulations that have an impact upon the speech of the tobacco industry but has included provisions to address the activity itself.

Third, while it is true that better enforcement of laws restricting sales to minors is complementary to FDA's approach, it does not eliminate the need for this action. As DHHS recognized in its final rule implementing the ADAMHA Reorganization Act of 1992, DHHS's action under that statute and FDA's regulations both address the need to reduce minors' access to tobacco products. FDA's action, however, in addition to reducing access, attempting, through the restrictions on advertising, to reduce "the powerful appeal of tobacco products to children and adolescents" (61 FR 1492, January 19, 1996).¹⁹⁹

¹⁹⁸ "Teen Smoking, Marijuana Use Increase Sharply, Study Shows; HHS Sees Alarming 'Culturewide' Change in Progress," *The Washington Times*, p. A2, December 16, 1995; quoting from "Results from the 1995 Monitoring the Future Survey," National Institute on Drug Abuse Briefing for Donna E. Shalala, Ph.D., Secretary of Health and Human Services, December 13, 1995.

¹⁹⁹ It is true that in its August 25, 1993, proposal (58 FR 45156), DHHS stated, as the comments say, that eliminating virtually all sales to minors does not present particularly difficult enforcement problems. This statement did not imply, however, that achieving this goal would be easy, nor did it reflect consideration of what ancillary measures would be useful to help to achieve this goal. It was,

Advertising, as explained in sections VI.B. and VI.D. of this document, plays a role in the decision of children and adolescents to use cigarettes and smokeless tobacco. As long as advertising continues to play that role, young people will be motivated to obtain access to tobacco products and to attempt to circumvent any access restrictions. Thus, the restrictions on speech are necessary to prevent advertising from undermining FDA's proposed restrictions on access. First, the agency notes that the voluntary educational campaigns conducted by tobacco companies have not been effective in reducing underage tobacco use. This fact is evidenced by the increase in prevalence of tobacco use among young people. (See, e.g., 60 FR 41314 at 41315.) Second, the agency finds that any educational campaign is likely to be undermined if the young people to whom it is aimed continue to be the target of advertising that fosters the perception that experimentation with tobacco by young people is expected and accepted.

The U.S. Court of Appeals for the Fifth Circuit considered a suggestion similar to that of an educational campaign in *Dunagin v. City of Oxford, Miss.* and found it not to be an alternative to restrictions on advertising:

We do not believe that a less restrictive time, place, and manner restriction, such as a disclaimer warning of the dangers of alcohol, would be effective. The state's concern is not that the public is unaware of the dangers of alcohol * * * The concern instead is that advertising will unduly promote alcohol consumption despite known dangers. (See 718 F.2d at 751; see also *Posadas de Puerto Rico Ass'n v. Tourism Co. of Puerto Rico*, 478 U.S. at 344.) This is exactly FDA's concern about the effect of advertising on underage tobacco use, and why an educational campaign, which may complement advertising restrictions, is not an alternative to them.

Thus, the agency concludes that there are no less burdensome alternatives to restrictions on advertising. In this respect, this proceeding is distinguishable from that considered in *Rubin v. Coors*, which was cited by a number of the comments. In *Rubin v. Coors*, the Supreme Court pointed to the fact that the respondent cited several options that could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights than the

rather, a statement of DHHS' view that this goal could be achieved.

statutory provision the Government had adopted (115 S.Ct. at 1593).²⁰⁰ Here, as in section VI.E. of this document, there are none believed to be nearly as effective.

In *U.S. v. Edge Broadcasting Co.*, 509 U.S. 418, 430 (1993), the Supreme Court said that “the requirement of narrow tailoring is met if ‘the * * * regulation promotes a substantial Government interest that would be achieved less effectively absent the regulation,’ provided that it did not burden substantially more speech than necessary to further the government’s legitimate interests.”

FDA’s restrictions on cigarette and smokeless tobacco advertising clearly meet this test. FDA’s restrictions directly and materially advance its compelling interest in the health of children and adolescents under the age of 18. The discussion of the lack of less restrictive alternatives demonstrates that the agency’s goals would be achieved less effectively in the absence of these restrictions. Finally, as the discussion on narrow tailoring and in the review of the comments on each of the regulations on advertising that follows makes clear, FDA is restricting only those aspects of advertising that have particular appeal to the young. Thus, the agency has crafted the advertising provisions with specificity to allow unrestricted advertising in those venues that are not seen by or used by children and adolescents. Accordingly, publications with adult readership and adult establishments may have unlimited print advertising. Moreover, companies are free to offer nontobacco items and events in their corporate names or unbranded. Companies, thus, can reward adult usage by providing these incentives but may not do so in a format (with brand identification and imagery) which is appealing to young people.

However, the agency has been unable to determine additional areas for unrestricted advertising. Thus, other than adult establishments, such as bars, there are no areas at other retail establishments that are not visible to young people. Billboards are ubiquitous and accessible to all ages. Nontobacco items can be restricted to dissemination to adults, but they would still serve as walking billboards. Finally, there are no adult only sponsored events—children are at the events or watching them on

television. As described more fully in section VI.E.8. of this document, in the case of auto racing, attendance by young people is on the rise.

2. Section 897.30(a)—Permissible Forms of Labeling and Advertising

Proposed § 897.30(a) would have established the scope of permissible forms of labeling and advertising for cigarettes and smokeless tobacco. Proposed § 897.30(a)(1) would have defined permissible forms of advertising as newspapers, magazines, periodicals, or other publications (whether periodic or limited distribution); billboards, posters, placards; and nonpoint of sale promotional material (including direct mail). Proposed § 897.30(a)(2) would have defined permissible forms of labeling as point of sale promotional material; audio and/or video formats delivered at a point of sale; and entries and teams in sponsored events.

In response to the comments, FDA has revised § 897.30(a) so that it no longer distinguishes between advertising and labeling, deletes teams and entries as permissible advertising, describes the procedure that FDA will follow when it is informed by advertisers of their intent to advertise in a medium not listed in the regulation.

In addition, the first sentence of § 897.30(a), which states that this subpart does not apply to cigarette or smokeless tobacco product package labels, has been redesignated as § 897.30(c).

(30) Several comments were received addressing the issue of permissible advertising outlets. Comments from the tobacco and advertising industries opposed the 1995 proposed rule. These comments criticized the 1995 proposed rule for not defining the term “advertising” and called the 1995 proposed rule unprecedented in the scope of its limitations on the forms of media, a violation of the First Amendment, a violation of the Administrative Procedure Act (APA), and beyond FDA’s statutory authority. Supporters of the 1995 proposed rule, including health and public interest groups, stated that it is a reasonable measure given the effect of advertising on children and that it provides manufacturers with a wide variety of means for communicating with their customers. Some supporting comments urged that the prohibition of certain media, such as the Internet, be stated explicitly.

Several comments from the tobacco industry expressed concern that FDA did not define the term “advertising”

“because § 897.30(a)(1) would limit the media in which cigarettes may be ‘advertised,’ the definition of ‘advertising’ as used by FDA is crucial; yet the term is not defined in the proposed regulations.”

Moreover, they expressed concern that the definition was so sweeping that it could literally “include reports to shareholders or potential shareholders; communications among manufacturers, wholesalers, distributors, and retailers; or even communications to the news media insofar as they might be deemed a ‘commercial use.’”

Other comments requested that the agency clarify the definition to ban product placements in movies and commercials shown in movie theaters. Several comments stated that § 897.30 should be extended to include tobacco product packages to reduce the means of a child expressing affinity with the image associated with a particular brand. One comment recommended tombstone packaging without an identifiable logo.

The agency carefully considered whether it should attempt to define the term “advertising” more explicitly than it did. “Advertising” as a term is constantly evolving, as new media and new techniques of marketing emerge. Although its boundaries are understood (and were provided in the preamble to the 1995 proposed rule), there is no one accepted definition. FTC is the Federal agency with general responsibility for regulating most consumer advertising. Yet neither FTC nor any of its rules define the general term “advertising.” The agency agrees with the approach taken by FTC and continues to believe that the term “advertising” should not be defined any more specifically. Thus, FDA finds that the description of advertising in the preamble to the 1995 proposed rule is appropriate:

Labeling and advertising are used throughout this subpart to include all commercial uses of the brand name of a product (alone or in conjunction with other words), logo, symbol, motto, selling message, or any other indicia of product identification similar or identical to that used for any brand of cigarette or smokeless tobacco product. However, labeling and advertising would exclude package labels, which would be covered under proposed subpart C. (60 FR 41314 at 41334)

The agency also agrees with comments that state that it must provide some context for the application of so open ended a definition. For example, comments contended that “commercial use” could be interpreted to include such items as trade advertising (communication between

²⁰⁰ One alternative that the respondents in *Rubin v. Coors* advanced was prohibiting marketing efforts emphasizing high alcohol strength (115 S.Ct. at 1593.) What FDA is doing here is analogous to that alternative. It is restricting marketing efforts that have particular appeal to the young.

manufacturers, wholesalers, distributors, and retailers), shareholder reports, and possibly even communications with the news media. This was not FDA's intent. This rule is a consumer based regulation; it is not the intention of FDA to include purely business related communications. Thus, noncommercial uses would not be affected. These would include such uses as unpaid press statements, signs on factories noting locations, business cards, and stockholder reports. While many of these uses would be ordinary and necessary business expenses, they would not be commercial uses in the context of the rule's restrictions on tobacco advertising affecting minors' tobacco use.

Furthermore, the preamble to the 1995 proposed rule explained that the agency intends to permit advertising with imagery and color in publications that are read primarily by adults. For that reason, under § 897.32(a), advertisements in publications (whether periodic or limited distribution) with primarily adult readership are not restricted to a text-only format. Trade advertising in trade press publications and trade show publications, trade catalogs, price sheets, and other publications for wholesalers, distributors, and retailers that will not be seen by consumers, including minors, are unaffected by the rule.

Also, the agency does not believe that the term "advertising" needs to be defined to clarify what is *not* a permissible advertising outlet. The 1995 proposed rule clearly specifies what advertising outlets are included within the regulation's coverage. However, the agency has been persuaded to make more clear its procedures for new or uncovered media. These procedures are described in this section.

The agency does not agree with comments that the rule needs to be clarified regarding infomercials or advertorials (program length commercials). Television infomercials are not allowed under the statutory broadcast ban, and magazine advertorials would be treated like any other magazine advertising. The agency recognizes that commercial advertising messages (videos) shown in a movie theater are not addressed by the 1995 proposed rule. If this becomes a desired medium, the companies would need to notify FDA 30 days prior to using a new medium. Finally, product placements in movies, music videos, and television, if not placed at the expense of a tobacco manufacturer, distributor, or retailer, would not be affected by this rule. The

agency does not intend to regulate a film producer's artistic expression—i.e., what the producer chooses to display in movies.

The agency has decided not to include restrictions on tobacco product packaging. The agency has attempted to narrowly tailor this rule and therefore has not included packaging restrictions at this time.

(31) Several comments from the advertising industry expressed concern that the wording of § 897.30(a)(1) would ban all advertising for tobacco products that is not expressly permitted. If so, the comment states, the rule would be arbitrary and capricious because the agency did not present evidence that these unnamed advertising techniques influence young people. Another comment pointed out that the channels available to tobacco companies for communicating with adults already have been severely restricted by Congress' ban on television and radio advertising.

In contrast, comments from organizations of health professionals and a public interest group supported the scope of permissible advertising. One specific comment stated that, "The media listed in § 897.30 provide manufacturers with a wide variety of means for communicating with their customers."

The agency has determined that the scope of the permissible outlets for tobacco advertising in the 1995 proposed rule is reasonable. The permissible forms are the known current forums for tobacco labeling and advertising and account for the vast majority of advertising expenditures. While the format of much of current tobacco advertising is being restricted to a text-only format, almost all of the current media outlets being used for tobacco advertising will still be permissible. Legal users will continue to be able to receive information about cigarettes and smokeless tobacco, in a text-only format in most cases, in virtually all the same media currently used for tobacco advertising. Moreover, if an advertiser intends to use a new media outlet not included in the list of permissible advertising, its responsibility is to notify FDA and provide the agency with information about the media and the extent to which the advertising is seen by young people. FDA will review any submission and make a determination whether provisions of the final regulation provide sufficient information for the advertiser to know how to disseminate its advertising or whether the

regulations need to be amended.

Advertising in any new media will be subject to the text-only format requirement if it is a medium used by young people. Therefore, FDA has created a new § 897.30(a)(2) to reflect this new process.

The agency believes this approach is reasonable and is fully consistent with its statutory authority and with the First Amendment. In *Central Hudson Gas & Electric Co.*, 447 U.S. at 571, n.13, the Supreme Court suggested that the Public Service Commission might consider a system of previewing advertising campaigns to ensure that they will not defeat conservation policy. The Court pointed out that "commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it" (*Id.*). Given the agency's significant interest in ensuring that the restrictions on access that it is imposing are not undermined, FDA finds that the requirement that firms consult with it before using a new advertising medium is a limited means of regulating commercial expression that is likely to vindicate FDA's public health interests. This approach will not prohibit the tobacco industry from advertising in new media but will protect young people by giving the agency an opportunity to review the problems presented by a new media and to design new regulations or adapt current ones.

(32) One comment from a public interest group concerned with electronic media urged FDA to explicitly prohibit tobacco advertising over the Internet, Worldwide Web, and other on-line services and interactive media. The comment stated that children and adolescents are increasingly using on-line services with up to 4 million Americans under age 18 using, or with access to, on-line services. The comment stated further that the interactive nature of the on-line services gives advertisements numerous advantages over traditional print advertisements. The comment emphasized that a ban on tobacco advertising over these media is necessary because the text-only format would not be as effective in reducing the appeal of tobacco advertising to minors given the interactive nature of these media.

One comment from an organization of health professionals stated that one tobacco company advertises its mail-order business through a Web site on the Internet and offers links to other tobacco-related sites. The comment wondered why this type of advertisement was not banned by FCC

since the Internet operates over telephone lines, a form of electronic media that is regulated by FCC and from which cigarette advertising is banned.

A few comments dealt with on-line advertising and recommended that the rule should limit format to black text on a plain background, require advertisers to demonstrate that significant numbers of children do not access ad sites, require use of any available blocking technology, and define "conspicuous" and "prominent" as they pertain to interactive media.

Some of these comments have suggested that advertising of tobacco products in on-line media should be banned under the Federal Cigarette Labeling and Advertising Act's (the Cigarette Act) (15 U.S.C. 1331) and the Comprehensive Smokeless Tobacco Health Education Act of 1996's (the Smokeless Act) (15 U.S.C. 4401) prohibition of advertising on any media subject to the jurisdiction of FCC. The agency leaves the issue of jurisdiction and the applicability of the broadcast ban to the Department of Justice, which has the appropriate jurisdiction over the Cigarette Act, and to FTC, which has along with the Department of Justice jurisdiction over the Smokeless Act. Were these agencies not to take action and were, tobacco advertising to continue in on-line media, then FDA is available to meet with advertisers regarding their responsibility under the final rule.

The agency recognizes the growing importance and use of on-line media and the Internet for communications of all sorts, including tobacco sales and advertising. On-line media are not included within the list of permissible outlets for tobacco advertising because the agency does not have sufficient information on the technology to include regulations in the final rule. However, advertisers interested in advertising on the Internet should notify the agency, after the rule is final, and provide the agency with sufficient information about use by young people so that the agency can make a proper determination. This notification is for discussion purposes only, and is not in any way intended to imply, or create a need for, prior approval.

The agency recognizes the concern expressed by one comment that a text-only format, without additional requirements, may not be as effective in protecting young people from on-line advertising as it would be for print advertising because of the interactive nature of on-line media. The agency would consider the unique qualities of

on-line media and the Internet in evaluating any requests to use these media. Any other statement about specific requirements for this new media or any other media would constitute speculation at this point.²⁰¹

Section 897.30(a)(1) provides a comprehensive listing of the permissible forms of advertising and labeling. The evidence that FDA has gathered in this proceeding establishes the need for and importance of such a comprehensive listing. In addition to the general evidence and support provided by expert opinion, advertising theory, studies and surveys, empirical studies, anecdotal evidence, industry statements, and two consensus reports (the IOM Report and the 1994 SGR) described in section VI.D.5. of this document, FDA has found specific support for a comprehensive listing in:

Empirical Studies—Various economic and econometric studies of international and cross-country data show that restrictions on advertising and promotional activities can result in a decline in tobacco use (see section VI.D.6.a. of this document).

Country Experience—The experience of countries, such as Norway and Finland, shows that comprehensive advertising restrictions can positively affect the smoking rates of young people over time (see section VI.D.6.a. of this document).

Advertising Theory—Each separate advertising media plays a critical role in shaping young people's beliefs about tobacco use, and ultimately their use of tobacco products (see sections VI.D.3.a. through VI.D.3.e. of this document). Therefore, regulation of advertising must address each type of media. As will be described in the following sections of the regulation, the restrictions on each media are necessary to reduce the appeal of tobacco for young people and to prevent unrestricted tobacco advertising from undermining the regulation's access provisions. Moreover, as international experience indicates (see section VI.D.6. of this document), when regulations that are not comprehensive are implemented, tobacco money can migrate to unregulated advertising venues (e.g., if publications are prohibited, money expended on sponsorship will increase) and can undermine the force of the regulation. Thus, in order to be effective,

restrictions must be as comprehensive as possible.

Based on all of the foregoing, FDA concludes that the comprehensive listing of permissible advertising in § 897.30(a)(1) will directly and materially advance the agency's efforts to reduce consumption of tobacco products by children and adolescents under the age of 18.

3. Section 897.30(b)—Billboards

The agency proposed in § 897.30(b) to prohibit outdoor advertising, including but not limited to billboards, posters, or placards, placed within 1,000 feet of any public playground or playground in a public park, elementary school, or secondary school. FDA proposed this provision because these are places where children and adolescents spend a great deal of time and should therefore be free of advertising for these products. The agency tentatively concluded that this was a reasonable restriction and noted that the cigarette industry's voluntary "Cigarette Advertising and Promotion Code," (the Code) revised in 1990, contains a similar provision concerning schools and playgrounds (60 FR 41314 at 41334 through 41335).

(33) FDA received over 2,500 comments concerning this part of the 1995 proposed rule. Comments opposing this measure pointed out that the tobacco industry has established a voluntary code similar to the proposed provision with which advertisers already comply, and that therefore, there is no reason to make this measure mandatory. These comments also stated that outdoor advertising does not target children and adolescents, and that parents, siblings, and friends have a much greater influence than billboards and posters on a young person's desire to start smoking. Further, they stated that there is no evidence that this measure would reduce any teenager's desire to smoke.

Most comments supported this provision, stating that children and adolescents should not be subjected to visual images promoting tobacco use around those areas where they attend school or play. The comments argued that children and adolescents want to be like the attractive models in the advertising, and, thus, the advertisements directly influence them to start using tobacco.

In the Federal Register of March 20, 1996 (61 FR 11349), the agency reopened the comment period for the August 1995 proposed rule to place on the public record a memorandum that provided further explanation of the

²⁰¹ In addition to the substantive changes, the following changes in language have been made: (1) Deletion of "only" in § 897.30(a)(1); (2) substitution of (a)(2) for (b) in 897.30; and (3) deletion of "and" before "in point of sale" in § 897.30(a)(1).

agency's proposal to ban outdoor advertising within 1,000 feet of schools and playgrounds. The document provided an additional 30 days in which to comment on this new information. The memorandum stated that the agency was aware of the industry's voluntary 500-foot ban on advertising from schools and playgrounds but also that it was cognizant, based on the experience of its employees, that billboards can loom large in the sight of children and adolescents at that distance and thus would be able to capture their attention. The agency also noted that 1,000 feet is about 3 blocks and that signage kept that far away from schools and playgrounds would not loom as large, if it would be visible at all. Moreover, the 1,000 feet will protect children as they travel to and from these locations.

In response to the comments, FDA has modified the provision to clarify the coverage of the provision. Thus, the final rule states that the 1,000-foot area is to be measured from the perimeter of the playground or school. Moreover, a definition of playground is included as well as an indication that the relevant area of a playground in a larger public park is limited to the play area itself. Section 897.30(b) reads:

No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(34) Several comments asked FDA to define what is meant by the term "playground." The comments stated that the term could be construed to include literally any place of outdoor recreation where children may play (i.e., a paved parking lot, a tennis court, or a city park), even places used primarily by persons 18 years of age or older. One of the comments noted that the industry code refers to "children's playgrounds" (i.e., playgrounds designed primarily for use by children), but that § 897.30(b) refers to "any playground."

Some comments suggested that the term "playground" should include the playgrounds of city parks, recreation facilities, theme parks (e.g., Disneyland), and national parks.

The agency agrees that it needs to clarify what is meant by the term "playground." A typical dictionary definition of "playground" states that it is: (1) An outdoor area set aside for recreation and play, especially one having equipment such as seesaws and

swings; or (2) a field or area of unrestricted activity. The intent of the proposal was not to preclude outdoor advertising within 1,000 feet of any area that would fall under this broad definition, but to preclude cigarette and smokeless tobacco advertising around those areas where children and adolescents are likely to spend a lot of time. Clearly, areas around schools with equipment such as swings and seesaws are areas where children are likely to play. Public parks for family recreational purposes with play equipment, and facilities for activities such as baseball or basketball are also areas where children and adolescents are likely to be present for hours at a time.

However, private enterprises, such as theme parks and recreational facilities, are not necessarily intended only for children and adolescents. Those that are, may require the presence of an adult for entry. There are usually entrance fees or required purchases for use of these areas. In addition, children and adolescents may not be present in these areas on any regular basis (e.g., an annual visit to a theme park). Therefore, the agency will not include these areas in the regulation. Moreover, because all outdoor advertising must be in black and white text, the agency sees no need to extend the prohibition beyond elementary and secondary schools and public playgrounds at this time.

The concern expressed that a decision by private parties to build a playground could destroy the value of a billboard sign should no longer exist. Because the agency is limiting its definition of playground to those publicly owned playgrounds, any interested party could object to the establishment of the playground.

FDA is modifying § 897.30(b) to state that outdoor advertising is prohibited within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., areas with equipment such as swings and seesaws, baseball diamonds, basketball courts), elementary school or secondary school. The agency concludes that this modification in § 897.30(b) is adequate to clarify the term "playground," and that a more specific definition for "playground" is not necessary at this time.

The agency notes that the definition makes clear that, when an area is set aside for a playground within a public park, the 1,000 feet is measured from the perimeter of the play area and not from the larger park.

(35) Several comments contended that the regulation should specify that the 1,000-foot rule should be measured from the perimeter of the property to avoid confusion. One comment asked that the provision be more clear as to what types of schools would be included within the definition.

The agency agrees with the first comment. The intent of the 1995 proposed rule was that the distance would be measured from the perimeter of the school or playground. Any other measurement could defeat the purpose of the regulation. For example, measuring from the edge of a building or from the center of a playground could allow outdoor advertising to be placed closer to the perimeter where children may be assembled or playing. In addition, for large schools or playgrounds, the outdoor advertising could feasibly be near the perimeter of the school or playground if the distance is measured from somewhere other than the perimeter. Therefore, to clarify the intent of the provision, FDA is modifying § 897.30(b) to state that no outdoor advertising may be placed within 1,000 feet of the perimeter of any playground, elementary school, or secondary school.

However, the agency does not believe that it needs to provide a definition of elementary and secondary schools, as those terms, as commonly used, include all such schools (kindergarten through 12th grade) whether public, private, or parochial.

(36) One comment stated that the tobacco industry Code of Advertising Practices (the Code) applies to outdoor advertising on billboards, and that § 897.30(b) applies to all outdoor signage, including signage on the exterior of retail establishments that sell tobacco, and conceivably even to advertising on buses, taxis, and other vehicles that might venture within the 1,000-foot zone.

Another comment stated that FDA should consider regulations that eliminate tobacco advertising via traveling vans and trailers because trailers and vans are mobile billboards and can be strategically placed to gain maximum exposure among young people.

FDA agrees that § 897.30(b) applies to more forms of advertising media than does the tobacco industry code (i.e., all outdoor advertising, not just billboards). FDA's regulation restricts all outdoor advertising of tobacco products, including, but not limited to, billboards, posters, and placards. However, the intent and purpose of § 897.30(b) is not

to prohibit signage on taxis and buses that are not located in, but may pass through, the school or play zone. Such signage is usually temporary or transient and does not present the same concern of a permanent sign.

(37) Several comments questioned the factual basis for the proposed ban on outdoor advertising of cigarettes and smokeless tobacco within 1,000 feet of schools and playgrounds and stated that "employee" experience is not a sufficient basis. One comment argued that FDA should give little weight to employee experience in light of the fact that cigarette manufacturers submitted expert testimony that children and adolescents pay relatively little attention to billboard advertising at any distance. In addition, some comments argued that FDA's analysis related solely to billboards, and that it had presented no evidence or analysis justifying a ban on store signage. Finally, several comments stated that the agency failed to take into account the "visibility" of the outdoor advertising. These comments suggested that any regulation must take into account whether obstructions exist (e.g., trees, winding roads, signage placed facing away from the prohibited area).

The agency disagrees that it has not provided an adequate basis for its proposed regulation. In addition to the analysis provided by the agency in its March 20, 1996, Federal Register document, the agency received two comments during the comment period with evidence regarding this issue. A professor of biophysics and optometry stated that he believed that there was a rational and quantitative basis for deciding on a given distance if that distance was to be based on the visibility of words on a billboard. Specifically, he stated that children and adolescents typically have 20/15 visual acuity. Therefore, it is possible, using a mathematical formula using a right-angled triangle and the definition of the tangent trigonometric function to compute the distance at which words are visible. He computed the distances from which it would be possible to see both words 1 foot high and 2 feet high. In addition, he computed the distances for a "normal" visual acuity of 20/20. If one were to average these numbers, the result would be approximately 1,200 feet, which could be rounded to 1,000 feet.

Table 1a.

	1-foot high letters	2-foot high letters
20/15 vision	917 feet	1,833 feet
20/20 vision	687.8 feet	1,376

(38) Another comment reminded the agency that two separate laws passed by Congress had provided for a 1,000-foot zone around schools as a means to protect youngsters from dangerous and unsafe behavior. The Controlled Substances Act (21 U.S.C. 860) provides additional penalties for anyone distributing or manufacturing drugs within 1,000 feet of schools, playgrounds, and universities, and 18 U.S.C. 922 prohibited possession of a firearm within 1,000 feet of schools.²⁰² Moreover, the comment contained scores of pictures of advertising billboards and signs within 500 and 1,000 feet of school and playgrounds as well as statements by children indicating that the signs are ubiquitous and attractive. The pictures and statements may only be anecdotal evidence of the proliferation of tobacco advertising near schools and playgrounds, but the number of children who provided pictures in such a short period of time indicates that the problem of advertising in proximity to schools and playgrounds is not isolated.

Moreover, the agency also disagrees that it has no basis for including other outdoor signage, including signs on stores, in the regulation. The agency provided evidence in the administrative record and comments refer to evidence,²⁰³ which showed that in a test area, those stores within 1,000 feet of schools had a significantly greater percentage of windows covered with tobacco signs than those further away. Moreover, the two RJR memoranda by sales representatives, described in section VI.D.3.d. of this document, mention the importance of supplying stores near high schools with "young adult" material.

This provides sufficient support for the agency's concern with signage on stores near schools. Young people are more likely to frequent stores near schools, especially older adolescents,

and these venues should therefore be free of advertising for tobacco products.

The agency also finds that it cannot address the comments' concerns with obstructions. It would not be possible to qualify a regulation to account for the fact that trees may obstruct a sign when they are in full bloom but not in winter, or that children may be able to see signage as streets wind or that face away from the school or playground as they walk to and from school. The line that the agency has drawn is narrowly tailored (see *Board of Trustees of State University of New York v. Fox* 492 U.S. at 480) and consistent with how a standard needs to be crafted for it to be enforceable.

Finally, FDA finds that the expert testimony referred to in the industry comment that indicates that young people do not pay attention to billboards is contradicted by other evidence in the record. The Roper Starch study mentioned in section VI.D.3.d. of this document, submitted by RJR, reported that 51 percent of 10 to 17 year olds surveyed reported that they had seen or heard of Joe Camel from a billboard advertisement. For this reason, FDA is not accepting the suggestion in the comment.

(39) A number of comments from the tobacco and outdoor advertising industries stated that the tobacco industry had adopted a code in 1990, which encouraged all billboard companies to establish and manage a program to prohibit alcohol and tobacco advertisements within 500 feet of places of worship and primary and secondary schools. They noted that over 16,000 billboards nationwide have been voluntarily identified as "off limits" for these categories of advertising. As a consequence, the comments asserted that Government action is unnecessary.

One of the comments stated that the fact that members of an industry have elected to submit to a code of advertising practices does not make it reasonable for the government to impose mandatory advertising restrictions backed by criminal sanctions. It stated that private parties may voluntarily take actions that the Constitution forbids the Government to mandate. The comment argued that few industries would risk any self-regulation if their decision to do so might establish a predicate for even greater Federal regulation.

Conversely, several comments raised concerns about the voluntary code and cited numerous examples of violations that continued after the sponsors and the billboard companies had been informed of the violations. One

²⁰² Although this statute was overturned in *United States v. Lopez*, 115 S.Ct. 1624 (1995), as inappropriate under the Commerce Clause, the congressional determination that 1,000 feet was an appropriate distance was not disturbed.

²⁰³ Rogers, T., E. C. Teighey, E. M. Tencoti, J. L. Butler, and L. Weiner, "Community Mobilization to Reduce Point-of-Purchase Advertising of Tobacco," *Health Education Quarterly*, 1995, in press.

comment stated that a survey found that in California tobacco advertising is more prevalent at stores within 1,000 feet of schools than at stores farther from schools. The comment asserted that statewide findings also revealed that there is more exterior store advertising in areas where at least 30 percent of the neighborhood is 18 years old or younger, and that the advertisements are placed near the candy or at a child's eye view (3 feet or below).

The agency is aware that the Code of Advertising Practices has not been uniformly observed, as several comments pointed out. Moreover, the industry code is significantly less inclusive than the proposed regulation as it covers only billboard advertising and not other forms of outdoor advertising such as posters and placards. These other forms are likely to be placed near retail establishments and in some cases, according to comments, have appeared on school fences. The agency finds that all outdoor advertising must be included in the regulation in order to provide comprehensive coverage. There is little difference between a billboard and a large poster to a child. Both are advertisements, and both are visible, so that children see them as they go to and from school and play.

In addition, the Code prohibits outdoor advertising only within 500 feet of schools, an area only a block or a block and a half from the school (there are 10 to 12 city blocks to a mile). One block will not provide sufficient protection as it would not cover the areas where many children congregate with their friends. Moreover, a child's vision does not stop at one block from school. A prohibition of 1,000 feet will ensure the absence of signs for 2 to 3 blocks from a school or playground which can be seen from these locations where children spend a significant amount of time each day. (Several comments stated that FDA had misused its math to calculate block distances in its March 20, 1996, Federal Register document (61 FR 11349).) If the misstatement caused any confusion, the agency regrets it but does not believe that the one-half block difference undermined the rationale.)

(40) One series of comments supported FDA's 1995 proposal, stating that the restriction on billboards near schools should not be compromised, nor the distance reduced.

A number of comments argued that the proposed regulation did not go far enough. One comment recommended excluding outdoor tobacco advertising

from neighborhoods where children live. Another comment stated the belief that the ban on billboards should be at least double the proposed 1,000 feet from schools, while others argued that outdoor advertising should be prohibited completely.

These comments stressed the importance of billboards and other outdoor advertising in creating cigarette brand awareness among children. For example, one comment discussed the results of a survey conducted for *Advertising Age*, which showed that 46 percent of children 8 to 13 years old said they most often saw cigarette advertising on billboards, outpacing magazines. It stated that 34 percent of children 14 to 18 years old cited billboards as the predominant advertising medium for tobacco products.²⁰⁴ The comment stated further that all billboards, regardless of placement, are seen by significant numbers of children, therefore, it clearly makes sense that, as a means to protect children from tobacco advertising, such advertisements should be prohibited from billboards and other outdoor advertisements. The comment emphasized its point by quoting from the billboard industry's own marketing material ("Outdoor: It's not a medium, it's a large"), "You can't zap it. You can't ignore it * * * It asks little time, but leaves a long impression." The comment stated that the same publication notes, "Outdoor is right up there. Day and night. Lurking. Waiting for another ambush."

One tobacco company presented evidence of the effectiveness of billboards in bringing tobacco advertising to children. RJR, in its comment on the 1995 proposed rule, as stated in section VI.D.3.d. of this document, attached a study conducted for it to test children's recognition of advertising characters and slogans (Roper Starch study). This study involved 1,117 children 10 to 17 years of age, with 86 percent of them recognizing Joe Camel using aided and unaided recall. When asked where they had seen Joe Camel, 51 percent said on billboards.²⁰⁵ That amount of recall shows that billboards represent a very effective advertising medium and belies the industry's assertion that billboards are not an effective source of advertising information for children.

²⁰⁴ Levin, G., "Poll Shows Camel Ads are Effective With Kids; Preteens Best Recognize Brand," *Advertising Age*, p. 12, April 27, 1992.

²⁰⁵ "Advertising Character and Slogan Survey," pp. 10, 22.

Finally, one comment from a public interest group warned that, the more complex a rule is, the more difficult enforcement becomes. It stated that spacing limitations, such as the proposed 1,000-foot zone around schools, begs a series of questions, for example: How is that distance measured, from what point to what point. It stated that these questions would make it virtually impossible for citizens to play an active role in enforcing this rule. The comment stated that without citizen participation, billboard control is extremely difficult, and that this situation has, in fact, contributed to the industry's disregard for local and State billboard control laws.

The agency finds that the comments, as well as the evidence spelled out in the 1995 proposal, have provided ample support to establish that outdoor advertising has a significant impact on children and adolescents. While the comments have presented significant evidence in support of a ban on all outdoor advertising, the agency is not convinced that a ban or a restriction on tobacco advertising of more than 1,000 feet would be appropriate. As discussed elsewhere in this document, the agency is requiring that all permissible outdoor advertising be in a black and white, text-only, format. Therefore, some of the concerns raised by the comments requesting a complete ban on outdoor tobacco advertising or of expanding the ban are addressed by that provision. Moreover, the agency's regulations are an attempt to balance the rights of adults to receive information about a legal product with its desire to protect children from the unavoidable appeal of advertising. Thus, although the line could be drawn elsewhere, the agency finds that the 1,000 feet limitation should ensure adequate protection from visible advertising where children spend a significant amount of time but will permit adults to get information.

(41) One comment stated that FDA's action violated the APA because the agency offered no evidence in support of its claim that children spend a great deal of time in areas as far as 1,000 feet from the places specified in § 897.30(b). It added that the justification for text-only advertising undercuts FDA's justification for its 1,000-foot ban.

Another comment stated that although tobacco product advertising is disseminated through a broad spectrum of media, outdoor advertising is the only such medium that is subject to additional specific prohibitions under the 1995 proposed rule beyond the

prohibitions applicable to all tobacco product advertising. It stated that the record does not contain evidence that would establish either that these prohibited outdoor advertising signs are viewed more often by minors than other advertising media, or that outdoor advertising in general has a greater impact on minors than other media. There is nothing, the comments argued, that indicates that the mandatory content restrictions and affirmative disclosure requirements imposed by the proposal would be less effective in outdoor advertising of tobacco products than when such an advertisement is placed in a rock and roll magazine, or in an exempt publication with 1 million adolescent readers.

One of the comments stated that because the text-only requirement itself is intended to render the advertising unattractive to young people, the additional "protection" offered by the 1,000-foot rule would be wholly gratuitous.

Several comments argued that there is no proof that this additional area of ban will reduce any teenager's desire to use tobacco: a desire that has withstood the ban of TV and radio advertisements and a massive educational program. The comment stated that the 1,000-foot rule seems particularly gratuitous in view of the fact that it would ban advertising that FDA, by virtue of its proposed text-only requirement, already has stripped of the features FDA deems make it appealing to young people.

FDA disagrees with these comments. The agency's bases for the text-only requirement for billboards and for the 1,000-foot ban are reasonable and supportable, and they are not in conflict. The text-only format requirement will reduce the appeal of cigarette and smokeless tobacco product advertising to persons younger than 18 years of age without affecting the information conveyed to adults (60 FR 41314 at 41335). It is an attempt to narrowly tailor the restriction by balancing the need to restrict advertising's appeal to children with the preservation of the informational function of advertising for adults.

The prohibition on outdoor advertising within 1,000 feet of schools and playgrounds is designed to address a different problem. The concern is not the appeal of the advertising. If the problem were only appeal, the 1,000-foot restriction would not be necessary because the text-only requirement would eliminate this concern. The concern is the nature of billboards themselves. Billboards near schools and

playgrounds ensure that children are exposed to their messages for a prolonged period of time. As the Supreme Court recognized in *Packer Corp. v. Utah*, 285 U.S. 105, 110 (1934), billboards are seen without the exercise of choice or volition, and viewers have the message thrust upon them by all the arts and devices that skill can produce. This is particularly true of billboards that are readily visible (i.e., within 1,000 feet) when children play or study at a playground or school, places where by design children spend a lot of time, or when children walk to and from a school or playground. Confronted daily and unavoidably with the advertised message, even in text-only, a child gets a sense of familiarity, normalcy and acceptability of the message and the product that is advertised.

(42) Several comments stated that placing a circle with a radius of 1,000 feet drawn from the perimeter of each school and playground would establish a "forbidden zone" that would be at least 2,000 feet in diameter (i.e., over one-third of a mile). They stated that in many communities, this would be tantamount to a de facto ban, for there would be virtually no outdoor location that could escape the rule's prohibition.

Several comments pointed out that even if advertisers wanted to disseminate advertisements on billboards that complied with the FDA proposal, there would be virtually no locations where such outdoor advertising signs could be located in some cities. They submitted results of computer assisted surveys of nine cities showing the areas where outdoor advertising of tobacco products would be allowed under the 1995 proposal. The survey showed that outdoor tobacco advertising would be prohibited in 94 percent and 78 percent of the respective land mass of Manhattan and Boston under the proposal. The comment stated that this range approximates the high and low percentages that could be anticipated in other metropolitan areas in the United States. Moreover, when it correlated the data collected from the study and other data regarding the actual location of billboards, the comment found that, even under the most expansive view, not a single billboard in Manhattan (including the commercial corridor of Times Square), and no more than 24 actual billboard locations in the entire city of Boston, would be permitted to display tobacco advertisements.

The comment stated further that even if the rule permits a few locations where tobacco advertising would be allowed in

a given municipality, there is no commercial utility in a limited number of outdoor advertising signs where the location of the advertisement is dictated by the 1,000-foot rule, rather than by market demographics and vehicle circulation. According to the comments, these latter factors are what actually control billboard placement. It concluded that, as a practical matter, FDA's proposed outdoor advertising restrictions would eliminate billboards as a medium for tobacco advertising even in those jurisdictions where a small number of such signs theoretically would be available.

FDA has carefully considered the possibility that its restrictions effectively outlaw outdoor advertising in most urban areas. The agency has concluded, however, that if this situation comes to pass, it would be a consequence of the density of population in cities. FDA's intent in adopting § 897.30(b) is to restrict the accessible and intrusive communication of information about cigarettes and smokeless tobacco to children and adolescents at school and at play. It was not to provide for distances that would have the effect of banning outdoor signs from urban areas. By limiting the restriction to 1,000 feet, FDA has tried to make it no more extensive than necessary to achieve its intended end. FDA has considered the cost of its restriction but concludes that a narrower restriction would not adequately advance its purpose of protecting young people from unavoidable advertising in settings in which they are essentially a captive audience.

The 1,000-foot restriction on outdoor advertising will serve to remove what has been shown is an effective means for tobacco companies to communicate with young people in a direct and unavoidable manner. Eliminating such billboards will thus mean eliminating a means by which the industry has influenced young people to engage in tobacco use behavior. Therefore, the agency concludes that § 897.30(b) is a necessary part of its effort to reduce underage use of tobacco products.

Several comments from the tobacco industry and from retailers pointed out that § 897.30(b) would prevent retail establishments within the 1,000-foot zone from informing potential customers that tobacco (or particular brands thereof) are available for purchase therein and at what prices. These comments stated that this restriction not only would hurt the retailers but would increase, in turn, the

search costs for adult smokers. The comments stated that retailers in the small slivers of a city in which outdoor advertising would continue to be permitted would be afforded an unfair competitive advantage.

One comment added that convenience stores located within 1,000 feet of a school or playground would not even be able to put a small black on white placard on top of a gas pump that merely indicates the price of tobacco, but that a billboard across the street and located a little over 1,000 feet away from the same school or playground could carry the brand name of a tobacco product in black letters as tall as the store's front door. The comment urged FDA to recognize this distinction.

The agency acknowledges that some retailers may be prohibited from placing advertising concerning tobacco products on or around their retail establishments, while others, perhaps just across the street, can. Any minimum distance that the agency establishes will preclude some retailers from outdoor advertising at their retail establishments but not others. However, FDA has determined that it is necessary to keep outdoor advertising away from areas where children are likely to congregate daily.

FDA notes that the Supreme Court cases that have considered restrictions on speech have recognized that such restrictions may not be perfectly tailored, see, e.g., *Board of Trustees of State University of NY v. Fox*, 492 U.S. at 479. Thus, while in a few instances there may be inequities created by the line FDA has drawn, because there is a reasonable fit, as explained in section VI.E.1. of this document, between FDA's ends and the restrictions that it is adopting, these minor problems do not doom FDA's rule (*Id.* at 480).

FDA's prohibition on signage on stores within 1,000 feet of schools and playgrounds will advance the agency's interest in protecting the health of children. Several of the studies submitted with comments showed that there is more signage in and around stores near schools and playgrounds than in stores generally. The ban on outdoor advertising within 1,000 feet of schools and playgrounds will ensure that signage near schools will be removed and thus minimize any sense of familiarity that would develop.

Thus, even though the agency has carefully considered these comments, it concludes that it is appropriate to establish a minimum distance from schools and playgrounds within which all outdoor advertising is prohibited.

(43) A number of comments argued that the prohibition on tobacco billboards within 1,000 feet of schools violates the Commerce Clause as recently interpreted by the Supreme Court in *United States v. Lopez*, 115 S.Ct. 1624 (1995). In *Lopez*, the Supreme Court held that Congress lacked the power under the Commerce Clause to criminalize the possession of a gun within 1,000 feet of a school. One comment argued that the Congress's commerce power only permits it to regulate, for example, the interstate transit of advertisements, but that once the advertisement is within a state, it is private property and not subject to regulation under the Commerce Clause.

The agency disagrees. Under the Commerce Clause, Congress may "regulate those activities having a substantial relation to interstate commerce, * * *, i.e., those activities that substantially affect interstate commerce." (See *Lopez*, 115 S.Ct. at 1629-30 (citation omitted).) As the Supreme Court noted in *Lopez*, "the possession of a gun in a local school zone is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce" (*Id.* at 1634; see also *id.* at 1640 (Kennedy, J., concurring)). As all advertising is inherently commercial in that it proposes a sale, the placement of tobacco billboards in a local school zone is economic activity that does substantially affect interstate commerce because it affects the demand for tobacco and smokeless tobacco. That the advertisements are private property after transportation in interstate commerce does not alter this analysis. Indeed, "[a]ctivities conducted within State lines do not by this fact alone escape the sweep of the Commerce Clause.

Interstate commerce may be dependent upon them." (See *United States v. Rock Royal Co-op., Inc.*, 307 U.S. 533, 569 (1939); see also *Wickard v. Filburn*, 317 U.S. 111, 127-28 (1942) (holding that, under Commerce Clause, Congress could control farmer's production of wheat for home consumption because cumulative effect of such consumption by many farmers might alter supply and demand in interstate wheat market).) As such, regulation of the placement of billboards advertising tobacco products does not violate the Commerce Clause.²⁰⁶

²⁰⁶ Moreover, cigarettes and smokeless tobacco products are nicotine delivery devices. Congress plainly provided for medical devices to be federally regulated as indicated by the provision allowing seizure of devices without proof of interstate

(44) A number of comments argued that § 897.30(b) would violate the First Amendment. These comments argued that, given the requirement for black text-only on a white background, the restriction on billboards within 1,000 feet of schools and playgrounds would not directly and materially advance a substantial government interest. The comments also argued that the billboard restriction could not be considered to be narrowly tailored. One comment from a public interest group, however, argued that FDA's proposal is fully constitutional because it is much more limited than the restrictions on billboards upheld in *Penn Advertising v. Mayor and City Council of Baltimore*, 63 F.3d 1318 (4th Cir. 1995) vacated, remanded 64 U.S.L.W. 3868 (U.S. July 1, 1996), and *Metromedia, Inc. v. San Diego*, 453 U.S. 490 (1981). The comment pointed out that in *Metromedia, Inc.*, the Supreme Court held that the City's interest in traffic safety and aesthetics were sufficient to justify a ban on commercial outdoor advertising (453 U.S. at 551, n. 23). Here, the comment said, the interest that FDA has asserted is more weighty.

FDA disagrees with the comments that argued that § 897.30(b) violates the First Amendment. As explained, this restriction does advance FDA's interest beyond what is accomplished by the text-only restriction. As explained in sections VI.B. and VI.D. of this document, the regular exposure of children to tobacco advertising, even in text-only form, builds a sense of familiarity and acceptability that, reports and studies say, contributes materially to the decisions of young people to experiment with and use tobacco products. Thus restrictions that eliminate such exposure will eliminate one factor that contributes to the process by which children and adolescents decide to smoke or use smokeless tobacco and, consequently, will directly advance FDA's interest.

Moreover, the restriction that FDA is adopting is narrowly tailored to advance its interest. FDA's concern is with the advertising that can be seen from schools and playgrounds, the place at which children and adolescents spend a significant amount of time each day. Three blocks or 1,000 feet is about the distance at which signs are readily visible. Thus, FDA has restricted outdoor advertising within this distance of schools and playgrounds.

shipment (section 304 of the act) (21 U.S.C. 334)) and by a presumption that devices are in interstate commerce (section 709 of the act (21 U.S.C. 379)).

The result of FDA's restriction is that children will not be confronted with tobacco advertising as they study and play, and thus there will be a corresponding reduction in the ability of tobacco advertisers to create the impression of acceptance and familiarity that is influential with youngsters. Consequently, there is a reasonable fit between FDA's interest in protecting the health of children and the restriction on outdoor advertising that it is adopting (see *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. at 416; *Board of Trustees of State University of New York v. Fox*, 492 U.S. at 480).

Thus, FDA concludes that, in fashioning the restriction on billboards, it has fully met its obligations under the First Amendment.

In summary, FDA finds that § 897.30(b) will contribute in a direct and material way to reducing underage tobacco use. The evidence establishes that billboards are one of the most effective forms of advertising for young people, and that their elimination near schools and playgrounds will directly and materially advance FDA's goals.

Studies—A Roper Starch survey submitted by R. J. Reynolds found that billboards were the most mentioned source of information about Joe Camel for children (see section VI.D.3.d. of this document), and a study conducted for *Advertising Age* (April 27, 1992) discussed in this section showed that 46 percent of children 8 to 13 and 34 percent of children 14 to 18 said that billboards are a predominant form of advertising for tobacco.

Advertising Theory—Billboards near schools and playgrounds give the child a sense of familiarity, normalcy, and acceptability of the message on the product. Therefore, regulation of the format and even the location of some billboards and other outdoor signs within 1,000 feet of a school or playground, is essential. As discussed in this section, comments submitted in this rulemaking include photographs that evidence the intrusive effect of billboards and signage around schools and playgrounds.

Evidence of Children's Visual Range—Data provided by a professor of biophysics and optometry, detailed in this section, support a finding that 1,000 feet is an appropriate distance to remove signage that would be visible and readable to students.

Congressional Finding—As detailed in this section, Congress mandated a 1,000 foot drug free zone around schools and playgrounds (Controlled Substances Act (21 U.S.C. 860)) as an appropriate

area in which to protect young people from drug dealing near schools and playgrounds.

Finally, the agency has tailored the ban as narrowly as possible by defining playgrounds narrowly and, as noted above, by restricting the area of the ban to that consistent with children's visual range.

4. Section 897.32(a)—Text-Only Format

Under proposed § 897.32(a), cigarette and smokeless tobacco product labeling and advertising, as described in § 897.30(a) and (b), would be required to use black text on a white background and nothing else. The agency tentatively concluded that this text-only requirement would reduce the appeal of cigarette and smokeless tobacco product labeling and advertising to persons younger than 18 years of age and preserve advertising's informative aspects—that is, to provide useful information to consumers legally able to purchase these products.

In response to comments, the agency has decided to permit another exception to the requirement that all permissible advertising appear in text-only. Thus, it has created an exception for advertising in adult facilities that meet the criteria of § 897.16(c)(2)(ii) provided the advertising is affixed to the wall or fixture in the facility and is not visible from outside the facility. FDA has added this provision, as paragraph (a)(1) of § 897.32 and renumbered the exception for adult publications as § 897.32(a)(2)(i) and (a)(2)(ii).

Several comments suggested that FDA should provide an appropriate definition of "text-only" for permissible audio and video advertising, specifically static black text on a white background with no music or sounds. Therefore, proposed § 897.32 has been revised in consideration of comments received. A new § 897.32(b) has been added to provide guidance for audio/video advertising. Proposed § 897.32(b) has been redesignated as (c), and proposed § 897.32(c) and (d) have been eliminated. New § 897.32(b) has been added to provide explicit format requirements for one form of permissible advertising that had been left out of the proposed regulation.²⁰⁷

²⁰⁷ In addition to the substantive changes made to § 897.32, the following changes in language have been made: (1) Addition of "Except as provided. * * * section," to § 897.32(a); (2) addition of "any" to § 897.32(a); (3) amended language in § 897.32(a)(2) starting with "any publication" and ending with "an adult publication" and, in the last sentence, "an adult publication,"; (4) two changes to § 897.32(a)(2)(i) "younger than 18 years of age"

Many comments were received specifically addressing the text-only proposal. That children and adolescents should not use tobacco products was the one point of agreement among them. However, many comments from adult smokers and nonsmokers, retailers, tobacco farmers, elected officials, and the tobacco, advertising, newspaper, and magazine industries strongly objected to the text-only requirement. Their major objections were that: (1) Cigarette advertising does not cause young people to start smoking; (2) the proposed advertising restrictions would violate the First Amendment; and (3) the restrictions would have the effect of a virtual ban on cigarette advertising. Some comments expressed the concern or suspicion that FDA was using this proposal, ostensibly directed at minors, as a pretext to try to ban cigarette advertising generally.

In contrast, nearly three-quarters of the comments—mostly from parents, teenagers, public health officials, teachers, doctors, public interest groups, medical organizations, and some individuals in the advertising business—supported the proposal for text-only advertisements. The major reason presented for their support was the need to eliminate the appeal for tobacco that the advertising creates among children and adolescents. Some supporters urged even stronger action such as a total ban on all tobacco advertising. Some comments expressed the opinion that even though the proposed regulations may also affect adults, any resulting reductions in smoking by adults would not necessarily be bad.

(45) A number of comments questioned the validity of the evidence cited by FDA as support for the proposal. Many of these comments came from groups representing the tobacco, advertising, and publishing industries. These comments argued that there is no evidence that advertising with color and images encourages use of tobacco by minors or that advertising converts nonsmokers or nonchewers into smokers or chewers. Moreover, these other comments argued that there is no evidence that limiting advertisements to text-only is essential to reduce youth smoking and that there is no evidence that black and white text will reduce underage smoking.

In contrast, a number of supportive comments stated that the evidence cited by FDA, as well as studies published

and "15 percent or less"; and (5) deletion of "labeling" from § 897.32(c).

since the proposal, demonstrate the special susceptibility of children and adolescents to pictures, cartoons, photographs, other graphic images and colors.

Specifically, many comments observed that the appearance of Joe Camel in traditional advertising forums (magazines, billboards) attracts children and adolescents. One child wrote that his father gave him two sports magazines. "There were eight smoking ads in them * * * the last one had two pictures of Joe Camel smoking. This can attract kids to start smoking."

Studies cited in the preamble to the 1995 proposed rule and in section IV.B. of this document, demonstrate the impact that images and colors, cartoons, and pictures and other graphic material have on children and adolescents. This does not mean that the same characteristics of advertising do not appeal to or affect adults. However, the effect of these techniques on children and adolescents is magnified because of their usual level of involvement in advertising as in everything else.²⁰⁸ As detailed more fully in section VI.B. of this document, children and adolescents respond to stimuli that interest them, and that provides them with information that is important. Young people do not have the information processing skills that adults possess, and as a result more often than not, the information that is relevant to them comes in the form of images and colors rather than with a lot of words. This fact provides an explanation why 86 percent of children and adolescents smoke the three most heavily advertised brands (all are promoted with attractive imagery), even though they are generally price sensitive.²⁰⁹ Adults buy generic products for price reasons or low tar brands for health concerns.²¹⁰ Advertising's colorful images are not as relevant to them as cost. Given these factors, FDA finds that the text-only requirement will significantly reduce the appeal of cigarette and smokeless tobacco advertising to young people and reduce its influence on them.

(46) Many comments, especially from the magazine, newspaper, advertising,

and tobacco industries, stated that the proposal will operate as a virtual ban on most types of cigarette and smokeless tobacco advertisements. These comments argued that the text-only format requirement will eliminate tobacco companies' ability to attract the attention of potential customers and to convey brand messages and will render advertising invisible to adults.

Therefore, tobacco advertisers would be far less likely to advertise in the text-only format. Also, not having a clear standard for when the text-only requirement applies (see also definition of adult publication) will cause tobacco advertisers to avoid more publications than may be necessary to ensure that they do not violate the rule. Many of these comments also argued that advertising would become ineffective. One comment said that advertising that passes unnoticed amounts to no advertising at all. This comment also asserted that, as a result of the text-only proposal, no viable alternative channels of communication would exist.

Comments from the tobacco and advertising industry suggested that the advertising industry would suffer revenue, profit, and job losses as a result of the text-only format; employees involved in graphics arts would especially be affected; and suppliers providing services and products to advertising agencies would also be adversely affected.

A number of comments supporting the proposal recommended a total ban on all tobacco advertising. Many comments stated that a ban on all tobacco advertising and marketing would be reasonable because the tobacco industry will use any available loopholes to market tobacco products and will test any partial ban.

Tobacco companies will be able to continue advertising in most of the same forums in a text-only format. Advertising with colors, pictures, and graphics will still be allowed in adult publications. Tobacco advertisers will still be able to convey information to adults about taste, price, and product development using text-only advertising. Many current advertisements for low tar cigarettes rely heavily on text formats.

The agency is not limiting fonts, font styles, or size of type because it believes that the tobacco industry and its advertising firms can use their creativity with a variety of print formats to produce text-only advertising that will effectively communicate their messages, including brand messages, to adults. However, the agency is also convinced

that print advertising, no matter how creative, will not be able to provide the attractive imagery that young people look for in advertising to explain the importance of a product to them, e.g., what to wear, whom to hang out with, how to look cool (see discussion of the importance of color and imagery in the introduction to this section).

Moreover, although the restriction to text-only advertisements may tend to solidify market position, it will not give any one company new competitive advantage over another since all companies must play by the same rules. Thus, the economic impact of the rule on the advertising business will be mitigated by a shifting of resources to create new advertising in compliance with the rule and to advertising for other businesses (see section XV. of this document entitled "Analysis of Impacts" for more information).

The agency does not support a total ban on all tobacco advertising as was suggested by a number of comments. The agency has been able to tailor the restrictions that it is adopting, by requirements such as the text-only advertisements requirement, to eliminate the appeal of tobacco advertising for children and adolescents while still allowing a means for companies to communicate with adult tobacco users. The use of text-only will mean that there can be continued advertising that is less likely to attract young people but that can convey information to adults.

(47) Several comments stated that limiting point of sale advertising to text-only would effectively ban point of sale advertising and impair retailers' ability to market tobacco products to adult customers.

Many comments noted the places one sees (and placement of) Joe Camel at point of sale, the nature of the items on which his image appears, and his ubiquitousness in and around stores, as evidence of the intent of at least one tobacco company to try to attract young people. A physician commented that he: recently was returning from an evening [of] helping to care for [a] patient who was dying of emphysema [a lung ailment caused by cigarette smoking]. I decided to stop at a convenience store * * * I was confronted with no less than 14 advertisements for cigarettes. From the Camel Joe sign beckoning in the parking lot * * * a customer is bombarded with ads urging them to buy cigarettes.

Another comment stated that "advertisements on convenience store doors are placed well below adult eye-level and features such popular advertising cartoons as Joe and

²⁰⁸ One such study tested the effect of different forms of advertising on children and found that they preferred pictures to text-only. (See Huang, P. P., D. Burton, H. L'Howe, and D. M. Sosin, "Black-White Differences in Appeal of Cigarette Advertisements Among Adolescents," *Tobacco Control*, vol. 1, pp. 249-255; 1992.)

²⁰⁹ "Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989-1993," in *MMWR*, CDC, DHHS, vol. 43, pp. 577-581, 1994.

²¹⁰ Teinowitz, I., "Add RJR to List of Cig Price Cuts," *Advertising Age*, pp. 3, 46, April 26, 1993.

Josephine Camel. It seems counter-intuitive to assume that such advertising is intended for adults." Another comment stated, "Tobacco companies say they do not want to entice our children to smoke, then why are Joe Camel ads above the candy counters?" One comment noted that at a major retailer near the commenter's neighborhood, Joe Camel posters are right behind an exhibit of pogs, a popular children's collectible toy.

Manufacturers and retailers are not prohibited from promoting tobacco products at the retail level. Adult consumers looking for price and product information about cigarettes and smokeless tobacco will be able to find that information by searching even without the images to attract them. Text-only point of sale advertising, like magazines or billboards, will be effective in communicating this information. Thus, FDA is not banning point of sale advertising.

While text-only point of sale advertising can be effective with adults, it will have less allure and be less appealing to children and adolescents. Children and adolescents, who are less willing to process print information in a leisurely setting (such as reading a magazine), will not find textual material appealing in the momentary time setting of a retail purchase.

(48) A comment from an advertising industry association stated that:

* * * FDA's prohibition on all direct mail promotion of tobacco products except for "tombstone" messages * * * is even more onerous than that imposed on publications, since at least some publications will be permitted to carry non-tombstone advertising. The disparate treatment of direct mail exposes the real purpose of the FDA to censor messages to adults, because that medium by definition can be addressed to a specific audience, i.e., adults, with little risk of inadvertent viewing by minors.

This comment also noted that this form of direct advertising is not insignificant to the industry and given the small likelihood of youth access to it, should not be severely restricted. The comment noted that total industry spending on direct mail advertising was \$33 million in 1993.

Some comments from mail-order firms noted that the text-only requirement would adversely affect catalogs for tobacco and related products, making them less appealing and less effective for marketing to adult smokers. One comment from the owner of a small (55 employees) tobacco products manufacturing business said the text-only requirement for its catalog, along with several other aspects of the

1995 proposed rule, would destroy his business:

It offends me as a good American running a clean, honest business that a cadre of bureaucrats in Washington, DC would propose a rule that could ruin my life's work. FDA has given no more thought to the impact on my business than I might give to swatting a mosquito.

A supportive comment stated that the tobacco industry has made increasing use of direct mail promotions, including contests, questionnaires, coupons, offers, and even birthday cards. It stated that no company can be certain its mailing lists do not include minors. In a 1993 survey of 12 to 17 year olds, 7.6 percent indicated they had received mail personally addressed to them from a tobacco company. This could project out to 1.6 million persons aged 12 to 17. This comment noted that a major tobacco company sent free packs of cigarettes to people on its mailing list as a holiday present "from the Camel family" and has not changed its practice despite the fact that as many as 1.6 million 12 to 17 year olds could be on tobacco company mailing lists.

Direct mail is a high involvement medium, that is, it requires the recipient to study the text in order to get the central message. In those circumstances, text-only can be effective with recipients who have an interest in the offer. There is less of a need to attract a consumer's attention with a direct mail promotion, including a catalog, than with a point of sale or magazine advertisement. A consumer opening a direct mail promotion he/she is interested in is in a high-involvement mode and is prepared to read the enclosed material and catalog. Although the material may be more easily ignored, current tobacco users who want to buy by direct mail can get the information from textual material.

Mailings in text-only to current customers and to other adult smokers are permitted under the rule. On the other hand, if a direct mail promotion or catalog is seen by a child, the text-only format would make it much less appealing and less interesting. This is especially important since there is evidence that as many as 1.6 million children aged 12 to 17 receive direct mail tobacco promotions. Thus, text-only direct mail is important to accomplish the purpose of this rulemaking. Moreover, contrary to being censorship, as some comments stated, the text-only format for direct mail will allow advertisers to send adults an encyclopedia of information about any aspect of smoking or tobacco products

while protecting children from the effects of advertising.

Although direct mail catalog advertising will be less interesting, sales should only be minimally affected. As the final rule does not include a prohibition on mail-order sales, the only restriction will be the text-only format. In addition, this should be less of an impediment than a total ban to small mail order company owners such as the commenter.

This compromise represents the agency's attempt to narrowly tailor its rule. Based on comments received from the industry, most mail-order customers purchase tobacco products for price, convenience, and uniqueness and to stockpile a long term supply. The agency believes that creative and effective advertising for adults can be designed in the text-only format for catalogs, especially for catalogs targeted to consumers purchasing tobacco products for these reasons. Therefore, FDA is not exempting direct mail promotion of tobacco products from the text-only requirement.

(49) One comment suggested that FDA create an exception for direct mail similar to that for publications. The comment said that direct marketers can target mailings so that children and adolescents are protected to, at the very least, the same degree that the regulations provide for the publishing industry.

FDA has considered this request but finds that it cannot grant it. The agency based the threshold for publications on the ground that publications with youth readership of less than 15 percent are not of interest to young people and thus would be unlikely to be read by them. The same cannot be said of direct mail advertisements that come addressed with the child's name on it. (As explained in this section, surveys show that a significant portion of tobacco direct mail advertising is sent directly to individuals under the age of 18.) The appearance of the child's name in the address will cause the child to look at the advertisement and thus will cause the message to be thrust on the child in a manner similar to messages on billboards or point of purchase (see *Packer Corp. v. Utah*, 285 U.S. 105, 110 (1934)). Thus, direct mail advertising is more similar in nature to billboards and point of purchase advertising than are publications. Consequently, as with the former types of advertising, FDA has concluded that to reduce the appeal of direct mail advertising to those youngsters who view it, it is appropriate

to require that this type of advertising be in the text-only format.

(50) A few comments said that in the same way the agency attempted to carve out an exception for publications with primarily adult readers, it should permit a similar exception for advertising in bars, clubs, etc., with customers over 21 years of age.

The agency agrees with these comments. The agency recognizes the need to precisely tailor its regulations and thus, has created an exception for advertising in adult only (18 years of age and older) facilities permitted to sell tobacco products from vending machines and self-service under § 897.16(c)(2)(ii). These facilities, which are required to ensure that no one under the age of 18 is present, or permitted to enter, the facility at any time, may display permissible advertising, i.e., with color and imagery, provided that the advertising is not visible from outside the facility and is affixed to a wall or fixture within the facility. These conditions will ensure that the advertising does not become a surrogate for outdoor advertising and is not carried from the facility.

(51) The agency received some comments from opponents and supporters of the 1995 proposed rule that stated that this provision might be counterproductive and result in increased demand for cigarettes and smokeless tobacco by minors. One comment from an association of advertising agencies stated that a reduction in spending on cigarette advertising, resulting from the proposal, could make cigarettes less expensive and increase demand for these products. In contrast, another comment from a tobacco company stated that reduced competition due to the text-only restrictions could lead to price increases for some brands which would harm the adult purchasers of those brands.

Some comments stated that the health warnings in cigarette advertising would become less effective in the proposed text-only format. This consequence could result in fewer people giving up smoking because of information in the health warnings. Some comments argued that the text-only format might actually attract more attention from minors because these advertisements would be so different from most advertising.

The agency finds that, on balance, the evidence does not support a conclusion that the text-only requirement will be counterproductive. This finding is based in part on the contradictory comments regarding the price of cigarettes. Some

comments from the advertising industry argued that tobacco companies would use the savings from doing less advertising to reduce the price of cigarettes, which would increase demand especially among young people who are price sensitive. Other comments from the tobacco industry argued that the requirement would reduce competition, which could lead to higher prices for adult consumers. This conflict points out the speculative, and therefore unconvincing, nature of the claims that the restrictions will be counterproductive.

Also, despite concerns expressed by the tobacco industry and others that the text-only format would make the Surgeon General's health warning less effective, there is evidence from the focus groups conducted by the agency that this warning is not very effective with young people now.²¹¹ The text-only format will not interfere with the ability of the Surgeon General's warning to warn adults of the health hazards of smoking. This format will, however, reduce the appeal to young people that advertising creates and therefore will lessen the need for the warning for young people.

The agency has considered the concern of some comments that the text-only format will be so unlike most advertising that young people will be attracted to it. Whatever attraction the novelty has for young people, the agency has concluded that it should be less than the attraction of the current imagery in tobacco advertising.

(52) A number of comments, especially from the tobacco industry, expressed concern about the 1995 proposed rule's adverse impact on competition. Many comments stated that advertising is critical to competition, brand choice, and product innovation. Comments from the tobacco industry stated that the primary purposes of its advertising are to promote brand competition and to maintain brand loyalty. Many of these comments argued that the text-only format would stamp out competition and freeze market shares. Some comments also stated that the 1995 proposed rule would serve as a barrier to new and improved products and product innovation, especially to products like lower tar cigarettes.

Although all firms will be subject to the same rules, some firms may still gain an advantage by dominant market position or by being more creative in their text-only advertising or more

effective in their placement of advertising. Tobacco companies will still be able to advertise in virtually all the same forums they use now, but companies may gain competitive advantages by developing new marketing techniques aimed at adults that are within the rules. All industries have to adapt to changing competitive circumstances, whether caused by government regulations, demanded by the public, self-imposed as in professional sports, affected by international competition and changing technologies, or in reaction to changes in consumer preferences. Creative companies can succeed by adapting better than their competitors within the new framework.

Additionally, these advertising restrictions could make it more difficult for a new competitive tobacco company to be formed and to enter the market. But, there are much greater barriers to entry for a new firm in terms of the nature of the tobacco business, capital requirements, and the existing large firms already in the business. Nevertheless, to the extent that the regulations do produce anticompetitive effects, these are outweighed by the public health benefits of the rule.

Finally, information on new products and on product innovations need not be "stamped out." This kind of information can be conveyed in the text-only format. One example of a new product that the tobacco industry claims might not have been developed if this rule had been in effect is the low tar cigarette. Yet advertising for low tar brands tends to use much more text than regular brands because the information is factual and specific. Therefore, the agency continues to find the text-only requirement to be an appropriately tailored remedy.

(53) Comments offered differing views on the function of advertising. Some stated that imagery is necessary to attract and hold the attention of adult smokers in order to convey useful information about the product and to effectively differentiate brands, while others saw images as being too appealing to children. These latter comments argued that FDA's rule is seeking to regulate only the presentation of the advertising that attracts children (the imagery), not its content.

One small business owner said the proposed ban on imagery would make established advertising logos with pictures worthless, not just for the major tobacco companies but also for small firms in tobacco related businesses. Others stated that the 1995 proposed

²¹¹ Focus group report in administrative record, December 1, 1995, 60 FR 61670.

rule is not strong enough. One comment said that FDA is mistaken in asserting that the black and white text format removes imagery and emotive content from the advertisement. It said that the regulation should also limit the type styles, font sizes, and shapes of borders and letters.

The agency continues to believe that it has created an appropriately tailored remedy. The tobacco and advertising industries argue that FDA's ban on imagery and color is overinclusive and not narrowly tailored. FDA disagrees, however. The restriction on the use of images and color preserves informational advertising because of its utility to adults while eliminating the aspects of advertising that are most attractive to young people. The agency is regulating only the manner in which advertising is presented, not the information contained in it. Also, the agency is allowing imagery in advertising in adult publications.

There is undoubtedly an impact on businesses that have established logos, pictures, and other graphics associated with their businesses or products. However, all businesses are subject to the same requirements, and thus no one business should receive any competitive advantage.

The agency does not agree with comments recommending restrictions on type styles, fonts, etc. Such a restriction on advertising is, given the currently available evidence, more restrictive than necessary. Text-only advertising should be sufficient to reduce the appeal of advertising based on imagery to children and adolescents, however creatively the text is displayed. The agency concludes that the elimination of imagery and color directly and materially advances its interest in protecting the health of young people by making tobacco advertising much less appealing to them and, therefore, it makes it less likely that they will be influenced to use tobacco products.

(54) Several comments requested that FDA provide specific regulation for audio and video formats. Specifically, the comments requested that audio be confined to a text-only format appropriate for audio (words) unaccompanied by music or sound and that video be limited to black text on a white background only. Restrictions, such as these, the comments continued, would apply the spirit of the text-only format to these media. Finally, one comment expressed the concern that without these restrictions, tobacco companies might create and disseminate

music tapes, similar to one distributed by RJR with music by "The Hard Pack." This would, the comment stated, provide aural imagery for young people.

The agency agrees that it should provide more specific guidance for permissible audio and video media and that this guidance should be a logical application of the text-only requirement. Therefore, the agency has amended § 897.32 to add a new paragraph (b), which requires text-only black and white text in video advertising, which should be static, and text-only, no music, in audio advertisements.

(55) Several comments challenged FDA's proposal to limit most advertising to the use of the text-only, black print on white background format on the grounds that this limitation would violate the First Amendment. These comments relied most heavily on three cases: *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), in which the Supreme Court struck down a restriction on the use of pictures in attorney advertising; *Shapero v. Kentucky Bar Association*, 486 U.S. 466 (1988), in which the Supreme Court held that the State may not restrict lawyer solicitations to those least likely to be read by the recipient; and *In re R. M. J.*, 455 U.S. 191 (1984), a case in which the Court struck down a requirement that lawyers use a fixed format in their advertising. One comment, however, argued that FDA's restriction is fully consistent with the First Amendment.

In *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. at 647, the Supreme Court said that "the burden is on the State to present a substantial governmental interest justifying the restriction * * * and to demonstrate that the restriction vindicates that interest through [narrowly tailored] means."²¹² FDA will apply this test here.

As explained in section VI.C.4. of this document, FDA has not merely a substantial, but a compelling, interest in the health of minors. It is this interest that led it to propose the restriction on the use of images and color in cigarette and smokeless tobacco advertising.

Several comments argued, however, that the restriction on images and color do not further FDA's interest. These comments argued that there is no evidence that the use of color and

images in advertising increases tobacco use among young people.

FDA has fully addressed this assertion. The available evidence demonstrates that pictures and colors have particular appeal to children and adolescents under 18 years of age, and that they are more important to underage individuals than other aspects of the advertisement.²¹³ Young people pay attention to peripheral cues in an advertisement, such as the models that appear in them, color, and scenery, and it is these components that tobacco advertisers use to create the images that are so important to people under the age of 18. Thus, the restriction on images and colors will have a particular effect on the appeal of advertisements to young people and make these advertisements a significantly less effective means of communicating to this group.

(56) Several comments also argued that FDA's restriction on the use of colors and images is not narrowly tailored, pointing to the fact that the agency proposed to eliminate the use of all visual images and graphic designs in cigarette and smokeless tobacco advertisements.

These comments misinterpret the rule. FDA has not restricted all use of color and images. FDA has provided that these mechanisms may continue to be used in publications with primarily adult readership and in adult-only establishments. The agency has endeavored to restrict as little speech as possible. FDA has found, however, that it could not limit the appeal of cigarette and smokeless tobacco advertising to the young if it did not restrict the use of image and color.

Each of the cases relied upon by the comments is fundamentally distinguishable from the current situation. In each of these cases, the body seeking to restrict the advertising in question failed to present any evidence that the restriction was addressing an actual harm (see *Zauderer*, 471 U.S. at 648-649; *Shapero*, 486 U.S. at 479-80; (see also *Florida Bar v. Went For It, Inc.*, 115 S.Ct. at 2378 ("Finally, the State in *Shapero* assembled no evidence attempting to demonstrate any actual harm caused by targeted direct mail."); *In re R. M. J.*, 455 U.S. at 206). Here, in contrast, the record fully establishes the reality of the harm, and that FDA's interest will be directly and materially advanced by the

²¹² *Zauderer* actually states "* * * through the least restrictive available means." However, in *Board of Trustees of State University of N.Y. v. Fox*, 492 U.S. at 479-481, the Court clarified this phrase as requiring narrowly tailored means.

²¹³ See, e.g., Petty, R. E., and J. T. Cacioppo, *Communication and Persuasion: Central and Peripheral Routes to Attitude Change*, Springer-Verlag, New York, 1986.

restriction on colors and images. For these reasons, FDA finds no merit to these comments.

In summary, FDA finds that the evidence amassed during this investigation and provided by comments provides ample support for its requirement that all forms of advertising that children see and are exposed to can have an effect upon their attitudes about tobacco use.

The empirical studies and surveys, expert opinion, anecdotal evidence, industry statements, and consensus report described in section VI.D.5. of this document implicate advertising as an important source of information for young people's attitudes about, and use of, tobacco products. This evidence shows that any regulation that hopes to be successful must be comprehensive and include some type of restriction upon all forms of advertising and promotions. FDA's regulation provides restrictions that will contribute directly and materially to that end but that are tailored as narrowly as possible. Except in the limited case of outdoor advertising within 1,000 feet of schools, no informational advertising will be disturbed. However, those aspects of advertising that have particular appeal to young people will be banned.

Color and Imagery—Color and imagery are necessary ingredients for advertising in conditions of "low involvement," such as occurs when skimming a magazine or seeing a billboard (see sections VI.B.1.b. and VI.B.1 c. of this document).

FDA's restriction will eliminate the color and imagery but will permit information to be communicated. This requirement is as important for in-store advertising, billboards, and direct mail, as it is for traditional publications. As discussed in this section, young people get their information and product imagery from all these sources: (1) Point of sale advertising confronts young people when they go to make a purchase. The imagery is as large as life and presents the child with an enticement at the time when purchase is immediately available. It can as effectively impart information to adults with words. (2) Direct mail can frequently wind up in the hands of a young person or be addressed personally to the child or adolescent. One study found that 7.6 percent of children 12 to 17 years questioned had received mail personally addressed to them from a tobacco company (1.6 million teens).

Billboards—Billboards provide a major source of information about

tobacco for young people. One study published in *Advertising Age* (April 27, 1992), found that 46 percent of children 8 to 13 years old and 34 percent of children 14 to 18 cited billboards as the predominant advertising medium for tobacco products (see section VI.E.3. of this document). The Starch Survey conducted for R.J. Reynolds found that 51 percent of children 10 to 17 who recognized Joe Camel as a tobacco mascot, reported seeing him on billboards (see section VI.D.3.d. of this document).

Cross-Country and International Studies—Studies described evidence that regulations that are stringent and comprehensive will have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones (see section VI.D.6.a. of this document). The text-only requirement, while not as stringent as a ban, will accomplish its purpose while preserving the informational function of advertising.

Finally, the regulation is narrowly tailored. It permits adult publications and adult locations to display advertising with images and colors. The agency has attempted to define these venues with as much precision as possible but recognizes that there may be some difficulties in application. It, therefore, has made it clear that it will work with the industry to try to establish as clear rules as possible. In-store, outdoor, and direct mail advertising do not lend themselves to such tailoring. Nonetheless, the agency is confident that adults seeking information about products can be adequately informed at time of purchase or by mail order catalogue using text-only.

5. Section 897.32(a)—Definition of "Adult Publication"

The preamble to the 1995 proposed rule explained that the agency was interested in permitting advertising in publications that are read primarily by adults to continue to use imagery and color. For that reason, under proposed § 897.32(a), advertisements in publications with primarily adult readership would not be restricted to a text-only format. The agency proposed to define such publications as those: (1) Whose readers age 18 or older constitute 85 percent or more of the publication's total readership,²¹⁴ or (2) that are read

by fewer than 2 million people under the age of 18, whichever method ensures the fewest young readers. The agency defined the readership of a publication as the total number of people that read any given copy of that publication and stated in the preamble that it should be measured according to industry standards and, at a minimum, by asking a nationally projectable survey of people what publications they read or looked at during any given time. The preamble to the 1995 proposed rule noted that a reader is one who said that he or she read the last issue of a publication. The 1995 proposed rule provided that before disseminating advertising containing images and colors, it would be the company's obligation to establish that the publication meets the criteria for a primarily adult readership.

Numerous comments were received by the agency regarding the exception from the text-only requirement for adult publications and the definition of an adult publication. Comments from the newspaper, magazine, and advertising industries were particularly critical of the readership thresholds chosen for the definition of an adult publication and were especially concerned about whether there would be any reliable and practical way to determine readership levels for most publications. Many comments from individuals who supported the text-only requirement saw this exception as a possible loophole for the tobacco industry to escape the text-only restrictions.

In a notice published in the Federal Register of March 20, 1996 (61 FR 11349), the agency reopened the comment period to place on the public record a memorandum that provided further explanation of the agency's proposal to exempt publications with primarily adult readership from the text-only requirement. The document provided an additional 30 days to comment on this new information. The memorandum stated that the agency had selected the 85 percent per 2-million threshold based on the public perception that certain magazines are likely to be of interest to young people under the age of 18. The agency extrapolated from the readership percentages for those publications to the proposed threshold levels. Data supporting this line had been placed in the administrative record for the proposed rule (vol. 105, document 1550) and additional readership data was

²¹⁴ This portion of the definition was edited in the final rule to make the two provisions parallel. Thus, § 897.32(a)(2)(i) now reads, "whose readers younger than 18 years of age constitute 15 percent

or less of the total readership as measured by competent and reliable survey evidence."

provided during the comment period. The agency noted additionally that at some point the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless of the percentage of the readership. The agency selected 2,000,000 as that level.²¹⁵

(57) Some comments objected to the proposed readership thresholds, calling them arbitrary and stating that FDA provided no basis, no rational justification, and no evidence for them. One tobacco industry comment stated that it used an FTC methodology based on readership and the number of pages of advertising to conclude that magazines with greater readership by minors tend to have less cigarette advertising than other publications.

Some comments also objected to the 2 million minor readers threshold because it would subject some adult-oriented magazines to the tombstone format even though their percentage of minor readers is very low. One comment cited the following examples and readership figures: *People Magazine* (3,020,000 minors: 7.8 percent of all readers) and *Better Homes and Gardens* (2,042,000 minors: 5.5 percent of all readers); *Time* (1,972,000 minors; 7.66 percent of all readers) and *Newsweek* (1,911,000 minors; 8.01 percent of all readers) are also close to the threshold. In addition, some comments suggested that FDA's explanation that 2,000,000 is a large number is not adequate basis for regulation.

Some comments stated that the proposed thresholds were unfair to the up to 85 percent, or more in some cases, of a publication's readers who were adults. "Such a regulation is inconsistent with the principle that the government may not 'reduce the adult population * * * to reading only what is fit for children.'"

In contrast, comments supporting the proposal stated that just because the line (i.e., thresholds) could be drawn differently was not important as long as FDA can rationally explain why it drew the line where it did. One comment suggested that FDA should require the text-only format in the 10 most read magazines by young people in addition to the present proposal. Some comments recommended requiring the text-only format for advertisements in all publications.

One comment stated that no tobacco advertising, even text-only, should be

allowed whatsoever in publications with youth readership, and adult publications should have text-only tobacco advertisements. This comment also said that the agency should monitor this exception to ensure that tobacco companies don't increase advertising in national adult publications that are widely read by the entire family including children and adolescents and to be wary of tobacco companies creating their own adult publications saturated with tobacco advertising.

Other comments supporting the proposal stated that some degree of overinclusiveness is acceptable and expected because of the difficulties in fine-tuning any regulation. Other comments saw any exception for any publications as a potential loophole that could be used by tobacco companies to continue using imagery in advertising. They said that experience in other countries with tobacco advertising restrictions showed that "the tobacco industry used all of its creativity to manipulate the system to take advantage of whatever opportunities were still available to reach their target audience, particularly young, impressionable individuals."

The comments received, especially from the magazine and newspaper industries, made clear that both defining an adult publication and determining whether a particular publication meets the definition are difficult issues. However, while these comments were helpful in pointing out the difficulty of defining an adult publication, they did not offer any realistic alternative definition in terms of a readership-by-minors threshold. Because of the concern about tobacco use by children and adolescents, which was voiced by virtually all comments pro or con, the agency believes it has sufficient evidence to justify a text-only requirement. However, the agency's concern is with advertising that affects minors and with tailoring the restrictions in this final rule to burden as little speech as possible. Therefore, FDA concludes that an exception from the text-only requirement for publications that are read primarily by adults is still reasonable and feasible.

The agency has decided to retain the exception for adult publications and to retain the readership thresholds in this final rule. The 15 percent young readers threshold is reasonable based on readership data submitted with comments. The 15 percent threshold would require text-only advertising in the following sports and racing magazines: *Sports Illustrated* (18

percent), *Car and Driver* (18.3 percent), *Motor Trend* (22.1), and *Road & Track* (20.6 percent) and in the following general circulation magazines: *Rolling Stone* (18.5 percent), *Vogue* (18 percent), *Mademoiselle* (19.7 percent), and *Glamour* (17.1 percent).²¹⁶ The agency's judgment is based on common public perception that these are the types of magazines that young people under the age of 18 will find of interest and read. Thus, based on public perceptions and inductively given the nature of the magazines involved, FDA finds a 15 percent cut-off to be appropriate.

The 2 million number is justified based upon the agency's concern for young people. The agency finds that at some point, the number of underage readers is so great that the magazine can no longer be considered to not be of interest to children and adolescents under 18 years of age. This threshold would require text-only advertising in a publication like *People*, where the percentage of readers who are minors is only 7.8 percent, but where the number of readers under 18 years of age is 3,020,000. Publications like *Time*, *Newsweek*, *Family Circle*, and *Popular Mechanics*, however, would not be subject to the text-only format under either threshold; based on how these publications are affected, FDA concludes that, on balance, the thresholds are reasonable.²¹⁷ The agency's concern is not with the "intended" audience of the publication because there is no magic curtain between the interests of young adults and adolescents. The agency's concern is to protect children from the appeal of advertising that they cannot avoid. Fifteen percent youth readership or 2 million young readers narrowly addresses this concern.

The agency does not agree with comments that the rule should be made more restrictive by, for example, allowing only text-only advertising in adult publications and no advertising at all in other publications. The text-only format will reduce the appeal of tobacco advertising to young people while allowing communication of important information to adults. The agency will continue to monitor the effect on young people of text-only advertising as well as the exception created for adult publications and will consider taking any additional action that is appropriate.

²¹⁵ See section XV. of this document, Analysis of Impacts, for a discussion of publications that would be affected.

²¹⁶ Barents Group, LLC, citing Publishers Information Bureau and Mediamark Research, Inc., pp. 53–54.

²¹⁷ *Id.*

Finally, the agency finds no basis to the comments' concern that the regulations will reduce the reading level of adults to those of children. The agency has crafted the exception for adult publications specifically to minimize the effect of the regulations on adults. Moreover, text-only, or the absence of color and imagery, will have significantly less impact on adults than on young people. As discussed more fully in the introduction to this section, adults generally have more capacity to engage in high involvement search than do young people. Furthermore, full information will be available to them in the text format. The First Amendment demands no more.

(58) Several comments recognized that FDA made the March 20, 1996, Federal Register document and the associated data in the record publicly available to meet its obligation under the APA to provide interested parties with an opportunity to comment meaningfully on the proposed rule. These comments stated, however, that one of the memoranda, dated March 11, 1996, placed on the public record by the Federal Register document makes clear that FDA had readership numbers in mind when it developed the proposal, but that the agency had failed to disclose those numbers to the public. The comments said that these numbers are neither reflected in the memorandum added to the record in the March 20, 1996, Federal Register document nor the administrative record that FDA has made publicly available. The comments said that the memorandum in question refers to readership numbers that were in comments submitted by the tobacco industry, and thus these numbers could not have been the numbers that FDA considered in developing its proposal. The comments said that FDA's failure to disclose this information rendered the proceeding arbitrary and capricious.

These comments are in error. FDA placed the information that it relied upon in developing the tentative 15-percent threshold on public display at approximately the time that it published the proposed rule. The data appear at pages 95T030074-75 of the administrative record (vol. 105, number 1550). (The numbers are similar but not identical to those supplied by the industry.) As one comment pointed out, in *Connecticut Light and Power Co. v. Nuclear Reg Com'n.*, 673 F.2d 525, 530 (D.C. Cir.), cert. denied 459 U.S. 835 (1982), the United States Court of Appeals for the District of Columbia Circuit stated, "In order to allow for

useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." The agency fully complied with this expectation by including the data that it had reviewed in the material that it made publicly available. Thus, the agency finds the claims in the comments summarized here to be without any basis in fact.

(59) Several comments asserted that the memorandum added to the record in the March 20, 1996, Federal Register document did not provide a reasoned explanation for the threshold that FDA had proposed. Several comments argued that there is no principle in, or discernible from, the memorandum that leads to the choice of 15 percent, as opposed to 49 percent, as the ceiling for the percentage of underage readers a publication could have and still be considered primarily adult. One comment said that FDA's reasoning was circular. Other comments said that FDA had pointed to no facts in the March 20, 1996, Federal Register document or the attendant memorandum that supports its judgment. These comments stated that FDA merely applied an arbitrarily chosen 15 percent figure to readership data and concluded that it had hit the right number. Some comments questioned why a publication with 84 percent adult readership was problematic, while a publication with 86 percent adult readership was not. Of all the comments that criticized FDA's proposed threshold, only one provided any alternative. This comment cited the tobacco industry's voluntary Cigarette Advertising and Promotion Code, Advertising 1(a), which prohibits advertising in publications directed primarily to those under 21 years of age.

In contrast to the foregoing comments, which were from the tobacco and advertising industries, a comment from a coalition of groups concerned about smoking and health stated that the agency's tentative judgment was unbiased, reasonable, and narrowly tailored to meet FDA's stated goal of limiting the specific forms of advertising that have the greatest impact on children to those publications that do not have a regular heavy readership of children.

FDA has carefully reviewed these comments. Based on this review, FDA first considered whether its March 20, 1996, Federal Register document and the memorandum added to the record under that notice had adequately

explained the basis for the proposed threshold.

The legislative history of the APA states that agency notice must be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or arguments thereto (S. Doc. 248, 79th Cong., 2d sess. 200 (1946)). The notice must disclose in detail the thinking that has animated the form of the proposed rule and the data on which that rule is based. (See *Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir. 1977).) In *Connecticut Light & Power v. Nuclear Reg. Com'n.*, 673 F.2d at 530, the court held that a notice of proposed rulemaking should provide an accurate picture of the agency's reasoning, so that interested persons may comment meaningfully on the proposed rule.

The March 20, 1996, Federal Register document and the associated data in the record clearly meet this standard. As stated in this section, FDA made clear that its tentative judgment was based on a review of available data (from Simons Market Research) on the readership profiles of various publications. By dividing the publications based on whether, in the FDA employees' experience, the publications were publicly perceived as being of interest to minors or not and then examining readership information on each publication, FDA employees found that the publications that were viewed as being of interest to young people had readerships that included individuals under the age of 18 at a level of 15 percent or higher. FDA also found that the information on additional publications that it received during the comment period produced results that were consistent with the pattern that emerged from its initial review.²¹⁸

Thus, FDA's reasoning is not circular. FDA based the threshold on its tentative finding, from the work that its employees had done, that the publications viewed as of interest to young people had readerships that were more than 15 percent under 18. Significantly, while the comments of the tobacco and advertising industry disagreed with the basis for the proposed threshold in various ways, none presented any data showing that publications with a youth readership of 15 percent or more are not viewed by consumers as of interest to young people.

It is important to keep in mind that the purpose of the threshold is to ensure

²¹⁸ See memorandum of March 11, 1996, added to the administrative record in the March 20, 1996, Federal Register.

that no more speech than necessary is burdened by FDA's restriction on advertising. Given that FDA wants to ensure that its restriction is as narrowly tailored as possible, in response to the criticisms in the comments, FDA considered whether there was a more appropriate basis on which to craft the restriction. Unfortunately, the comments criticizing the proposal were not helpful. The only suggested alternative to the proposed threshold that they put forward was the provision in the Code. This provision is inadequate on its face, however, because it is based on a minimum age of 21, rather than 18, which is the minimum provided in the laws of all the States and section 1926 of the PHS Act. Moreover, the comment that suggested this alternative gave no indication of how the age group to which a publication is primarily directed would be determined.

As a matter of common sense, FDA focused on the percentage of readers under the age of 18 in the general population and on comparing that percentage to the percentage of readers under 18 years of age for a particular publication. Certain conclusions can logically be drawn on the basis of such a comparison. If the percentage of young readers of a publication is greater than the percentage of young people in the general population, the publication can be viewed as having particular appeal to young readers. A publication with a youth readership percentage that is approximately equal to the percentage of young people in the general population can be viewed as one of general appeal, including appeal to young readers. A publication with a lower percentage of young readers than in the general population, however, would obviously be one of limited appeal to young people, and thus one that could appropriately be considered of interest primarily to adults.

Given the logic of this approach, FDA turned to the U.S. census. What the agency found is that young people between the ages of 5 and 17 constitute approximately 15 percent of the U.S. population.²¹⁹ Since this percentage is the same as the one that FDA used in developing the proposal, this approach fully supports the approach that FDA proposed. (Although 5 and 6 year olds may not be reading magazines, utilizing this age group builds in a margin for error.) It ratifies the judgments that FDA

employees made in arriving at the proposed threshold.

Some may assert that it is mere coincidence that the two approaches produce the same result. FDA disagrees. The congruence of the two approaches, the FDA employee anecdotal search and the use of the census data, is attributable to the basic validity of the premise underlying FDA's initial approach. Magazines have reputations as to the audiences to which they appeal, and those reputations are generally earned based on the nature of their contents. Thus, contrary to the assertions in some of the comments, the 15 percent threshold is well-supported and appropriate.

As for the question as to why a publication with 84 percent adult readership would be problematic, while a publication with 86 percent adult readership would not, the agency turns to the case law on narrow tailoring, which is, as stated in section VI.E. of this document, what this exercise is about. In *Board of Trustees of State University of N.Y. v. Fox*, the Supreme Court stated:

In sum, while we have insisted that "the free flow of commercial information is valuable enough to justify would-be regulators the costs of distinguishing * * * the harmless from the harmful," * * * we have not gone so far as to impose upon them the burden of demonstrating that the distinguishment is 100% complete, or that the manner of restriction is absolutely the least severe that will achieve the desired end. What our decisions require is a "fit between the legislature's ends and the means to accomplish those ends," * * * —a fit that is not necessarily perfect but reasonable * * *. (492 U.S. at 480 (citations omitted))

FDA has done its best to distinguish publications that are likely to be read by children and adolescents from those that are not. FDA finds that, if its restriction on advertising is to be meaningful, it must be based on a line that is enforceable. While only 2 percentage points separate a publication with 84 percent adult readership from one with 86 percent (although those 2 percentage points can mean a difference of tens of thousands of youngsters), the underrepresentation of underage readers in the readership of the latter publication establishes its limited appeal to young readers, and thus that it is less likely to be read by them.

For the foregoing reasons, FDA is adopting the 15-percent threshold.

(60) Comments from an association of magazine publishers and others expressed a number of concerns about the adequacy of current data for determining whether a publication met

the definition of an adult publication. Some comments said that current data and methodology to determine youth readership, while adequate for marketing purposes, are totally inadequate to justify their use as measuring devices for the imposition of criminal or civil liability on the exercise of First Amendment rights. These comments noted that the vast majority of magazines do not subscribe to either adult or youth surveys. Two comments stated that only about 2 percent of all magazines participate in the two major adult audience surveys. One comment stated that participation in the youth readership surveys, Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK, is even more limited, just over one-half of one percent of all magazines.

One comment noted that to comply with the 1995 proposed rule, publications must identify readers of all ages but that current audience measurement systems do not provide this comprehensive coverage especially for readers younger than 12 years of age. Another comment noted that since the survey organizations do not survey individuals on college campuses, in the armed services, or in institutional settings, adult readership would be underestimated. Several comments noted the difficulty in determining readership data for any one issue of a magazine. Another comment noted that multi-issue advertisements would be a problem for publications right around the threshold if the publication crosses back and forth.

Several comments noted that the survey organizations would have to make substantial methodological changes to the surveys to meet the 1995 proposed rule's standard. One comment said that some problems would include adding magazines to the surveys, and dealing with unreliable results. Another comment asked who would decide the research design for the surveys since different research methodologies could be competent and reliable yet result in different conclusions. Another comment said that it could be prohibitively expensive to increase audience samples to create a legally enforceable standard, and that changes to audience measurement procedures could undermine the usefulness of the surveys for their designed marketing information purpose.

One supporting comment from an association of addiction specialists stated that "the agency should require the industry to monitor with surveys of ad recall (correlated with tobacco use

²¹⁹ U.S. Bureau of the Census, Population Paper Listing 21, 1994.

and intention to use patterns) among the population under age 18 years to help the agency understand the extent to which image-based messages continue to reach the young.”

One comment pointed out that it would be virtually impossible to determine a legally enforceable standard for the 15 percent youth readership threshold since there is substantial variation in audience estimates between survey organizations and over time. Several comments noted that FDA’s definition of a reader is not consistent with the definition used by Simmons and MRI.

Some comments suggested that a more realistic measure of who reads a publication would be who subscribes to it. Other comments opposed this alternative stating that the key criteria should be regular readership, not paid subscribers. One comment said that “[t]his alteration of the proposed exemption would destroy the intent and purpose of the advertising limitation.”

Several comments said that the proposal would violate due process by punishing publishers or advertisers who are unable to determine whether their conduct violates the law because the survey data are not sufficiently comprehensive and reliable. Several comments, including one from an association of newspaper publishers, expressed concern about who would determine readership. One comment asked whether a newspaper would be subject to criminal liability based on readership data it supplies, and whether the responsibility for ascertaining whether a publication qualifies as an adult publication would be on those running the advertisements.

The agency recognizes the limitations of current readership data and the difficulties of using current readership surveys to meet the requirements of this rule. However, the agency concludes that the exception from the text-only format for adult publications is feasible as well as reasonable. First of all, the burden of proof for determining youth readership is placed by the rule on the tobacco company doing the advertising, not on the publication or the advertising agency. Under § 897.32(a)(2), the tobacco company will need to be able to demonstrate that a publication in which it is running an advertisement with images and colors meets the definition of an adult publication. Therefore, only the tobacco company will be subject to any penalties for improperly placing advertisements, even if it used data provided by the publication as part of its determination.

Second, either of the two methodologies can be used to measure readership. In addition, the agency has modified § 897.32(a)(1) and (a)(2) to make clear that any other competent and reliable private sector survey evidence may be used. A tobacco company may use one of the two major customary and reasonable readership surveys (such as MRI and Simmons). The agency does not believe that there is only one acceptable methodology. The agency is willing to accept the standard methodology currently used by MRI and Simmons as evidence. Moreover, the agency is willing to use the age range of 12 to 17, which appears to be the current standard for defining youth, in determining youth readership.

If a particular publication is not currently covered by one of the major surveys, it is the tobacco company’s responsibility to develop the readership data necessary to justify a decision to advertise in that publication. The company could request a survey by one of the major survey firms, or it could develop an acceptable alternative. In either case, the agency will be available to work with the company. The company will always have the alternative to advertise in any publication in the text-only format.

The agency also acknowledges the difficulty in determining the youth readership for any particular issue of a publication. Thus, data from a survey for the most recent issues of a publication can serve as proof of readership for comparable upcoming issues unless a particular upcoming issue is being targeted at younger readers. The survey schedule used by the major survey organizations would be acceptable to the agency. A tobacco company could utilize a more frequent survey schedule if it believed the readership had changed in its favor. A rolling average of a certain number of issues could be used, for example, to determine youth readership. The problem of multi-issue contracts for advertising could be solved by a survey for a comparable period of time (e.g., winter months) preceding the contract.

The agency is willing to accept the definitions of a reader that are customarily used by the major survey organizations. The agency does not agree that using subscribers to a publication in lieu of readers is a better measure. Many children who read a publication will not be listed as subscribers (for example, *Sports Illustrated* has a youth readership of 18 to 20 percent but a youth subscriber rate

of only 6.5 or 7 percent).²²⁰ Also, adults are more likely to subscribe for their families, thereby creating an underestimation of youth exposure.

(61) Several comments assumed that the purpose of the March 20, 1996, Federal Register document was to justify the restriction on advertising format that the agency had proposed for other than adult-oriented publications. These comments argued that explaining how the agency arrived at the 15 percent and 2 million readership thresholds does not approach the factual justification necessary to restrict First Amendment freedoms.

Other comments asserted that FDA’s assumption that certain magazines were of interest to those under 18, as the starting point in arriving at the 15 percent threshold, shows that the limits were content based. These comments argued that basing restrictions on content violated the First Amendment.

The comments misunderstood FDA’s purpose in proposing, and in adopting, the 15 percent and 2 million under 18 readership thresholds and of the memoranda added to the public record in the March 20, 1996, Federal Register document that indicated how the agency tentatively arrived at those thresholds. As discussed in section VI.D. of this document, the evidence in this proceeding establishes the effect of cigarette and smokeless tobacco advertising on those under 18 years of age. This evidence fully justifies FDA’s decision to restrict the advertising for these products.

However, in imposing such a restriction on commercial speech, FDA has an obligation to ensure that the restriction is no more broad than necessary to serve the agency’s substantial interests (*Board of Trustees of State University of N.Y. v. Fox*, 492 U.S. at 476). The purpose of the memorandum was to document FDA’s efforts to tailor the restriction to ensure that it did not restrict advertising in those publications that were not likely to be read by children or adolescents and thus were not likely to have an effect on the group that FDA is trying to protect. Consequently, contrary to the claims of the first group of comments, the agency’s goal in the memorandum was not to justify a restriction on First Amendment freedoms but to explain how it sought to ensure, and why its tentative decision was that, the limits it proposed to place on the coverage of the

²²⁰ Interview on “The News Hour With Jim Lehrer,” Public Broadcasting Systems, May 16, 1996.

restriction are reasonable (see *Id.* at 480).
On the other hand, other comments that opposed FDA's proposed restriction on format said that the threshold would have different impacts on similar publications. One comment provided the following examples of publications that would be considered "youth oriented" or primarily adult under the 15 percent threshold (the comment argued that the effects of the 2 million readership threshold were not relevant to the rationality of the 15 percent threshold):

Table 1b.—Examples of Publications

Youth Oriented Publications	Primarily Adult Oriented Publications
Popular Science	Popular Mechanics
Soap Opera Weekly	Soap Opera Digest
Outdoor Life	Field and Stream
Cable Guide	TV Guide
Mademoiselle	Cosmopolitan

The positions taken by these comments makes clear that the thresholds were not content based. If the thresholds were content based, then publications that have similar content would be subject to the same restriction. They are not. The reason they are not is that FDA's goal in arriving at the thresholds was to ensure that cigarette and smokeless tobacco advertisements that are likely to be seen by children and adolescents are the kinds of advertisements that are likely to appeal to them. The agency's only way of judging the likelihood that an advertisement that appears in a publication will be seen by those under the age of 18 is by considering the readership profile of that publication. Thus, the agency has tailored the threshold to either reflect the percentage of readership that are under 18 years of age or to ensure that publications with an extensive youth readership are covered.
The comments that complained about the differing impact of FDA's threshold on similar publications, given the purpose of the threshold, serve to underline its significance. The information submitted by the comments shows that there are significant differences in the readership of similar publications and thus in the likelihood that the material contained in these publications will be seen by young people. The treatment of publications under the agency's restriction reflects the latter fact, not the former.
Popular Science magazine has a readership that is 6 percent more

youthful than *Popular Mechanics*; *Soap Opera Weekly* has a 3 percent more youthful readership than *Soap Opera Digest*; and there is a 9 percent bigger youth audience for *Outdoor Life* than for *Field and Stream*. These differences are not minor or meaningless and demonstrate that, although the 15 percent threshold is not perfect, it will serve, as it was designed to, protect those under 18. *TV Guide* and *Cosmopolitan* are not excluded although, as mass distribution magazines the percentage of young readers is less than 15 percent, because they attract over 2 million young readers—a number of young people too large to ignore.²²¹
(62) Many comments, especially from the magazine and newspaper industries, expressed concerns about the impact of this proposal on their way of doing business. One comment stated that the proposed text-only format would provide financial disincentives for magazines and newspapers to attract young readers, especially if the publication were near the borderline of being required to use the text-only format. This comment suggested that the provision would affect editorial and content decisions regarding young readers.
Some comments noted that newspapers have been struggling to attract young readers raised on television, but that success in doing this might cause the loss of significant tobacco advertising revenue. One newspaper industry association comment stated that the rule would discourage newspaper programs promoting youth reading and literacy. Some comments stated that the loss of advertising revenue could cause publications to decrease content and increase prices. Some comments thought the result of these effects of the rule would be losses in jobs in the newspaper and magazine industries.
The agency is not sure what impact the exception for adult publications will have on incentives for magazines and newspapers to attract young readers, on editorial content, and on youth literacy programs. The comments that raised these issues mostly speculated about these effects and did not provide any data as to how many of the thousands of newspapers and magazines in the United States carry tobacco advertising, or on what portion of their total advertising revenue comes from tobacco companies. Many business factors affect

a publication's decisions regarding its target audience and editorial content, and these are likely to change for a variety of reasons. Those publications affected by this regulation will have to adjust just as they would if a major advertiser reduced its advertising. Under the rule, all publications could still accept text-only advertising. The cigarette and smokeless tobacco industries are capable of designing their advertising to be attractive to adult readers (see section VI.E.4. of this document). Thus, it seems as likely that the effects of the rule in these areas will be minimal and will be far outweighed by the overall benefits of reducing youth smoking. The effect of the rule on prices and jobs in the magazine and newspaper industries is addressed in the section on the economic impact of the rule.
(63) Several comments argued that FDA's restrictions on the format of advertising, and the standard that it proposed for deciding whether a publication has a predominantly adult readership, interfere with the rights of newspapers and magazines to decide what to print. One comment said that some publications will not want to give up revenue from tobacco advertising. Therefore, the comment continued, these publications will base decisions about editorial content on how appealing a particular story would be to readers under the age of 18. Because of the impact of the restrictions on editorial content, the comment concluded, they should be subject to strict scrutiny rather than the more limited scrutiny given to commercial speech.
FDA finds no merit to this argument. A similar argument was made in *Pittsburgh Press Co. v. Pittsburgh Com'n on Human Relations*, 413 U.S. 376 (1973). The newspaper company in that case, which involved a First Amendment challenge to a municipal ordinance that prohibited a newspaper from carrying gender-designated advertising for nonexempt job opportunities, argued that the focus of the case must be on the exercise of editorial judgment by the newspaper rather than on the commercial nature of the ads in question.
The Supreme Court rejected this argument. The Court said that under some circumstances, at least, a newspaper's editorial judgments in connection with an advertisement take on the character of the advertisement. In those cases, "[t]he scope of the newspaper's First Amendment protection may be affected by the content of the advertisement"

²²¹ Barents Group, LLC, citing Publishing Information Bureau and Mediamark Research, Inc., pp. 53–54.

(*Pittsburgh Press Co.*, 413 U.S. at 386). The Court said that, at least under some circumstances, a commercial advertisement remains commercial in the hands of the media (*Id.* at 387). The Court found that nothing about the decision to accept a commercial advertisement for placement in a gender-designated column lifts the newspaper's actions from the category of commercial speech. The Court said that the ad was in practical effect a commercial statement (*Id.* at 387–88; see also *United States v. Hunter*, 459 F.2d 205, 212 (4th Cir. 1972) (“But it has been held that a newspaper will not be insulated from the otherwise valid regulation of economic activity merely because it also engages in constitutionally protected dissemination of ideas”)).

Here, the question that is raised is whether or not a publication will decide to put itself in a position of being able to accept an advertisement that is particularly appealing to individuals under 18 years of age or not. Nothing about this judgment distinguishes it from the commercial speech itself. Because nothing about FDA's restrictions would prevent the publication from carrying a cigarette or smokeless tobacco advertisement no matter what judgment the publication makes, essentially the editorial judgment comes down to the question of what will be the format of the advertisement that it will carry. This judgment clearly comes within the category of commercial speech, and FDA has fully justified its regulation of commercial speech under the *Central Hudson* test.

6. Advertising—§ 897.32 Requirements for Disclosure of Important Information

a. *Established name and intended use*—§ 897.32(c). Proposed § 897.32(b) (now renumbered as § 897.32(c)) provided that each manufacturer, distributor, and retailer (of tobacco and smokeless tobacco) advertising or causing to be advertised, disseminating or causing to be disseminated, advertising, but not labeling, permitted under § 897.30(a), shall include, as provided in section 502(r) of the act, the product's established name and a statement of its intended use as follows: “Tobacco—A Nicotine Delivery Device,” “Cigarette Tobacco—A Nicotine-Delivery Device,” or “Loose Leaf Chewing Tobacco,” “Plug Chewing Tobacco,” “Twist Chewing Tobacco,” “Moist Snuff” or “Dry Snuff,” whichever is appropriate for the

product, followed by the words “A Nicotine-Delivery Device.”

The preamble to the 1995 proposed rule explained that section 502(r)(1) of the act requires, for any restricted device, that all advertising or other descriptive printed material contain a true statement of the device's established name. Under section 502(r)(2) of the act, a restricted device is misbranded unless all advertising contains “a brief statement of the intended uses of the device.” The agency explained in the preamble to the 1995 proposed rule that it is necessary to require that the product's established name and intended uses be placed on all advertising, under section 520(e) of the act, as a measure that affirmatively identifies the products to persons reading the advertising (the other brief statement requirements under section 502(r)(2) of the act are discussed in section IV.E.6.b. of this document).

The agency did not receive any comments on the “established name” provision and has thus codified the provision in the final rule as § 897.32(c). The agency has modified the “intended use” provision in this final rule to require that cigarette and smokeless tobacco advertising contain the statement “A Nicotine-Delivery Device for Persons 18 or Older.” For clarity, the agency has referenced subpart D generally rather than § 897.30(a) specifically. As stated in the 1995 proposed rule, the established name requirement applies to both tobacco and smokeless tobacco.

(64) Several comments opposed the proposed “intended use” provision. One tobacco industry comment stated that FDA's proposal is not authorized under section 502(r) of the act because: (1) The “intended use” of tobacco products is for smoking taste and pleasure, not a “nicotine delivery device;” (2) the “intended use” provision of the act does not require that manufacturers list all information related to all purposes for which a drug is intended; and (3) FDA is not free to prescribe an “intended use” of its own invention. The comment also argued that FDA's statement, which communicates only that a cigarette yields nicotine, is not a statement of “intended use” and is of no value to consumers who obtain more complete nicotine information that cigarette manufacturers already provide in advertising.

The agency disagrees with the comments stating that it is not free to prescribe an intended use. As discussed in this section, the agency is required by

section 502(r)(2) of the act to require a brief statement of intended use for all restricted devices.

Additionally, it is within FDA's primary jurisdiction and expertise to determine a device's intended use. FDA has decades of experience evaluating the intended uses of FDA-regulated products, including restricted devices, prescription and over-the-counter drugs, biological products, and dietary supplements through its review and approval process for those products.

As described in the 1996 Jurisdictional Determination annexed hereto, the available evidence demonstrates that manufacturers intend to affect the structure and function of the body by delivering pharmacologically active doses of nicotine to the consumer. Although the agency proposed that the intended use include the language “Nicotine Delivery Device,” the agency has determined, based on the comments received, that a more accurate statement of the intended use would provide more value to consumers. Because cigarettes and smokeless tobacco products can legally be sold only to those persons 18 years of age and older, the agency believes the intended use statement should reflect the target population for which the product is intended. Often, the intended use statement for a drug or device includes the patient population by whom the product may be used. Accordingly, the intended use statement has been revised to require the following language on all advertisements for cigarette and smokeless tobacco: “A Nicotine-Delivery Device For Persons 18 or Older.”

b. *Section 897.32(d) Brief statement.* Proposed § 897.32(c) and (d) would have required that each manufacturer, distributor, and retailer of cigarettes include in all advertising, but not labeling, a brief statement, printed in black text on a white background that was readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning. Because the Smokeless Act preempts other statements about tobacco use and health in advertising, the 1995 proposed rule stated that the provision only applied to cigarettes (and not smokeless tobacco). The 1995 proposed rule provided one brief statement as an example (“ABOUT 1 OUT OF 3 KIDS WHO BECOME SMOKERS WILL DIE FROM THEIR SMOKING”) (60 FR 41314 at 41338). The agency requested comment on what other information should be included in the brief statements concerning relevant

warnings, precautions, side effects, and contraindications and on how best to ensure that the statement will be clear, conspicuous, and prominently displayed. The agency also requested comment on whether it should require a listing of the component parts or ingredients of these restricted devices.

The preamble to the 1995 proposed rule explained that the agency was proposing to require this brief statement under section 502(r)(2) of the act. The preamble stated that the act specifically excludes labeling from the requirements in section 502(r) of the act. The 1995 proposed rule stated that the agency would specify the design, content, and format of the brief statements, in part based on focus groups with young people, to ensure that the information would be communicated effectively to young people.

The agency received numerous comments on this brief statement, and about half of the comments supported the provision and half opposed it. Most of the comments that supported the brief statement requirement recommended other information to be included in the brief statement, and offered suggestions on how best to ensure that the statement will be clear, conspicuous, and prominently displayed.

During the comment period, FDA performed extensive focus group testing on the brief statement to evaluate the content and various formats for the brief statement to determine if the information would be communicated effectively to young people. Those results were placed on the public record and made available for comment, 1 month prior to the close of the comment period. FDA received a few comments on the focus group results from the tobacco industry and concerned individuals.

The final rule does not specify a particular statement to be placed in all cigarette advertisements, as proposed in § 897.32(c), nor does it require the brief statement to be targeted to young people. Rather, the agency has concluded that the current Surgeon General's warnings contain important health information, concerning the risks related to the use of cigarettes, of the sort required under section 502(r) of the act and, consequently, has decided not to require a specific, different statement. Specifically, the Surgeon General's warnings currently required to be included in cigarette advertisements and on cigarette packages contain the following information: Cigarettes cause lung cancer, heart disease and

emphysema, may complicate pregnancies, and contain carbon monoxide; smoking by pregnant women may result in fetal injury, premature birth and low birth weight; and quitting reduces serious risks.

The agency has also considered the fact that there is a heightened public awareness by adults of the addictiveness of cigarettes, as well as the serious health effects that can result from their use. Much of this awareness stems from: (1) The publicity of the numerous Surgeon General's reports that have issued in the last few decades, (2) the campaigns supported by health groups and State and local governments, as well as (3) the attention generated by the agency's investigation of these products.

Under the current circumstances, the agency has determined that the current Surgeon General's warnings, which must be in virtually all advertisements, contain the type of important health information required under section 502(r) of the act. Accordingly, the agency has determined that advertisements that contain the current Surgeon General's warnings meet section 502(r) of the act.

Finally, because the agency has determined that the Surgeon General's warnings are adequate, and those warnings must be displayed in a format prescribed by law, there is no longer any need for proposed § 897.32(d), which required that the brief statement be readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning.

(65) One comment argued that the proposed warning requirement for tobacco is not a warning, nor is it part of a brief statement, as those terms are used in section 502(r) of the act. The comment stated that because FDA proposes to allow tobacco to be marketed as devices subject only to general controls, one of which is the brief statement provision, then the "brief statement" must be capable of providing, with other general controls, "reasonable assurance of the safety and effectiveness" of tobacco under the act. The comment argued that because FDA regards tobacco as having "dangerous health consequences" (60 FR 41314 at 41349), and does not believe that tobacco can be "safe and effective" for anyone, then FDA's proposed "brief statement" provision is not within the scope of the act. The comment stated that the only warning that is consistent with FDA's view would be one that warned against anyone using the device at all.

The comment miscomprehends the purpose of the brief statement, which is to provide information about the risks and benefits regarding the product. This provision is not intended to serve, on its own, as a mechanism to provide reasonable assurance of safety for these products.

(66) One comment argued that even if FDA could validly require a brief statement for tobacco as an exercise of its statutory authority, the imposition of a warning requirement as part of the brief statement is invalid because advertisements for tobacco are already required to bear the Surgeon General's warning under 15 U.S.C. 1333(a)(2) and (a)(3). In addition, the comment stated that FDA is not authorized to require that the information be presented "in a lurid fashion to achieve an ulterior purpose" or as "a threat intended to scare people," and that the warning information is meant only for the purposes of enabling the physician or patient to make a rational risk/benefit judgment.

Another comment argued that the contention that the Surgeon General's warning is "ineffective" is without merit. The agency agrees that the current Surgeon General's warnings contain the type of important health information that advertisements must contain under section 502(r)(2) of the act. Accordingly, the agency has determined that advertisements that contain the current Surgeon General's warnings sufficiently meet the brief statement requirement of the act.

(67) One comment stated that the brief statement provision would "cause so much visual clutter in tobacco advertising as to render effective communication nearly impossible."

Another comment stated that FDA will be unable to justify the economic burdens on communication with adults that are created by the brief statement requirement because, in order to include all the mandated statements, advertisers would be required to purchase additional space and thus would have to reduce, because of budgetary pressures, the number of advertisements they could place.

Because the agency has determined that the current Surgeon General's warnings will be sufficient as a brief statement, the issue raised by these comments is no longer pertinent.

(68) Several comments which supported the 1995 proposed rule suggested alternative statements and submitted recommended language for the brief statement. Many comments suggested specific types of information

for inclusion in the brief statement. Several comments provided recommendations on how the statement could be "clear and conspicuous." One comment stated that messages must be carefully pretested on members of the target audience to ensure that labels: (1) Attract attention; (2) are personally relevant; and (3) do not elicit psychological reactance, i.e., behaviors directly counter to those desired due to irritation, rebellion, or misinterpretation. The comment recommended that messages be varied periodically to ensure that they remain attention-getting and pertinent.

Several comments recommended that the rule be more specific in what is meant by "readable, clear, conspicuous, prominent" by giving either a detailed set of format specifications of the lettering and background or by giving a set of performance criteria. One comment enclosed an unpublished review on warnings, which recommended that warnings should attract attention of the target audience by using high contrast and color; separating warnings from other information; considering size (relative to other information in the display) and location (since people tend to scan left to right and top to bottom warnings should be located near the top or to the left, depending on the overall design of the display); and by using signal words to capture attention, such as "CAUTION," OR "WARNING," pictorials, rotational warnings to avoid habituation, and auditory warnings. In addition, the review stated that warnings should describe the hazard, without "overwarning," and describe the nature of the injury, illness or property damage that could result from the hazard. The review recommended that written warnings should be organized with an attention getting icon and signal word at the top, then hazard information, then instructions. Finally, the review recommended that warnings should instruct about appropriate and inappropriate behaviors, motivate people to comply, be as brief as possible, and should last and be available as long as needed.

One comment recommended that the relevant warnings, precautions, side effects, and contraindications be in a language understandable and appealing to even the youngest potential tobacco user. Several comments recommended that a minimum size should be required, expressed as a percentage of the advertisement (e.g., 25 percent of the advertisement). Several comments recommended that a border be placed

around the brief statement and suggested other graphic enhancements to make the information in the brief statement more noticeable.

The agency recognizes that there are several ways to communicate the requirement for "relevant warnings, precautions, side effects, and contraindications" set forth in section 502(r) of the act. In this case, however, the agency has determined that the current Surgeon General's warnings are sufficient as at least one way of complying with section 502(r) of the act. In addition, the agency appreciates the numerous suggestions on how to make the brief statement readable, clear, conspicuous, and prominent. However, since no additional information will be required at this time, and the format for the Surgeon General's warnings is determined by law, the agency has deleted proposed § 897.32(d).

(69) One comment stated that FDA's attempt to gather information through the focus group studies about adolescents' perceptions of the adequacy of the Surgeon General's warnings for use in designing its own additional warning underscores the direct conflict between the Cigarette Act and the proposed regulation.

This comment has misinterpreted the purpose and the results of the focus group testing. FDA's focus groups were intended to explore how adolescents perceive various messages. The Surgeon General's warnings, as well as other warnings, were tested with the focus groups merely to serve as a basis for reactions to messages that currently exist in the public domain.

(70) FDA received few comments concerning the focus group results. In general, these comments questioned the validity and usefulness of focus groups. Further, some comments asserted that the warnings preferred by the young people in the focus groups may have unintended consequences.

As discussed in this section, the focus groups tested a variety of specific brief statements that were intended to be directed towards young people. However, the agency has decided that the final rule will not specify a particular brief statement, but will accept the current Surgeon General's warnings as sufficient. Moreover, section 502(r) of the act does not require that the brief statement be directed to young people, but rather that it provide "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications." This function is adequately filled by the intended use

statements required by § 897.32(c) and the Surgeon General's warnings. Thus, because the final rule is not based on the focus group results, the agency need not address the previous comments concerning the focus group results.

7. Section 897.34(a) and (b)—Promotions, Nontobacco Items, and Contests and Games of Chance

The agency proposed in § 897.34(a) to prohibit the sale or distribution of all nontobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. FDA stated in the 1995 proposal that this requirement is intended to reach such items as tee shirts, caps, and sporting goods and other items bearing tobacco brand names or other indicia of product identification (60 FR 41314 at 41336).

As discussed in the preamble to the 1995 proposed rule (60 FR 41314 at 41336), a Gallup survey found that about one-half of adolescent smokers, and one-quarter of all nonsmokers, own at least one promotional item. The IOM found that this form of advertising is particularly effective with young people. Young people have relatively little disposable income, so promotions are appealing because they represent a means of "getting something for nothing." In many cases, the items—tee shirts, caps, and sporting goods—are particularly attractive to young people. Some items, when used or worn by young people, also create a new advertising medium—the "walking billboard"—which can come into schools or other locations where advertising is usually prohibited (60 FR 41314 at 41336). Moreover, this form of advertising has grown in importance over the last 20 years. The portion of annual expenditures of the cigarette industry devoted to these promotions rose from 2.1 percent in 1975 to 8.5 percent in 1980.²²²

On the basis of the evidence before it, the agency tentatively concluded that the ban on nontobacco items was necessary to eliminate the something-for-nothing appeal of these items, as well as to prevent wearers or users of these items from becoming image-laden walking advertisements.

FDA proposed in § 897.34(b) to prohibit all proof of purchase transactions of nontobacco items as well as all lotteries, contests, and games of chance associated with a tobacco purchase. The agency stated that, because contests and lotteries are

²²² IOM Report, p. 109.

usually conducted through the mail, it was not able to devise regulations that would reduce a young person's access to contests or lotteries.

(71) FDA received a substantial number of comments concerning the 1995 proposed rule to prohibit these promotional activities. Comments opposing these provisions argued that tobacco companies should be allowed to advertise in a fair manner however they wish. Many comments from individuals stated that they like the "freebies." They contended that the agency does not have authority to regulate the clothes people wear or to ban contests and promotional activities that are only available to adults. A number of comments from individuals stated that what they did with their lives was their business.

Comments also objected to the agency's proposed ban on contests and games of chance. These comments stated that existing laws and regulations already provide a sufficient regulatory framework.

The majority of comments, however, supported these provisions and stated that children and adolescents should not be "walking billboards." Moreover, these comments argued that even though young people cannot participate in the contests, they can easily get caught up in the excitement of promotional activities. Comments declared that prohibiting tobacco product-related gifts, items, contests, and games of chance will break the enticing connection between sports and tobacco use.

The agency agrees with the comments that said that existing laws and regulations of lotteries, contests, and games of chance are sufficient. First, there appears to be little evidence about these practices and young people's participation in them. Secondly, current laws prohibit all games of chance and the like that are advertised on a product label or that are conditioned on the sale of the product. Therefore, participation, if any, by minors is not necessarily related to a purchase. Third, any promotional material associated with the advertising of the games, which is of primary concern, will be required to appear in text-only format. Therefore, the agency has modified this section to delete the ban on these practices. In addition, the agency has modified § 897.34(a) to clarify that responsibility for complying with this provision rests with the manufacturer and the distributor of imported tobacco, but not other distributors or retailers.

(72) Comments differed on whether proposed § 897.34(a) is beyond FDA's

authority under the act. The comments addressed a number and variety of legal issues. One comment stated that FDA has no authority to ban the items and services covered by § 897.34(a). It stated that items and services (e.g., travel agencies) bearing indicia of tobacco product identification are not foods, drugs, cosmetics, or devices as defined in the act and, therefore, are outside the agency's jurisdiction.

Another comment stated that nontobacco items cannot be regulated as advertising in the way FDA proposes because: (a) The 1995 proposed rule extends to goods and services provided to product users in connection with cigarette purchases, most of which are not displayed or disseminated to the general public, and thus do not constitute advertising (see *Marcy v. Nissen Corp.*, 578 F. Supp. 485, 507 (N.D. Ind. 1982), *aff'd sub nom. Marcy v. Marcy Gymnasium Equip. Co.*, 725 F.2d 687 (7th Cir. 1983)); and (b) many of the types of items covered by § 897.34(a) are promotional items but not advertising (e.g., a logo-bearing mug given away or sold by a manufacturer is not an advertisement).

One comment, which favored the provision, provided support for the classification of promotional items as advertising. The comment referenced *Public Citizen v. FTC*, 869 F.2d 1541 at 1556 (D.C. Cir. 1989), in which the U.S. Court of Appeals for the D.C. Circuit held that the Smokeless Act requirement that "advertisements" carry health warnings "plainly covers utilitarian items [nontobacco items] that are distributed for promotional purposes." FTC defined utilitarian objects as items that are sold or given or caused to be sold or given by any manufacturer, packager, or importer to consumers for their personal use and that display the brand name, logo, or selling message of any tobacco product (16 CFR 307.3n). FDA's interpretation of what is covered by § 897.34(a) and (b) is consistent with this definition. The comment also stated that as a result of that court case, FTC's smokeless tobacco rules now require that utilitarian items promoting smokeless tobacco bear specific health warnings required of all smokeless tobacco advertising (16 CFR 307.9).²²³

²²³ The FTC comment also indicated that although nontobacco items are "advertising" under the Smokeless Act, a different legislative history exempts these items from the Cigarette Act. The comment stated that the definition of advertising under the Cigarette Act is understood to exempt utilitarian items because of legislative history expressly stating Congress's intent to preserve the arrangement under consent agreements entered into

Another comment pointed out that the *Public Citizen* case provides ample legal precedent not only for the conclusion that promotional materials are advertising, but also that they have a direct impact on a minor's tobacco use. The court, relying on evidence compiled by the FTC, found that "in the case of adolescents, utilitarian items might be among the most effective forms of promotion" (869 F.2d at 1549 n. 15). In addition, the lower court provided an additional rationale for restriction based upon the items' longevity and durability.

[P]rinted advertising is customarily quickly read (if at all) and discarded (as, of course, are product packages) by typical consumers. "Utilitarian objects," on the other hand * * * are retained, precisely because they continue to have utility. They are also likely to be made of durable substances: fabric, plastic, glass, or metal. They may be around for years. And each use of them brings a new reminder of the sponsor and his product * * *

(688 F. Supp. 667, 680 (D.D.C. 1988), *aff'd*, 869 F.2d 1541 (D.C. Cir. 1989))

The agency finds that the reasoning in the *Public Citizen* case is persuasive and compels the conclusion that branded nontobacco items are advertising. It also finds that young people acquire and use these products.

Moreover, the agency finds nothing in the *Marcy v. Nissen Corp.* case is to the contrary. In relevant parts, that case involved an endorsement that appeared in the front of a users' manual. The court held that this endorsement did not constitute "advertising" because it is not "distributed to the general public for the purpose of promoting plaintiffs' products: it is a user's manual and is provided to a purchaser of the defendants' equipment together with the equipment in order to describe its proper use" (578 F.2d at 507). Promotional items are distributed or sold to the general public. They are festooned with the product's brand name or identification, and they are intended to remind the user and others who see the item about the product. As the court in *Public Citizen* found, "each use of them brings a new reminder of the sponsor and his product" (688 F. Supp. at 670). Therefore, the comments' suggestion that these advertising items are beyond FDA's jurisdiction is plainly wrong.

(73) One comment, which had argued that promotional items were not drugs or devices nor were they advertising, objected as well to FDA's alternative

by the tobacco industry in 1972 and 1981 (*Public Citizen*, 869 F.2d at 1555).

categorization of these items as labeling. The comment stated that nontobacco items could constitute "labeling" only if there were a "textual relationship" between them and the product (*Kordel v. United States*, 335 U.S. 345, 350 (1948)). The comment argued further that items that provide no more substantive information than a brand name, logo, or recognizable color or pattern of colors simply do not explain the use of the product, and therefore do not constitute labeling. The comment concluded that if the items are not advertising or labeling, FDA would not have authority to take the actions required by this provision.

The agency agrees that these promotional items are neither devices nor drugs; however, this fact is not relevant to the agency's authority to proscribe their use. As explained earlier in this document, FDA has authority to impose restrictions on the access to and promotion of devices under section 520(e) of the act, and this authority provides the basis for restrictions on advertising, including those that FDA is imposing on promotional items. FDA also derives authority for these restrictions from section 502 of the act. Likewise, it is not relevant in this instance whether the items are described as advertising or labeling. The agency has the authority to restrict them because they promote the use of restricted devices, cigarettes and smokeless tobacco, by young people and thus undercut the restrictions on access to these products that FDA has imposed. Therefore, FDA has authority to regulate how these promotional items are used by manufacturers, distributors, and retailers of the restricted devices.

(74) Many comments challenged FDA's evidentiary basis for this provision. Those opposing the provision made the point that promotional items do not cause young people to use tobacco, and that banning them will not reduce tobacco use. These comments fall into two categories: Those that rely on theoretical or policy arguments and those that provide or criticize studies or other evidence.

a. Theoretical or policy considerations. Several comments argued generally that it is well-documented that the significant factors associated with regular underage tobacco use are peer pressure and smoking by friends, older siblings and parents. They noted that FDA cited no evidence that the use of a tobacco trademark on a nontobacco product, such as a lighter or jacket, has any impact on underage tobacco

consumption, or that its removal will reduce youth tobacco use. Consequently, they argue, banning the use of tobacco brand names on nontobacco products will fail to achieve FDA's goal of curbing teen smoking.

One comment maintained that people, including those under age 18, do not wear these items in order to advertise anything or to be "walking billboards." Rather, according to this comment, they wear them to make a public statement, because they find the items aesthetically pleasing, or for other reasons. Moreover, the comment argued, FDA has no authority to regulate the attire of adults, school students, or anyone else.

In addition, the comment argued, the goal of these programs is to reinforce brand loyalty among existing customers. Their purpose is to expand market share among existing smokers, not to induce nonsmokers to start smoking. These programs are, by their very nature, aimed at people who already are smokers, that is, the merchandise is provided only to consumers who have accumulated and submitted significant numbers of proofs of purchase. No one would be persuaded to start smoking by a cents-off coupon or by the offer of a free cigarette lighter, but a smoker might be tempted by the offer. The comment argued that in the hard fought battles for market share among cigarette companies, discounts and premiums represent a way to promote and retain brand loyalty and to weaken loyalty to competitors' brands.

Some comments bolstered their arguments with a citation to the decision of the Supreme Court of Canada, which, they claimed, invalidated a similar ban. The Canadian court concluded that there was no direct or indirect evidence of any causal connection between the objective of decreasing tobacco consumption and the absolute prohibition on the use of a tobacco trademark on articles other than tobacco products. These comments argued that FDA should follow the Canadian judgment (see section VI.D.3.f. of this document for a complete discussion of this case).

On the other hand, one comment stated that U.S. and international experience provide substantial support for a ban. It stated that in the United States, nontobacco items were heavily used by RJR to market its Camel tobacco to young people.

In addition, one comment that supported FDA's action stated that young people participate to a marked extent in tobacco company promotions. It noted that these promotions all use

attractive imagery and prizes that are intrinsically interesting to adolescents. Other comments stated that these promotions are particularly effective with young people, who have less disposable income. The items are a way for young people to get something for nothing and provide added incentive for young people to purchase tobacco products. One comment that supported this provision stated that these items can become "walking billboards," that can come into schools and other places where tobacco advertising is generally prohibited.

Another comment stated that the ban serves as an important corollary to the advertising restrictions, specifically, it argued that the impact of removing tobacco product advertisements from minors' magazines would surely be reduced if minors themselves continued wearing the advertisements on their heads and bodies. The comment asserted that there is a correlation between participation in a promotion and susceptibility to tobacco use.

b. Studies and evidence. One comment referenced a new study²²⁴ that found that participation in tobacco company promotions by 12 to 17 year olds is more predictive of susceptibility to use tobacco products than smoking by those close to the individual. The measure of "participation" was the possession of a catalog, the ownership of any promotional item, or the saving of coupons that could be redeemed for promotional items. The study found that catalog ownership was the most common form of participation in tobacco company promotions.

A comment that opposed this provision argued that FDA had cited no credible studies that demonstrate either that these items are especially appealing to young people, or that possessing these items causes young people to start smoking or to smoke more. It stated that although FDA relied on a study by Dr. John Slade²²⁵ that reported that there is an association between participating in promotions and a person's susceptibility to tobacco use, FDA did not describe the study thoroughly. The comment stated that the notion of susceptibility is itself problematic. It stated that even if this study is taken at face value, it does not support FDA's conclusions. While the study reported that 83.5 percent of

²²⁴ Evans, N., et al., "Influence of Tobacco Marketing and Exposure to Smokers on Adolescent Susceptibility to Smoking," *Journal of the National Cancer Institute*, vol. 87, pp. 1538-1545, 1995.

²²⁵ Slade, J., et al., "Teenagers Participate in Tobacco Promotions," presented at the 9th World Conference on Tobacco and Health, October 10-14, 1994.

respondents age 12 to 17 were aware of at least one tobacco company promotion, it also reported that only 10.6 percent of respondents owned a nontobacco promotional item. These numbers, the comment asserted, do not support the theory that nontobacco items are appealing to youth or have a discernible impact on youth smoking rates.

Moreover, the comment took exception with Dr. Slade's finding that 25.6 percent of 12 to 13 year olds and 42.7 percent of 16 to 17 year olds participate in promotional programs such as Camel Cash or Marlboro miles. The comment stated:

the reason for these apparently high percentages is clear from the most cursory analysis of the data * * * [I]n this supposedly random survey, fully 45.7 percent of the households of 12–13 year olds interviewed had someone at home who smoked (37.9 percent in households of 16–17 year olds), and yet, in reality only 25 percent of the American public—half the rate of the population relied upon by Dr. Slade—smoke. [Thus], the unrepresentative sample population Dr. Slade employed created a significant bias, which distorts the results of this survey and renders them entirely unreliable.

Finally, one comment stated that the primary basis for the provision appeared to be data²²⁶ that allegedly show that 44 percent of teenage smokers and 27 percent of teenage nonsmokers have received nontobacco promotional items. The comment stated that the study is irrelevant because it drew no conclusion as to the significance of the number, nor did it indicate how the teenagers received the items.

In response, the agency concludes that the evidence presents a compelling case to prohibit the sale and distribution of all nontobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. The evidence establishes that these nontobacco items are readily available to young people and are attractive and appealing to them with as many as 40 to 50 percent of young smokers having at least one item (60 FR 41314 at 41336). The imagery and the item itself create a badge product for the young person and permit him/her the means to portray identification.

FDA has shown that tobacco advertising plays out over many media, and that any media can effectively carry the advertising message. Moreover, the

agency recognizes that the tobacco industry has exploited loopholes in partial bans of advertising to move its imagery to different media. When advertising has been banned or severely restricted, the attractive imagery can be and has been replicated on nontobacco items that go anywhere, are seen everywhere, and are permanent, durable, and unavoidable. By transferring the imagery to nontobacco items, the companies have “thwarted” the attempts to reduce the appeal of tobacco products to children.

In addition, items, unlike advertisements in publications and on billboards, have little informational value. They exist solely to entertain, and to provide a badge that, as the Tobacco Institute asserted, allows the wearer to make a statement about his “social group” for all to see. But because tobacco is not a normal consumer product, it should not be treated like a frivolity. Advertising that seeks to increase a person's identification with and enjoyment of an addictive deadly habit has the ability, particularly among young people, to undermine the restriction on access that FDA is imposing. For these reasons, the agency continues to find sufficient evidence to support a ban on these items.

Finally, regarding the unpublished paper by Dr. Slade, the comment has confused the household smoking rate with the overall population smoking rate. The smoking rate per household can be as high as twice the overall adult smoking rate. For example, if the smoking rate for adults were 25 percent and assuming two adults per household and only one of the pair smokes, then the household smoking rate could be as high as double that of the individual rate. Therefore the range of possible household smoking rates would be 25 percent to 50 percent, with 44 percent being quite plausible.

Lastly, the comments that state that peer pressure and smoking by friends and family are significant factors in influencing a young person's tobacco use, rather than promotional items, fail to recognize that if a young person is influenced by what a peer says about tobacco use, he or she will also likely be influenced by that same peer wearing a tobacco promotional item.

(75) One comment from a small smokeless tobacco company expressed concern because much of the packaging used for its products also bears its corporate logo. Moreover, several of its brand names include words in its corporate logo. Thus, the comment argues that FDA might find that its

corporate logo is an “inducium of product identification” covered by the restrictions in § 897.34. The comment stated that promotional items are a small but important part of its advertising and promotional activity, and these items allow its customers to feel like a part of an extended family. It would be unfair, the comment argued, as well as harmful to the company, if FDA were to determine that a corporate logo may not be used on promotional items.

One comment stated that the total merchandising and ban in § 897.34(a) is unreasonably broad in scope. It stated that it virtually limits all merchandising, because all colors or patterns of colors are associated with some brand or another of tobacco product. The comment stated that the proposed regulation is so confusingly vague that one could argue that a “distributor” would be prohibited from using the color red in any event for any product category, brand, or corporation because Marlboro brand tobacco products utilize the color red.

Another comment stated that because the definitions of “cigarette” and “smokeless tobacco product” are limited to tobacco products with nicotine, the agency should consider the possibility that a tobacco company could market a nicotine-free brand extension of a cigarette or a smokeless tobacco product and advertise this product free of restrictions. The comment stated that the advertising for such a product could have carryover value for the nicotine containing versions of the product thereby undermining the intent of the regulations.

The agency agrees that it needs to clarify the scope of § 897.34(a). The regulation covers any item with indicia of the brand identity. If the corporate logo is not an indicium of a brand identity, its use would not be prohibited in nontobacco labeling or advertising. On the other hand, if a corporate logo includes an identifiable brand name or image, it must comply with the restrictions. Any other position would permit a company to evade the intent of this regulation by using a corporate logo to continue to display brand imagery. For example, RJR may continue to sell or distribute hats and tee shirts with the name “R. J. Reynolds” on them, but not the name “Camel.” Nor can it put the Camel inside the Reynolds logo. The agency, therefore, has amended § 897.34(a) to state that the indicia of product identification cannot be identical or similar to, or identifiable

²²⁶ “Teenage Attitudes and Behavior Concerning Tobacco—Report of the Findings,” the George H. Gallup International Institute, Princeton, NJ, p. 59, September 1992.

with those used “for any brand of cigarettes or smokeless tobacco”.

In addition, it is not the agency’s intention to ban the use of registered or recognizable colors for all advertising. Only the owner or user of the brand identification is prohibited from using that color or pattern of colors in a manner so as to advertise tobacco or smokeless tobacco. For example, Philip Morris would be prohibited from using the distinctive red, black, and white pattern of colors which identify Marlboro, but neither RJR nor Joe’s Garage would be prohibited by the regulations from using those colors.

Finally, in response to the last comment, the agency has restricted the coverage of this regulation to promotions of cigarettes and smokeless tobacco products containing nicotine. It has no evidence justifying a broader coverage of the regulation to nicotine-free products at this time. However, a company could not give a nontobacco product (a nicotine free product) a tobacco brand name. This is exactly what this section of the final rule forbids.

(76) Several comments argued that § 897.34(a) constituted a restriction on symbolic expression that cannot be characterized as commercial speech. The comments argued that these items do not propose a commercial transaction. One comment argued that in *Cohen v. California*, 403 U.S. 15 (1971), the Supreme Court recognized that otherwise objectionable words worn on a jacket are fully protected speech.

FDA finds no merit to these comments. Section 897.34(a) on its face is limited only to manufacturers and to distributors of imported cigarettes or smokeless tobacco. It does not limit the rights of individuals to express themselves by wearing an article of clothing that bears a picture of a cigarette or a logo.²²⁷ What it does limit is the ability of manufacturers and some distributors of tobacco and smokeless tobacco to do what is the essence of commercial speech—to take actions to call public attention to the products whose logo the items bear, so as to arouse a desire to buy those products. (See *Public Citizen v. FTC*, 869 F.2d at 1554.) Because this is what the nontobacco items that are the subject of

§ 897.34(a) are designed to do, they share all the characteristics of the pamphlets that the Supreme Court in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 66–67 (1983), found to be commercial speech. Consequently, FDA may regulate the nontobacco items as commercial speech, as long as its regulation passes muster under the *Central Hudson* test (see 463 U.S. at 68).

(77) Some comments challenged the constitutionality of the prohibition on the use of a cigarette or smokeless tobacco brand logo on nontobacco products under the *Central Hudson* test. The comments argued that the prohibition does not directly advance FDA’s interest because the prohibition is unrelated to the goal of protecting children. The comments also argued that the prohibition is not narrowly tailored because it is not limited to children and not limited to products that are particularly attractive to children.

Several comments disagreed and argued that the prohibition is a constitutionally permissible restriction on speech. One of these comments pointed to the finding in the IOM’s Report *Growing Up Tobacco Free* of the effectiveness of this type of advertising with young people. The comment said that FDA would therefore be justified in prohibiting its use.

FDA has carefully considered these comments. The agency concludes that the prohibition on the use of a cigarette or smokeless tobacco brand logo on nontobacco items is a permissible restriction under the First Amendment.

First, this restriction will directly advance FDA’s interest in protecting the health of people under 18 years of age. In *Public Citizen v. FTC*, 869 F.2d at 1549 n. 15, the Court of Appeals for the D.C. Circuit recognized that the nontobacco “utilitarian items might be among the most effective forms of promotion with respect to adolescents.” This judgment is consistent with much of the other evidence in the administrative record. A 1992 Gallup survey found that 44 percent of all adolescent smokers and 27 percent of adolescent nonsmokers owned at least one promotional item from a tobacco company.²²⁸ Testing by RJR in 1988 found that nontobacco items performed best among young adults.²²⁹

The IOM Report pointed out that the ubiquity of nontobacco items conveys the impression that tobacco use is the norm.²³⁰ As stated in section VI.D.3.c. of this document, this impression, that tobacco use is widespread and accepted, fosters experimentation with tobacco and smokeless tobacco by young people. This fact led the IOM to recommend that the use of tobacco product logos on nontobacco items be prohibited.²³¹ The IOM said that this and several other related steps (including requiring the use of the text-only format) were necessary to eliminate those features of advertising that tend to encourage tobacco use by children and youths.

Thus, the prohibition on the use of these logos will directly advance FDA’s interest. The IOM’s recommendation provides significant evidence of this fact.

Second, even though FDA is prohibiting the use of brand logos on nontobacco items, this restriction meets the requirement of narrow tailoring. The Supreme Court has held that a ban may satisfy this requirement if the agency’s judgment is that it is “perhaps the only effective approach” (*Board of Trustees of the State of N.Y. v. Fox*, 492 U.S. at 479). In this case, FDA has determined that a ban of these items is necessary for several reasons. The appeal of something for nothing items for youngsters is great, and the extent of the appeal makes it virtually impossible to distinguish among items, as suggested by one comment. As the IOM pointed out, these items, when worn or used by children, are capable of penetrating areas of a child’s world that might be off-limits to other forms of advertising.²³² Because they penetrate the young persons’ world, they are very effective in creating the sense that tobacco use is widely accepted, which, as stated in section VI.D.3.c. of this document, is extremely important to children and adolescents. These items act like a badge that marks an individual as a member of a group, another attribute that makes them particularly attractive for young people. There is no way to limit the distribution of these items to adults only. The industry claims that it already is taking sufficient action to ensure that only adults get these items²³³ but as the evidence

²²⁷ The fact that individuals would be free to make their own articles of clothing with brand names of tobacco products on them does not make the regulations fatally underinclusive. (See *U.S. v. Edge Broadcasting Co.*, 509 U.S. 434 (“Accordingly, the Government may be said to advance its purpose by substantially reducing lottery advertising, even where it is not wholly eradicated.”).)

²²⁸ “Teenage Attitudes and Behavior Concerning Tobacco—Report of the Findings,” The George H. Gallup International Institute, Princeton, NJ, pp. 17, 59, September 1992.

²²⁹ Bolger, M. R., *Marketing Research Report, entitled Camel “Big Idea” Focus Groups-Round II*, September 21, 1988.

²³⁰ IOM Report, p. 110.

²³¹ *Id.*, p. 133.

²³² *Id.*, p. 110.

²³³ The Cigarette Advertising and Promotion Code, subscribed to by the major cigarette manufacturers, contains three provisions that

indicates, a substantial number of young people have them. As noted in this section, almost one-half of young smokers and one-quarter of nonsmokers have one or more items. Moreover, even were items to be distributed to adults only, this would not prevent the wearers from becoming walking advertisements that would continue to display the attractive imagery.

For all these reasons, FDA finds that all nontobacco items that bear cigarette or smokeless tobacco brand logos are capable of playing a significant role in a young person's decision to engage in tobacco use. Because no distinction among these products is apparent, and no way of limiting their availability to adults is possible, FDA finds that the most direct and effective means of controlling their appeal to adolescents and children under the age of 18 is to prohibit manufacturers, distributors, and retailers of tobacco products from distributing or selling them.

(78) One comment opposed § 897.34(a) because the comment argued that the provision would impose restrictions on an otherwise lawful use of trademarks. It stated that § 897.34(a) would prohibit the right of any trademark owner to use a trademark for the sole reason that the trademark is used by another party on tobacco products. The comment stated that § 897.34(a) also would prevent large distributors and retailers, who handle a wide variety of both tobacco and nontobacco products, from distributing or selling any product which happened to bear the same or similar mark as that used on a tobacco product. The comment stated that, for example, grocery markets could not stock or sell Beechnut baby food or chewing gum because Beechnut also is used as a trademark for chewing tobacco even though the manufacturers are two different companies with the same name. It stated that the Lanham Act (15 U.S.C. 1051 (1996)) would, and in fact does, permit such identically branded products to coexist in the marketplace because of the absence of any likelihood that these products would be associated or confused with each other.

FDA recognizes that § 897.34(a) as proposed created unintended confusion and therefore will amend the provision to clarify the agency's meaning. Changes have been made that are intended to clarify § 897.34(a) so that retailers and distributors of domestic tobacco products are not included, thus

avoiding the problem identified with the comment and making it possible for grocers to sell Beechnut baby food and Beechnut tobacco products.

(79) Several comments stated that § 897.34(a) would unlawfully constrain the separate and distinct activity of trademark diversification in connection with products that are unrelated to the marketing of tobacco products by cigarette manufacturers. One comment contended that general bans on the licensing of brand logos pertaining to tobacco products are incompatible with long-established principles of international trademark law. The comment asserted that the use of such trademarks in a nontobacco context is not an indirect means of advertising or promoting tobacco products. The comment stated further that it is an increasingly common practice in many industries to "spin off" new products by marketing them under a trademark that has acquired some cachet or represents quality. It stated that such licensed products are not marketed in an effort to sell the "root" product, rather, the trademark has some "detachable" qualities that help build demand for the licensed goods. It stated that the same is true of marketing a nontobacco product under the trademark of a tobacco product.

FDA cannot agree with the comments' claims. While the agency recognizes that the use of these trademarks on hats and tee shirts promotes the underlying tobacco product by continuing the extensive imaging in these venues. Moreover, as the court in *Public Citizen*, 869 F.2d at 1549, n. 15, recognized, branded nontobacco items might be the most effective type of promotion to young people. Therefore, failure to include this form of advertising and promotion in the regulation, would weaken considerably FDA's efforts to reduce the appeal of these products to young people under 18, and would undermine the agency's access restrictions.

The agency also disagrees with the comment's suggestion that § 897.34(a) effects a taking (or deprivation of a property right) by prohibiting the use of tobacco trademarks to market nontobacco products. Section 897.34(a) clearly relates to commercial speech and the comment is merely attempting to cloak commercial messages with the issues of registrability and value of well-known trademarks. As discussed in section XI. of this document, the agency has determined that this regulation does not effect a taking compensable under the Fifth Amendment.

One comment that supported FDA's proposal stated that smokeless tobacco makers circumvent the FTC regulation that covers the use of brand names of smokeless tobacco products on promotional items such as caps and tee-shirts. For instance, rather than stop making such items, U.S. Tobacco has registered Skoal Bandit Racing, Skoal—Copenhagen Pro Rodeo, and Skoal Music as service marks and places these names on many of the items it offers the public, thereby evading FTC's regulation. The comment stated that this experience demonstrates the need for regulations of this sort to be comprehensive.

The comment stated further that there may be other relatively easy ways around § 897.34(a). It stated that if the rights to a brand name were transferred to an entity that was not a manufacturer, distributor, or retailer that this separate entity could then license back the use of the brand name to the tobacco company and proceed to market, license, distribute, or sell other goods and services using that same brand name. The comment stated that one way to close this loophole would be to require manufacturers to own the trademarks and the rights to all associated symbols for each brand they produce.

FDA disagrees with these comments and believes that the concerns expressed are misplaced. Section 897.34(a) prohibits all use of the Skoal brand name on nontobacco items, whether used alone, i.e., "SKOAL," or with other words, such as "Skoal Racing Bandit." In addition, the provision forbids not just the use of the brand name, logo, etc. by the manufacturer but also the marketing, licensing, distributing, selling of them, or the causing of any of those activities; thus, effectively preventing the type of license-transfer arrangement described in the comment.

(80) Several comments stated that FDA cannot ban contests and lotteries under section 520(e) of the act, because they are not devices. Moreover, the comments stated that existing laws and regulations provide adequate protection and to the extent that the participation of minors in these activities is a problem the States already have ample power to regulate them.

In addition, a comment stated that FDA offered no evidence, or citation to studies, that contests, lotteries, or games involving tobacco products have particular appeal to adolescents. Moreover, the comment stated, that any inability to quantify participation by youth does not mean that the agency

address the necessity of preventing anyone under the age of 21 from getting promotional items.

can ban an entire form of promotion to adults.

One comment pointed out that, by law, customers wishing to participate in games of chance or similar promotional activities must be adults. The comment stated that banning such activity bears no relationship to achieving FDA's stated purpose. The sole effect of FDA's ban would be to unjustly impair the relationship between tobacco manufacturers, retailers, and their adult customers.

One comment stated that the agency should not prohibit all use of contests or games of chance by the tobacco industry because regulations already exist and are enforced by the Bureau of Alcohol, Tobacco, and Firearms (BATF).

Another comment stated that the proposed rule misunderstands the nature of such activities, misrepresents the appeal of promotions, and assumes without proof that promotions induce young people to smoke. It stated that promotional activities are not undertaken to encourage people, young or old, to smoke, but rather to introduce existing smokers to the brand being promoted and to provide them with incentives to choose that brand over others. Moreover, participation in such games is expressly limited to smokers who are 21 years of age or older.

Conversely, one comment provided support for the 1995 proposed rule. It stated that, while it is unlikely that anyone under 18 years of age actually has ever received any of the major prizes or offers from the give-aways, the award of prizes is not the point of these marketing tools. It stated that the consumer's participation in the fantasy of the prize in association with the brand being promoted is the reason these contests are used.

FDA has been persuaded by the comments to modify § 897.34(b) regarding lotteries and games of chance in connection with nontobacco items. Federal law already prohibits "any certificate, coupon, or other device purporting to be or to represent a ticket, chance, share, or an interest in, or dependent on, the event of a lottery to be contained in, attached to, or stamped, marked, written, or printed on any package of tobacco products" (26 U.S.C. 5723(C)). BATF has issued regulations enforcing this provision (27 CFR 270.311).

In addition, although no Federal agency has issued specific restrictions on games of chance and lotteries in connection with advertising of tobacco products, Federal and State law prohibit games, contests, and lotteries if based on

product purchase (18 U.S.C. 1302–1307, 1341 (1995)). Given these existing Federal requirements, the agency has concluded that there is no need to add FDA regulations. Therefore, § 897.34(b) has been modified to delete the provision concerning lotteries and games of chance but to continue to the prohibition of gifts and proof of purchase acquisitions.

It must be understood, however, that advertising for games, lotteries, or contests may not contain any indicia of product identification other than black text on a white background, since the advertisement for a contest in the name of a tobacco brand, or identifiable as a tobacco brand, is restricted to text-only format as required in § 897.32(a). The agency points out that, as part of the review of the regulation that it plans to undertake in 2 years, FDA intends to consider the effect of games of chance and lotteries on young people and determine whether additional regulations are necessary.

Based on the evidence amassed during its investigation, and the surveys described in the preamble to the 1995 proposed rule (60 FR 41314 at 41336) and submitted during the comment period, FDA has concluded that nontobacco items (identified with a tobacco brand), either sold, given away, or provided for proof of purchase are an instrumental form of advertising in affecting young people's attitudes towards and use of tobacco. Moreover, banning this form of advertising is essential to reduce tobacco consumption by young people. This form of advertising has grown in importance over the last 20 years. As discussed in this section, expenditures rose from 2.1 percent in 1975 to 8.5 percent in 1980 (60 FR 41314).

Studies—A Gallup survey found that about one-half of young smokers and one quarter of all non-smokers, own at least one promotional item (60 FR 41314 at 41336). Another study, detailed more fully in this section, found that participation in tobacco company promotions (owning an item, collecting coupons for gifts, or having a catalogue) by 12 to 17 year olds is more predictive of susceptibility to use of tobacco products than smoking by those close to the individual. Another study, by Slade, found that 25.6 percent of 12 to 13 year olds and 42.7 percent of 16 to 17 year olds participate in promotional programs such as Camel Cash and Marlboro miles (60 FR 41314 at 41336).

Evidence Provided by Industry Members—Two separate studies done for R.J. Reynolds, and described in this

section, found that tee shirts were a significant source of information about tobacco for some young people and that these items performed best among young people.

A ban on this type of advertising will prevent the "something for nothing appeal" of give aways and proofs of purchase and will eliminate the walking billboard, who can enter schools and other locations where advertising is inappropriate. Thus, FDA concludes that the restriction it is adopting on this type of promotional material will directly advance FDA's efforts to substantially reduce consumption of tobacco products by children and adolescents under 18.

8. Section 897.34(c)—Sponsorship of Events

Proposed § 897.34(c) provided that "no manufacturer, distributor, or retailer shall sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event, in the brand name, logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of a product identification similar or identical to those used for tobacco or smokeless tobacco products." Proposed § 897.34(c) would have permitted a manufacturer, distributor, or retailer to sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event in the name of the corporation that manufactures the tobacco product, provided that both the registered corporate name and the corporation were in existence before January 1, 1995.

The preamble to the 1995 proposed rule explained that sponsorship by cigarette and smokeless tobacco companies associates tobacco use with exciting, glamorous, or fun events such as car racing and rodeos, and provides an opportunity for "embedded advertising" that actively creates a "friendly familiarity" between tobacco and sports enthusiasts, many of whom are children and adolescents. The preamble to the 1995 proposed rule cited several studies that demonstrate the impact of sponsorship on consumer attitudes (60 FR 41314 at 41337 through 41338). The proposed restriction was intended to break the link between tobacco company-sponsored events and use of tobacco and reduce the "friendly familiarity" that sponsorship generates for a brand.

(81) FDA received a substantial number of comments concerning the agency's 1995 proposal on sponsorship, including comments submitted by the

tobacco industry, motorsport industry, advertising agencies, adult smokers, medical professionals, public interest groups, and racecar drivers. Approximately 300,000 individuals submitted a form letter that was produced by 1 tobacco manufacturer. The form letter inaccurately referred to the 1995 proposal as a "ban on tobacco sponsorship of events including concerts, State fairs and consumer promotions" whereas the agency proposed to permit tobacco company sponsorship of all events to continue as long as they are in the corporate name. Other comments submitted by the tobacco industry, adult smokers, and motorsport industry strongly objected to the provision. In contrast, those comments submitted by public interest groups, medical professionals, and some racecar drivers strongly supported the provision.

In response to comments, the agency has modified this provision to prohibit all sponsored entries and teams using the brand name in addition to the prohibitions that were proposed. Moreover, the final rule clarifies that the corporate entity that can sponsor events, teams and entries must not only be registered but that the registration must be in active use in the United States, and the corporate name cannot include any indicia of product identification "that are identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco."

(82) Several comments addressed the issue of whether young people attend, or even see, sponsorship events. Some comments opposed the provision, arguing that sponsored events (such as motorsport events and seniors golf tournaments) are created for and attended by adult smokers, and that there is no credible evidence that these events are targeted at, created for, attended by, or even seen by significant numbers of children and adolescents. One comment stated that "contrary to FDA's assertions," the industry takes special steps to ensure that material distributed at events is not attractive to minors. One comment stated that "[r]ecent industry studies demonstrate that the overwhelming majority of fans at motorsports events are adults," and that "for example, 97 percent of NASCAR Winston Cup Series race attendees are 18 years of age and older [and] [m]ore than 90 percent of NHRA Winston Drag Racing Series attendees are 21 years old and older." The underlying studies were not, however, cited or attached to the comment.

One comment added that motorsport events are not seen by "significant" numbers of children under the print media standard proposed by FDA (i.e., the "15 percent/2 million benchmark"). The comment argued that:

[o]n the one hand, the agency concedes that image advertising is permissible in publications with a primarily adult readership because "the effect of such advertising on young people would be nominal," but on the other hand, it attempts to measure the impact of cigarette brand sponsorships * * * by using statistics on the viewing audience of sponsored motorsport events without recognizing that these figures demonstrate the fact that the vast majority of viewers of such events are adults.

The comment stated that:

[I]n fact, the 64.05 million underage viewers of the 354 motorsport broadcasts studied represents only 7 percent of the total viewing audience of these broadcasts. This averages out to 180,806 underage viewers per event. These figures are far below the 15 percent and two million readership benchmarks that are permitted for image advertising in print media.

* * *

The comment also stated that FDA made no attempt to measure the percentage of adolescents in the live gate of sponsored events, and that industry estimates indicate that the overwhelming percentage of fans attending motorsport events are adults.

One comment stated that the price of a typical ticket to a stock car race event is expensive enough to preclude adults from taking their children to events and to preclude children themselves from attending these events.

Other comments supported the provision, stating that tennis tournaments, sports car, motorcycle and powerboat racing, and rodeos all are aimed at sports enthusiasts, many of whom are children or teenagers, and that rock concerts and country music festivals are "magnets" for adolescents.

One comment stated that:

[it] is also no coincidence that when the tobacco industry sponsors events where the audience is almost entirely educated adults, the sponsorship is in the name of the corporation (i.e., art exhibits, modern dance companies), but when the event fits the psychological image the tobacco industry needs to attract adolescents, the sponsorship is in the name of the brand most likely to appeal to those children (Virginia Slims, Marlboro, Winston, Skoal Bandit).

The agency, which acknowledges the comments' reports on the number of young people at events, did not receive any data to support or refute these numbers. However, recent reports in the press indicate that the number of young people attending these events may be growing.

In NASCAR we found a great kids' business. I was astounded by their information, statistics and demographics regarding kids. [Fred Siebert, president of Hanna-Barbera, Inc., explaining why the company is sponsoring a cartoon race car to appear in NASCAR races emblazoned with Fred Flintstone and other cartoons on the hood.] After reviewing the 1995 NASCAR season, we concluded that a sizable number of attendees at NASCAR events were families with kids ages 6–11. Yet we felt NASCAR was not specifically serving that audience. [Gary Bechtel, owner Diamond Ridge Motorsports, who will field a NASCAR car and team named Cartoon Network Wacky Racing.]²³⁴

* * * * *

We looked at NASCAR and saw how quickly it was growing nationally and the fact that so many families go to the races it seemed like a natural fit.²³⁵ Moreover, the agency finds that 64.05 million underage viewers (or 180,806 underage viewers per event) is clearly not "insignificant." As discussed in the preamble to the 1995 proposed rule, the "Sponsor's Report," which estimated the value of all product exposure for most U.S. automobile races, found that 354 motorsport broadcasts "had a total viewing audience of 915 million people, of whom 64 million were children and adolescents." The preamble to the 1995 proposed rule stated: "the impact of sponsoring televised events such as these automobile races is perhaps most apparent when one realizes that over 10 million people attended these events, while 90 times that number viewed them on television" (60 FR 41314 at 41337). In addition, recent news accounts indicate that televising of races has increased both in volume and diversity. For example, television can often support three major races in 1 day. The two cable ESPN channels had 150 hours of auto racing programming in May, 1996, including 95 hours of live races, time trials, qualifying and practice laps.²³⁶

The effect of sponsored events on the young people who attend or see these events is enormous. Advertising affects young people's opinion of tobacco products, first, by creating attractive and exciting images that can serve as a "badge" or identification, second, by utilizing multiple and prolonged exposure in a variety of media, thereby

²³⁴ "Diamond Ridge Motorsports and Hanna-Barbera, Inc., to form Wacky Racing Team Changing Face of NASCAR; Deal Launches Cartoon Network Consumer Branding Initiative," *Business Wire*, November 10, 1995.

²³⁵ "Automobile Racing's Widening Appeal Gets the Flintstones in Sponsor Table," *The Times Union*, p. B11, March 30, 1996.

²³⁶ Moore, S., "Ladies and Gentlemen, Start Your Televisions," *Washington Post*, May 26, 1996.

creating an impression of prevalence and normalcy about tobacco use, and finally, by associating the product with varied positive events and images. The sponsorship of events by tobacco companies uniquely achieves all three objectives. Sponsorship creates an association between the exciting, glamorous or fun event with the sponsoring entity. Whether at the live gate, or on television, young people will repeatedly see and begin to associate the event, which they are enjoying, with the imagery and appeal of the product. All of the attendant concerns of hero worship of the sports figures and glamorization of the product by identification with the event are present, whether there are thousands or hundreds of thousands of young people in attendance. Race car drivers are extremely popular with young people and often are looked up to as heroes. According to one promoter of NASCAR properties, "We've found that boys look to NASCAR drivers the same way they do to heroes, such as firemen, policemen, professional fighters, or astronauts."²³⁷

Furthermore, sponsorship events present a prolonged period of time in which to expose the audience, including young people, to the imagery. Sponsorship events do not provide people with a momentary glimpse at the imagery, but from 1 to 2 or 3 hours of constant attractive imagery. The audience has more than enough time to associate the images of the sporting event or the concert with the product.

The agency agrees that there may be some events (such as seniors golf tournaments) that are primarily attended by adult audiences. The agency also does not claim that *all* sponsorship events are *attended* primarily by young people, but that the *exposure* (which includes television broadcasts) of young people to sponsored events is substantial. Even if a small percentage of young people attend certain sponsorship events, the amount of television exposure that young people receive is substantial.

In addition, the agency recognizes that numbers or percentages of the audience less than 18 may be lower than the threshold established for "adult" publications. However, the type of exposure in these two media are dramatically different. Young people reading or flipping through a magazine

may momentarily glance at advertisements if they are interesting or eye-catching, and as a result, the exposure, if any, to one particular advertisement may be brief (the average time spent viewing an advertisement is about 9 seconds²³⁸). However, young people who attend sponsorship events or view them on television are unavoidably bombarded with posters, signs, hats, t-shirts, cars, and the like, linked with a fun, exciting, or glamorous event that they enjoy for a prolonged period of time. Often, celebrities participating in these events are wearing clothes and hats bearing the brand name and attractive imagery, and young people come to associate athletes who they admire with tobacco products. The amount of time viewed and the positive association with the event are incalculable as persuasive messages. Thus, the agency rejects the idea of setting a minimum attendance threshold for brand name advertising.

(83) FDA received many comments addressing its use of the concept of "friendly familiarity" in connection with tobacco sponsorship of events. Several comments stated that FDA misunderstood the theory,²³⁹ arguing that sponsorships and promotions do not cause young people to smoke, and that FDA has failed to meet its burden of demonstrating that a ban of such activities will result in any decrease in underage smoking. In fact, according to this comment, the studies demonstrate that young people are most familiar with the brands of tobacco that are most heavily advertised.

One comment asserted that since motorsport advertising and promotion comprises a small percentage of overall tobacco advertising (on the order of 4 or 5 percent of total tobacco advertising), there is little support for the conclusion that tobacco sponsorship of motorsports has any significant effect on the rate of youth smoking.

One comment from a 26-year old ex-smoker (who began smoking at age 10, and smoked for 13 years) and NASCAR racing fan stated:

[M]y favorite driver is sponsored by a beer company. I don't drink and I'm not going to start because my favorite driver has that

sponsor. However- if I DID drink already, I may switch brands to support my driver. All the advertising in the world will not sway me (or most-intelligent people) to do something I wouldn't do anyway.

In contrast, several comments labeled the 1995 proposed rule a "reasonable measure" and stated that "the evidence cited by FDA in support of this proposal is substantial and entirely consistent with the best available evidence." One comment supported FDA's sponsorship restrictions because sponsorship heightens product visibility, molds consumer attitudes, links the product with a particular lifestyle, and thus increases sales.

One comment commended FDA for drawing a "reasonable line—one that allows tobacco companies to continue to sponsor events and therefore to reap the corporate good will that flows from sponsorship, but compels the companies to jettison the hard-sell message that now typifies these events."

Several comments stated that the events sponsored by tobacco companies have a direct and powerful impact on young people because they are fun, exciting, and glamorous, and events such as tennis tournaments (Virginia Slims), sports car (NASCAR), motorcycles and powerboat racing, rodeos, rock concerts, and country music festivals are aimed at sports and music enthusiasts, including children or teenagers. The comment stated that when minors view these events, either in-person or on the television, they are: "inundated with images of the brandname or product logo (which are pasted on uniforms, vehicles, signs and virtually every surface imaginable), creating a direct and compelling association between the product and an enjoyable event."

The comment stated that children and young adults are particularly vulnerable to this sort of product advertising, because adolescence is the time of life during which identities are shaped. The comment further stated that there is ample evidence that demonstrates that the sponsorship of events leads to strong associations between the event and the brandname, that in turn influences the purchasing decisions of minors.

One comment stated that Virginia Slims' sponsorship of tennis was vital to the image advertising Philip Morris used to sell Virginia Slims tobacco to adolescent girls, and that Marlboro sponsorship of racing events is no less effective with adolescent boys. The comment stated that sports sponsorship has a secondary impact because "[t]he athletes who participate in the sponsored event, whether they be race

²³⁸ Fischer, P., J. Richards, and E. Berman, "Recall and Eye Tracking Study of Adolescents Viewing Tobacco Advertisements," *JAMA*, vol. 261, pp. 84-89, 1989.

²³⁹ The comment stated that "[t]he need to establish a 'friendly familiarity' with a brand name is not about deciding to smoke * * * nor about deciding to use a commodity at all—the decision to make a category purchase within a mature product category is ALREADY made before advertising affects the brand choice within the category."

²³⁷ Williams, S., "NASCAR Races into Kid's Licensing, National Association for Stockcar Auto Racing Seeking Promotional Appeal and Other Products," *Children's Business*, vol. 9, No. 7, p. 28, July 1, 1994.

car drivers or tennis players, become walking advertisements and role models." The comment stated that "[a]s reflected by the Industry's own Code, everyone agrees that athletes should not endorse tobacco products because of her potential impact on children, but being a spokesperson for the Virginia Slims Tennis Tournament, NASCAR racing, etcetera is no less effective."

The agency finds that the evidence regarding the effect of advertising and sponsorship on children's smoking behavior is persuasive and more than sufficient to justify this regulation. The preamble to the 1995 proposed rule described the available evidence and explained why the agency is regulating sponsored events. The evidence demonstrates that sponsorship of sporting events by tobacco companies can lead young people to associate brand names with certain life styles or activities and can affect their purchasing decisions (60 FR 41314 at 41336 through 41338). The industry, in its comments, has questioned the relevance of the evidence but has failed to demonstrate that FDA's tentative views were wrong (the industry's criticisms of the individual studies are described below).

Sponsorship events actively create an association between tobacco and event enthusiasts. People under the age of 18 are still forming attitudes and beliefs about tobacco use, see smoking and smokeless tobacco use as a coping mechanism, a gauge of maturity, a way to enter a new peer group, or as a means to display independence (60 FR 41314 at 41329). This final rule is intended to break the link between tobacco brand-sponsored events and images and use of tobacco by young people. In addition, the tobacco industry itself has recognized the vulnerability of young people to advertising featuring sports heroes and other celebrities. In its 1994 Code, the cigarette industry promised that "No sports or celebrity testimonials shall be used or those of others who would have special appeal to persons under 21 years of age."²⁴⁰ The impact of tobacco's association with the race driver, the car, or the event is no less powerful and no less persuasive.

Finally, although motorsport advertising comprises only a small percent of overall tobacco advertising, its effect, like that of magazines, or hats and tee shirts, is cumulative. Each separate advertising venue, in and of itself, does not produce the entire effect.

However, taken together, the effect of each advertising exposure is magnified beyond each discrete exposure, to create the impression that cigarette and smokeless tobacco use is widespread and widely accepted. These impressions, as stated in section IV.D.3.c. of this document, are very influential to children and adolescents.

(84) Several comments criticized in detail the studies relied on by FDA to show the effect that sponsorship has on young people.

One comment stated that the studies relied on by FDA (40 FR 41331 and 41332) do not provide scientifically valid support for the conclusion that there is a causal relationship between the promotional and sponsorship activities banned under § 897.34(c) and the problem of underage smoking.

The agency proposed to regulate sponsored events based upon its tentative finding that the best evidence supported such regulation. Although the comments argued that the studies are inadequate, the comments offered no new evidence to suggest that the conclusions are invalid.

(85) One comment argued that although the conclusion reached by an unpublished paper by John Slade²⁴¹ is that 7 percent of the viewing audiences for NASCAR races are youths, the NASCAR Demographics brochure states that "NASCAR records of the age of persons who attend motorsport events show that only 3 percent are youths." The comment stated that this does not constitute a principled basis for outlawing tobacco company sponsorship of these races even if every other assumption FDA makes about the impact of event sponsorship were true.

The agency disagrees with the comments on the paper by Dr. Slade. Slade's paper established that these events are attended by and seen by a large number of young people. The study measured its stated objective, it establishes the important fact that children are being unavoidably exposed over and over again to attractive and appealing images associated with tobacco products at NASCAR events. The study establishes that young people are present at events where a popular sport is associated with tobacco on signs, cars, people, etc.

The agency also disagrees with the comment that suggested that the price of tickets to motorsport events was

sufficiently high to preclude adults from taking their children to see them. In fact, some motorsport events allow children to attend free of charge or offer discount tickets for children.²⁴²

(86) One comment stated that the study performed by Aitken, et al.²⁴³ (the Aitken study) did not attempt to gauge whether exposure to tobacco-sponsored events or teams engendered favorable feelings for tobacco products in the surveyed young people and stated that the study only addressed the effect of factors such as sex, age, and socioeconomic status on awareness of cigarette sponsorships. The comment also stated that the Aitken study did not test the effect of sponsorship activities in this country, and that FDA ignores the fact that tobacco companies sponsor a wider variety of more popular sports in the United Kingdom, such as "snooker, cricket and darts." Finally, the comment accused FDA of "selective reading," citing FDA's omission of a statement made by the authors when discussing past studies that even though minors may be aware of the sponsorships, "[t]his of course does not mean that cigarette advertising plays a part in inducing children to start smoking." The comment also criticized the author of the study for stating that even though very few of the primary schoolchildren named John Player Special or Marlboro as being associated with racing, "[t]his suggests that linkages or associations between brand names (or their visual cues) and exciting sports are often unconscious, or at the very least, not readily retrieved by consciousness (Aitken et al., p. 209)." The comment claims "[t]hat astonishingly biased hypothesis was not tested by any questions that attempted to probe the "unconscious" or the "consciousness" of the interviewees."

The agency disagrees with the comment's criticism of the Aitken study. This study conducted in the United Kingdom demonstrated that primary schoolchildren who said that they intended to smoke when they were older tended to be more favorably disposed to cigarette advertising. Moreover, Aitken's comment that this

²⁴² See, e.g., Rosewater, A., "Retirement is no Drag for Prudhomme," *Plain Dealer*, p. 7D, June 4, 1996; "Fun Book 96/ This Spectator Sport: Easy Over," *Newsday*, p. 80, May 19, 1996; Schmiedel, M., "Motor Sports World Motorcycle Trials in Exeter Next Weekend," *The Providence Journal-Bulletin*, p. 13D, May 19, 1996.

²⁴³ 60 FR 41314 at 41337, n. 226; citing Aitken, P. P., D. S. Leather, and S. I. Squair, "Children's Awareness of Cigarette Brand Sponsorship of Sports and Games in the UK," *Health Education Research, Theory and Practice*, vol. 1, pp. 203-211, 1986.

²⁴⁰ Cigarette Advertising and Promotion Code, 1990.

²⁴¹ 60 FR 41314 at 41337, n. 225; citing Slade, J., "Tobacco Product Advertising During Motorsports Broadcasts: A Quantitative Assessment," presentation at the 9th World Conference on Tobacco and Health, October 10-14, 1994.

study did not mean that advertising plays a part in inducing children to start smoking" is an accurate statement of the study. The purpose of the study was to examine the effect of sponsorship on children's awareness of tobacco sponsorship and brand name identification with that sport, not on their smoking behavior. This fact is not a flaw but a description of the study design and the study's limitations. The study, however, is quite useful in showing the effect of sponsored events on young people's awareness of brands.

In addition, the comment selectively quoted a portion of the Aitken study (regarding linkages), while ignoring the reason the statement was made. The author of the study made this statement in the context of the finding that whereas only 9 percent of the primary schoolchildren named John Player Special or Marlboro as sponsoring or being associated with racing cars, 47 percent of primary schoolchildren chose John Player Special or Marlboro as being liked by "someone who likes excitement and fast racing cars." The authors also found that linkages or associations between cigarette brand names (or their visual cues) and exciting sponsored sports can be elicited by simple advertisements, even among children who do not have a critical awareness of the purpose of commercial sponsorship. This type of linkage is the primary issue, rather than whether such information is "conscious" or "unconscious" in nature.

(87) One comment stated that the study performed by Ledworth²⁴⁴ (the Ledworth study), which found that even a fairly brief exposure to tobacco sponsored sporting events on television may increase children's brand awareness, failed to control for other sources of information that could result in brand awareness (i.e., if a family member smokes), and that even the author of the study stated that further investigation needed to be done to determine whether tobacco sports sponsorship persuades children to smoke. The comment also stated that FDA cannot extrapolate the study results to the United States because the study was based on foreign sponsorship and viewership practices, which differ significantly from those in this country. The comment stated that the differences are highlighted by the fact that 74 percent of the surveyed children watched at least part of the snooker

match, and that the child viewership of NASCAR is "* * * significantly more limited, at most, even by Slade's number, to 7 percent."

The agency disagrees with the comment's criticism of the Ledworth study. The Ledworth study demonstrates the power of association between an event and brand awareness among young people. The study is evidence of the important link formed by that association.

(88) One comment stated that the study performed by Hock et al.²⁴⁵ (the Hock study), which showed that nonsmoking boys who saw a tobacco sponsorship advertisement had a diminished concern that tobacco hurt sports performance, "has no real relevance to the issue of event sponsorship and suffers from obvious, significant methodological flaws." The comment explained that the video viewed by one of the groups contained an advertisement promoting a cigarette company's sponsorship of a sporting event and thus reports the effect of a particular advertisement, not the effects of the types of sponsorships at issue here. The comment also stated that American tobacco companies are not permitted to advertise sponsorships in this fashion under 15 U.S.C. 1335 (the television advertising ban). The comment argued that the portion of the conclusion quoted by FDA overstates the results of the flawed research because the authors themselves emphasized that "nonsmokers'" general attitudes to smoking were not significantly affected by exposure to sponsorship events. Finally, the comment argued that, among the group of smokers, the authors reported that exposure to the sponsorship advertisement did not affect the smokers' brand choices, and that the authors cautioned that "these findings do not, in themselves, constitute a case for legislation."

The agency disagrees with the comment's criticism of the Hock study. Although the advertisement used in the Hock study may have been different than advertisements that appear in the United States, and only a single advertisement was tested, these factors alone do not render the author's conclusions invalid. Again, most importantly, the study provides evidence that brand sponsorship produces awareness of the product and the brand in young viewers. The agency

also disagrees with the comment's assertion that FDA overstated the findings of the study. The agency specifically acknowledged in the preamble to the 1995 proposed rule that exposure to the particular advertisement did not affect overall attitudes toward smoking (60 FR 41314 at 41338).

Moreover, the agency disagrees with the comment regarding brand preferences of smokers. As the study authors noted, the study primarily focused on nonsmokers. Thus, the fact that there were few smokers in the study makes it more difficult to find significant effects on smokers. In addition, the authors note more than once that the effects of sponsorship appear to be primarily on nonsmokers.

The important point of this study and the others cited by the agency is that sponsorship of events helps create a positive association between the event and the tobacco company. The child relates the event to the product and this contributes to the perception that tobacco use is acceptable and not dangerous. This attitude helps an environment that fosters experimentation with tobacco products.

Finally, the comment asserted that FDA's reliance on the two-page memorandum from Nigel Gray²⁴⁶ is "not only disingenuous, but demonstrates that FDA has not evaluated the data on which it purports to rely." The comment stated that "the statistics cited in this study lack any explanation or support." The comment also states that "[t]he conclusions stated in the memorandum are at odds with those in the studies by Aitken and Hock cited by FDA." The comment stated that the author cited a "Western Australian survey" that found that 65 percent of 10 to 11 year olds surveyed believed that tobacco sponsorship of sports is advertising for tobacco, whereas the Aitken study "found that only 4 percent of 10 to 11 year olds identified advertising as a component of sports sponsorships by tobacco companies." The comment also argued that the study by Hock found no effect of the sponsorship advertisement on brand choice, whereas the memorandum by Gray revealed that sponsorship did effect brand choice.

The agency recognizes that there are problems with the two-page memorandum from Nigel Gray because the data on which it was based have not been made available. Therefore, the

²⁴⁴ 60 FR 41314 at 41338, n. 227; citing Ledworth, F., "Does Tobacco Sports Sponsorship on Television Act as Advertising to Children," *Health Education Journal*, vol. 43, no. 4, 1984.

²⁴⁵ Hock, J., P. Gendall, and M. Stockdale, "Some Effects of Tobacco Sponsorship Advertisements on Young Males," *International Journal of Advertising*, vol. 12, pp. 25-35, January 1993.

²⁴⁶ 60 FR 41314 at 41338, n. 228; citing memorandum from Gray, N., (Anti-Cancer Council of Victoria), to all members of the Federal Parliament, December 15, 1989.

agency has placed no weight on its findings and does not rely on it in the final rule.

On the other hand, the memorandum cannot be used to diminish the usefulness of the other studies that have been cited. A careful reading of the data presented by the Aitken study reveals that indeed 17 percent of 10 to 11 year olds identified advertising as a component of sports sponsorship by tobacco companies. While it is true, as the comment indicated, that 4 percent mentioned only the advertising component, the comment has overlooked the fact that an additional 13 percent of 10 to 11 year olds mentioned both advertising and economic components.

In summary, these studies provide ample support that brand name sports sponsorship produces, for young people, memorable associations between the sport and the tobacco product and brand name. As shown in section VI.B.1. of this document, young people pay attention to and rely on peripheral cues such as the color and the imagery of advertising for some of their information about products. Tobacco sponsorship creates powerful images of fun and excitement to add to that "information" mix.

(89) FDA had proposed that entries, such as racing cars, or events or teams that participate in events be permitted to display a brand name in a black and white text only format. Thus, although the Skoal 500 would be prohibited, the Skoal Bandit racing car could participate in a race event.

Several comments supported the provision's requirement for teams and entries but recommended that the agency go further to restrict labeling on entries and teams in sponsored events. One comment, which was submitted by a "participant in motorsport events," stated that "even when the Marlboro name, for example, is removed from a racing car body, the distinctive color scheme still sends the Marlboro message, loud and clear."

One comment stated that "under the rationale applied to the regulation on event sponsorship, * * * FDA would be justified in restricting tobacco companies from entry and team sponsorship." The comment recommended that FDA "limit the scope of the terms 'entries' and 'sponsored events,' for the breadth of possible entries and possible events is enormous." The comment stated that for instance, professional sporting events such as football, basketball, baseball, and hockey games, should be excluded

from 'sponsored events,' so that tobacco product brand names cannot be used as the name of a professional sports team." The comment stated that the term "entries" is ambiguous because, for example, a race car competing in a sponsored race would qualify as an "entry" under the proposed rule, "but would the Company X Choir be considered an 'entry' when it appears in a sponsored concert?"

The agency has carefully considered the comments and has decided to delete "entries and teams in sponsored events" from the list of permissible advertising media in § 897.30(a) and to specifically include teams and entries within the scope of the ban on sponsored events. The agency is persuaded that sponsored teams and entries, such as cars: (1) Create the same associations with sports figures and other "heroes," (2) create a linkage between a tobacco product and an enjoyable and exciting event when they appear as part of an event, (3) are displayed for a significant period of time. They have the same potential to create images and influence children and adolescents as does sponsorship of events, and (4) are able to leave the event and be seen at fairs and malls and other places frequented by young people.

The agency appreciates the comment's suggestions that color and imagery are as problematic as the brand name but advises that the comment has misinterpreted the 1995 proposed rule. Proposed § 897.34(c) stated that sponsorship would be prohibited in "the brand name, logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of a product identification similar or identical to those used for tobacco or smokeless tobacco products." Thus, a car sponsored by Philip Morris may not be named after the Marlboro brand nor be painted in the distinctive tri-color pattern.

(90) Some comments addressed the issue of whether sponsorship is advertising. One comment argued that the International Events Group's (IEG) "IEG Complete Guide to Sponsorship" states that sponsorship is not advertising, and that the guide explains that advertising involves the delivery of messages about specific product attributes, while sponsorship merely shapes the consumer's image of the brand. Moreover, to the extent the IEG is identifying sponsorship as advertising, the comment asserted that the IEG guide is a publication by an organization that depends on sponsored events for its existence, and is not in the

business of conducting objective, statistically sound studies on the effects of sponsorship. Thus, the comment asserted, FDA has not cited any scientific study supporting the theory that sponsorship is advertising.

The comment argued that the position that sponsorship and advertising are one and the same is inconsistent with pronouncements from Congress and from the FTC. The comment argued that both Congress and the FTC have recognized that advertising includes messages about product attributes or appealing visual imagery, and the use of a brand name to identify an event includes neither. The comment asserted that "nothing in the [FTC]'s findings suggests a rationale that would apply to the mere display of a logo, trademark, or other product identifier when divorced from a selling message." The comment asserted that Congress has never classified sponsorship of events using brand names as advertising, and that the few times it has addressed this issue, Congress has issued laws that distinguish advertising from other forms of promotion that do not have the same impact as advertising.

The comment referred to an FTC order *In the Matter of Lorillard Tobacco*, 80 FTC 455, 457 (1972), which the comment argues defines "advertising" to include only those practices that typically contain a selling message; and *United States v. R.J. Reynolds Tobacco Company*, No. 76-Civ-814 (JMC) (SDNY 1981), which the comment argued confirms the Government's view that the selling message in advertising, not the mere display of a logo, was the focus of its concern.

In addition, the comment argued that another Federal agency agrees with this interpretation. The comment stated that the FCC, expressly permits "logos or logograms" as long as such announcements do not contain "comparative or qualitative descriptions, price information, calls to action, or inducements to buy, sell, rent or lease."

In contrast, some comments supported the assertion that sponsorship is very effective advertising. One comment included in its appendices the transcript of an ABC News Day One story broadcast August 10, 1995, that reported on the commercial value of sponsorship. The comment also included a recent story in *Winston Cup Scene* (October 19, 1995) which describes the advertising value that sponsors expect to receive from their sponsorships.

Contrary to the comments cited, the FTC asserted, in its comment, that sponsorship is advertising, citing its 1992 consent order involving the Pinkerton Tobacco Co., (Consent Order) C-3364 (1992).

The comment also stated that in 1995, the Department of Justice announced consent decrees resolving allegations that Philip Morris, Inc., and the owners of Madison Square Garden in New York City violated the Cigarette Act's ban prohibiting advertising for tobacco on television and other media regulated by FCC through the display of cigarette brand names and logos at live sporting events that were broadcast on television (*United States v. Madison Square Garden, L. P.*, No. 95-2228 (S.D.N.Y., April 7, 1995); *United States v. Philip Morris, Inc.*, No. 95-1077 (D.D.C. June 6, 1995)). The consent decrees prohibit Philip Morris and Madison Square Garden from placing cigarette advertising in places regularly in the camera's focus where they might be seen on television.

The agency finds that sponsorship is advertising within the scope of this regulation. The claim by the comments that the *Lorillard* and *Reynolds Tobacco* consent orders demonstrate that the FTC does not find sponsorship to be advertising is incorrect. The two cited cases are consent orders that did not provide a definition of advertising but limited the coverage of the consent order to the specific types of advertising mentioned in the order. The two orders clearly excluded categories of obvious advertising from the coverage of the order (see, e.g., point of sale advertisements less than 36 square inches).

Although the agency acknowledges that the "IEG Complete Guide to Sponsorship" (IEG guide) states that sponsorship is not advertising, IEG is creating a semantical distinction between one form of advertising (traditional media advertising) from other types of advertising (e.g., promotional items, sponsorship). The IEG guide states that "[w]hat sponsorship generally accomplishes *better* [emphasis added] than advertising is establishing qualitative attributes, such as shaping consumers' image of a brand, increasing favorability ratings, and generating awareness." In addition, the IEG guide states that sponsorship is more effective than advertising in increasing "propensity to purchase." This latter description of sponsorship falls within the courts definition of advertising in *Public Citizen v. FTC*, 869 F.2d at 1554, as

"any action to call attention to a product so as to arouse a desire to buy."

The agency finds for all these reasons that sponsorship can be regulated as advertising under the act.

(91) Several comments argued that FDA does not have the authority to restrict sponsorship events. One comment stated that FDA has no authority to regulate cigarette advertising to "break the link" between sponsored events and use of tobacco, and reduce the "friendly familiarity" that sponsorships generate among young people. The comment stated that FDA can prohibit only false or misleading restricted device advertising and cannot prohibit advertising that simply links a name to a product. One comment stated that it is difficult to understand how the sponsorship of the IndyCar Marlboro 500 or the National Hot Rod Association Winston Drag Racing Series, promotional activities that would be prohibited under the 1995 proposed rule, involve the "misbranding" of tobacco products.

Several comments addressed the issue of whether FDA's proposed ban on brand name sponsorship violates the First Amendment. Several comments argued that the proposed restrictions on advertising and promotional activities are overly broad and violate the First Amendment because the 1995 proposed rule would prohibit virtually all forms of tobacco sponsorship and advertising at motorsport events, and FDA made no attempt to limit the restrictions to advertisements directed at minors. One comment argued that the provision would not directly and materially advance the government's interest, because there is no reasonable basis for asserting that sponsorship causes youth tobacco use. The comment stated that FDA did not attempt to differentiate between those events that attract children and adolescents and those that attract adults. Thus, according to the comment, a ban on tobacco sponsorship of an event that few or no children or adolescents attend will not directly and materially advance a reduction in underage tobacco use.

In contrast, one comment which supported the provision stated that sponsored events have a direct and powerful impact on young people, and thus there is a "reasonable fit" under the final two prongs of the *Central Hudson* test. The comment argued that the 1995 proposed rule is narrowly tailored because "FDA has selected the approach that best effectuates its goal of reducing tobacco consumption by minors, without needlessly restricting

the industry's ability to sponsor events and garner the good will that flows from such sponsorship."

FDA concludes that sponsorship of events and sponsored teams and events is an advertising medium that is effective in influencing young people's decision to engage in smoking behavior and tobacco use.

As explained in this section, the agency has authority to restrict advertising of restricted devices like tobacco and smokeless tobacco under sections 520(e) and 502(q) of the act. As the studies described in this section²⁴⁷ demonstrate, sponsorship associates the advertised brand with the event and thus shapes the image of the brand and the individual's image of tobacco use. Sponsorship of rodeos and car racing, for example, associates the product with events where risks are high but socially approved and are taken by individuals who brave the odds.²⁴⁸ This type of situation fits in very well with the image concerns of adolescent males described in section VI.D.4.a. of this document.

Youths who attend the sponsored event are directly and unavoidably confronted with messages for the sponsoring product. This exposure creates a sense of familiarity and acceptance similar to that created by billboards near schools and playgrounds.

In addition, the sponsored events are televised. As a result of this fact, through mention of the sponsor and camera shots that pan the place where the event is held, awareness of the brand is created, along with the associations described above.

Given these factors, a restriction on sponsorship will be effective in limiting the influences on children and adolescents to use tobacco products and thus in protecting their health. Moreover, there is a reasonable fit between the restriction and FDA's interest. The restriction focuses on the use of the brand because of the association between the brand and tobacco use.²⁴⁹ By building associations with the brand, sponsorship and the advertising displayed at the event creates a desirable image for young people that contributes to a positive feeling about the product that sponsors

²⁴⁷ See e.g., Aitken, P. P., D. S. Leathar, and S. I. Squair, "Children's Awareness of Cigarette Brand Sponsorship of Sports and Games in the U.K.," *Health Education Research*, vol. 1, pp. 203-211, 1986.

²⁴⁸ IOM Report, p. 112.

²⁴⁹ Hock, J., P. Gendall, and M. Stockdale, "Some Effects of Tobacco Sponsorship Advertisements on Young Males," *International Journal of Advertising*, vol. 12, No. 1, January 1993.

the event. This positive image not only provides a brand that the young person might select but also adds to the young person's positive feelings about using the product. It is the creation of this association that FDA will prevent by restricting sponsorship.

FDA is not aware of any way to limit the restriction to events that are attended by young people. However, FDA has no desire to restrict manufacturers' abilities to contribute to the community by sponsoring athletic, cultural, or other events. Thus, the agency has narrowly tailored the restriction on sponsorship to use of brand identification because it presents the harm that FDA is trying to eliminate. For these reasons, FDA concludes that its restrictions on sponsorship are consistent with its legal authority and with the First Amendment.

(92) Several comments (including one from a participant in motorsport events) argued that allowing tobacco companies to place brand names and logos at highly visible locations during broadcast sporting events has afforded tobacco companies the opportunity to circumvent the Cigarette Act, which prohibited broadcast advertising of cigarettes. One comment stated that tobacco companies receive millions of dollars of free brand name television and radio exposure during these events and use messages in these advertisements that are particularly effective with children. One comment stated that "the degree to which sponsoring events gives tobacco companies television time is staggering," and "[j]ust in the televising of the Indiana 500 [sic], Marlboro received almost 3½ hours of television exposure and 146 mentions of its brand name." The comment cited cases where Congress and the courts have already recognized and upheld the importance and the constitutionality of keeping tobacco advertising off the airwaves (*Capital Broadcasting Co. v. Mitchell*, 333 F. Supp. 582 (D.D.C. 1971), *aff'd sub nom. Capital Broadcasting Co. v. Acting Attorney General*, 405 U.S. 1000 (1972)), and concluded that a reviewing court would likely sustain the provision regarding event sponsorship simply because it has become a pervasive tool used by the tobacco industry to evade the restriction on television advertising.

The agency finds that there is adequate support for its ban on brand name sponsorship of events. As stated in the preamble to the 1995 proposed rule and in response to an earlier comment, "[t]he amount and financial value of television exposure gained by

a firm can be substantial." The preamble to the 1995 proposed rule cited two studies which discussed the impact of sponsoring televised events and concluded that:

[t]he impact of sponsoring televised events such as these automobile races is perhaps most apparent when one realizes that over 10 million people attended these events, while 90 times that number viewed them on television.

(60 FR 41314 at 41337)

By restricting brand name sponsorship of events, the final rule will eliminate those brand name sponsored events that continue to permit tobacco product brand names to appear on television.

(93) Several comments expressed concern that the 1995 proposed rule was not sufficiently inclusive; specifically, it did not prohibit the incorporation of an event in a brand name by someone other than the tobacco company and did not explicitly ban the use of the name of a foreign tobacco company in U.S. sport events. Some comments stated that restricting sponsorship of entertainment and sporting events to corporate name only for corporate sponsors that had been in existence prior to January 1, 1995, "leaves open many shadow entities incorporated under tobacco brand names because tobacco transnationals have been creating these front groups for years to escape promotion restrictions in other countries."

One comment stated that Canada, after it had banned brand name sponsorship, found that industry used new "corporations" such as Camel Racing PLC to continue sponsoring in a brand name. Thus, the comments recommended that the regulation ensure that corporate sponsorship of events be allowed only if the corporate name is the name of the manufacturing entity and that the name has no similarity to a brand name of any of that manufacturer's tobacco products.

Several comments expressed concern about a recent trend among U.S. manufacturers to develop brands that are made by a corporate entity. For example, one comment stated that RJR has developed a series of brands with an art deco style of pack design and is selling them through a wholly owned subsidiary named Moonlight Tobacco.

Another comment stated that Philip Morris has been test marketing a brand called "Dave's," which it produces through a boutique company named "Dave's Tobacco Company." These comments stated that the agency should amend the 1995 proposed rule to prohibit any corporate name or logo that

had a brand name or product identification within it.

Finally, a comment stated that there are many other existing brand names that are also corporate names, such as "Rothmans" and "Sampoerna" (a brand of clove cigarette (Kretek) imported from Indonesia) that are manufactured overseas. This comment argued that non-U.S. corporate names must also be included in the final rules proscription.

The agency recognizes the concern expressed by the comments. As stated in the preamble to the 1995 proposed rule, the requirement that the corporation be in existence on January 1, 1995, is intended to prevent manufacturers from circumventing this restriction by incorporating separately each brand that they manufacture for use in sponsorship (60 FR 41314 at 41336). The comments have suggested that manufacturers may circumvent this restriction by the use of shadow entities, many of which have already been incorporated under tobacco brand names in other countries (or have been incorporated as events). The agency agrees that the proposed restrictions do not prevent this type of circumvention.

Thus, in response to the comments' suggestions, the agency has modified the proposed regulations to reflect that the registered corporate name and corporation must have been in existence and registered in the United States and have been in active use in this country before January 1, 1995. Thus, FDA has modified § 897.34(c) to state: "Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered, and in use in the United States prior to January 1, 1995, * * *." This provision makes clear that manufacturers are free to sponsor events in their corporate name but contains language that will prevent the type of circumvention of the restriction that was posited by the comments.

The agency also agrees with the comments that suggest that manufacturers may also attempt to circumvent this restriction by placing within the corporate name or logo elements of brand identification such as names (Smokin' Joe), colors (the tricolor decoration), etc. Tobacco products can be promoted using more than just the brand name. In fact, the name may be less important than the attractive

imagery, recognizable colors and patterns of colors (Marlboro), characters and heroes (Joe Camel racecar drivers) all of which provide the user with a desired image. A yellow motorcross bike with a head of a Camel conveys the image of Joe Camel without the name of the product. Therefore, it is necessary in order to break the link between the event and the product to restrict the images in addition to the name. Thus, FDA has modified § 897.34(c) so that it concludes with the following statement:

“* * * and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco products.

The agency also recognizes that at some time in the future, corporate entities may be formed to sell tobacco products, which are new to the tobacco business and in no way associated with current manufacturers. Should those entities desire to sponsor events, they would be precluded by the language of § 897.34(c) from doing so. The agency envisions that such entities could petition the agency, under 21 CFR part 10, for an exemption from this provision.

(94) One comment stated that FDA's proposed ban on brand-name sponsorship is an unjustified limitation on the right of private individuals to select their own sponsors.

This comment has misinterpreted the 1995 proposed rule. The rule does not limit the “right” of private individuals to select sponsors. Individuals are free to select any sponsor they choose. The rule, however, prohibits the event from including any brand name, logo, symbols, motto, selling message, or any other indicia of product identification similar or identical to those used for any brand of cigarette or smokeless tobacco. However, the final rule does not prevent corporate sponsors that were in existence and registered in the United States before January 1, 1995, from advertising in their registered corporate names.

(95) Several comments stated that sponsorship restrictions would have a negative impact on sports events. Approximately 300,000 copies of one form letter were submitted as comments. All included the statement: “I am 21 years of age or older and oppose the new regulations proposed by the Food and Drug Administration (Docket No. 95N-0253) that would prohibit tobacco company sponsorship

of entertainment and sporting events.” The form letter also stated that “If FDA gets control of tobacco and bans tobacco sponsorships, ticket prices could rise as well. And there might be fewer events. All this adds up to consumers being the big losers.”

One comment stated “I oppose any attempt by President or FDA to deny RJR the right to sponsor the Winston Cup Racing Series!” One comment stated “[b]y banning the sponsorship of NASCAR, the races won't get any money, and if they have to stop racing, that will make me mad, and I am too old to be getting mad—75 years [old].”

One comment stated that because of the potential loss of economic support, many events will not be viable if cigarette company sponsorship is no longer available. Several comments argued that FDA's proposed ban on sponsorship, promotional programs, and contests would eliminate events enjoyed primarily by adults. One comment stated that “[w]e believe that we and millions of other middle class fans like us, will no longer be able to afford the NASCAR we love.” One comment stated that the provision “will adversely affect the economy of the tobacco industry and that affects many people in many States, not just the racing industry and communities.”

One comment stated that the loss of sponsorship revenue to race track owners, operators, and promoters would negatively affect the motorsports industry because racing fans will suffer in the form of increased ticket prices or decreased services at motorsports events, and increased ticket prices will decrease attendance at race events, forcing racetrack operators to cut jobs and other employee benefits, further depressing the economies of hundreds of communities around the nation. The comment also stated that since motorsports injects hundreds of millions of dollars into local and regional economies, particularly in rural and suburban communities that have been the hardest hit by recession and job losses, FDA's proposed regulation would have a substantial impact on local and regional economies across the country and hurt the future of motorsports.

In contrast, one comment that supported the proposal was from a “dedicated car racer,” and stated that “the truth is that car racing will do just fine without tying its wonderful image to the interest of the cancer promoters.” The comment stated that:

in Europe where racing cars run without any cigarette advertising whatsoever, people

camp out for days trying to get into the events, and that the recent Formula One European Grand Prix was run in cold miserable, weather with packed stands and not a single cigarette logo in sight.

The comment stated that “I hope [FDA] will look out for the rest of us and stand firm in favor of a ban on tobacco advertising at all sporting events.”

One comment stated that “many of the millions of dollars spent on these promotions are available to the cigarette industry only because 3,000 children start smoking each day,” and “[t]his situation can be viewed as an industry demanding a bounty of 3,000 lives per day in exchange for its financial support of the sports, music, and other entertainment appealing to children and youth.”

One comment stated that:

the abundance of other sponsors indicates that auto racing would not fail if tobacco products are not allowed to be event sponsors and if teams sponsored by tobacco products are restricted to black and white uniform and car designs. Similar fears were expressed when cigarette commercials were banned from electronic media, but they proved groundless.

The comment stated that sponsors do not make a sport such as auto racing or rodeo popular because auto racing and rodeo are “compelling, popular spectator sports in their own right.” The comment stated that “popular sports attract sponsors who want to advertise.” The comment stated that “[t]he Olympics would remain a premier sporting event without Coca-Cola or Kodak” and “NASCAR stock car racing is among the most popular spectator sports to thrive.” The comment stated that “the audience is not there because of tobacco: tobacco is there because of the audience.”

The agency advises that the concerns expressed by some of these comments have misinterpreted the rule. The rule does not “prohibit tobacco company sponsorship of entertainment and sporting events” or “ban tobacco sponsorships, promotional programs, and contests.” The rule prohibits a sponsored event from being identified with a cigarette or smokeless tobacco product brand name or any other cigarette or smokeless tobacco brand identifying characteristic. All athletic, musical, artistic, or other social or cultural events would be permitted to be sponsored in the name of the tobacco company as long as the other conditions in § 897.34(c) are met.

In addition, the tobacco industry accounts for only 4 percent of all sponsored events. This rule does not prohibit the other 96 percent of

nontobacco forms of sponsorship (60 FR 41314 at 41337). Thus, even if the restriction on sponsorship of tobacco products resulted in a decrease of tobacco company sponsored events, the events will still exist through the support of the nontobacco forms of sponsorship. The agency agrees with the comment that "auto racing would not fail if tobacco products are not allowed to be event sponsors." Thus, restricting tobacco product brand name sponsorship clearly will not "ban all sponsorship events."

Finally, recent news stories quote persons knowledgeable about car racing saying racing would survive without tobacco sponsorship, for example, one quote: "If this happened 10 years ago, it would have been crushing to the racing industry. Now people are lining up to take Winston's place."²⁵⁰

In conclusion, FDA finds that sponsorship of events (such as car races, tennis matches, and rodeos) and entries in those events (race cars and drivers, tennis players) can have a profound effect on young people's attitude about and use of tobacco by providing multiple and prolonged exposure to the brand name and logo in a variety of media, thereby creating an impression of prevalence and normalcy about tobacco use (see section VI.D.3.c. of this document), by associating the product with varied positive events, images, and heroes, and by creating attractive and exciting images that can serve as a "badge" or an identification (see section VI.D.4.a. of this document). The industry itself recognizes the concern that sports figures as endorsers can create problems of hero worship and emulation; its Code promises not to employ sports or celebrity testimonials or those of others "who would have special appeal to persons under 21 years of age." Sponsorship creates no less of an association than an endorsement. Moreover, FDA finds that restrictions on sponsorship identified with a tobacco brand are necessary to reduce tobacco use by young people. These findings are based on studies and recent reports that the number of young people who attend these events or see them on television is significant and growing.

Studies—Four different studies, one each by Slade, Aitken, Ledworth, and Hock (60 FR 41314 at 41337 and 41338) and described further in this section,

provide evidence that sponsored events of all types are attended, and seen on television, by a substantial number of young people, and that the effect of the exposure is to increase brand awareness and association between the brand and the event. This attitude contributes to a sense of friendly familiarity about tobacco use and a perception that tobacco use is acceptable and common place.

Surveys on attendance and TV audience, described further in this section, establish that attendance by children at events and viewership by children and adolescents on television are significant. The preamble to the proposed rule used the number 64 million as an annual approximation of underage viewers of motorsport events in addition to those at the event (60 FR 41314 at 41337). In addition, newspaper articles detailed in this section describe the increasing importance of young people to sponsored events as a growing part of the live audience. Moreover, although less data is available on other types of sponsored events, comments received by the agency in response to the proposed rule, and described further in this section, state that many children and teenagers watch tennis, motorcycle and powerboat racing, and rodeos on television and attend and watch on television rock concerts and country music festivals.

Finally, the agency has tailored the restriction narrowly. The agency recognizes the importance of corporate sponsorship in engendering goodwill for a company with its customers and in providing support to sports, the arts, and music. Therefore, the agency has crafted the regulation to not interfere with this aspect of sponsorship but has merely denied the companies the right to use brand and product identification, which are most appealing to young people.

9. Proposed § 897.36—False or Misleading Statements

The agency proposed in § 897.36 that labeling or advertising of any cigarette or smokeless tobacco product:

is false or misleading if the labeling or advertising contains any express or implied false, deceptive, or misleading statement, omits important information, lacks fair balance, or lacks substantial evidence to support any claims made of the product. This provision would have explicitly implemented sections 201(n), 501(a) (21 U.S.C. 351), and 502(q)(1) of the act. Section 897.36 was meant to be illustrative rather than exhaustive.

The agency stated in the 1995 proposed rule that its regulations

concerning prescription drug advertising provide great specificity as to what constitutes violative advertising (part 202 (21 CFR part 202)) but that this same degree of specificity is not practical in the case of a widely used consumer product like tobacco because the advertising for it contains an unlimited variety of claims that make categorization difficult. Therefore, the agency tentatively concluded that it would provide general guidance for the types of advertising claims that will be considered violative, rather than to attempt to identify every possible type of false and misleading claim (60 FR 41314 at 41339 and 41340).

(96) Several comments objected to various portions of the definition, for example the phrases "omits important information" and "lacks fair balance." They asserted that the phrases expand the definition of what constitutes "misleading" advertising, are subjective, and make compliance burdensome because the phrases are not defined. Moreover, the comment complained that neither "fair balance" nor "substantial evidence" were appropriately included in the definition of false and misleading.

Additionally, the comments argued that laws regarding false and misleading advertising are well established, and that false and misleading advertising is subject to the jurisdiction of the FTC. The comment stated that it was, therefore, inappropriate for FDA to establish vague and overreaching parameters of "unfair and deceptive" advertising.

One comment stated that what "information" is important is undefined. It stated that there is always information that someone may consider "important" (e.g., price, availability, freshness, taste research), and that it would be unreasonable to allow FDA, or any regulatory organization or entity, to review tobacco advertising in the capacity of determining information that should have been included. This comment argued that the legal precedent defining deceptive advertising is already established and should not be changed by FDA.

One comment stated that by introducing the word "important" into the proposed standard for misbranding of tobacco, FDA has impermissibly gone beyond the "materiality" test for misbranding set forth by Congress in section 201(n) of the act, acted arbitrarily and capriciously, and proposed a new standard that is unconstitutionally vague.

²⁵⁰ Quoting Ardy Arani, a director of the Atlanta-based Championship Group, a sports marketing agency in Jacobsen, G., "Mass Merchandisers Jostle With Tobacco Companies to Cash in on the Auto Racing Craze," *The New York Times*, p. D71, February 21, 1996.

One comment stated that FDA also proposes that labeling or advertising would be false or misleading if it "lacks fair balance." It stated that FDA has obviously borrowed this concept from the prescription drug regulations (§ 202.1(e)(5)(ii)), but it is inapplicable to tobacco. The comment stated that, first, the "fair balance" requirement for drugs is based not on the section 502 "false or misleading" prohibition but rather on section 502(n)(3), which requires that prescription drug advertising contain a "true statement" relating to "side effects, contraindications, and effectiveness."

The comment stated that, second, as the drug regulation makes clear, the "fair balance" required is between information about a product's therapeutic benefits and information about its adverse effects when used. It stated that because no therapeutic claims are made for tobacco, the "fair balance" concept is simply inapplicable.

One comment, however, stated that, under this regulation, advertising for cigarettes and smokeless tobacco will be considered false or misleading if it "omits important information." It stated that this is a reasonable rule, and that it should be part of the final rule, but it is one that may be difficult for manufacturers to comply with absent guidance from FDA.

FDA has been persuaded that the proposed general guidance in proposed § 897.36 on what might constitute false and misleading advertising has created unintended confusion. Under section 502(a) and (q)(1) of the act, any restricted device is misbranded if its advertising or labeling is false or misleading in any particular. Section 201(n) of the act states that:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

After review of the applicable provisions of the act concerning labeling and advertising, the agency has determined that those provisions are adequate and that the definition in proposed § 897.36 is unnecessary.

Because cigarette and smokeless tobacco advertising remains subject to regulatory action if it is false or misleading in any particular, FDA has decided to delete § 897.36 from the final rule.

(97) Some comments supporting proposed § 897.36 recommended that specific restrictions be placed on advertising that emphasizes tar and nicotine levels and implies a weight benefit to tobacco products.

Other comments suggested requiring the disclosure of ingredients. These comments argued that consumers do not know the ingredients of these products or the functions that these ingredients serve. It added that consumers do not know the doses of nicotine and other critical materials that they ingest with these products. The comment stated that terms such as "light" and "low tar" have little meaning in view of the tendency of consumers to smoke cigarettes differently depending upon the way nicotine delivery has been engineered. A comment from a tobacco company opposed disclosure of ingredients fearing loss of valuable trade secret information.

The agency has decided that these comments fall outside the scope of this rulemaking. The agency did not propose labeling or advertising restrictions concerning the levels of tar, nicotine, or other components of cigarettes or smokeless tobacco, or perceived benefits of tobacco products, only that labeling or advertising not be false or misleading. It did not receive comments sufficient to warrant restrictions addressing these issues. Consequently, advertising and labeling claims will be evaluated on a case by case basis for compliance with sections 201(n), 502(a), (q), and (r), 510(j) (21 U.S.C. 360(j)), and 520(e) of the act. Therefore, FDA is not modifying part 897 to address these concerns at this time.

F. Additional First Amendment Issues

Finally, several general issues were raised by commenters concerning the nature of the protection afforded commercial speech by the First Amendment.

(98) One comment argued that the original understanding of the First Amendment was that truthful commercial messages are fully protected.

In response to this comment, FDA points out that the Supreme Court took the position that the First Amendment does not protect commercial speech (see *Valentine v. Chrestensen*, 316 U.S. 52 (1942)), until it repudiated that position in *Virginia State Bd. of Pharmacy v.*

Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976). Since 1976, the Court has decided numerous cases, most recently *Rubin v. Coors, Florida Bar v. Went For It, Inc.*, and 44 *Liquormart Inc. v. Rhode Island*, that address the level of protection afforded commercial speech by the First Amendment. FDA has followed that case law in its development of this final rule. Therefore, FDA has developed this final rule in accordance with the applicable law.

(99) A comment filed by an association of advertising agencies warned that the proposed regulations "establish a dangerous precedent that could open the floodgates to dramatic government intrusion into the process of communication * * * and [are] a dangerous blueprint for government censorship of other kinds of advertising." The comment expressed concern that regulations of advertising for tobacco products will permit, in fact will encourage, the future regulation of other "controversial products."

Tobacco products are not "controversial" products as these comments contend. They represent the single most preventable cause of death in the United States (1989 Report to the Surgeon General at p. i). Not only is the harm caused by tobacco use real (the comment refers to "imagined harm"), but the product that produces the disease and death is addictive. Moreover, tobacco use begins among young people, who may be able to describe the risks of tobacco use, but who do not personalize that risk to themselves. These young people begin to use tobacco before they can adequately weigh the consequences of use and thus, become addicted and subject to the real long term harms caused by tobacco use. That is why all 50 States and the District of Columbia outlaw the sale of tobacco products to those under 18 years of age. Finally, as discussed in section VI.D. of this document, advertising does affect young people's decision to use tobacco products in a significant and material way. This is not an "assertion" made out of whole cloth but a reality. Thus, regulation of tobacco advertising may set a precedent for future government action, but it sets a high threshold for such regulation.

The Supreme Court has granted ample protection to commercial speech, but the Court has also stressed, nothing in the First Amendment prevents the Government from ensuring "that the stream of commercial information flows cleanly as well as freely." (See *Edenfield*

v. *Fane*, 506 U.S. 761, 768.) One comment noted: "This concern takes on special force where, as here, crucial public health concerns are implicated, and where a particularly powerful seller * * * has used its virtually limitless resources to saturate the marketplace with its promotional messages."

The Government's interest in protecting the health of children and teenagers through measures designed to prevent them from beginning a lifetime of addiction and disease is of the highest order and is sufficient justification for the restrictions finalized here.

VII. Education Campaign

In the Federal Register of August 11, 1995 (60 FR 41314), the Food and Drug Administration (FDA) proposed to require that tobacco companies establish a national education program, using television as its predominant medium, to discourage children and adolescents from using cigarettes and smokeless tobacco (the 1995 proposed rule). The agency received more than 1,500 comments concerning the program, nearly three-quarters of which favored going forward with it. The comments raised many issues concerning the program as proposed, including whether the proposed funding would be either equitable or sufficient, whether industry's level of involvement would jeopardize its effectiveness, whether current industry educational programs are sufficient, about the design of the educational programs, the manufacturer's obligations to carry them out, the agency's statutory authority to require an education campaign under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360j(e)), and the constitutionality of the campaign as proposed.

The agency has reexamined its statutory authority for requiring an education campaign and believes that section 518(a) of the act (21 U.S.C. 360h(a)) is more appropriate and practicable than the restricted device authority in section 520(e) of the act under which FDA had proposed the education campaign. Under section 518(a) of the act, if the agency finds that a device presents an unreasonable risk of substantial harm to the public health, that notification is necessary to eliminate this risk, and that no more practicable means is available under the act, then, after consultation with device manufacturers, the agency may issue a notification order that requires them to notify the appropriate persons in a form appropriate to eliminate the risk. The

agency has used section 518(a)'s separate, affirmative grant of statutory authority on a number of occasions to compel medical device manufacturers to provide notice to users or potential users of their products about risks presented by their use or misuse.

The agency believes that, with respect to cigarettes and smokeless tobacco, it could make the findings required by section 518(a) of the act and so could order tobacco manufacturers to notify young people about the substantial health risks that tobacco products present in a form appropriate to eliminate the risk. That is, the agency believes that it could find that cigarettes and smokeless tobacco present an unreasonable risk of substantial harm to the public health, that notification is necessary to eliminate this risk, and that no more practicable means is available under the act.

The agency has concluded, therefore, that it will not require an education campaign as part of this tobacco rule. The agency intends, however, to send letters that indicate that the agency believes that it could make the statutory findings necessary to issue notification orders under section 518(a) of the act to cigarette and smokeless tobacco manufacturers. As section 518(a) of the act requires, these consultation letters will offer tobacco companies an opportunity to consult with the agency about the necessity for, and specific requirements of, any notification orders before the agency issues any orders to the companies.

Because the education campaign will not be a requirement of this final rule, the agency need not respond to the many comments that it received concerning the proposed campaign. Nevertheless, because the agency intends to pursue implementation of an education campaign using the notification provision of section 518(a) of the act, the agency will respond briefly to comments that questioned the effectiveness and design of the proposed education campaign.

(1) The agency received comments questioning the effectiveness of other educational campaigns and the agency's use of these campaigns to support the position that a national educational campaign would be effective in helping reduce tobacco use among young people. Comments from the tobacco industry argued that studies cited by FDA are scientifically flawed and therefore that the agency overstated the likely effects of the provision. One industry comment argued that FDA

misinterpreted a study by Simonich²⁵¹ (the Simonich study), cited in the preamble to the 1995 proposed rule to demonstrate that the media campaign conducted under the Fairness Doctrine (FD) reduced cigarette consumption by 6.2 percent (60 FR 41314 at 41327). The comment concluded that the data from the Simonich study indicated that the overall effect of the Fairness Doctrine was merely a 0.4 percent decline in per capita consumption.

FDA disagrees with the industry's interpretation of the Simonich study. The agency believes that the Simonich study results, correctly interpreted, indicate that the FD education campaign reduced per capita cigarette consumption an average of 4.5 percent,²⁵² that is, a 4.5 percent reduction in consumption over the period of time over which the FD was in effect for entire quarters. Thus, the FD education campaign did play an important role in reducing per capita cigarette consumption.

(2) Comments also questioned the effectiveness of education programs cited by the agency. The tobacco industry's comment argued that California's \$26 million multi-year media campaign actually confirmed that televised education campaigns do not influence youth smoking. Further, the comment stated that it was not possible to say what impact, if any, a national media campaign's introduction or termination had on consumption in Greece because Greece's educational television and radio advertising campaign was only one element of an overall education campaign.

With regard to the California media campaign, FDA notes that this campaign was directed to adults, not young people. Moreover, the media campaign was countered by increased per capita spending by the tobacco industry in the types of imagery-based advertising that influences children and adolescents. Therefore, the agency would have expected the media campaign to have had a greater negative impact on tobacco use by adults than by children and

²⁵¹ Simonich, W. L., "Government Antismoking Policies," Peter Lang Publishing, Inc., 1991.

²⁵² Simonich modeled the effect of the FD as: $\Delta \text{Consumption} = -0.063(X_t + .46416X_{t-1} + .46416^2X_{t-2} + .46416^3X_{t-3})$ where X_t represents antismoking advertising expenditures in quarter t and -0.063 is the coefficient for the FD stock variable obtained from the analysis (*Id.*, p. 153). FDA used Simonich's model and his "Estimated Fairness Doctrine Real Advertising Expenditure per Capita 14+" data series (*Id.*, pp. 250, and 259-260) to calculate the quarterly percent reduction in per capita cigarette consumption from March 1967 through April 1970. The average percent reduction in consumption for this period was 4.5 percent.

adolescents. FDA continues to believe that California's efforts indicate that education campaigns, over time, can counter and reduce the impact of prosmoking efforts.

Further, while the comment correctly notes that Greece's national effort to reduce smoking included posters, booklets, and similar educational materials distributed through schools, health centers, and other channels, the primary and most significant element of its program consisted of antismoking messages broadcast on television and radio. FDA continues to believe the Greek experience indicates, as stated in the preamble to the 1995 proposed rule, that intensive education and media messages about the health risks associated with tobacco use can be effective.

(3) Many comments from the tobacco and media industries and from adult smokers argued that an education campaign is unnecessary because cigarette manufacturers, individually and through the Tobacco Institute, have undertaken voluntarily a variety of educational programs aimed at discouraging underage smoking, and because antismoking lessons are taught in schools.

By contrast, other comments questioned industry's commitment to reduce underage use of tobacco products. For example, several comments emphasized that a voluntary program run by industry in the mid 1980's failed to acknowledge that tobacco is addictive or causes disease.

FDA agrees with comments that the tobacco industry has failed to include in its voluntary youth educational programs important information, such as the addictive nature of tobacco and the association between tobacco use and disease. FDA further agrees that this lack of complete information about tobacco products makes it necessary to require that messages about the risks of tobacco use be directed to children and adolescents. The recently observed decline in the proportion of youth who see smoking as dangerous, despite the widespread dissemination through schools of information about the health hazards associated with tobacco use, supports the need for an immediate response to this problem. Moreover, recent evidence suggests that school-based education programs most effectively reduce underage smoking when used in conjunction with media messages.

VIII. Additional Regulatory Requirements

Subpart E of part 897 in the Food and Drug Administration's (FDA's) August 11, 1995, proposed rule (60 FR 41314) would have consisted of three provisions: § 897.40 would have required manufacturers to submit certain reports and would have required manufacturers, distributors, and retailers to make records available to FDA upon inspection; § 897.42 would have instructed manufacturers, distributors, and retailers to comply with any more stringent State or local requirements relating to the sale, distribution, labeling, advertising, or use of cigarettes and smokeless tobacco and would have notified State and local governments how to request an advisory opinion concerning the preemptive effect of part 897 on any particular State or local requirement; and § 897.44 would have required the agency to take additional regulatory measures if, 7 years after the date of publication of the final rule, the percentage of people under age 18 who smoke cigarettes had not decreased by 50 percent since 1994 and/or the percentage of males under 18 who use smokeless tobacco had not decreased by 50 percent since 1994.

Proposed § 897.40 Records and Reports, would have implemented sections 510(j) and 704(a) of the act (21 U.S.C. 360(j) and 374(a)) with respect to cigarettes and smokeless tobacco. Section 510(j) of the act requires the submission of labels, labeling, and a representative sampling of advertising to FDA, and section 704(a) of the act gives the agency inspection authority, which also includes the authority to examine records, files, papers, processes, controls, and facilities:

bearing on whether * * * restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act.

Proposed § 897.42 Preemption of State and Local Requirements and Requests for Advisory Opinions, was intended to reflect the preemption provision in section 521(a) of the act (21 U.S.C. 360k(a)); that section states, in relevant part, that:

no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which

relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Proposed § 897.42 was also intended to recognize that many States and local governments have enacted innovative and effective laws and regulations pertaining to cigarettes and smokeless tobacco and to encourage further activity in these areas (60 FR 41314 at 41340).

In proposed § 897.44 Additional Regulatory Measures, FDA recognized that many different factors influence a young person's decision to start smoking or to use smokeless tobacco and that the affected industries have historically shown their ability to find new ways of promoting their products whenever restrictions were imposed (60 FR 41314 at 41341). Consequently, to guard against the possibility that its comprehensive regulations might be circumvented and to give firms an incentive to take appropriate actions to discourage cigarette and smokeless tobacco sales to people under 18, the agency proposed to require additional regulatory measures if the outcome-based objectives specified in proposed § 897.44 were not met.

In response to comments and upon further examination of existing statutory and regulatory requirements, the agency has deleted §§ 897.40, 897.42, and 897.44 from the final rule.

§ 897.40—Records and Reports

Proposed § 897.40(a) would have required each manufacturer to submit, on an annual basis, copies of all labels (or a representative sample of labels if the labels would be similar for multiple products), copies of all labeling, and a representative sample of advertising. Proposed § 897.40(b) would have provided an address for such materials.

(1) The agency received a number of comments from distributors, wholesalers, and retailers stating that it would be too costly and time-consuming, and thus too burdensome for small businesses to submit the information required by proposed § 897.40(a) and further, that the information collected would not be useful in prohibiting young people from using tobacco products.

These comments misread proposed § 897.40(a) by interpreting the section to apply to distributors of tobacco products. By its terms, this provision only applied to manufacturers of cigarettes and smokeless tobacco. FDA agrees with the comments that it is unnecessary for the agency to receive labels, labeling, and a representative

sampling of advertising for cigarettes and smokeless tobacco handled by distributors. In order to clarify this point further, FDA has deleted proposed § 897.40(a) and (b), and is explicitly exempting distributors of cigarettes and smokeless tobacco from the registration requirement in section 510 of the act. Exempting distributors from the registration requirement results in their exemption from the record submission requirements in section 510(j) of the act. The agency has amended the existing device registration and listing regulations in part 807 by adding a new provision, at § 807.65(j), to reflect this exemption.

FDA is authorized, under section 510(g)(4) of the act, to exempt persons from the requirement of registering under section 510 of the act. The agency agrees with the comments discussed above that stated that reporting by distributors would be too burdensome and would not result in any useful information. FDA believes that it will receive all the information it needs from manufacturers, who are required to list information with FDA under section 510 of the act. Further, there was virtually no public comment supporting a registration and listing requirement for distributors. Based on these considerations, FDA finds that it is appropriate to exempt distributors of cigarettes and smokeless tobacco, as defined in § 897.3(c), from the registration requirement in section 510 of the act as originally proposed because compliance with section 510 of the act by distributors "is not necessary for the protection of the public health."

A comment from the cigarette industry argued that § 897.40(a) was inconsistent with the recordkeeping requirements in part 807 (21 CFR part 807) (the device registration and listing regulations) by requiring annual submissions. A comment from a public health organization supported proposed § 897.40, and stated that the reporting requirements were the same as those faced by other manufacturers of drug delivery devices.

Cigarette and smokeless tobacco manufacturers are required to register and list under section 510 of the act. Upon consideration of the industry comment, the agency believes it is more appropriate for manufacturers to comply with the existing device registration and listing requirements in part 807 than to create new requirements in this regulation. Therefore, as stated earlier, FDA has deleted proposed § 897.40(a) and (b) from the rule.

(2) A comment from the country's largest association of health professionals supported proposed § 897.40, but suggested that FDA expand the reporting requirements to have each manufacturer monitor brand-specific uptake by children and adolescents. The comment suggested that these data could be used to supplement information from the Monitoring the Future project and other surveys that do not currently contain brand-specific data. The comment also stated that cigar and loose-leaf tobacco manufacturers should be required to monitor and report on use of their products by people under 18.

The agency declines to accept the comment's suggestions. FDA believes it is not necessary to obtain such data at this time. Rather, it is more appropriate to allow the provisions of the final rule to become effective and to monitor the effectiveness of the program before considering the addition of new requirements. FDA also notes that it is not asserting jurisdiction over cigars; cigar manufacturers are not subject to the requirements of this rule.

Proposed § 897.40(c) would have required manufacturers, distributors, and retailers to make records and other information available to FDA inspectors for purposes of inspection, review, copying, or any other use related to the enforcement of the act.

(3) An industry comment argued that proposed § 897.40(c)—which required manufacturers, distributors, and retailers to "make all records and other information collected under this part and all records and other information related to the events and persons identified in such records" available to FDA officials—so exceeds FDA's authority that it fails the test set out in *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950), and, therefore, violates the Fourth and Fifth Amendments to the Constitution. The comment argued that § 897.40(c) may require the release, for example, of marketing strategies, sales figures, profits, personnel data, and proprietary information.

FDA disagrees with this comment, but nevertheless, the agency has deleted § 897.40(c). Part 897 does not add records requirements beyond those applicable to devices generally under existing regulations, e.g., part 803 (21 CFR part 803) (medical device reporting), part 804 (21 CFR part 804) (medical device distributor reporting), part 807 (registration and listing), and part 820 (21 CFR part 820) (good manufacturing practice). Section

897.40(c), as proposed, is therefore unnecessary, since FDA retains the records, reports, and inspection authority with respect to cigarettes and smokeless tobacco that it has with respect to other restricted devices. This authority is found, for example, in sections 510, 519, 702, 703, and 704 of the act (21 U.S.C. 360, 360i, 372, 373, and 374). In particular, section 704 of the act explicitly authorizes the agency to inspect records regarding restricted devices, including records and reports (and the related research) required under section 519 of the act, shipment data, and data as to the qualifications of technical and professional personnel performing functions subject to the act, except that such inspections may not extend to financial, sales, pricing, or other personnel and research data.

Warrantless inspections of drug and device manufacturers authorized by section 704 of the act are "reasonable" and therefore consistent with the Fourth Amendment, in part because section 704 delineates the scope of inspections with respect to prescription drugs and restricted devices. (See *United States v. Jamieson-McKames Pharmaceuticals*, 651 F.2d 532, 538 and n.9 (8th Cir.), *cert. denied*, 455 U.S. 1016 (1981).)

In particular, section 704 of the act meets the test established by the Supreme Court, and cited in the comment, that is applied to scrutinize administrative subpoenas under the Fourth Amendment's proscription of unreasonable searches and seizures and the Fifth Amendment's Due Process Clause: "the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant" (*Morton Salt*, 338 U.S. at 652 (regarding order requiring report about compliance with earlier agency order); see also *EEOC v. Shell Oil Co.*, 466 U.S. 54, 72 n.26 (1984) (citing *Morton Salt* regarding administrative subpoena); *Reich v. Montana Sulphur and Chem. Co.*, 32 F.3d 440, 448 (9th Cir. 1994) (same), *cert. denied*, 115 S.Ct. 1355 (1995); *Resolution Trust Corp. v. Walde*, 18 F.3d 943, 946 (D.C. Cir. 1994) (same)).

The comment stressed that § 897.40(c) as proposed failed to satisfy the first part of the *Morton Salt* test because the act does not grant FDA authority to regulate tobacco products and because Congress has repeatedly refused to give FDA such authority. As discussed in detail in the 1996 Jurisdictional Determination annexed hereto, FDA is extending jurisdiction over tobacco products by a lawful application of the act. Moreover, the records, reports, and

inspection provisions in sections 510, 519, 702, 703, and, in particular, section 704 of the act, clearly specify the agency's authority to inspect regarding restricted devices, including records and reports required pursuant to section 519 of the act. An inspection of records from manufacturers, distributors, or retailers regarding tobacco products—which are restricted devices and which pursuant to this rule are subject to the reporting requirements of parts 803 and 804—is therefore “within the authority of the agency” as required by the Supreme Court in *Morton Salt* (338 U.S. at 652). Moreover, because sections 704 and 519 of the act define the scope of such requests, by their terms, such requests would meet the second and third parts of the *Morton Salt* test, since they would not be “too indefinite and the information sought [would be] reasonably relevant” to enforcement of the provisions of part 897 (*Id.*).

Even in the absence of proposed § 897.40(c), manufacturers, distributors, and retailers of cigarettes and smokeless tobacco are subject to the same records access and inspection requirements as are any manufacturers, distributors, and retailers of restricted medical devices. As discussed in this section, these requirements are fully consistent with the Fourth and Fifth Amendments.

(4) Several comments from distributors and retailers asserted that the recordkeeping requirements in proposed § 897.40(c) would be expensive and especially hard on small businesses. A few comments also claimed that proposed § 897.40(c) would not affect sales to children and adolescents, but would instead result in lost business as distributors or retailers would have to take the time to prepare and to maintain records. A small number of comments simply opposed proposed § 897.40(c) without providing any reason or said it was “offensive,” “intrusive,” or would not produce any useful information during an inspection.

As stated previously in this section, FDA has revised the rule to delete § 897.40(c) entirely. The agency believes that the existing reporting requirements in other regulations (such as part 803 for medical device reporting (as amended by this rule), part 804 for medical device distributor reporting (as amended by this rule), part 807 for registration and listing (as amended, to exclude distributors of cigarettes and smokeless tobacco), and part 820 for good manufacturing practices) make proposed § 897.40(c) unnecessary. The agency has also amended the rule to exempt distributors of cigarettes and

smokeless tobacco from part 807. Thus, distributors are only expected to comply with the medical device distributor reporting requirements in part 804.

Retailers have no recordkeeping or reporting requirements under part 897.

Notwithstanding these changes to the rule, FDA believes that the comments misunderstand the purpose of recordkeeping and reporting. The records and reports that were described in the 1995 proposed rule were never intended to have a direct role in reducing illegal sales to children and adolescents. Neither were they intended to divert distributor or retailer staff to ministerial functions or to intrude into business activities. To the contrary, records and reports can help firms and FDA ensure compliance with the regulations. For manufacturers, distributors, and retailers, records and reports demonstrate whether they have complied with a particular requirement. Records are especially valuable in this respect because FDA's enforcement strategy relies heavily on site inspections to determine whether a party has complied with a statutory or regulatory requirement, and records can show or help an agency inspector determine whether a firm has a good compliance history. Firms that have good compliance histories usually are inspected less frequently than others, whereas firms with poor compliance histories may be inspected more frequently or more rigorously.

Inspections have other important benefits for firms. Inspections can reveal areas where firms can improve their operations. Inspections also apply to firms equally, regardless of their size, so firms that manufacture, distribute, or sell the same or similar products meet the same conditions or requirements. Furthermore, inspections, and FDA enforcement generally, give consumers greater assurance in the products they purchase because those products are held to the same standards or requirements.

For FDA, records and reports can provide information on current industry practices and trends, help identify potential problems in a regulatory program or in a firm's or industry's practice, and even conserve agency resources by letting the agency concentrate its inspection efforts on firms with poor compliance histories.

Thus, for these reasons, FDA disagrees with those comments suggesting that recordkeeping and reporting requirements or FDA inspections will have no useful purpose.

§ 897.42—Preemption of State and Local Requirements and Requests for Advisory Opinions

(5) FDA received several comments that opposed proposed § 897.42, claiming that it was inconsistent with the process for requesting exemptions from the preemption requirement in section 521 of the act. The agency also received some comments supporting proposed § 897.42 precisely because it would have recognized and would have preserved more stringent State and local requirements.

After careful consideration and closer review of the act, the agency has deleted proposed § 897.42 from the rule. This issue is addressed in greater detail in section X. of this document.

Under § 897.44 of the 1995 proposed rule, FDA would have established goals of a 50-percent reduction in cigarette use by individuals under the age of 18 years; a 50-percent reduction in smokeless tobacco use by males under the age of 18 years; and no increase in smokeless tobacco use by females under the age of 18 years. The agency stated it would take additional regulatory measures if these goals were not met 7 years after the publication date of the final rule.

FDA derived its outcome-based goals from the “Healthy People 2000” objectives. “Healthy People 2000” sets national health promotion and disease prevention objectives for Americans. The report was a joint effort by the U.S. Public Health Service (PHS), the Institute of Medicine (IOM) at the National Academy of Sciences (NAS), almost 300 national membership organizations such as the American Medical Association (AMA), the American Academy of Pediatrics (AAP), and the Blue Cross and Blue Shield Association, and all State health departments. “Healthy People 2000” established a basic goal to reduce by half the initiation of cigarette smoking by children and youth by the year 2000.

The agency proposed measuring progress toward the stated goals by use of an objective, scientifically valid, and generally accepted survey, such as the Monitoring the Future Project (MTFP). MTFP, funded by the National Institute on Drug Abuse (NIDA) and administered by the Institute for Social Research at the University of Michigan, has collected data on daily smoking by 12th graders every year since 1976 and on smokeless tobacco use by 12th graders for the years 1986 to 1989 and 1992 to 1995.

The agency did not include any specific additional requirements in the

1995 proposed rule, but stated that FDA would propose specific additional measures when it publishes a final rule and invited public comment on what additional requirements should be considered.

The agency received a number of comments arguing that the agency should wait until it knows specifically what progress has been made toward the goals before proposing additional regulatory measures. This approach would allow the agency to identify specific barriers to achieving the goals and to tailor any additional requirements to these barriers. Other comments argued that FDA must provide the public an opportunity to comment on specific additional regulatory measures before they would take effect. FDA has decided that there is merit to these comments. At this time, therefore, the agency is not proposing additional regulatory measures beyond the restrictions in this regulation and the requirements under section 518 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h). The agency instead plans to monitor industry compliance with the agency's requirements as well as the progress made toward meeting the stated goals of reducing the use of tobacco products by individuals under the age of 18 within 7 years. In the event that additional measures are necessary to achieve the goals, the agency retains the authority to propose and issue additional regulatory requirements in a future rulemaking proceeding.

FDA received approximately 60 individual comments related to this provision, about evenly divided in support and opposition. Opposition came primarily from the tobacco manufacturing and advertising industries and from tobacco retailers. Comments from several State legislators also opposed additional measures, as did one from a State department of agriculture. Some comments maintained the provision was invalid and unconstitutional; others objected that "when regulations fail, the answer is not more regulations."

Support for the measure came from national health organizations, State health departments, and individuals who identified themselves as parents, public health professionals, educators, and former smokers. Supporters stressed the importance of effective measures to improve the health of current and future generations.

(6) One comment opposing the proposed provision contended that imposing additional regulatory

measures at the time that the final rule is published would be unreasonable because it would not permit a flexible response to future circumstances. It argued, for example, that the same additional regulatory measures "apparently would be triggered at the specified date regardless of whether the reduction in the next 7 years is 49.8 percent or 2 percent."

Several comments in support of the provision also advocated greater flexibility, but for different reasons. Because of the serious adverse health effects linked to the use of tobacco products, these comments urged the agency not to wait 7 years to evaluate progress and institute corrective measures. Instead, they recommended interim or ongoing review of compliance with the regulations and progress toward achieving the goals.

FDA agrees it is useful to put in place a system that will allow flexibility in responding to future circumstances. Therefore, the agency has decided to review on an ongoing basis the effectiveness of specific provisions. It will rely on data from the MTFP and other surveys recognized as using sound methodology to help measure compliance with the provisions, detect loopholes, and evaluate progress in achieving the goals. This will permit FDA to identify problem areas in a timely manner and seek public comment on whether additional measures should be considered.

(7) Some comments objected to any further restrictions. Others argued specifically against further advertising restrictions, saying it is illogical to impose such additional measures without first considering and attacking other causes for continued smoking among youth. A few comments were concerned that the proposed provision would inevitably result in a complete ban of all tobacco products, with a few of those charging that this was FDA's true intent.

One comment objected to the agency announcing as part of a final rule specific measures it will impose, rather than simply propose, some time in the future, maintaining that " * * * the agency will have failed to provide meaningful notice and opportunity to comment."

Many comments supported additional regulatory measures, if needed, to achieve the desired reductions in tobacco use by young people. Some advocated further restrictions on advertising, including: (1) Eliminating all tobacco product advertising except for point-of-purchase announcements of

product availability limited to black and white text only; (2) prohibiting all point of purchase advertising; (3) eliminating direct mail marketing for cigarettes and smokeless tobacco; (4) prohibiting all outdoor advertising; (5) prohibiting advertising in publications marketed to youths, and possibly revising the definition of "adult publications"; and (6) outlawing all marketing of cigarettes and smokeless tobacco. One comment recommended plain packaging of cigarettes, and one suggested broadening the proposed education program.

Comments also proposed additional sales restrictions on tobacco products, including stringent licensing requirements, increasing the age of sale to 19, and selling cigarettes in cartons only.

FDA rejects the comments suggesting that the agency intends to eventually ban all tobacco products, as the agency has repeatedly stated that such an outcome is not the appropriate public health response under the act. FDA is not proposing the additional restrictions on advertising or access suggested in the comments because FDA does not anticipate at this time that these additional measures will be required.

IX. Implementation Dates

The Food and Drug Administration (FDA) has concluded that the provisions of this rule should become effective 1 year after its date of publication in the Federal Register, with three exceptions. A 6-month effective date is established for the requirements in § 897.14(a) and (b) prohibiting retailers from selling cigarettes or smokeless tobacco to persons under age 18 and requiring retailers to check photographic identification of young purchasers for proof of age. The requirement in § 897.34(c) prohibiting sponsorships using cigarette or smokeless tobacco brand names or other indicia of product identification will be effective 2 years from the date of publication of this final rule. Finally, manufacturers will be required to comply with the registration and listing requirements in part 807, and the good manufacturing practice requirements in part 820, 2 years from the date of publication of this final rule.

Although the agency specifically requested comment on when the various provisions in the proposed rule should become effective, FDA received relatively few comments on this subject.

(1) One comment that opposed the rule argued that FDA should give industry an opportunity in a hearing to challenge the "factual underpinnings"

of the rule before proceeding to implementation. In contrast, a supporting comment strongly favored immediate action to implement the rule, and a second comment stated that postponing implementation by even a year "means that another 500,000 young people will become regular users of tobacco products." Another supporting comment recommended that the effective date for provisions that prohibit sales to persons under 18 be no more than 90 days from the date the final regulations are issued, and that the effective date for provisions affecting advertising and labeling be 6 months from the date the final regulations are issued.

FDA is not persuaded that a hearing is needed on the "factual underpinnings" of the rule. In the preamble to the 1995 proposed rule, the agency provided its rationale and evidentiary basis for each provision of the regulation; interested persons have had a full opportunity to submit their comments and any factual supporting data for the agency to consider. Informal notice and comment rulemaking does not require more. Moreover, the agency believes that there would be little to gain from holding such a hearing, and that this step would needlessly delay implementation of the final rule. Full responses to the challenges made by this and other comments on the factual bases for the rule are provided in this document.

Because FDA has found that thousands of children purchase cigarettes every day, the agency agrees with the supporting comments that restrictions on such sales should be put into effect as soon as possible. FDA recognizes, however, that the States also have laws restricting youth access to tobacco products, some of which may be preempted under section 521 of the act by this final regulation. The agency intends to allow sufficient time for applications for exemption from preemption to be requested, considered by the agency, and acted upon. Therefore, FDA has determined that § 897.14(a) and (b), which prohibit the sale of tobacco products to individuals under the age of 18 and require retailers to examine a photographic identification to ensure that the purchaser is at least 18 years of age, and is basic to the goals of this final rule, will become effective 6 months from the date of publication of this final rule in the Federal Register. This should allow adequate time for the agency to process the applications for exemption from preemption while not unduly delaying

the implementation of a very important part of the regulation.

(2) As for the recommendation by one comment that the advertising and labeling provisions of the rule become effective 6 months after the final rule is issued, FDA believes that this period of time is not consistent with the agency's policy of allowing sufficient time for affected entities to learn about and comply with new regulatory requirements. Instead, based on its own experience and that of other Government agencies in regulating product advertising and labeling, FDA has arrived at a period of 1 year from the date of publication of this final rule in the Federal Register for manufacturers, distributors, and retailers to meet most of the requirements of the rule. In reaching this conclusion, FDA has taken into consideration the time needed to comply with all the requirements of the rule, including time for designing new labeling and advertising, for printing or filming these new materials, for affixing new product labels and disseminating new advertising materials, and for using up existing inventories of products, supplies of promotional materials, and coupons that do not comply with the new requirements.

Examples of activities that will become violative and must cease 1 year from the date of publication of this rule in the Federal Register include vending machine sales of cigarettes and smokeless tobacco and sales from self-service displays (except in the narrowly-defined locations that are exempted), sales of single cigarettes from opened packages ("loosies"), sales of packages with fewer than 20 cigarettes, mail-order redemption of coupons for tobacco products, distribution of free tobacco samples, and the sale or distribution of nontobacco items showing the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern or colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Examples of additional requirements that must be met 1 year from the date of publication include all advertising requirements (except as noted below), and the requirement that manufacturers not use a trade or brand name of a nontobacco product on a cigarette or smokeless tobacco product except as specified in § 897.16(a).

The agency is excepting from the 1-year implementation period the requirement that manufacturers comply with the existing registration and listing

requirements, found in part 807. The agency recognizes that manufacturers are not accustomed to complying with these recordkeeping and reporting requirements and will require additional time in which to develop appropriate compliance procedures. Therefore, FDA is granting manufacturers 2 years from the date of publication of this final rule to begin complying with the requirements under part 807. The same reasoning has led the agency to allow manufacturers the same 2-year-period to prepare before they are required to comply with the good manufacturing practice requirements in part 820.

Finally, the agency is also excepting from the 1-year implementation period the prohibitions in § 897.34 (c) of sponsorship using cigarette or smokeless tobacco brand names or other indicia of product identification. The agency recognizes that sponsorship of events is often arranged well in advance and that some event promoters may be disadvantaged if they are not allowed adequate time to replace tobacco sponsors who elect to cease sponsoring the event, rather than switch to their corporate name. Accordingly, this final rule provides that § 897.34(c) will become effective 2 years from the date of publication of this final rule.

X. Relationship Between the Rule and Other Federal and State Laws

This section of the document discusses issues concerning the relationship between this rule and other Federal and State laws. More specifically, sections X.A. and X.B. of this document analyze comments that addressed the potential effect upon this rule of other Federal statutes that contain express provisions that restrict some areas of Federal regulation of tobacco products. Section X.C. of this document analyzes comments that raised the issue of whether this rule conflicts with the congressional purpose behind the current regulatory scheme for tobacco products. Section X.D. of this document analyzes comments that addressed the issue of whether Congress intended for the current regulatory scheme for tobacco products to be exclusive, such that this rule might be foreclosed. Finally, sections X.E. and X.F. of this document analyze comments that addressed the preemptive effect under the Federal Food, Drug, and Cosmetic Act (the act) that the Food and Drug Administration's (FDA's) regulation of tobacco products as drug delivery devices will have upon

State and local requirements and upon State product liability claims.

A. The Federal Cigarette Labeling and Advertising Act

(1) A number of comments argued that FDA's August 11, 1995, proposed rule (60 FR 41314) (the 1995 proposed rule) is precluded by section 5 of the Federal Cigarette Labeling and Advertising Act (the Cigarette Act (15 U.S.C. 1334)). Other comments expressed the opposite view, stating that 15 U.S.C. 1334 did not preclude the 1995 proposed rule. Some of the comments that found no preclusion noted that the scope of 15 U.S.C. 1334 is narrow, and applies only to cigarette packages, thereby allowing for regulation of cigarette advertising and promotion as contemplated by the 1995 proposed rule. After considering all of the comments, FDA has concluded that none of the rule's provisions, as embodied in the final rule, is expressly precluded by the Cigarette Act. The following analysis explains this conclusion.

The Cigarette Act contains the following provisions pertaining to regulation of cigarettes:

(a) No statement relating to smoking and health, other than the statement required by [15 U.S.C. 1333], shall be required on any cigarette package.

(b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

(15 U.S.C. 1334 (emphasis added))

15 U.S.C. 1334(b) is expressly limited to requirements or prohibitions imposed under State law, that relate to advertising or promotion of cigarettes. Thus, 15 U.S.C. 1334(b) is inapplicable to FDA's regulation under part 897 and does not foreclose FDA from regulating cigarette advertising or promotion.

15 U.S.C. 1334(a), which applies to statements on the cigarette package, extends to both Federal and State regulation. However, the scope of 15 U.S.C. 1334(a) is narrow, precluding Federal and State regulation of cigarettes only to the extent that such regulation would require any statement (other than the statement required by 15 U.S.C. 1333) "relating to smoking and health" to appear on the cigarette package.

There are two types of information that the final rule requires on cigarette packages. The first is the "established name," such as "Cigarettes," which is required by section 502(e)(2) of the act (21 U.S.C. 352(e)(2)), and which the

agency is implementing under § 897.24. The established name requirement is applicable to all devices regulated under the act, and it serves merely to aid consumers in the identification of the product.

The second type of information that the final rule requires on cigarette packages is the statement of intended use and age restriction required under § 897.25. This statement informs consumers about the products' intended uses and that the products may not be sold to persons under the age of 18.

Neither the established name nor the statement of intended use and age restriction is "relat[ed] to smoking and health." Any indirect relationship these requirements might have to smoking and health is incidental and would be too "tenuous, remote, or peripheral" to trigger preclusion under 15 U.S.C. 1334(a). (See *District of Columbia v. Greater Washington Bd. of Trade*, 113 S. Ct. 580, 583 n.1 (1992) ("Pre-emption does not occur * * * if the [law at issue] has only a 'tenuous, remote, or peripheral' connection with [the subject to which preemption is applicable], as is the case with many laws of general applicability") (citations omitted).) To find otherwise could render the limiting language of 15 U.S.C. 1334(a) meaningless. (See *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995) (finding that overly broad construction of the phrase "relate to" "would * * * read Congress's words of limitation as mere sham, and [would] read the presumption against pre-emption out of the law whenever Congress speaks to the matter with generality").)

The agency notes that the established name requirement under § 897.24 is analogous to requirements imposed by the Bureau of Alcohol, Tobacco and Firearms (BATF) on cigarette packages. Under 26 U.S.C. 5723(b), "[e]very package of tobacco products * * * shall * * * bear the marks, labels, and notices, if any, that the Secretary by regulation prescribes." Under this statutory provision, BATF has issued regulations requiring, for instance, that "[e]very package of cigarettes shall * * * have adequately imprinted thereon, or on a label securely affixed thereto, the designation 'cigarettes', the quantity of such product contained therein, and the classification for tax purposes, i.e., for small cigarettes, either 'small' or 'Class A', and for large cigarettes, either 'large' or 'Class B'." (See 27 CFR 270.215.) In the same way that the requirement under 27 CFR

270.215 does not run afoul of 15 U.S.C. 1334 because it does not relate to smoking and health, the established name requirement under § 897.24 is also not precluded.

Further guidance on the scope of preclusion under the Cigarette Act can be found in the legislative history and purpose behind the Cigarette Act. The history and purpose make clear that Congress intended 15 U.S.C. 1334 to preclude only those "statements" that constituted warning or cautionary statements on cigarette packages. (See *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608, 2618–19 (1992) (finding that "no statement relating to smoking and health" language in 1965 version of the Cigarette Act referred to the sort of warning provided for in section 4 of that statute).)²⁵³ (See also H. Rept. 449, 89th Cong., 1st sess. (1965), reprinted in 1965 U.S. Code Cong. & Admin. News 2350, 2350 (the Cigarette Act prohibits "the requirement of any other caution statement on the labeling of cigarettes under laws administered by any Federal, State, or local authority").)

Clearly, neither § 897.24 nor § 897.25 is a warning or cautionary statement of the type Congress intended to preclude under 15 U.S.C. 1334. Accordingly, the requirements under these sections of the final rule are not foreclosed by the Cigarette Act.

B. The Comprehensive Smokeless Tobacco Health Education Act

(2) Several comments noted that the 1995 proposed rule would prohibit advertisements for smokeless tobacco from appearing in certain locations and media. One comment stated that any prohibition on advertising under the 1995 proposed rule amounts to a "compelled absence of advertising," and is as much a "statement relating to the use of smokeless tobacco and health" as is an explicit message requirement. Thus, the comment asserted that such restrictions are expressly precluded by the Comprehensive Smokeless Tobacco Health Education Act (the Smokeless Act).

²⁵³ Some of the comments take issue with FDA's application of Federal-State preemption law, pointing out that the Supremacy Clause and Tenth Amendment upon which this law is based have no application in determining the relationship between different Federal statutes. FDA is fully aware that Federal-State preemption law, as well as those cases such as *Cipollone* that apply it, do not directly govern the present situation concerning preclusion of Federal regulations by Federal law. However, the principles contained in Federal-State preemption law provide some general guidance for determining the scope of preclusion intended by Congress, regardless of whether that preclusion is directed at State or Federal law.

Another comment stated that FDA's proposed restrictions on the advertising of smokeless tobacco are foreclosed because they directly affect such advertising in a manner that is "so nearly identical" "in purpose and effect" to the advertising requirements mandated by the Smokeless Act that they fall within that statute's express prohibition of any other Federal "statement" related to smoking and health. In contrast, some comments stated the position that the 1995 proposed rule is not expressly precluded by the Smokeless Act.

After considering all comments, FDA has concluded that none of the 1995 proposed rule's provisions, with one exception, is expressly precluded by the Smokeless Act. The following analysis explains this conclusion.

The Smokeless Act contains the following provision pertaining to regulation of smokeless tobacco:

No statement relating to the use of smokeless tobacco and health, other than the statements required by [15 U.S.C. 4402], shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

(15 U.S.C. 4406(a) (emphasis added))

15 U.S.C. 4406(a) precludes only "statement[s]." Most requirements under the final rule, such as those that limit the locations or media in which smokeless tobacco may be advertised, do not constitute "statements" within the meaning of 15 U.S.C. 4406(a). (See *Banzhaf v. Federal Communications Commission*, 405 F.2d 1082 (D.C. Cir. 1968) (holding that the FCC ruling was not precluded by the Cigarette Act because the ruling did not require inclusion of any "statement * * * in the advertising of any cigarettes"), *cert. denied*, 396 U.S. 842 (1969).) Thus, those sections of the final rule that limit the location or media in which smokeless tobacco may be advertised, as well as other requirements in the final rule that do not actually mandate an affirmative statement, are not expressly precluded by the Smokeless Act.

Only three sections of the final rule actually require inclusion of a "statement" on the packaging or in the advertising of smokeless tobacco. These sections are §§ 897.24, 897.25, and 897.32(c). In addition, proposed § 897.36, which is being omitted from the final rule for reasons discussed later in this section, would have required such a statement.

As with cigarettes, § 897.24 requires that packages of smokeless tobacco bear the products' established names.

Section 897.25 mandates, in part, that packages of smokeless tobacco bear a statement of the products' intended uses and age restriction. Section 897.32(c) requires that advertising for smokeless tobacco include the products' established names and statements of their intended uses. (See section 502(r)(1) and (r)(2) of the act.)

For reasons similar to those discussed with regard to the Cigarette Act, none of the statements required under §§ 897.24, 897.25, and 897.32(c) are precluded under 15 U.S.C. 4406(a). (See section X.A. of this document.) First, the required statements do not directly "relat[e] to the use of smokeless tobacco and health." Second, the required statements are not "statements" of the sort precluded by 15 U.S.C. 4406(a) because they do not convey any type of cautionary message or warning of the sort Congress intended to foreclose. Accordingly, the statements are not precluded by 15 U.S.C. 4406(a).

Proposed § 897.36 would have declared the labeling or advertising of cigarettes and smokeless tobacco to be false or misleading if it contained "any express or implied false, deceptive, or misleading statement, omit[ted] important information, lack[ed] fair balance, or lack[ed] substantial evidence to support any claims made for the product." Upon review of the comments and reconsideration of this provision, FDA believes that, in some instances, manufacturers of smokeless tobacco might have been required under FDA's proposed rule to incorporate a statement relating to the use of smokeless tobacco and health on the package or in the advertising of a smokeless tobacco product in order to correct an omission of important information or a lack of fair balance. Similarly, cigarette manufacturers might have been required to include a statement relating to smoking and health on the cigarette package. Such requirements would be precluded under the Smokeless Act or the Cigarette Act. Thus, FDA has omitted § 897.36 from the final rule.

The agency notes, however, that tobacco products, like other products regulated under the act, are still subject to section 502(a) of the act, which provides, in part, that a device shall be deemed to be misbranded "[i]f its labeling is false or misleading in any particular." Any requirement imposed under section 502(a) of the act upon tobacco products is limited, however, to the extent that it is precluded by the Smokeless Act or the Cigarette Act.

C. Conflict With Congressional Purpose Behind Current Regulatory Scheme For Tobacco Products

A number of comments asserted that the 1995 proposed rule conflicts with other Federal statutes that regulate tobacco products. These comments focused on three specific statutes: The Cigarette Act, the Smokeless Act, and the Public Health Service Act (the PHS Act)

1. The Cigarette Act and The Smokeless Act

(3) A number of comments argued that the 1995 proposed rule would conflict with, and would nullify, some of the congressional objectives behind the Cigarette Act and the Smokeless Act. Based on the alleged conflict, some of the comments asserted that the general provisions of the act must give way to the specific provisions of the Cigarette Act and the Smokeless Act.

FDA disagrees. As explained in sections X.A. and X.B. of this document, FDA regulation of tobacco products under the authority of the act does not conflict with the Cigarette Act or the Smokeless Act, and thus such regulation is clearly capable of coexisting with these statutes. (See *Connecticut National Bank v. Germain*, 112 S. Ct. 1146, 1149 (1992) ("so long as there is no 'positive repugnancy' between two laws, a court must give effect to both") (citation omitted); *Morton v. Mancari*, 417 U.S. 535, 551 (1974) ("The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective").)

The comments asserted a number of areas in which the 1995 proposed rule would allegedly conflict with Federal law and congressional intent:

(4) Numerous comments argued that the 1995 proposed rule is precluded because Congress, through enactment of the Cigarette Act and the Smokeless Act, intended to foreclose all Federal agencies other than the Federal Trade Commission (FTC) and the Federal Communications Commission (FCC) from regulating the labeling and advertising of tobacco products. Some of the comments criticized the 1995 proposed rule, asserting that it would cause tobacco product manufacturers to be held to separate and conflicting standards of conduct by different agencies, thus conflicting with congressional intent to prevent "diverse, nonuniform, and confusing cigarette

labeling and advertising regulations.” As a specific example of potential separate and conflicting Federal standards, some of the comments noted that proposed § 897.34 would completely prohibit the use of some promotional items that are exempted by FTC from the congressionally mandated warning under the Cigarette Act.

FDA disagrees with these comments. When Congress enacted the Cigarette Act and the Smokeless Act, it very carefully considered the proper scope of preclusion applicable to Federal agencies in the regulation of tobacco products. The express terms of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a) clearly reflect the full scope of preclusion of Federal agencies intended by Congress.

Had Congress believed more preclusion to be necessary, it could have easily expanded the express scope of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a). (See *Banzhaf*, 405 F.2d at 1089 (Had Congress intended to foreclose other types of Federal regulation, “it might reasonably be expected to have said so directly—especially where it was careful to include a section entitled ‘Preemption’ specifically forbidding designated types of regulatory action”); *Central Bank of Denver v. First Interstate Bank*, 114 S. Ct. 1439, 1448 (1994) (Congress knows how to enact legislation expressly).) Indeed, Congress took this very approach with respect to the scope of preemption applicable to States under the Cigarette Act when it drafted 15 U.S.C. 1334(b) in a broad manner to encompass “requirement[s]” and “prohibition[s].”

The discrepancy in Congress’ choice of words with regard to the scope of 15 U.S.C. 1334(a) and (b) is significant in its implications. By not including “requirement or prohibition” in 15 U.S.C. 1334(a) and expressly foreclosing only “statements” relating to smoking and health, Congress clearly intended to narrowly limit the scope of foreclosure of regulation applicable to Federal agencies. (See *Brown v. Gardner*, 115 S. Ct. 552, 556 (1994) (“[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion”) (citation omitted).) In a similar fashion, Congress demonstrated an intent to restrict the scope of Federal preclusion under 15 U.S.C. 4406(a) by narrowly tailoring the language of that subsection.

Thus, given the narrow scope of 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a), the Cigarette Act and the Smokeless Act

do not foreclose “separate” Federal requirements, other than cautionary health-based statements as discussed in sections X.A. and X.B. of this document. Although the final rule imposes requirements on tobacco product manufacturers, these requirements do not conflict with the Cigarette Act or the Smokeless Act and, consequently, are not precluded by those statutes. Moreover, that FTC might allow certain actions under its statutory mandate does not preclude FDA from prohibiting such actions under a different statutory mandate. (See *New York Shipping Ass’n v. Federal Maritime Comm’n*, 854 F.2d 1338, 1367 (D.C. Cir. 1988) (“there is no anomaly if conduct privileged under one statute is nonetheless condemned by another”), *cert. denied*, 488 U.S. 1041 (1989).)

(5) Some of the comments asserted that Congress intended that the sole health-based restraints that were to be imposed on the commerce of tobacco products were to be those provided in the Cigarette Act and the Smokeless Act.

FDA disagrees with this assertion. First, FDA clearly may exercise legal authority to regulate tobacco products when the evidence establishes that the products have intended uses that fall within the act’s definition of a “drug.” Indeed, the agency has done so in several instances. (See, e.g., *United States v. 354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes claimed to reduce weight were drugs because they were intended to affect the structure or function of the body); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 338–39 (D.N.J. 1953) (cigarettes claimed to prevent respiratory diseases were drugs because they were intended to treat or prevent disease).) Moreover, the comments’ assertion that health-based constraints can be imposed upon tobacco products only under the Cigarette Act and the Smokeless Act necessarily leads to the erroneous conclusion that much Federal and State regulation, such as health-based workplace smoking restrictions and health-based age limits on access, is foreclosed. As other comments recognized, Congress obviously did not intend for such broad preclusion to be the case. (See *Banzhaf*, 405 F.2d at 1089 (finding that “[n]othing in the [Cigarette Act] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation”).)

(6) Some comments asserted that FDA’s proposed restrictions on certain advertising for tobacco products are at odds with congressional intent to allow the continued use of advertising for these products in conjunction with the statutorily required warnings.

FDA disagrees. As discussed in sections X.A. and X.B. of this document, preclusion of Federal regulation of advertising for tobacco products is very narrow in scope and does not encompass FDA’s final rule. Moreover, as one court has noted:

[T]here is no anomaly if conduct privileged under one statute is nonetheless condemned by another; we expect persons in a complex regulatory state to conform their behavior to the dictates of many laws, each serving its own special purpose. (*New York Shipping Ass’n*, 854 F.2d at 1367)

Thus, the mere fact that certain advertising for tobacco products is permitted under the current regulatory scheme for those products does not preclude FDA from placing restrictions on such advertising.

(7) Some comments alleged that the 1995 proposed rule would conflict with Federal law and congressional intent because it would have an impact on the commerce of tobacco products.

FDA disagrees. Any proscriptive regulation of tobacco products inevitably imposes economic burdens upon commerce of those products. Thus, following the comments’ line of argument, all proscriptive regulation of cigarettes is foreclosed by the Cigarette Act and the Smokeless Act. As explained in this section, however, by enacting 15 U.S.C. 1334(a) and 15 U.S.C. 4406(a), Congress chose the proper level of limitation on Federal regulations that it concluded was necessary to protect the commerce of tobacco products from being unduly economically burdened. Because requirements contained in the final rule are not precluded under those provisions, the fact that the requirements will have economic consequences upon the commerce of tobacco does not mean those requirements are foreclosed.

(8) One comment argued that the 1995 proposed rule is precluded because Congress could not have intended for any agency to have the authority to prohibit the sale of cigarettes. The comment derived this “intent” from pieces of legislation enacted by Congress that provide for the regulation of specific aspects of cigarettes but do not prohibit their sale.

FDA disagrees. Enactment of legislation giving other agencies authority over particular aspects of

cigarettes means only that Congress has decided to take those particular actions; it does not imply that Congress has determined that other Federal regulation is prohibited. Congress can implement policy in only one way: passage of a bill by the House and the Senate that is either signed by the President or approved by an overridden veto. (*INS v. Chadha*, 462 U.S. 919, 954–58 (1983); *Central Bank*, 114 S. Ct. at 1453.) Because Congress has not adopted any legislation that specifically prohibits FDA from regulating tobacco products, the final rule is not precluded.

In summary, FDA's final rule has been narrowly tailored so that it does not conflict with the existing statutory scheme governing tobacco products, and the final rule is not precluded.

2. The PHS Act

Section 1926 of the PHS Act conditions a State's receipt of the full amount of Federal block grants (to be used for prevention and treatment of substance abuse) upon the recipient State having in effect a law that makes it "unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18" (42 U.S.C. 300x-26(a)(1)).

(9) Some of the comments argued that section 1926 of the PHS Act demonstrates an intent on the part of Congress to preserve, and encourage enforcement of, State youth access restrictions. The comments asserted that because FDA regulation of youth access to tobacco products would have a preemptive effect upon some State regulation in this area, the 1995 proposed rule conflicts with this congressional intent. Accordingly, argued the comments, section 1926 of the PHS Act precludes FDA from regulating youth access.

While FDA agrees that section 1926 of the PHS Act indicates a congressional intent to encourage States to establish age limits on the purchase of tobacco products, neither the statute's language nor its legislative history prohibits Federal regulation of youth access. The restrictions in the final rule regarding the sale and distribution of tobacco products do not conflict with section 1926 of the PHS Act, and, in fact, facilitate the end result that Congress sought—reducing youth smoking—by "reducing the appeal of cigarettes and smokeless tobacco to, and limiting access by, persons under 18 years of age." (See 60 FR 41314 at 41321.) Accordingly, FDA's regulation of youth access is not precluded by the existence

of section 1926 of the PHS Act. (See 61 FR 1492, January 19, 1996.)

(10) One comment asserted that the 1995 proposed rule is precluded by section 1926 of the PHS Act because, "in the legislative process that led to enactment of [section 1926], Congress considered and rejected a variety of specific requirements of the very type that FDA now proposes." The Supreme Court, however, has made clear that courts are "reluctant to draw inferences from Congress' failure to act." (*Brecht v. Abrahamson*, 113 S. Ct. 1710, 1719 (1993) (citations omitted).) The mere fact that Congress, in enacting section 1926 of the PHS Act, did not incorporate requirements of the type FDA is now imposing in no way precludes FDA's final rule which was issued under the agency's regulatory authority under the act.

D. Occupation of the Field

(11) Numerous comments asserted that the 1995 proposed rule is impliedly precluded by the comprehensiveness of existing legislation relating to regulation of tobacco products. Several comments argued that Congress has specifically reserved the power to regulate tobacco for itself, and thereby has occupied the field. A number of comments asserted that the present system of congressional control over tobacco products precludes FDA regulation absent a new mandate from Congress.

FDA disagrees with these comments. The statutes enacted by Congress for regulation of tobacco products do not amount to a comprehensive scheme. Rather, they address only a few specific aspects relating to regulation of tobacco products. Moreover, even if Congress' actions in this area were "comprehensive," Congress clearly did not intend for regulation under the Cigarette Act and the Smokeless Act to be exclusive. (See *Banzhaf*, 405 F.2d at 1089 (finding that Congress did not intend to foreclose Federal regulation of cigarettes outside the narrow scope of preclusion contemplated by the Cigarette Act).) As explained in greater detail in sections X.A., X.B., and X.C. of this document, the statutes that the comments cite, whether viewed individually or collectively, do not preclude FDA from regulating tobacco products.

First, as some comments noted, Congress has not taken action to exclude from FDA's jurisdiction tobacco products that fall within the act's definitions of "drug" and "device." The face of the statute is the first place that a court must look to determine whether

Congress has spoken to a particular issue and whether congressional intent in regard to that issue is clear. (*Kofa v. INS*, 60 F.3d 1084, 1088 (4th Cir. 1995); *Metropolitan Stevedore Co. v. Rambo*, 115 S. Ct. 2144, 2147 (1995).) Under the act, FDA has jurisdiction over products that are intended to address disease or to affect the structure or any function of the body. (See section 201(g) and (h) of the act, 21 U.S.C. 321(g) and (h); 60 FR 41314 at 41463.) Thus, the relevant language of the act—"intended to affect the structure or any function of the body"—does not on its face exclude tobacco products.

Congress is able to exclude and has excluded specific products, including tobacco products, from a statute's reach when it wishes to do so. For example, Congress has expressly excluded other products from FDA's jurisdiction under the act. (See, e.g., section 201(i) of the act (21 U.S.C. 321(i)) (excluding "soap" from definition of "cosmetic"); section 201(s) of the act (excluding "color additive" from definition of "food additive").) Moreover, Congress has expressly excluded tobacco products from the reach of other regulatory statutes. (See, e.g., 15 U.S.C. 2052(a)(1)(B) (Consumer Product Safety Act); 15 U.S.C. 1261(f)(2) (Federal Hazardous Substances Act); 15 U.S.C. 2602(2)(B)(iii) (Toxic Substances Control Act); 21 U.S.C. 802(6) (Controlled Substances Act); 15 U.S.C. 1459(a)(1) (Fair Packaging and Labeling Act).) Indeed, tobacco is excluded from the definition of "dietary supplement" under the act, but no similar exclusion appears in the definition of "drug" or "device." See section 201(g), (h), and (ff) of the act (21 U.S.C. 321(g), (h), and (ff)). The absence of an express exclusion for tobacco products from the act's definitions of "drug" and "device" eviscerates the contention that Congress clearly intended to preclude FDA from regulating tobacco products.

Second, as recognized by some comments, the fact that statutes such as the Cigarette Act and the Smokeless Act delegate some regulatory authority over tobacco products to other Federal agencies does not preclude FDA's rule. Numerous Federal agencies have overlapping and complementary jurisdiction that arises from their differing missions and expertise. (See, e.g., *Rueth v. EPA*, 13 F.3d 227, 228 (7th Cir. 1993) (EPA and Army Corps of Engineers have concurrent jurisdiction under the Clean Water Act); *Public Utility Dist. No. 1 v. Bonneville Power Admin.*, 947 F.2d 386, 395 (9th Cir. 1991) (FERC has concurrent jurisdiction

with other Federal agencies as well as States over hydroelectric projects), *cert. denied*, 112 S. Ct. 1759 (1992); *United Packinghouse, Food and Allied Workers Int'l Union v. NLRB*, 416 F.2d 1126, 1133–34 n.11 (D.C. Cir.) (NLRB and EEOC have concurrent jurisdiction over racial discrimination claims), *cert. denied*, 396 U.S. 903 (1969).) As discussed in section X.C. of this document, the fact that several agencies are already charged with regulating certain aspects of tobacco does not preclude FDA from asserting jurisdiction for different purposes. (See *Banzhaf*, 405 F.2d at 1089 (“Nothing in the [Cigarette Act] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation”).)

In conclusion, FDA's final rule is not precluded by the existing regulatory scheme for tobacco products.

E. Preemption of State and Local Requirements Under Section 521(a) of the Act

Under proposed § 897.42, State or local requirements that are more stringent than, and do not conflict with, requirements imposed under FDA's final rule would not have been preempted under section 521 of the act (21 U.S.C. 360k).

(12) Several comments supported the intended exclusion from preemption under proposed § 897.42, noting that it is essential that State and local officials retain the ability to enact and enforce laws which they believe are most effective when actively enforced at the local level.

In contrast, several comments took issue with the proposed exclusion and asserted that regulation of tobacco products by FDA as drug delivery devices would result in the preemption of State and local laws. The comments characterized the “blanket” exclusion from preemption under proposed § 897.42 as being at odds with the statutory preemption established by section 521(a) of the act and with the exemption procedures established by section 521(b) and by FDA's regulations.

Several comments argued that proposed § 897.42 would conflict with congressional intent behind the act. One comment noted that preemption under section 521(a) of the act was intended to establish national uniformity in medical device regulation, protecting such products from onerous burdens on interstate commerce created by a patchwork of State and local

requirements. The comment argued that the proposed exclusion from preemption would cause uniform Federal standards to become displaced by diverse State and local requirements. Another comment asserted that, by allowing more stringent State and local requirements, proposed § 897.42 was at odds with the act because Congress did not intend for FDA's device regulations to be minimum standards; rather, it intended for those regulations to be the governing standards unless local circumstances justified an exception.

Finally, one comment pointed out that the 1995 proposed rule would permit only those State and local requirements that are at least as “stringent” as the requirements imposed under FDA's rule. The comment asserted that FDA may not preempt any State laws, however, without first showing a “clear and manifest congressional intent” to authorize preemption of those State laws.

As a preliminary matter, two points of clarification are necessary. First, proposed § 897.42 would not have caused State and local laws to become Federal requirements, as one of the comments anticipated. Rather, the 1995 proposed rule would have allowed State and local laws to remain in force subject solely to State or local enforcement.

Second, proposed § 897.42 would not have “resuscitated” State and local laws that would otherwise be preempted by the Cigarette Act or the Smokeless Act, as some of the comments anticipated. Instead, the exclusion from preemption in proposed § 897.42 would have applied only to preemption under section 521 of the act.

Upon consideration of all of the comments relating to proposed § 897.42, the agency recognizes that significant concerns have been raised with regard to the validity of FDA's proposed preemption exclusion for all more stringent State and local legislative enactments. Most notably, the agency concurs that the notice and comment process of the current rulemaking does not provide the type of opportunity for an oral hearing contemplated under section 521(b) of the act. In light of this concern, FDA has deleted proposed § 897.42.

The agency's 1995 proposed rule to exclude all more stringent State and local requirements from any preemptive effect under this rule was based on a recognition of the pioneering and continuing role in the area of regulation of youth access to tobacco products that States have played, particularly certain active tobacco-control States. Federal

cooperation with, and continued reliance upon, innovative and aggressive State and local enforcement efforts is essential.

FDA believes the requirements it is establishing in this final rule set an appropriate floor for regulation of youth access to tobacco products but do not, as a policy matter, reflect a judgment that more stringent State or local requirements are inappropriate. For example, FDA chose 18 as the age below which cigarettes and smokeless tobacco may not be marketed to children and adolescents. This choice reflected a finding that all but four States have a comparable restriction which addresses the most vulnerable population. However, many comments argued that a higher age would be more effective. While FDA has decided not to establish an age above 18 in the final rule, the agency may, under the exemption process established under section 521(b) of the act, defer to those States that conclude that a higher age is more effective and that apply for an exemption.

In implementing section 521 of the act, FDA has historically interpreted that provision narrowly and found it to have preemptive effect only for those State and local requirements that in fact clearly impose specific requirements with respect to specific devices that are manifestly in addition to analogous Federal requirements. (See § 808.1(d) (21 CFR 808.1(d)).) Moreover, section 521 of the act “does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act” (§ 808.1(d)(2)).

The agency's assertion of jurisdiction over tobacco products does not preclude any State or local requirements other than those expressly preempted by section 521(a) of the act. Moreover, consistent with FDA's interpretation of section 521(a) of the act, only a limited number of State and local requirements are preempted and even those may qualify for exemption from preemption under section 521(b) of the act.

Examples of State and local laws FDA believes are preempted, consistent with its longstanding approach to implementing section 521 of the act, are the following:

- *More stringent age restrictions*—Three States restrict cigarette sales to anyone under 19 years of age, and one State has 21 years as the minimum age. These restrictions are preempted because they are more stringent than the final rule, which prohibits sales only to individuals under age 18.

• *Restrictions on the distribution of free samples of tobacco products*—

Approximately 40 States, the District of Columbia, and many local governments restrict the distribution of free samples of tobacco products. For example, Nebraska bans samples, coupons, and rebate offers for smokeless tobacco. Oklahoma and several other States prohibit the free distribution of tobacco to individuals under 18 and within 500 feet of schools, playgrounds, or other locations used primarily by individuals under 18. Approximately 12 States restrict where free samples may be distributed. These restrictions are preempted to the extent that they are different from, or in addition to, the final rule, which prohibits any distribution of free samples.

• *Restrictions on placement of vending machines*—Most States, the District of Columbia, and several local governments impose restrictions on the placement of vending machines. These restrictions are preempted to the extent that they are different from, or in addition to, the final rule, which prohibits the use of vending machines except in certain locations and under certain conditions.

• *Restrictions on outdoor advertising*—Restrictions on outdoor advertising are preempted to the extent that they are different from, or in addition to, the final rule, which restricts the location, format, and content of such advertising. For example, Ordinance 307, which was enacted by the Mayor and City Council of Baltimore, MD, prohibits the placement of any sign that “advertises cigarettes in a publicly visible location,” i.e., on “outdoor billboards, sides of building[s], and free standing signboards.” This ordinance was upheld by the Fourth Circuit in the face of a challenge based on preemption under the Cigarette Act and on First Amendment grounds. (See *Penn Advertising of Baltimore, Inc. v. Mayor and City Council of Baltimore*, 63 F.3d 1318 (4th Cir. 1995), *vacated and remanded*, 116 S. Ct. 2574 (1996).) Subsequently, the Supreme Court vacated judgment in *Penn Advertising* and remanded the case to the United States Court of Appeals for the Fourth Circuit for further consideration in light of *44 Liquormart, Inc. v. Rhode Island*, 116 S. Ct. 1697 (1996). If Ordinance 307 is ultimately upheld in its present form, it will be preempted under section 521 of the act to the extent that it is different from, or in addition to, the final rule.

• *Prohibitions and restrictions relating to free-standing displays*—Prohibitions and restrictions relating to free-standing

displays are preempted to the extent that they are different from, or in addition to, the final rule, which allows free-standing displays but restricts the location, format, and content of such displays.

• *Requirements relating to identification checks for purposes of age verification*—Requirements relating to identification checks for purposes of age verification are preempted to the extent that they are different from, or in addition to, the final rule, which requires identification checks for anyone under the age of 26.

Examples of State or local laws or regulations that are not preempted include:

• *Equivalent age restrictions*—Most States establish 18 years as the minimum age for purchasing cigarettes or smokeless tobacco. These restrictions are not preempted because they are equal to, or substantially identical to, requirements imposed under the final rule. (See § 808.1(d)(2).)

• *Restrictions on the sale or distribution of tobacco products*—Several local governments restrict the locations (such as public parks, public buildings, etc.) at which tobacco products may be sold or distributed. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to the locations at which tobacco products may be sold or distributed.

• *Restrictions on smoking in public places*—Approximately 48 states, the District of Columbia, and many local governments have some restrictions on smoking in public places. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to restrictions on smoking in public places.

• *Penalties on underage persons who purchase tobacco products*—These penalties are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to penalties on underage persons who purchase tobacco products.

• *Prohibition on use or possession of tobacco products by underage persons*—These prohibitions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to prohibitions on the use or possession of tobacco products by underage persons.

• *Age restrictions on persons who sell tobacco products*—Some local governments have statutes or regulations that establish a minimum

age for persons selling tobacco products. These restrictions are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to age restrictions on persons who sell tobacco products.

• *Tobacco excise taxes*—All 50 States and the District of Columbia have excise taxes on cigarettes, and 42 States have excise taxes on smokeless tobacco. These excise taxes are not preempted because they are not “requirements applicable to a device” within the meaning of section 521(a) of the act. (See § 808.1(d)(8).)

• *Access-control mechanism requirements for vending machines*—Approximately six States and some local governments require access-control mechanisms on vending machines, such as locking devices or token acceptors. These requirements are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to access-control mechanisms for vending machines.

• *Posting of signs*—Approximately 24 States have statutes requiring certain parties to post signs at vending machines stating that sales to underage persons are prohibited. One State requires owners or operators of vending machines to post signs warning of the dangers of cigarette use during pregnancy. In addition, many local governments require that signs be posted in areas in which smoking is prohibited by law. These requirements are not preempted because the final rule does not establish specific counterpart regulations or other specific requirements relating to the posting of signs.

• *License requirements*—Some local governments impose license requirements upon retailers of tobacco products. These requirements are not preempted because they are not “requirements applicable to a device” within the meaning of section 521(a) of the act. (Cf. § 808.1(d)(3).)

The examples set forth above reflect the types of State or local requirements of which the agency is currently aware.²⁵⁴ There may be other State or local requirements pertaining to cigarettes and smokeless tobacco. With regard to particular State or local requirements that are not described above, any State, political subdivision, or other interested party may, in accordance with § 808.5 (21 CFR 808.5),

²⁵⁴ State Legislated Actions on Tobacco Issues, Coalition on Smoking OR Health, Bartelt, J., ed., December 31, 1995.

request an advisory opinion from the agency as to whether such State or local requirements are preempted.

State and local requirements that are preempted by the requirements of FDA's final rule may be exempted from preemption in accordance with section 521(b) of the act and its implementing regulation, part 808 (21 CFR part 808). Section 521(b) of the act and part 808 provide that FDA may, by regulation issued after notice and an opportunity for an oral hearing, exempt a State or local device requirement from preemption under such conditions as the Commissioner of Food and Drugs (the Commissioner), may prescribe if the requirement is: (1) More stringent than Federal requirements applicable to the device under the act; or (2) required by compelling local conditions, and compliance with the State or local requirement would not cause the device to be in violation of any requirement applicable under the act.

By a separate document to be published in the Federal Register, FDA will be informing all State and local governments that they may submit applications to exempt from preemption under section 521(b) of the act those State and local requirements pertaining to cigarettes and smokeless tobacco that are preempted by the final rule. A State or local requirement will be exempted from preemption under section 521(b) of the act if the State or local requirement: meets the exemption requirements established under that section and is consistent with the goals in the final rule. Exemptions from preemption that FDA grants apply only to preemption under section 521 of the act.

Because the issues raised by these applications for exemption will be similar or related, the Commissioner has determined that it would be advantageous for all concerned to propose a single regulation granting or denying exemptions for each particular State or local requirement, and, if necessary, to hold a single hearing covering all applications for exemption from preemption for requirements pertaining to cigarettes and smokeless tobacco. Although each application will be considered as part of a single proceeding, each individual application will be evaluated on its merits and the circumstances applicable to the particular submitting jurisdiction.

F. Preemption of State Product Liability Claims Under Section 521(a) of the Act

(13) Several comments asserted that, under section 521(a) of the act, State product liability claims would be

preempted if FDA asserts jurisdiction over tobacco products as drug delivery devices.

Based on FDA's understanding of the theories of recovery advanced in tobacco product liability cases, and the nature of the Federal requirements being established in the final rule, FDA does not expect any of these Federal requirements to preempt any tort claims relating to tobacco products. The following analysis explains this conclusion.

The Supreme Court recently held that the scope of preemption under section 521(a) with regard to State product liability claims is very narrow. Indeed, a plurality of the Court noted that "few, if any, common-law duties have been pre-empted by [section 521(a)]." *Medtronic, Inc. v. Lohr*, 64 U.S.L.W. 4625, 4634 (U.S. June 26, 1996) (Nos. 95-754 and 95-886) (plurality opinion).

Preemption occurs "only where a particular state requirement threatens to interfere with a specific federal interest." *Medtronic*, 64 U.S.L.W. at 4634. Thus, State requirements of "general applicability" such as State product liability claims are not preempted, except where they have "the effect of establishing a substantive requirement for a specific device" that is "different from, or in addition to," a specific requirement imposed under the act (§ 808.1(d); *Medtronic*, 64 U.S.L.W. at 4633-34). Moreover, Federal requirements must be "applicable to the device" in question, and they preempt State product liability claims only if the Federal requirements are "specific counterpart regulations" or "specific" to a "particular device" (§ 808.1(d); *Medtronic*, 64 U.S.L.W. at 4634).

In summary, FDA is aware of no tort claims against tobacco products that will be preempted by the Federal requirements being established in the final rule.

XI. Miscellaneous Constitutional Issues

A. Takings Under the Fifth Amendment

(1) Several industry, retail, and individual comments argued that parts of the regulations effect takings compensable under the Fifth Amendment's Takings Clause (the Takings Clause), which provides that "private property [shall not] be taken for public use, without just compensation." For example, comments argued that proposed § 897.34 will restrict or even prohibit tobacco manufacturers' use of their trademarks and copyrighted property, or that it will deprive industry members both of the goodwill generated by their sponsorship of sports and

cultural events and of valuable tobacco trademarks. Comments argued that § 897.16(a) effects a taking of intellectual property because it prohibits the use of nontobacco trademarks (with grandfathered exceptions) to market tobacco products. Several comments argued that § 897.16(c) effects a taking of vending machines and self-service displays, as well as contractual rights to place tobacco vending machines on other people's property. Comments argued that the requirement that advertising use only black text on white background in § 897.32(a) effects a taking because nonconforming signs—for buses and on billboards, for example—will have to be destroyed, as would tobacco advertisements on billboards and signs within 1,000 feet of schools and public playgrounds under § 897.30(b).

Comments also argued that the proposed ban on mail-order sales of tobacco products would effect a taking of mail-order businesses. Mail-order sales, however, are not prohibited under the final rule. Many retailers argued that the prohibition of self-service displays and the corresponding requirement that tobacco products be shelved behind sales counters violate the Fifth Amendment.

The Food and Drug Administration (FDA) disagrees that any of these provisions effects a taking in violation of the Fifth Amendment.

In its final form, § 897.16(a) prohibits manufacturers from using the trade or brand name of a nontobacco product as the trade or brand name of a cigarette or smokeless tobacco product, with the exception of those names on both tobacco and nontobacco products that were sold in the United States on January 1, 1995. In its final form, § 897.16(c) prohibits the use of vending machines and self-service displays to sell cigarettes and smokeless tobacco, except that vending machines (including those that sell packaged, single cigarettes) and self-service displays may be used to sell these tobacco products in adult-only establishments. (As proposed in the 1995 proposed rule, § 897.16(c) would have prohibited their use entirely.)

In its final form, § 897.30(b) prohibits tobacco product advertisements within 1,000 feet of a public playground or a secondary or elementary school. In its final form, § 897.32(a) permits only advertising that uses black text on a white background (except in adult publications and in facilities where persons under 18 are not present or permitted). In its final form, § 897.34(a)

prohibits the sale of nontobacco items or services that bear the brand names or other indicia of identification for cigarettes or smokeless tobacco. In its final form, § 897.34(c) prohibits the sponsorship of athletic, musical, cultural, or other social or cultural events in the brand names or other indicia of identification for cigarettes or smokeless tobacco.

A takings analysis begins with a determination of what interest a person has in the thing that is allegedly taken—in this case, in vending machines and self-service displays, copyrighted material, and trademarks and goodwill—and whether that interest “can be considered property for the purposes of the Taking Clause of the Fifth Amendment.” (See *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001 (1984).) If a cognizable property interest is identified, the Supreme Court has developed three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) its economic impact; and (3) its interference with reasonable investment-backed expectations (*Id.* at 1005).

1. The Interests at Issue

Some of the interests affected by the final rule—vending machines, self-service displays, and existing nonconforming advertising on signs and billboards, for example—is tangible property, whereas contract rights, trademarks and goodwill, and copyrighted material (e.g., the nonconforming copyrighted material on signs and billboards) affected by these provisions are intangible property interests.

Tangible personal property—such as vending machines, self-service displays, and signs and billboards advertising tobacco products—is property for purposes of the Takings Clause (see *United States v. General Motors Corp.*, 323 U.S. 373, 383–84 (1945)), although personal commercial property is afforded less protection than real property under the Takings Clause (see, e.g., *Lucas v. South Carolina Coastal Council*, 112 S. Ct. 2886, 2899 (1992)).

Intangible interests may be compensable under the Takings Clause as well. For example, in *Ruckelshaus*, the Supreme Court determined that trade secret information—which is intangible—was property compensable under the Takings Clause. The Court noted that the extent of the property right in trade secret information “is defined by the extent to which the

owner of the secret protects his interest from disclosure to others,” (that is, it is property only insofar as others are excluded from its use) and that it has “many of the characteristics of more tangible forms of property”—for example, trade secret information is assignable, it can form the res of a trust, and it passes to a trustee in bankruptcy (*Ruckelshaus*, 467 U.S. at 1002).

Vending machine owners may have contracts that give them exclusive rights to sell tobacco products at a particular location. These contract rights would typically be assignable, they may form the res of a trust (see, e.g., *Wadsworth v. Bank of California*, 777 P.2d 975, 978 (Or. Ct. App. 1989)), and rights of action based upon them can become part of a bankruptcy estate (e.g., *In re Ryerson*, 739 F.2d 1423, 1425 (9th Cir. 1984)). (See also U.C.C. 9–106.) Such vending machine owners’ contracts may therefore create contract rights that would be compensable property under the Takings Clause.

Material can be copyrighted if it is an original work of authorship—such as written, musical, pictorial, or graphic work—that is fixed in a tangible medium of expression from which the work can be reproduced (17 U.S.C. 102(a)). By Federal statute a copyright is assignable (17 U.S.C. 201), and there are rights to exclusive use (17 U.S.C. 106), subject to certain limitations (17 U.S.C. 107–20) and enforceable through infringement actions (e.g., 17 U.S.C. 501). A copyright can form the res of a trust (*Bartok v. Boosey & Hawkes, Inc.*, 523 F.2d 941, 948 (2d Cir. 1975)) and it can become property of an estate in bankruptcy (*United States v. Inslaw, Inc.*, 932 F.2d 1467, 1471 (D.C. Cir. 1991), *cert. denied*, 502 U.S. 1048 (1992)). Sharing many of the characteristics of more tangible property, a copyright is also compensable property under the Takings Clause.

Trademarks are words, names, symbols, devices, or combinations thereof that a person uses, or intends to use and has applied to register, to identify or distinguish his or her goods from others on the market and to identify their source (15 U.S.C. 1127). The primary purpose of trademarks is to protect consumers by preventing deceitful marketing of one product or service as another. As the Supreme Court has stated,

[t]he law of unfair competition has its roots in the common-law tort of deceit: its general concern is with protecting consumers from confusion as to source. While that concern may result in the creation of “quasi-property rights” in communicative symbols, the focus

is on the protection of consumers, not the protection of producers as an incentive to product innovation.

(*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 157 (1989))

When associated with goodwill, trademarks also share—with trade secret information and copyrights—the features of more tangible property. For example, the Lanham Act (15 U.S.C. 1053 *et seq.*) allows assignment of a trademark only “with the goodwill of the business in which the mark is used or with that part of the goodwill of the business connected with the use of and symbolized by the mark” (15 U.S.C. 1060). Indeed, when Congress amended the Lanham Act in 1988 to allow intent-to-use applications for registration of trademarks, it prohibited assignment of such applications to be “consistent with the principle that a mark may be validly assigned only with the business or goodwill attached to the use of the mark” (S. Rept. 515, 100th Cong., 2d sess. 31 (1988), reprinted in 1988 U.S.C.C.A.N. 5577, 5593–5594).

Owners of trademarks also have rights of exclusive use of marks—that is, against infringement—because “[b]y applying a trademark to goods produced by one other than the trademark’s owner, the infringer deprives the owner of the goodwill which he spent energy, time, and money to obtain” (*Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 854 n.14 (1982)). “Registration bestows upon the owner of the mark the limited right to protect his goodwill from possible harm by those uses of another as may engender a belief in the mind of the public that the product identified by the infringing mark is made or sponsored by the owner of the mark” (*Societe Comptoir de L’Industrie Cotonniere Etablissements Boussac v. Alexander’s Dep’t Stores, Inc.*, 299 F.2d 33, 36 (2d Cir. 1962)). Like trade secret information, a trademark can be the res of a trust (see *Coca-Cola Bottling Co. v. Coca-Cola Co.*, 988 F.2d 414, 430–432 (3d Cir. 1993)) and it can pass to the trustee in bankruptcy (*Inslaw*, 932 F.2d at 1471).

The agency notes that a trademark itself, unaccompanied by goodwill, lacks these characteristics of property. The agency therefore believes that a trademark itself is not property cognizable under the Takings Clause. Based on the foregoing analysis, however, the agency believes that a trademark and the accompanying goodwill together are property cognizable under the Takings Clause. These conclusions are consonant with the recognition that a trademark has

value as property for the owner "only in the sense that a man's right to the continued enjoyment of his trade reputation and the good will that flows from it, free from unwarranted interference by others, is a property right, for the protection of which a trademark is an instrumentality" (*Hanover Star Milling Co. v. Metcalf*, 240 U.S. 403, 413 (1916); see also S. Rept. 1333, 79th Cong., 2d sess. (1946), reprinted in 1946 U.S. Code Cong. & Admin. News 1274, 1277 ("the protection of trade-marks is merely protection to goodwill")).

Nevertheless, this conclusion must be reconciled with Supreme Court precedent on takings of goodwill. In particular, the comments cited *Kimball Laundry Co. v. United States*, 338 U.S. 1 (1949), for the proposition that the Takings Clause requires compensation for a regulatory taking of goodwill. The general rule is that the Takings Clause does not require compensation for goodwill when the Government takes a place of business because the business's goodwill may be transferred to a new place of business (338 U.S. at 11–12 and 15; see also *General Motors*, 323 U.S. at 379 (when Government permanently takes land, "compensation for that interest does not include * * * [even] the loss of goodwill which inheres in the location of the land")). In *Kimball*, however, the Court allowed compensation for loss of a laundry business's goodwill, or going-concern value, incident to the physical taking of the laundry. It did so because the Government intended to operate the laundry temporarily during wartime, after which the laundry would revert to the business; the business could not invest in a new laundry because it would someday be the owner of two laundries, neither of which it could then operate profitably (338 U.S. at 14–15). The Court therefore likened the situation to those in which the Government takes a utility with the intention of operating it itself; the going-concern value of the utility is taken in those cases and is therefore compensable (*Id.* at 12–13).

Kimball and *General Motors* therefore indicate that goodwill is compensable under the Takings Clause only when no business remains after a taking to whose benefit the goodwill may inure. (See also *District of Columbia v. 13 Parcels of Land*, 534 F.2d 337, 349 & n.7 (D.C. Cir. 1976).) With respect to goodwill associated with a trademark, use of which is limited by a regulation, these cases indicate that the property interest may be compensable only if the

regulation allows no goodwill to inure to the benefit of the owner.

For purposes of the following analysis of whether the regulations effect a taking, the agency assumes that copyrighted material, the interests in trademarks and associated goodwill, contracts, self-service displays, vending machines, and tobacco advertising on signs and billboards are property interests that may be compensable under the Takings Clause if taken.

2. The Takings Analysis

[W]hat constitutes a "taking" for purposes of the Fifth Amendment has proved to be a problem of considerable difficulty. While this Court has recognized that the "Fifth Amendment's guarantee * * * [is] designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole," this Court, quite simply, has been unable to develop any "set formula" for determining when "justice and fairness" require that economic injuries caused by public action be compensated by the government, rather than remain disproportionately concentrated on a few persons.

(*Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 123–24 (1978) (citation omitted) (alterations and deletions in original); Ruckelshaus, 467 U.S. at 1005) Still, the Supreme Court has identified three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) its economic impact; and (3) its interference with reasonable investment-backed expectations (*Ruckelshaus*, 467 U.S. at 1005; *Penn Central*, 438 U.S. at 124).

The force of any one of these factors may be "so overwhelming * * * that it disposes of the taking question" (*Ruckelshaus*, 467 U.S. at 1005 (finding interference with reasonable investment-backed expectations by use of trade secret information in pesticide approval process to be decisive)). So, for example, if the economic impact is to rob real property of "all economically beneficial uses," the regulation effects a taking (*Lucas*, 505 U.S. at 1019 (emphasis in original); see also *id.* at 1027–1028 (limiting holding to real property)). When examined in light of these three factors, FDA's proposed regulations do not effect a compensable taking under the Fifth Amendment of the Constitution.

3. The Character of the Governmental Action

With respect to the first factor, courts are more likely to find a taking when the interference with property can be

characterized as a physical invasion by the Government (e.g., *United States v. Causby*, 328 U.S. 256, 261–62 (1946) (characterizing Government's use of flight path just over property as physical invasion)) than when the interference is caused by a regulatory program that "adjust[s] the benefits and burdens of economic life to promote the common good" (*Penn Central*, 438 U.S. at 124). Courts have accorded particular deference to governmental action taken to protect the public interest in health, safety, and welfare. (See *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 488 (1987); *Penn Central*, 438 U.S. at 125–26; *Atlas Corp. v. United States*, 895 F.2d 745, 757–58 (Fed. Cir.), cert. denied, 498 U.S. 811 (1990).) In addition, the Supreme Court has repeatedly rejected compensation claims when the Government has regulated in order to prevent harmful activity:

The power which the States have of prohibiting such use by individuals of their property as will be prejudicial to the health, the morals, or the safety of the public, is not—and, consistently with the existence and safety of organized society, cannot be—burdened with the condition that the State must compensate such individual owners for pecuniary losses they may sustain, by reason of their not being permitted, by noxious use of their property, to inflict injury upon the community.

(*Mugler v. Kansas*, 123 U.S. 623, 669 (1887) (holding that State law prohibiting manufacture or sale of alcohol effected no taking of brewery even though law entirely destroyed brewery's beneficial use); see also *Keystone*, 480 U.S. 470 (1987) (no taking by law prohibiting mining of coal); *Goldblatt v. Town of Hempstead*, 369 U.S. 590 (1962) (no taking effected by regulation that closed gravel pit); *Miller v. Schoene*, 276 U.S. 272 (1928) (no taking effected by State-ordered felling of cedar trees); *Hadacheck v. Sebastian*, 239 U.S. 394 (1915) (no taking effected by ordinance prohibiting operation of brickyard in residential area); *Reinman v. City of Little Rock*, 237 U.S. 171 (1915) (no taking effected by ordinance prohibiting stable in residential area); *Powell v. Pennsylvania*, 127 U.S. 678 (1888) (no taking effected by law preventing manufacture of margarine)).

First, the final rule's interference with property interests cannot be characterized as a physical invasion of property. The final rule prohibits some uses of some types of property, but the Government is neither using nor acquiring property under the regulations (*Penn Central*, 438 U.S. at 128). For example, certain uses of vending

machines, self-service displays, and signs and billboards are prohibited, but the Government is itself neither using nor acquiring them. The same is true of the intangible property at issue, contracts, copyrights, and trademarks and the associated goodwill: The agency is prohibiting certain uses—indeed, all uses of tobacco trademarks on nontobacco items, including when tobacco companies have also registered the tobacco mark as a mark for nontobacco products or services—but the Government is not itself using these contract rights, copyrights, or trademarks (and thereby tobacco companies' goodwill). It "has taken nothing for its own use" (*Connolly v. Pension Benefit Guar. Corp.*, 475 U.S. 211, 224 (1986)).

Second, these final regulations seek to promote the public health by limiting access to tobacco products by consumers in the age group most likely to become addicted to them: Those under the age of 18. The regulations are intended to help reduce significantly the harms that use of tobacco products among this age group causes. They do so by prohibiting the sale of tobacco products to persons under the age of 18; that is, the regulations require modes of sale through which the retailer can verify the age of the purchaser or to which only those 18 or over will have access. In particular, the final rule permits vending machines and self-service displays and accompanying advertising only in places to which young people do not have access.

The final regulations also limit promotion of tobacco products to persons under the age of 18. They do so by prohibiting certain venues for tobacco advertising, namely, within 1,000 feet of schools and public playgrounds. They also require black text/white background advertisements in remaining venues with the exception of adult newspapers, magazines, periodicals, and other publications, and in adult-only establishments. They also prohibit use of tobacco trademarks on nontobacco products and in the sponsorship of events. As a consequence, use of tobacco industry trademarks, copyrights, and advertising techniques is limited, although not ended. Nonconforming signs and billboards will be prohibited, thereby reducing the remaining useful life of those currently in use when the regulations become effective. Use of nontobacco trademarks is limited only by prohibiting their use on tobacco products (except for nontobacco

trademarks used on tobacco products in the United States on January 1, 1995).

These regulations substantially advance, and are rationally related to, FDA's legitimate interest in promoting the public health and reducing harm by limiting both youth access to tobacco products and, as discussed in the context of the First Amendment, their promotion to youth. (See *Keystone*, 480 U.S. at 485; see also *Pace Resources, Inc. v. Shrewsbury Township*, 808 F.2d 1023, 1030 (3d Cir.) ("[T]he governmental action is entitled to a presumption that it does advance the public interest."), *cert. denied*, 482 U.S. 906 (1987).) Moreover, they are directed at stopping activity that is illegal in every State: Sales of tobacco products to those under the age of 18 (*Keystone*, 480 U.S. at 492 n.22). This factor of the takings analysis indicates that these regulations effect no takings.

4. The Economic Impact of the Governmental Action

The second factor to consider is the economic impact of the governmental action. "There is no fixed formula to determine how much diminution in market value is allowable without the fifth amendment coming into play" (*Florida Rock Indus., Inc. v. United States*, 791 F.2d 893, 901 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1053 (1987)). It is clear, however, that a regulation's economic impact may be great without rising to the level of a taking. (See *Pace Resources*, 808 F.2d at 1031 (citing *Hadacheck v. Sebastian*, 239 U.S. 394 (1915)) (no taking even given reduction in value from \$800,000 to \$60,000); *Village of Euclid v. Ambler Realty Co.*, 272 U.S. 365 (1926) (no taking despite 75 percent diminution in value).) Mere denial of the most profitable or beneficial use of property does not require a finding that a taking has occurred. (See *Florida Rock*, 791 F.2d at 901; see also *Andrus v. Allard*, 444 U.S. 51, 66 (1979).) Rather, courts look for drastic interference with a property's possible uses. (See *Pace Resources*, 808 F.2d at 1031.)

In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the "economically viable use" of his property. (See, e.g., *Keystone*, 480 U.S. at 499.) Courts focus on the remaining uses permitted and the residual value of the property. (See *Pace Resources*, 808 F.2d at 1031.)

Although certain uses of copyrights and copyrighted material developed by tobacco companies and of tobacco and nontobacco trademarks will be

prohibited or curtailed, other uses will remain once the final rule takes effect. That is, under § 897.16(a), nontobacco trademarks may not be used to market tobacco products (with the exception of trademarks that had such uses before January 1, 1995) and so they may lose the (speculative) value of such licensing arrangements, but they retain the vast bulk of their value as trademarks for the product or brand for which they were originally developed, and they retain the value of their potential use to market all legal, nontobacco products. Under §§ 897.30(b) and 897.32(a), some copyrighted advertising material that appears on billboards or signs within 1,000 feet of a school or playground or that is not black text/white background may be rendered useless when the rule becomes effective (the copyrighted design itself may be used in other venues, such as adult publications or in adult-only establishments). Under § 897.34(a), tobacco product brand names and logos may be used only to market tobacco products; they therefore lose the value of any use on nontobacco products and, under § 897.34(c), they lose the value of any use to sponsor events when the rule becomes effective. By and large, however, tobacco copyrights and trademarks will retain significant, economically viable uses when the rule becomes effective.

Tobacco companies have, however, registered some of their tobacco trademarks (e.g., Skoal Bandit on a race car as an entertainment service mark, Marlboro on tennis caps), or marks that incorporate a tobacco trademark (e.g., The Marlboro Country Store on, for example, hats and boots; Skoal Pro Rodeo promoting and sponsoring rodeos; Winston West promoting and sponsoring auto racing events), as marks for nontobacco products, services, or events. Under § 897.34, all use of these registered nontobacco marks will be prohibited when the rule becomes effective. With respect to these registered nontobacco trademarks, and indeed with respect to all tobacco company trademarks, their associated goodwill will remain with the tobacco companies and will inure to their benefit in the sale of tobacco products. Accordingly, this factor of the takings analysis indicates that the final rule effects no taking of these interests.

Section 897.16(c) prohibits the use of tobacco product vending machines and self-service displays except in adult-only establishments (where graphic advertisements will also be permitted). This restricted use may limit the number of venues in which these

vending machines and self-service displays may be used and may exclude venues where their use is most profitable. The value of vending machines and self-service displays may therefore drop. But diminutions in property value do not establish a taking. (See *Penn Central*, 438 U.S. at 131.) Indeed, “[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law” (*Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 413 (1922)). Vending machines and self-service displays may have to be moved from currently legal venues to adult-only establishments or to warehouses, or they may need to be retrofitted for use with other products if retrofitting is possible. Although compliance may require vending machine and self-service display owners to spend money, “[r]equiring money to be spent is not a taking of property” (*Atlas Corp.*, 895 F.2d at 756 (discussing regulatory requirement that mining corporations reclaim uranium and thorium tailings and decommission mills)). Finally, if there are not sufficient numbers of adult-only establishments, some vending machines and self-service displays may have no economically viable use because of the final regulation, but a regulation that makes personal commercial property “economically worthless” does not effect a per se taking, as it would with real property. (See *Lucas*, 505 U.S. at 1027–1028.) Contracts to offer exclusively tobacco products in vending machines at nonadult-only establishments may also become “economically worthless” once the regulation becomes effective. Likewise, although §§ 897.32(a) and 897.30(b) may shorten the useful life of advertising materials on placards and billboards that are not black text/white background or that are near schools and playgrounds (albeit with a grace period of at least the delayed effective date) and such materials may be “economically worthless” as a result, this does not effect a taking per se.

In summary, examination of the economic impact factor of the takings analysis suggests that the regulations, when they finally become effective, will effect no takings of trademarks and goodwill, copyrights, and many vending machines and self-service displays. It leaves open the possibility, however, that the rule may effect a taking of some vending machines and contracts, and of some self-service displays and of nonconforming signs and billboards.

5. Interference with Reasonable Investment-backed Expectations

The final factor to consider is whether a company has a reasonable investment-backed expectation in continuing to use the property at issue, whether it be vending machines, self-service displays, nonconforming signs and billboards, copyrighted material, or trademarks and goodwill. To be reasonable, expectations must take into account the power of the State to regulate in the public interest. (See *Pace Resources*, 808 F.2d at 1033.) Reasonable expectations must also take into account the regulatory environment, including the foreseeability of changes in the regulatory scheme. “In an industry that long has been the focus of great public concern and significant government regulation,” *Monsanto*, 467 U.S. at 1008, the possibility is substantial that there will be additional regulatory requirements. “Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end” (Connolly, 475 U.S. at 227 (citation omitted)). Given a long history of Government regulation of an industry, its members are “on notice that [they] might be subjected to different regulatory burdens over time” (*California Hous. Sec., Inc. v. United States*, 959 F.2d 955, 959 (Fed. Cir.), cert. denied, 506 U.S. 916 (1992)).

Commerce in tobacco products has been regulated for years on the Federal, State, and local levels. For example, States first began restricting tobacco sales to minors, distribution of free samples, and vending machine sales in the 1970’s. By 1994 all 50 States prohibited tobacco sales to young people, 38 States restricted the distribution of free tobacco products, and 28 States imposed restrictions on vending machine sales (“State Legislated Actions on Tobacco Issues,” Coalition on Smoking OR Health (Washington, DC 1994)). Tobacco manufacturers as well as distributors and retailers who have chosen to distribute or sell tobacco products have therefore had reasonable notice that the regulatory scheme to limit use of tobacco products by minors might change.

Moreover, the particular restrictions on access and on promotion adopted in these regulations, or variations thereof, have been proposed or considered for several years by Government bodies, including Congress, the States, and public health agencies. (See, e.g., H. Rept. 5041, 101st Cong., 2d sess. (1990); H. Rept. 1250, 101st Cong., 1st sess.

(1989).) For example, on at least two occasions a tobacco industry representative testified before Congress that pending legislation would, like several previous legislative proposals, effectively ban advertisements for tobacco products (“Tobacco Control and Marketing: Hearings on H. Rept. 5041 Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce,” 101st Cong., 2d sess. 491–494 (1990) (statement of Charles O. Whitley on behalf of The Tobacco Institute); “Tobacco Issues: Hearings on H. Rept. 1250 Before the Subcomm. on Transp. and Hazardous Materials of the House Comm. on Energy and Commerce,” 101st Cong., 1st sess. 302 (1989) (statement of Charles O. Whitley on behalf of The Tobacco Institute)), making for far more restrictive limits on advertisements and promotion than those imposed by this rule. Given these facts, a reasonable person should have expected the possibility of regulations such as these. In addition, when sales to young people are illegal, investments in promotions designed to appeal to young people cannot be considered reasonable (see discussion of R. J. Reynolds’ use of promotional materials in the Joe Camel Campaign in section VI. of this document). In any case, once the agency gave notice of its proposed rulemaking with respect to tobacco, tobacco manufacturers, distributors, and retailers had notice that certain investments were risky, and they will enjoy the economic benefit of those investments and of investments that they had previously made until the rule is finally effective.

As discussed in section IV. of this document, the number of tobacco product vending machines fell by half between 1988 and 1993 and, since 1990, virtually no new tobacco product vending machines have been manufactured (60 FR 41314 at 41325); because the market in tobacco product vending machines is declining, investment-backed expectations in both vending machines and vending machine contracts are not reasonable. Moreover, many self-service displays were given to retailers by tobacco manufacturers (see 60 FR 41314 at 41323); to that extent, the retailers have no investment-backed expectation in them.

Finally, the Supreme Court has stated that it is unreasonable to have high investment-backed expectations in personal property:

[I]n the case of personal property, by reason of the State’s traditionally high degree of control over commercial dealings, [the

property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless (at least if the property's only economically productive use is sale or manufacture for sale).

(*Lucas*, 505 U.S. at 1027–1028)

Since all of the property at issue here—vending machines, self-service displays, the advertising material on signs and billboards, contract rights, copyrights, and trademarks and associated goodwill—is personal property, there can be no reasonable investment-backed expectation that regulation will not render them economically worthless. Consideration of this factor of the takings analysis indicates that the final rule effects no takings of any property.

6. Summary

With respect to trademarks and goodwill and copyrights, the three factors in a takings analysis indicate that these regulations will effect no takings. Only the economic impact of the rule on advertising materials on signs and billboards and on some vending machines and related contract rights and some self-service displays leaves open the possibility that a taking may occur, but the impossibility of reasonable investment-backed expectations with respect to personal property used for sale strongly counters this factor, as stated by the Supreme Court in *Lucas*, as does the harm-prevention character of this regulation. Analysis of the three factors considered together shows that these final regulations do not effect a taking of vending machines, self-service displays, signs and billboards advertising tobacco products, contract rights, or copyrights and trademarks and goodwill. The agency concludes that the comments that argued that the regulation effects takings are, for the above-stated reasons, unpersuasive.

B. Substantive Due Process, Equal Protection, and Restrictions on Use of Trade Names

(2) Comments argued that § 897.16(a) (which restricts the use of nontobacco trade or brand names as the trade or brand name of cigarettes or smokeless tobacco) and § 897.34(a) (which prohibits the marketing of nontobacco items and services that bear tobacco brand names and other symbols of cigarettes and smokeless tobacco) violate the Due Process Clause of the Fifth Amendment to the Constitution and the Equal Protection Clause of the Fourteenth Amendment. One comment asserted that each of these provisions

prevents companies from entering a completely legal business using their own trade names but provided no further explanation of its reasoning; FDA therefore understands it to suggest that these provisions classify companies as either tobacco or nontobacco companies, that this classification violates equal protection, and that these provisions violate due process in that they infringe on property interests in trade names by prohibiting companies from entering legal businesses using their own trade names. Another comment echoed this latter point and argued that the agency was denying tobacco companies due process because it has no authority to prohibit the lawful use of tobacco trademarks on other products.

The agency disagrees with these comments. The Fifth Amendment Due Process Clause states that “[n]o person shall * * * be deprived of life, liberty, or property, without due process of law.” Under due process as applied to economic regulation, “[i]t is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it” (*Williamson v. Lee Optical of Oklahoma, Inc.*, 348 U.S. 483, 488 (1955)). (The agency has addressed why it has the statutory authority to issue this rule in section II. of this document.)

The Fourteenth Amendment's Equal Protection Clause states that “[n]o State shall * * * deny to any person the equal protection of the laws.” By its terms, the Fourteenth Amendment does not apply to action by the Federal Government, as it is directed at the States. But the Supreme Court has held that the Fifth Amendment's Due Process Clause includes an equal protection component equivalent to the Fourteenth Amendment's Equal Protection Clause. (See *Bolling v. Sharpe*, 347 U.S. 497 (1954); see also *Buckley v. Valeo*, 424 U.S. 1, 93 (1976) (per curiam) (“Equal protection analysis in the Fifth Amendment area is the same as that under the Fourteenth Amendment”).) Under equal protection review, an economic regulation is valid as long as the classification that it makes is “rationally related to a legitimate state interest” (*City of New Orleans v. Duke*, 427 U.S. 297, 303 (1976)).

Sections 897.16(a) and 897.34(a) easily pass muster under the requirements of both due process and equal protection. FDA's interest in the health and well-being of children and adolescents is certainly legitimate (indeed, it is a compelling interest). (See

New York v. Ferber, 458 U.S. 747, 757–58 and n.9 (1982).) Moreover, because they limit trade and brand name uses that enhance the appeal and promote the use of cigarettes and smokeless tobacco to young people, the provisions are rationally related to this interest and are a rational way to reduce addiction to tobacco products and the health consequences that follow.

C. Procedural Due Process Under the Fifth Amendment

(3) An industry comment asserted that the regulation of tobacco manufacturers' use of their copyrights and trademarks affects a property interest so as to require an adjudication; put another way, the comment argued that use of rulemaking to adopt a regulation effecting these property interests violates the Fifth Amendment Due Process Clause, which states that “[n]o person shall * * * be deprived of life, liberty, or property, without due process of law.”

The agency disagrees. The agency has issued this final rule under its “authority to promulgate regulations for the efficient enforcement of the Act” under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)) and its authority under section 520(e) of the act (21 U.S.C. 360j(e)) to issue regulations to restrict the sale, distribution, or use of a device. The agency issues such regulations under the rulemaking procedures established by the Administrative Procedure Act (APA) in 5 U.S.C. 553 and its own regulations in part 10 (21 CFR part 10), in particular § 10.40. Neither the act, the APA, nor the agency's regulations require a hearing for a rulemaking under sections 701(a) and 520(e) of the act.

The comment nevertheless contended that due process requires that tobacco manufacturers be provided the opportunity for a formal hearing (i.e., more than just an opportunity to provide written comments). A formal hearing is required, according to the comment, because FDA is asserting jurisdiction over cigarettes and smokeless tobacco based upon a determination of the intent of all tobacco manufacturers, but it is relying on evidence of intent with regard to only a subset of tobacco manufacturers.

As discussed in the 1996 Jurisdictional Determination annexed hereto, the evidence shows that cigarettes and smokeless tobacco are highly addictive, cause other psychoactive effects (such as relaxation and stimulation), and affect weight

regulation, and that these effects are widely accepted in the scientific community. Based on this evidence, it is foreseeable to any reasonable manufacturer that consumers will use such products for their addictive, psychoactive, and other pharmacological effects. The evidence also shows that actual consumer use of these products for their pharmacological effects is predominant and, in fact, nearly exclusive. Based on this evidence of the foreseeable and actual consumer use of these products for their pharmacological effects, the agency has concluded that all cigarette and smokeless tobacco manufacturers "intend" their products to affect the structure or function of the body, and that these products are, therefore, nicotine delivery devices under the act. In addition, the agency collected evidence of the tobacco industry's statements, actions, and research demonstrating awareness of the addictive and other pharmacological effects of these products, the industry's knowledge that consumers use these products for these effects, and the industry's deliberate manipulation of levels of nicotine in these products to ensure that adequate amounts of nicotine are delivered to consumers. These internal documents are further evidence in support of the conclusion that cigarette and smokeless tobacco manufacturers intend their products to be drug delivery devices, but they are not necessary for that conclusion. The agency, therefore, has not inferred the intent of one company based exclusively on the internal documents of another. Moreover, assuming that copyrights and trademarks are property protected by the Fifth Amendment's Due Process Clause, due process does not require that FDA provide tobacco manufacturers with a hearing beyond the opportunity for notice and comment that it has already provided. The Supreme Court has stated that the APA established "the maximum procedural requirements" that the courts can impose upon agencies in conducting rulemaking procedures and that the circumstances in which courts may require additional procedures, "if they exist, are extremely rare" (*Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519, 524 (1978)). The Court further stated that due process may "in some circumstances" require "additional procedures" beyond those required by the APA "when an agency is making a 'quasi-judicial' determination by which a very small number of persons are

'exceptionally affected, in each case upon individual grounds'" (*Id.* at 542 (quoting *United States v. Florida East Coast Ry.*, 410 U.S. 224, 242-245 (1973))).

By this test, due process does not require that the agency provide tobacco manufacturers with a hearing. Simply put, the agency is not making "a quasi-judicial determination by which a very small number of persons are exceptionally affected, in each case upon individual grounds" (*Vermont Yankee*, 435 U.S. at 542 (quotations omitted)). The final rule at issue here prospectively limits the sale and promotion of cigarettes and smokeless tobacco to individuals under the age of 18; it imposes conditions on all manufacturers, distributors, and retailers of tobacco products and will affect the access to tobacco products of millions of individuals under the age of 18. The final rule is therefore "an agency statement of general * * * applicability and future effect designed to implement, interpret, or prescribe law or policy" (5 U.S.C. 551(4)); in other words, it is a rule under the APA, and the agency followed APA rulemaking in formulating it (5 U.S.C. 551(5)). Like the nuclear fuel cycle rulemaking in *Vermont Yankee*, 435 U.S. at 528-530, and the rulemaking about ambient air quality standards for lead in *Lead Indus. Ass'n v. Environmental Protection Agency*, 647 F.2d 1130, 1136-1144 (D.C. Cir.), cert. denied, 449 U.S. 1042 (1980), this process is "a rulemaking proceeding in its purest form," and not a "quasi-judicial determination" to which due process requirements beyond the requirements of the APA might apply. (See *Vermont Yankee*, 435 U.S. at 542 n.16; *Lead Indus. Ass'n*, 647 F.2d at 1171 n.119.)

In any case, manufacturers have had ample opportunity during the comment period for this rulemaking to submit evidence—including other internal tobacco industry documents or affidavits from their employees—that contradicts any evidence, including internal tobacco industry documents, that the agency has placed in the administrative record. And they have submitted voluminous comments with supporting documentation to the agency. The manufacturers have therefore been "afforded a meaningful opportunity to be heard and to controvert the evidence. Fairness demands no more" (*Lead Indus. Ass'n*, 647 F.2d at 1170 (quotations omitted)).

In summary, due process does not require that FDA provide manufacturers with an adjudicative hearing. The notice

and opportunity for comment provided in this rulemaking are all that fairness and due process require here. And, as discussed in greater detail in section XII. of this document, this rulemaking meets all the requirements of the APA for informal rulemaking.

XII. Procedural Issues

A. Introduction

The Food and Drug Administration (FDA) went to great lengths to involve the public in this proceeding. On February 25, 1994, David A. Kessler, Commissioner of Food and Drugs (the Commissioner) wrote to Scott Ballin, chairman of the Coalition on Smoking OR Health, regarding the possibility of FDA regulation of cigarettes in response to certain petitions that had been filed with the agency. The Commissioner explained:

[T]he agency has examined the current data and information on the effects of nicotine in cigarettes * * *. Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers * * *. This evidence * * * suggests that cigarette vendors intend the obvious—that many people buy cigarettes to satisfy their nicotine addiction. Should the agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis on which to regulate these products * * *.

In the months that followed, the Commissioner testified twice before Congress regarding the accumulating evidence relating to the intended use of cigarettes.²⁵⁵ That testimony was extensive and detailed.

In July and August of that year, FDA Associate Commissioner for Regulatory Affairs, Ronald G. Chesemore wrote to the major cigarette and smokeless tobacco companies requesting all documents relating to "all research on nicotine * * *, including their pharmacological effects, and all documents relevant to the nicotine" in their products. On August 1, 1994, FDA held a Drug Abuse Advisory Committee meeting that was fully open to the public on the subject of the abuse potential of nicotine.

On August 11, 1995, FDA provided the public with an extensive Federal Register document setting forth its

²⁵⁵ Statement by the Commissioner on Nicotine-Containing Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (Mar. 25, 1994); Statement by the Commissioner on the Control and Manipulation of Nicotine in Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (June 21, 1994).

rationale for proposing to restrict the sale of cigarettes and smokeless tobacco in a 60 page discussion supported by 442 endnotes (the 1995 proposed rule) (60 FR 41314 to 41375). The agency carefully documented each of the essential propositions offered in support of its reasoning. Indeed, most of the 442 endnotes in the 1995 proposed rule contain multiple authorities for the agency's position and, in all cases, the agency provided the reader with specific page references to the numerous studies, reports, and industry documents on which it relied.

In the same issue of the Federal Register in a document entitled "Analysis Regarding The Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products," FDA also provided an analysis of the agency's authority to assert jurisdiction over cigarettes and smokeless tobacco based on the evidence before the agency at that time (the 1995 Jurisdictional Analysis) (60 FR 41453 to 41787). In the text of the 1995 Jurisdictional Analysis, the agency supported its reasoning with appropriate citations to case law, statutes, and regulations. In addition, the 1995 Jurisdictional Analysis was supported by over 600 footnotes, each of which provided the factual context for the agency's legal position.

On August 16, 1995, the agency placed on public display some 20,000 pages of materials that it cited in the 1995 proposed rule and in the 1995 Jurisdictional Analysis. With the exception of three documents, which the agency referenced only in the 1995 Jurisdictional Analysis, the agency made available to the public all of the materials on which it was relying on as of that time for support.

On September 29, 1995, the agency supplemented the administrative record by putting on public display approximately 13,000 documents comprising some 190,000 pages of factual and analytical materials the agency considered in the course of issuing the 1995 proposed rule and the 1995 Jurisdictional Analysis. Although it was under no legal obligation to do so, the agency made these additional materials available because of the importance of this proceeding.

The agency also made two other significant additions to the public record. On December 1, 1995, the agency announced the findings of focus group studies concerning possible brief statements to be included on all cigarette advertising (60 FR 61670), and added to the record for the rulemaking

proceeding a report of these findings and approximately 1,500 pages of supporting documentation. Second, in the Federal Register of March 20, 1996 (61 FR 11349), the agency published notice of an additional 30 day comment period limited to specific documents the agency added to the proposed rulemaking docket, and to the docket in support of the agency's analysis of its jurisdiction (61 FR 11419). These materials consisted of two declarations and a report from three former tobacco industry employees, as well as FDA memoranda to the record regarding adult publications and billboards.

In addition, the agency has added to the final record of this proceeding a comparatively small number of documents that expand upon or confirm information made available in the 1995 proposed rule or the 1995 Jurisdictional Analysis, or that address alleged deficiencies in the agency's initial record.

The administrative record now also includes the comments received from the public. The agency received over 700,000 comments, some directed to the 1995 Jurisdictional Analysis, some directed to the 1995 proposed rule, and many with overlapping discussions. Though many comments consisted of form letters, the agency received over 95,000 distinct or unique sets of comments. Five major cigarette manufacturers jointly submitted 2,000 pages of comments and 45,000 pages of exhibits. The major smokeless tobacco manufacturers jointly submitted 474 pages of comments and 3,372 pages of exhibits. The initial comment period remained open for 144 days.

(1) Despite the agency's extraordinary efforts to involve the public in this proceeding, FDA received several comments regarding the procedures the agency followed in providing notice of the 1995 proposed rule and in publishing the 1995 Jurisdictional Analysis. Some of these comments complained that the agency designated certain documents in the administrative record as "confidential," and that the shielding of these documents denied the public a meaningful opportunity to participate in the rulemaking process. One of these comments also contended that FDA refused to disclose certain nonconfidential information on which the agency had relied. Some comments also argued that FDA failed to set forth a balanced view of the issues presented by the 1995 proposed rule, thereby rendering the notice inadequate and "misleading" under the Administrative Procedure Act (the APA). In their view,

FDA concealed certain issues in order to deny the public the right to participate in the rulemaking process. Finally, at least one interested person maintained that the comment period for the 1995 proposed rule was so short as to be arbitrary and capricious.

As the discussion that follows in this section of the document demonstrates, the agency's notice, the public availability of the information the agency relied upon at the notice stage of this proceeding, and the opportunity for comment, went well beyond the requirements of the APA, well beyond what is required by case law construing the APA, and well beyond the agency's own procedural requirements for informal rulemaking.

B. Adequacy of the Record

(2) Several industry comments complained about the adequacy of the record in support of the 1995 proposed rule. They contended that the agency violated the APA, 5 U.S.C. 553(b) and (c), and the Due Process Clause of the Fifth Amendment to the Constitution, by failing to disclose all of the information the agency "considered or relied upon in the proceeding."²⁵⁶ In particular, these comments complained that the public was deprived of the opportunity to comment meaningfully because, according to these comments, the agency relied on confidential documents and on substantial amounts of undisclosed data. One comment went so far as to claim that "a substantial portion" of the material FDA relied upon was not made available for public scrutiny.

The record in support of the 1995 proposed rule provided the public not only with a "reasonable opportunity" for comment, but with an extraordinary opportunity to examine the agency's position. The claim that the agency withheld "a substantial portion" of the materials on which it relied is simply unfounded.

1. The Administrative Record

In an informal rulemaking proceeding, the APA itself requires only that the "notice of proposed rule making" include a statement of the time, place, and nature of the proceeding, "reference to the legal

²⁵⁶ Because the APA in this context provides the public at least as much protection as the Due Process Clause of the Constitution, the agency will address these procedural objections solely under the APA. See *Forester v. Consumer Prod. Safety Comm'n*, 559 F.2d 774, 787 (D.C. Cir. 1977); *Ass'n of Nat'l Advertisers, Inc., v. Federal Trade Comm'n*, 627 F.2d 1151, 1166 (D.C. Cir. 1979), cert. denied, 447 U.S. 921 (1980).

authority under which the rule is proposed,” and “either the terms or substance of the proposed rule or a description of the subjects and issues involved” (5 U.S.C. 553(b)). The APA, thus, does not expressly require disclosure of the information on which the agency relies in proposing a regulation.

Nevertheless, courts have implied under the APA a requirement that an agency give notice of the information on which it actually relies to support a proposed rule, and make that information available to the extent it is not readily accessible to the public. (See Davis, K. and R. Pierce, Jr., *Administrative Law Treatise*, vol. 3, section 7.3 at 305–09 (3d ed. 1994) (discussing one of the seminal cases on disclosure of data relied on to support a rulemaking proceeding, *Portland Cement Ass’n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974)).) No court, however, has required the degree of public disclosure at the notice stage of a rulemaking proceeding that FDA undertook here.

Indeed, the primary cases cited by the comments, namely, *Portland Cement Ass’n*, *supra*, *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), and *United States Lines, Inc. v. Federal Maritime Comm’n*, 584 F.2d 519 (D.C. Cir. 1978), address agency conduct that bears little resemblance to FDA’s efforts in this proceeding. While FDA has provided a remarkable degree of factual support and procedural openness, these cases involved instances in which agencies provided the public with no information whatsoever or otherwise excluded a study that was critical to the administrative proceeding. In *Portland Cement*, the Environmental Protection Agency altogether failed to provide the public an opportunity to comment on the test results and procedures on which the agency relied as the critical” basis for the emission control level adopted by the agency. That is, the agency set very specific pollution control limits, but failed to make public until after the close of the comment period the details of crucial tests relied upon to determine these limits (486 F.2d at 392).

In *Nova Scotia Food Prods.*, “all the scientific research was collected by the agency, and none of it was disclosed to interested parties as the material upon which the proposed rule would be fashioned” (568 F.2d at 251) (emphasis added). And in *United States Lines*, where a common carrier challenged an order of the Federal Maritime

Commission amending a contract between two competitors, the court found that the Commission had made “critical findings” on the basis of data which was neither identified in its decision nor included in the administrative record. Rather, the Commission based its decision on “reliable data reposing in the files of the Commission” (584 F.2d at 533). The reviewing court simply had no idea of the factors or data on which the Commission had relied (*Id.*).

Thus, at best, the case law requires agencies to disclose studies and data actually relied upon by the agency. Even then, the cases that have struck down agency rulemaking are generally confined to instances in which the agency provided woefully inadequate information to the public or failed to disclose a critical piece of information. (See, e.g., *Kennecott Corp. v. Environmental Protection Agency*, 684 F.2d 1007, 1018–19 (D.C. Cir. 1982) (agency acted arbitrarily and capriciously when it failed to include in the public docket during the comment period any documents supporting a particular proposed regulation); compare *Personal Watercraft Indus. Ass’n v. Department of Commerce*, 48 F.3d 540, 544–45 (D.C. Cir. 1995) (while agency must disclose information critical to its decision to regulate a particular activity, absent prejudice an agency may rely on studies developed after close of comment period that are not critical to the underlying proposal).)

Finally, FDA’s own procedural regulations require that the agency include with the notice of proposed rulemaking, among other things, “references to all information on which the Commissioner relies for the proposal * * *” (§ 10.40(b)(vii) (21 CFR 10.40(b)(vii)) (emphasis added); see 21 CFR 10.3 (defining the term “administrative record” to mean the materials on which the agency “relies to support the action”). Thus, even under the agency’s own procedural regulations, FDA is required—when it initiates informal rulemaking—to supply the public only with the materials the agency is relying upon to support the proposed action.

Here, the materials the agency relied on are the materials the agency cited in the 1995 proposed rule and the 1995 Jurisdictional Analysis. Not only did the agency provide these materials to the public, but it also provided the roughly 190,000 pages of factual and analytical materials the agency considered but did not rely upon in either the 1995 proposed rule or the 1995 Jurisdictional

Analysis. Moreover, the agency provided over 1,000 endnotes and footnotes directing readers to each and every document, including every study, Government report, journal article, industry document, and agency record on which FDA relied to support the 1995 proposed rule and the 1995 Jurisdictional Analysis.

Out of all this material, the only nonpublic materials on which the agency relied were two confidential documents²⁵⁷ and two lines of text the agency redacted from a document the agency placed on the public record.²⁵⁸ The agency relied on this material only in the context of the agency’s 1995 Jurisdictional Analysis. None of these documents is pivotal to the analysis of jurisdiction in that none provides the sole or principal basis for the agency’s conclusion that cigarettes and smokeless tobacco are drug delivery devices under the Federal Food, Drug, and Cosmetic Act (the act). Further, as discussed in the 1996 Jurisdictional Determination annexed hereto, the decision to keep these materials confidential did not in any way undermine the quality of the public participation in this proceeding. In sum, the procedures the agency followed in assembling a public record in this proceeding simply are not in line with the facts described in cases like *Portland Cement*, *Nova Scotia Food Products*, and *United States Lines*.

²⁵⁷ The two confidential documents the agency directly referenced are the 1991 Handbook on Leaf Blending and Product Development (Confidential Document 75) and the unredacted summary of notes of FDA trip visits (Confidential Document 74). The summary was compiled from notes and handouts that are also designated as confidential (Confidential Documents 69, 70, 71, 72, and 73). The agency views the summary as a stand-alone document to the extent it distills a large volume of disparate handwritten notes and handouts. Also, the agency cited only to the summary itself. Nevertheless, even if the summary were counted as five documents rather than one, the agency at most relied on six confidential documents. The agency’s basis for relying on these documents in the 1995 Jurisdictional Analysis is discussed in detail in the 1996 Jurisdictional Determination, annexed hereto.

²⁵⁸ On page 255 of the 1995 Jurisdictional Analysis (60 FR 41453, 41716), the agency redacted several lines of text along with a footnote that identified the sources for the redacted text. The footnote consisted of references to two sources, both of which appeared on the agency’s public docket for the 1995 Jurisdictional Analysis: J. E. Kiefer, “Cigarette Filters for Altering the Nicotine Content of Smoke” (Report No. 71 5003 7), Tennessee Eastman Co., pp. 1–2; August 18, 1971, and J. G. Curran, Jr., and E. G. Miller, “Factors Influencing the Elution of High Boiling Components of Cigarette Smoke from Filters,” *Beitr. Tabakforsch.*, pp. 5 and 67, 1969. The Kiefer document appeared on the public docket with certain trade secret information redacted from the document. The Curran document was made available to the public in full.

2. The Agency's Use of Confidential Documents

a. *Confidential documents on which the agency did not rely.* The agency placed in a confidential docket 75 documents from the approximately 210,000 pages of materials the agency made available at the opening of this proceeding. The agency identified each of these 75 documents for the public in an index filed on September 29, 1995, on the public docket. (See 60 FR 66981 at 66982, December 27, 1995.) Of these 75 documents, 73 were not even relied upon by the agency to support either the 1995 proposed rule or the 1995 Jurisdictional Analysis.

Sixty-one of these 73 confidential documents consisted either of commercial information and trade secrets that the industry urged FDA to keep confidential (Confidential Documents 1–12, 16–21, and 62–73), or unpublished manuscripts for which the agency lacked the authors' permission, as of September 29, 1995, to make them available for widespread dissemination (Confidential Documents 22–52). The remaining 12 documents were either proprietary reports and other copyrighted information—such as financial reports generated by Dun and Bradstreet—which the agency lacked permission to reprint (Confidential Documents 13–15, and 53–58), or confidential documents that supported a pending new drug application (Confidential Documents 59–61).

Again, the agency did not rely on any of these 73 documents as support for the 1995 proposed rule. Therefore, the agency was not even required to include these documents in the administrative record of the notice of proposed rulemaking. (See 21 CFR 10.40(b)(vii).) It likewise follows that because the agency did not rely upon these documents, the decision to protect them cannot be said to have unfairly interfered with the public's ability to question the agency's rationale for the rule. (See *Mid-Tex Electric Coop., Inc. v. Federal Energy Regulatory Comm'n*, 773 F.2d 327, 344 (D.C. Cir. 1985) (agency's failure to disclose two studies was "manifestly harmless" because the agency did not rely on the studies to support any finding or conclusion); *Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 843 (D.D.C. 1992) (there is no violation of the APA's notice requirements where the agency has declined to disclose materials on which it did not rely in proposing the rule); *B.F. Goodrich Co. v. Department of Transp.*, 541 F.2d 1178, 1184 (6th Cir.

1976) (only the basic data "upon which the agency relied in formulating the regulation" must be published for public comment), *cert. denied*, 430 U.S. 930 (1977); K. Davis, *Administrative Law Treatise*, section 7.3 at 307 (3d ed. 1994) ("If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators.") The agency went well beyond existing requirements to make publicly available thousands of additional documents for public review—in recognition of the uniqueness and public importance of this proceeding. This effort by the agency should not be used now as a basis for suggesting that the agency was required to publish all information that it had on hand.

Finally, at the close of this rulemaking proceeding and with the publication of the annexed 1996 Jurisdictional Determination, the agency will supplement the public docket with copies of those confidential items for which the agency previously lacked permission to publish, but for which permission has now been granted. Most of the unpublished manuscripts in the confidential docket—none of which were relied upon by the agency to support the rule—will be available through this addition to the public record.

b. *Confidential documents on which the agency relied.* In support of the 1995 Jurisdictional Analysis, FDA relied on only 2 of the 75 documents designated as confidential: A summary of notes taken by FDA investigators during site visits to manufacturing plants run by Brown and Williamson, Philip Morris, and R. J. Reynolds (Confidential Document 74); and a 1991 Brown and Williamson handbook on leaf blending and product development (Confidential Document 75).²⁵⁹ In addition, the agency relied in its 1995 Jurisdictional Analysis on two lines of text that were redacted from a document that appeared on the public docket.²⁶⁰ The 1995 proposed rule itself did not rely on any

of these documents.²⁶¹ A thorough discussion of these three documents, and the agency's basis for relying on them to support its analysis of jurisdiction, is provided in section VI. of the 1996 Jurisdictional Determination, annexed hereto.

3. The Claim that FDA Relied on "Unknown" Undisclosed Data

(3) An association representing the tobacco industry also claimed that the agency withheld certain data and calculations used to construct a series of charts showing that nicotine and tar levels in smoke have risen steadily from 1982 to 1991. (See 60 FR 41453 at 41728 to 41731.) These charts appeared only in the context of the agency's 1995 Jurisdictional Analysis. A thorough discussion of how the agency constructed these charts, and on what data the agency relied, is provided in sections II. and VI. of the 1996 Jurisdictional Determination, annexed hereto.

²⁶¹ One comment noted that the agency relied in the 1995 proposed rule on undisclosed information gathered from former industry sales representatives and managers. (See 60 FR 41314 at 41323.) The reference in the rule to interviews with former sales representatives and managers appears in the discussion of proposed § 897.12 *Additional Responsibilities of Manufacturers*. The agency used the information gathered from these individuals to support the proposition that manufacturers direct their sales representatives to police retailers' cigarette and smokeless tobacco displays. Accordingly, the agency proposed to require sales representatives to be responsible for removing violative visual displays and advertising used in retail outlets. In light of comments received, the agency has decided to revise § 897.12 to eliminate this requirement. Because manufacturer sales representatives will no longer be held responsible for maintaining retailers' fixtures, the agency's reliance on the interviews in the 1995 proposed rule, and the issue of whether the agency should have made more information on this matter available to the public, is moot. Davis, K. C., and R. J. Pierce, Jr., *Administrative Law Treatise*, vol. 1, section 7.3 at p. 307 (3d ed. 1994) ("If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators"). Finally, as the agency explained in its December 27, 1995, Federal Register notice, the agency has not made such information available to the public because of the need to protect the identity of individuals who came forward during the agency's investigation and who might not otherwise have come forward (see 60 FR 66981, 66982). As discussed in section VI. of the 1996 Jurisdictional Determination, FDA believes there are circumstances in which an agency may rely on confidential information in a rulemaking proceeding, and that there are ways in which an agency may present such information in order to preserve the public's right to a reasonable opportunity to participate in the proceeding (60 FR 66981). The agency, however, has not relied on any such material in this final rulemaking.

²⁵⁹ The agency did not acknowledge ownership of the handbook in the 1995 Jurisdictional Analysis, or in the September 29, 1995, index to the administrative record. However, in a set of comments filed by Brown & Williamson, the company itself acknowledged publicly its ownership of the handbook. (See Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), pp. 37–38).

²⁶⁰ Kiefer, J. E., "Cigarette Filters for Altering the Nicotine Content of Smoke," Tennessee Eastman Co., Report No. 71 5003 7, pp. 1–2, August 18, 1971.

4. The Claim that FDA Failed to Include in the Record New Drug Application (NDA) Data on Which it Relied

(4) One comment claimed that the agency relied on studies in seven NDA's for the proposition that a high proportion of smokers are addicted to nicotine, but failed to make adequate disclosure of these NDA's. In particular, this comment stated that the agency failed to include any information in the public docket for NDA 18-612 (Nicorette gum, 2 milligrams (mg)) and NDA 20-385 (Nicotine nasal spray), and included only summaries for five other NDA's the agency cited. To the extent the agency relied on any of these NDA's, it did so only in the context of the 1995 Jurisdictional Analysis. A comprehensive discussion of the agency's reliance on this material is provided in section VI. of the 1996 Jurisdictional Determination, annexed hereto.

5. The Agency's Reliance in the Final Rulemaking on New Materials

In an FDA informal rulemaking proceeding, the final administrative record must contain the proposed rule, including all information that the Commissioner identifies or files with the proposal, all comments received on the proposal, including all information submitted as part of the comments, and the notice issuing the final regulation, including all information that the Commissioner identifies or files with the final regulation (§ 10.40(g)). An agency may rely on information and data that were not included at the proposal stage that expands on or confirms information in the proposal or addresses alleged deficiencies in the preexisting data, provided that no prejudice is shown.²⁶² Otherwise, "[r]ulemaking proceedings would never end if an agency's response to comments must always be made the

subject of additional comments" (*Community Nutrition Inst. v. Block*, 749 F.2d 50, at 58). Accordingly, the agency has cited in this preamble and in the 1996 Jurisdictional Determination annexed hereto, a small amount of information that is needed to respond fully to the comments or that otherwise supplements the information contained in or filed with the 1995 proposed rule. These documents include published scientific articles, reference texts, letters to tobacco industry counsel, an abstract that the tobacco industry asked to include in the record, three publicly released tobacco company documents, Congressional hearing transcripts, and newspaper articles. The agency has placed this cited information in the administrative record.

C. Adequacy of the Notice

(5) Two industry comments argued that the public's participation in the rulemaking process has been frustrated because the agency presented a "one-sided" view in its 1995 notice of proposed rulemaking. They claimed that FDA failed to satisfy the APA's notice requirement for informal rulemaking because the agency neither disclosed nor discussed the supposedly "large body" of information that is "inconsistent with, or otherwise not supportive of, the proposed rule." Further, the agency did not, in their view, provide a "reasoned explanation" for departing from past precedent on the issue of whether FDA should regulate all cigarettes and smokeless tobacco.

These comments provided no legal authority to support the proposition that, at the notice stage of a proceeding, the agency is required to anticipate all challenges to its reasoning, and must attempt to answer those challenges. Rather, at the notice stage of a rulemaking proceeding, the agency's obligation is to include sufficient detail on the content of the rule, and on the basis in law and fact for the rule, to allow for meaningful and informed comment. (See *American Medical Ass'n v. Reno*, 57 F.3d 1129, 1132 (D.C. Cir. 1995); *Home Box Office, Inc. v. Federal Communications Comm'n*, 567 F.2d 9, 35-36 (D.C. Cir.), cert. denied, 434 U.S. 829 (1977).)

More specifically, in an informal rulemaking proceeding, the APA requires public notice of an agency's intention to issue a regulation (5 U.S.C. 553(b)). The notice must include "reference to the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and

issues involved" (5 U.S.C. 553(b)(2) and (b)(3)). FDA's own regulations require that a notice of proposed rulemaking include "a preamble that summarizes the proposal and the facts and policy underlying it, * * * all information on which the Commissioner relies for the proposal, * * * and cites the authority under which the regulation is proposed" (21 CFR 10.40(b)(vii)).

Under case law construing section 553 of the APA, notice of informal rulemaking must be "sufficiently descriptive of the 'subjects and issues involved' so that interested parties may offer informed criticism and comments" (*Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 48 (D.C. Cir.) (en banc), cert. denied 426 U.S. 941 (1976)). Notice is sufficient under the APA "if it affords interested parties a reasonable opportunity to participate in the rulemaking process" (*Forester*, 559 F.2d at 787; *accord State of South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 885 (4th Cir. 1983), cert. denied, 465 U.S. 1080 (1984)). And, insofar as the 1995 proposed rule relied on a technical study or specific data essential to an understanding of the rule, the notice should have disclosed this information to the extent needed to allow for "meaningful commentary" (*Connecticut Light and Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530-31 (D.C. Cir.), cert. denied, 459 U.S. 835 (1982)).

In this instance, the 1995 proposed rule met both the APA's notice requirements (as interpreted by prevailing case law), as well as FDA's own procedural requirements. The agency by any standard "fulfilled its obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible" (*Air Transport Ass'n of America v. Civil Aeronautics Board*, 732 F.2d 219, 225 (D.C. Cir. 1984) (quoting *Home Box Office, Inc.*, 567 F.2d at 36)).

1. The Agency Provided Adequate Notice of the Key Legal and Factual Issues

Although the APA's notice requirements could have been met by a far briefer presentation, the agency chose to supply the public with a notice that explored in full the wide range of factual and legal issues presented. In doing so, the agency discussed the most significant issues that the two industry comments claimed were missing from the notice.

(6) The comments contended that the agency failed to discuss past instances

²⁶² See, e.g., *Personal Watercraft v. Department of Commerce*, 48 F.3d 540, 544 (D.C. Cir. 1995) ("Agencies may develop additional information in response to public comments and rely on that information without starting anew unless prejudice is shown."); *Solite Corp. v. Environmental Protection Agency*, 952 F.2d 473, 484 (D.C. Cir. 1991) ("[C]onsistent with the APA, an agency may use 'supplementary' data, unavailable during the notice and comment period, that expands on and confirms information contained in the proposed rulemaking and addresses alleged deficiencies in the preexisting data, so long as no prejudice is shown."); *Community Nutrition Inst. v. Block*, 749 F.2d 50, 57-58 (D.C. Cir. 1984) (agency may rely on information that "expanded on and confirmed" information in the 1995 proposed rule and addressed alleged deficiencies in the record); see also Davis, K. C. and R. J. Pierce, Jr., *Administrative Law Treatise*, section 7.3 (3d ed. 1994).

in which it declined to exercise jurisdiction over cigarettes and smokeless tobacco, including FDA's response to a 1977 citizen petition. One comment in particular insisted that such a discussion would have alerted the public to the idea that Congress enacted preemptive legislation in reliance on FDA's past pronouncements, legislation which the comments argue bars FDA from regulating these products.

The agency acknowledged in the 1995 Jurisdictional Analysis, published in conjunction with the 1995 proposed rule, that it has in the past refrained from exercising jurisdiction generally over all cigarettes and smokeless tobacco (unless claims were made for the product) (60 FR 41453 at 41482 n. 5). Among other things, the agency referred readers to the published decision in *Action on Smoking and Health [ASH] v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). That decision discussed, and indeed arose from, the 1977 citizen petition which, as one comment claimed, the agency "conscientiously avoid[ed]" in order to "mislead[]" the public. Not only does the ASH opinion discuss the petition and the agency's position at that time with respect to exercising jurisdiction generally over cigarettes, it also recounts for the reader the agency's historical position on the issue (*Id.* at 237–241). Moreover, the agency placed in the administrative record copies of documents in which FDA declined to exercise jurisdiction, including FDA's response to ASH's 1977 citizen petition.²⁶³

In addition, the agency attached as part of an appendix to its 1995 Jurisdictional Analysis copies of the Commissioner's testimony before the House Subcommittee on Health and the Environment of the Committee on Energy and Commerce on March 25, 1994 (Appendix 7). At the outset, the Commissioner stated:

Although FDA has long recognized that the nicotine in tobacco products produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. One of the obstacles has been a legal one. A product is subject to regulation as a drug based primarily on its intended use. * * * With certain exceptions, we have not had sufficient evidence of such intent with regard to nicotine in tobacco products. * * *

²⁶³ Letter from D. Kennedy (FDA) to J. Banzhaf (ASH) of Dec. 5, 1977, (denial of 1977 petition); Letter from J. E. Goyan (FDA) to J. Banzhaf (ASH) of Nov. 25, 1980; Public Health Cigarette Amendments of 1971, Hearings Before the Consumer Subcommittee of the Committee on Commerce, U.S. Senate, 92d Cong., 2d sess., pp. 239–246.

Mr. Chairman, we now have cause to reconsider this historical view. * * * This question arises today because of an accumulation of information in recent months and years. In my testimony today, I will describe some of that information. (Appendix 7 at 1–2 (footnote omitted)) This testimony, like the reference to the ASH decision, adequately put the public on notice of FDA's past position.²⁶⁴

Nor does FDA agree with the comment's argument that Congress, in reliance on past FDA pronouncements, enacted legislation precluding FDA from regulating tobacco products under the act. As discussed in detail in sections IV. and V. of the annexed 1996 Jurisdictional Determination, the agency has never categorically disclaimed jurisdiction over tobacco products and Congress has never expressly forbidden FDA from asserting jurisdiction over these products. The agency has no affirmative obligation to posit in its notice of proposed rulemaking arguments it believes are legally infirm. (Cf. *Florida Power and Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988), *cert. denied*, 490 U.S. 1045 (1989).)

Two tobacco industry comments also claimed that the agency unfairly underplayed the complexity of issues such as "intended use," product categorization, regulatory authority over combination products, and the applicability of the medical device provisions of the act to cigarettes and smokeless tobacco. Instead, one of these comments asserted that all the agency had done was publish "a tendentious anti-tobacco, pro-FDA-regulation manifesto" and, as such, the agency's notice was "fraudulent." The agency disagrees with this characterization. More to the point, the agency disagrees with the argument that the agency

²⁶⁴ As discussed in section IV. of the 1996 Jurisdictional Determination, the agency's decision not to include a prolonged discussion of past agency decisions is based on the fact that the agency is now operating under a different set of facts. The agency did not commit a procedural error by failing to chronicle exhaustively decisions it made in a factually distinguishable context. Moreover, one of the comments faulted the agency for failing to give notice of the "several" citizen petitions filed since 1977 that requested that the agency regulate cigarettes. In fact, the agency incorporated by reference into the opening docket for the 1995 Jurisdictional Analysis all significant dockets opened since the conclusion of the ASH litigation that relate to the agency's jurisdiction over cigarettes and other nicotine delivery systems. The index the agency provided to the public on September 29, 1995, in conjunction with the public display of the administrative record (as of that date), included a description of nine dockets the agency incorporated by reference into the record supporting the 1995 Jurisdictional Analysis.

somehow deprived the public of fair notice.

Again, to satisfy the APA's notice requirement, the agency must specify with particularity the legal authority on which its proposal is based (K. C. Davis & R. J. Pierce, Jr., *Administrative Law Treatise* (vol. 1, 3d ed. 1994) section 7.3 at 299). Notice must be "informative" and must "fairly apprise" interested persons (*Id.* at 299 and 300). The agency need not, however, unravel for the public each and every theoretical step in the analysis. (See *Chemical Waste Management, Inc. v. Environmental Protection Agency*, 869 F.2d 1526, 1535 (D.C. Cir. 1989) (even where agency statement in notice of rulemaking assumes rather than invites comments on an issue, notice is sufficient if it provides interested parties "with a clear indication of the agency's intended course of action * * *")); *Center for Auto Safety v. Peck*, 751 F.2d 1336, 1361 (D.C. Cir. 1985) ("It is simply not the case, however, that all of the essential postulates for an agency rule must be contained in the record.")).

Nevertheless, the agency provided the public a detailed explanation of why it regards cigarettes and smokeless tobacco as drug/device combination products, and why it believes the device provisions of the act may, and should, be used to regulate these products. The agency set forth its rationale for regulating these products as devices in both the August 11, 1995, proposed rule (see 60 FR 41314 at 41348 to 41350) and again in the August 11, 1995 Jurisdictional Analysis (see 60 FR 41453 at 41521 to 41525). Further, the agency identified the precise statutory provisions under which it proposed to regulate these products (see 60 FR 41314 at 41346 to 41352, and 41372).

The agency also put the public on notice, by referencing the Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, that preloaded drug delivery systems are often regulated using the drug authorities under the act. The agency adequately explained—for notice purposes—why in this instance it proposed a different approach (60 FR 41314 at 41348 to 41350).

With respect to the application of the concept of "intended use," the lengthy discussion in Part II of the 1995 Jurisdictional Analysis provided the public with full disclosure of the agency's rationale for regulating cigarettes and smokeless tobacco based on the "intended use" of these products. The core facts and precedents on which

the agency relied were displayed in a manner the agency believes invited maximum public scrutiny. The agency even provided the public with 11 different examples (9 from the 1980's and 1990's) of the application of the intended use concept to the determination of whether a product, absent express claims, may be regulated as a drug or a device (60 FR 41453 at 41527 to 41531). This level of explanation more than satisfied the notice requirements of the APA as interpreted by the relevant case law.

Finally, the quantity and quality of comments the agency received on the 1995 proposed rule and the 1995 Jurisdictional Analysis suggest that, in fact, the public was adequately notified of the relevant issues. The agency received more comments in this proceeding than it has ever received on any other subject, with over 700,000 comments (including form letters) and over 95,000 distinct or unique sets of comments. More important, the agency received hundreds of pages of comments on the very issues the agency is said to have hidden from the public. Indeed, the two industry comments who complained most vigorously about the supposed deficiencies in the agency's notice of proposed rulemaking themselves filed volumes of comments on the issues they claim the agency concealed.²⁶⁵ Even the comments of interested nonindustry persons evidenced fair notice of the agency's reasoning for applying the device provisions of the act to cigarettes and smokeless tobacco.²⁶⁶

In *Chemical Waste Management*, the plaintiff complained that the Environmental Protection Agency's (EPA) notice of proposed rulemaking treated a certain controversial issue "as an accomplished fact" (869 F.2d at 1535). Like two of the comments here, the plaintiff in *Chemical Waste Management* argued that the APA required the agency to highlight the fact

that its position was subject to debate and to solicit comments on the issue. The United States Court of Appeals for the District of Columbia rejected this argument because EPA had provided notice of its intended course and because the agency in fact received numerous comments on the issue (869 F.2d at 1535). (See also *Shell Oil Co. v. EPA*, 950 F.2d 741, 757 (D.C. Cir. 1991) (recognition of a certain issue in comments may be used to infer that adequate notice of the issue was given); *Haralson v. Federal Home Loan Bank Board*, 678 F. Supp. 925, 926 (D.D.C. 1987) (same).)

As in cases such as *Chemical Waste Management*, the comments FDA received demonstrate that there is no serious claim to be made that the agency has concealed issues from the public. Interested persons representing both sides in this controversial proceeding commented on the very issues the agency supposedly underplayed in its notice of proposed rulemaking.²⁶⁷

The comments that challenge the adequacy of the agency's notice confuse the merits of the issue with procedure. The supposed deficiencies in FDA's legal reasoning, and the supposed failure to discuss contrary authorities, raise substantive issues to be resolved during the comment and response-to-comment phase of the proceeding. The possibility that some of the agency's legal conclusions may be subject to debate does not render the notice inadequate. (See *Chemical Waste Management, Inc.*, 869 F.2d at 1535; *Natural Resources Defense Council, Inc. v. Hodel*, 618 F. Supp. 848, 864–65 (E.D. Cal. 1985).)

2. The Agency Provided a "Reasoned Explanation" for its Current Position

Several tobacco industry comments also claimed that the agency violated the APA's notice provisions by failing to include a "reasoned explanation" for departing from past precedent on the issue of whether to regulate all cigarettes and smokeless tobacco. In their view, the 1995 proposed rule and the 1995 Jurisdictional Analysis were procedurally infirm because the agency did not adequately explain its basis for past decisions not to regulate these

products, and did not distinguish those decisions from its present position. One of these comments likewise asserted that the agency was required to include in the administrative record each and every document "that formed the basis for, or was an expression or reflection of, FDA's consistent position over more than 80 years that it does *not* have jurisdiction to regulate cigarettes." The absence of this material, according to the comment, demonstrates that the agency failed to consider "obviously relevant" contrary information in proposing to regulate these products.

The authorities cited in the comments at best require that, by the close of an administrative proceeding, the agency must provide a "reasoned explanation" to the extent the agency has departed from a prior formal position. (See, e.g., *RKO Gen., Inc. v. FCC*, 670 F.2d 215 (D.C. Cir. 1980) *cert. denied*, 456 U.S. 927 (1982) (challenge to final order of Federal Communications Commission denying renewal of television license); *Baltimore and Annapolis R. R. v. Washington Metro. Area Transit Comm'n*, 642 F.2d 1365 (D.C. Cir. 1980) (challenge to final order of transit commission); *Greyhound Corp. v. ICC*, 551 F.2d 414 (D.C. Cir. 1977) (challenge to final decision of the labor board); *International Union, United Auto Workers v. NLRB*, 459 F.2d 1329 (D.C. Cir. 1972) (challenge to final decision of labor board); see also *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto Ins.*, 463 U.S. 29, 43 (1983) (challenge to final rule rescinding passive restraint seatbelt requirement contained in a Department of Transportation standard).) None of these cases, which involved challenges to final agency orders and final rules, holds that at the notice stage of a proceeding, when an agency is proposing to depart from a prior position, the agency must provide a comprehensive "reasoned explanation."

The agency nevertheless agrees that the rulemaking proceeding, taken as a whole, should clearly and rationally justify changes in existing policies. Thus, FDA included in its notice of proposed rulemaking and 1995 Jurisdictional Analysis ample reference to its prior policy and a more than ample discussion of the agency's rationale for changing its policy. Indeed, the very intent of the 1995 Jurisdictional Analysis, and the 622 footnotes supporting the analysis, was to provide the public with a full view of the evidence that supports the need for the agency to take a different approach to the regulation of these products.

²⁶⁵ See, e.g., Joint Comments of the Smokeless Tobacco Manufacturers, Comment (January 2, 1996), at 43 to 73 (discussing the agency's historical position on agency jurisdiction over tobacco products), at 99–258 (discussing the agency's application of the concept of intended use to tobacco products), and at 259–307 (analyzing the agency's position that cigarettes and smokeless tobacco are combination products that may be regulated as restricted devices); Joint Comments of Cigarette Manufacturers at, among other places, Vol. I (discussing FDA's historical position on jurisdiction), Vol. II (discussing the concept of intended use), and Vol. V (discussing the regulation of cigarettes as medical devices).

²⁶⁶ See, e.g., Public Citizen Litigation Group, comment (January 2, 1996); American Heart Association, comment (December 26, 1995).

²⁶⁷ The agency also received a comment criticizing the agency for failing to discuss the June 1994 Federal Trade Commission's (FTC) decision regarding the "Joe Camel" advertising campaign. In section VI. of this document, the agency discusses the FTC's decision, showing that the FTC's decision in 1994 with respect to the "Joe Camel" campaign was neither relevant to, nor contradicted, FDA's discussion of the campaign in the 1995 proposed rule.

As FDA made clear at the outset of its 1995 Jurisdictional Analysis, its decision to propose to regulate these products, when in the past it chose not to (except where claims were made), is based on the fact that "[t]he quality, quantity, and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless products." (60 FR 41453 at 41464, n. 1.) Footnote 5 of the 1995 Jurisdictional Analysis, in particular, made clear that: (1) The agency in the past had declined to exercise jurisdiction generally over these products; and (2) the reason for taking a different position today is that the evidence before the agency regarding the intended use of these products "has changed dramatically." (60 FR 41453 at 41482, n. 5). In addition, the agency repeatedly stated that its analysis was based on "evidence now available to the agency" (60 FR 41453 at 41464), "current evidence" (60 FR 41466), evidence accumulated since 1980 (60 FR 41482, n. 5), and evidence that has emerged since 1980 or was not widely known until recently (60 FR 41453 at 41483 to 41484, and 41539).

Neither the APA nor the case law cited in the comments requires an agency to provide a thorough "reasoned explanation" for departing from precedent at the notice stage of a proceeding. Rather, the APA at best requires that the agency give notice of its proposal to take a different position or view, and give enough information to allow the public a reasonable opportunity to comment. Not until the close of the proceeding, after public comment has been received, must the agency ensure that it has provided a "reasoned explanation." The agency believes in this instance that its discussion at the notice stage met the standard that courts ordinarily do not impose until the close of an administrative proceeding. Nonetheless, the agency has provided a detailed discussion of the legal and factual bases for taking its current position in section IV. of the 1996 Jurisdictional Determination, annexed hereto.

Finally, the agency does not agree that it was required to include in the record, at the notice stage of the proceeding, each and every prior agency "decision, statement, and finding." Rather, the agency appropriately included in the record enough documentation to give the public notice of the agency's prior position, and notice of the agency's prior reasoning for declining to exercise jurisdiction generally over these

products (absent express claims). For example, the agency incorporated by reference into the administrative record supporting the 1995 Jurisdictional Analysis all significant dockets opened since the conclusion of the 1977 ASH litigation that relate to the agency's jurisdiction over these products. In addition, the agency included in the record in support of its 1995 Jurisdictional Analysis its response to the original ASH citizen petition. The response to the ASH petition outlines in detail the "contrary" view the agency allegedly concealed, including full discussions of the agency's enforcement history with respect to tobacco products and the agency's significant past pronouncements on the subject. In any case, the tobacco industry itself, through its comments, has introduced many of the agency's earlier statements into the administrative record for this proceeding. Thus, unlike the facts presented in cases such as *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) or *Walter O. Boswell Memorial Hospital v. Heckler*, 749 F.2d 788 (D.C. Cir. 1984), as referenced in the comment, the administrative record for this proceeding already contains the "adverse" information claimed to be lacking, by virtue of the agency's inclusion of documents in the record and the comments received by the agency.

D. Adequacy of the Comment Period

FDA received at least one comment urging that the comment period was unreasonably short in light of the complexity of the proposed rule, the number of materials the agency put on public display, and the possible impact of the rule on the tobacco industry. This comment argued that the agency acted arbitrarily and capriciously in deciding to "limit" the comment period to 144 days from the publication of the August 11, 1995, proposal and 95 days from the public release of the documents FDA considered but did not rely upon.

Far from having "limited" the comment period, FDA provided more than twice as much time for comment as the agency's regulations require. (See 60 FR 53560, October 16, 1995 (extending comment period for the proposed rule); 60 FR 53620, October 16, 1995 (extending comment period on Jurisdictional Analysis).)

The APA requires only that an agency "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments * * *." (5 U.S.C. 553(c).) This is all the APA requires;

there is no statutory requirement concerning how many days an agency must allow, nor is there a requirement that an agency must extend the period at the request of an interested person. (See *Phillips Petroleum Co. v. EPA*, 803 F.2d 545, 559 (10th Cir. 1986).)

FDA's own regulations generally afford the public 60 days to comment on a proposed rule, unless the Commissioner shortens or lengthens the period for good cause (21 CFR 10.40(b)(2)). Executive Order 12889 implementing the North American Free Trade Agreement prescribes a minimum comment period of 75 days on certain proposed rules, except when good cause is shown for a shorter comment period. (See 58 FR 69681, December 30, 1993.)

Here, the agency provided the public with 144 days from the publication of the notice, 139 days from the release of the documents the agency cited in support of the rule and the 1995 Jurisdictional Analysis (on August 16, 1995), and 95 days from the release of the materials the agency considered but did not directly rely upon (on September 29, 1995). Thus, even when counting from the date the agency released additional documents of no direct relevance to the 1995 proposed rule, the agency provided much more time for comment on the notice of proposed rulemaking than its regulations, or the Executive Order, require.

Further, on March 20, 1996, the Federal Register published a notice providing an additional 30-day comment period limited to specific documents the agency added to the proposed rulemaking docket (see 61 FR 11349, March 20, 1996) and to the docket in support of the agency's analysis of its jurisdiction (see 61 FR 11419, March 20, 1996). Although the agency expressly limited the scope of the matters on which interested persons could comment, the March 20, 1996, action did provide the public with yet another 30 days on which to comment on issues related to such core subjects as the manipulation of the nicotine content of cigarettes and smokeless tobacco. The March 20, 1996, action also reopened the comment period with respect to the record in support of the agency's proposal to regulate the advertising of these products in "adult publications" and billboard advertising.

The agency is not persuaded that any interested person has been unfairly prejudiced by the length of the comment period. First, FDA considers requests to extend the comment period on a case-by-case basis. Here, on the one hand, the

authors of the comment (the Tobacco Institute together with five major tobacco companies) presented in their request for additional time no compelling reasons to extend the period (such as a new, material study). On the other hand, FDA is faced with a matter raising serious public health concerns. For those reasons, the agency denied the request to extend the period for as long as had been requested (see 60 FR 53560).

Second, each of the five tobacco companies who submitted this joint comment complaining about the length of the comment period also filed suit against FDA 1 day before the Federal Register published FDA's notice of proposed rulemaking. The timing appears to indicate that these firms had been preparing to respond to an FDA proposal to regulate cigarettes and smokeless tobacco for some time. In any case, they were able, jointly, to submit 2,000 pages of comments and 45,000 pages of exhibits within the time allotted for commenting on the Jurisdictional Analysis and the proposed rule. Their submissions far outweigh any others. The agency, therefore, is not persuaded that these interested persons suffered prejudice as a result of FDA's allowing twice as much time as the agency's regulations require. (See *Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 844 (D.D.C. 1992) (in light of the comments received, court declined to find that 30-day comment period was insufficient to allow opportunity for meaningful public participation); *Phillips Petroleum Co.*, 803 F.2d at 559 (citing cases in which courts have upheld notice periods of 45 days or less).)

In sum, the agency believes it provided ample additional time for comments—nearly 90 days more than is provided for in the agency's own procedural regulation. Given that it received over 95,000 distinct sets of comments, the agency is not persuaded that the length of the comment period unfairly hampered the quality of the public debate on this matter.

E. Conclusion

Because of the importance of the issues involved in this proceeding, the agency compiled the most extensive administrative record in support of a proposed rulemaking in its history. FDA employed procedures that exceeded all legal requirements in giving the public a reasonable opportunity to participate in this matter.

XIII. Executive Orders

A. Executive Order 12606: The Family

Executive Order 12606 (E.O. 12606) directs Federal agencies to determine whether policies and regulations may have a significant impact on family formation, maintenance, and general well-being. The preamble to the 1995 proposed rule stated that the rule would have "no potential negative impact on family formation, maintenance, and general well-being." Specifically, the Food and Drug Administration (FDA) said that the rule would not affect family stability or marital commitments, would not have a significant impact on family earnings, and would not impede parental authority and rights in the education, nurture, or supervision of children. To the contrary, the preamble to the 1995 proposed rule said that the rule would "help the significant majority of American families that seek to discourage their children from using cigarettes and smokeless tobacco" because "[t]he pervasive promotion and easy availability of these products * * * severely hinder the individual family from carrying out this function by itself" (60 FR 41314 at 41356).

In the Federal Register of August 11, 1995, the preamble to the proposed rule (60 FR 41314) (the 1995 proposed rule) also stated that, under section 1(g) of the Executive Order (which instructs agencies to ask about a rule's "message" to young people concerning their behavior, their personal responsibility, and societal norms), the rule would "help reduce the conflict between the anti-smoking messages issued by Federal and State authorities and the pro-tobacco messages seen in advertising" that are attractive to children. This would enable young people "to understand how prevalent tobacco use is in society and also appreciate how their decisions regarding cigarette and smokeless tobacco use can affect their health" (60 FR 41314 at 41356).

In the 1995 proposed rule, FDA invited comments and suggestions on the rule's effect on the family.

FDA received several comments that disagreed with FDA's analysis.

(1) One comment said that the rule would have a significant economic effect on family earnings through increased costs (in order to comply with the rule) or the possible loss of jobs. Another comment said that the rule would destroy some family businesses, especially those dependent on vending machines selling cigarettes or on

sponsorships by cigarette or smokeless tobacco manufacturers.

The agency disagrees with the comments. FDA reiterates that the rule does not affect sales to adults. It is narrowly drawn to reduce young people's access to cigarettes and smokeless tobacco and to reduce the appeal of those products to young people. In short, the rule is intended to prevent illegal sales to young people, and the agency has no evidence to suggest that a significant number of families depend on such sales.

FDA also notes that the final rule, as amended, permits vending machines in facilities that are inaccessible to young people and also permits sponsorships under certain restrictions. These changes to the rule should reduce the potential economic impact on families dependent on vending machine earnings or sponsorships or enable them to adjust their affairs to maintain family earnings.

(2) Several comments said that the rule interferes with parents' ability to raise their children, but did not elaborate on how the rule supposedly interfered in child-rearing.

The agency disagrees with the comments. The rule does not direct parents to educate or raise their children in any particular manner and, insofar as adults are concerned, does not regulate the use of cigarettes or smokeless tobacco by adults. It does reduce both their access and appeal to young people and, as a result, should help those parents who are trying to prevent their children from becoming regular users of these products. Thus, the rule does not interfere with parental authority or the manner in which parents educate, nurture, or supervise their children.

FDA, therefore, reiterates that the rule does not have a negative impact on family formation, maintenance, and general well-being and is consistent with Executive Order 12606.

B. Executive Order 12612: Federalism

Executive Order 12612 (E.O. 12612) requires Federal agencies to carefully examine regulatory actions to determine if they have a significant impact on the States, on the relationship between the States and the Federal government, and on the distribution of power and responsibilities among the various levels of government. E.O. 12612 directs Federal agencies that are formulating and implementing policies to be guided by certain federalism principles, such as encouraging a "healthy diversity in the public policies adopted by the people of the several States according to their own

conditions, needs, and desires" (section 2 of E.O. 12612).

Although § 897.42 of the 1995 proposed rule would have excluded from preemption under section 521 of the act more stringent State and local requirements that do not conflict with requirements imposed under FDA's final rule, FDA has deleted § 897.42 from the final rule because of significant concerns with regard to the validity of that section's proposed preemption exclusion. See discussion in section X. of this document. Thus, under the express provisions of section 521(a) of the act, FDA regulation of cigarettes and smokeless tobacco as nicotine-delivery devices will result in preemption of State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco when such requirements are different from, or in addition to, the requirements under FDA's final rule.

FDA received many comments on the 1995 proposed rule regarding its possible impact on State and local governments. Most comments came from individual State legislators in over 15 States (often using the same text or paragraphs). FDA also received comments from United States Senators and Representatives, four State governors, three lieutenant governors, as well as a number of State and local health departments, substance abuse programs, and law enforcement agencies. In addition, FDA received comments from industry trade associations and individual retailers. After careful consideration of these comments, FDA has assessed the rule's impact on the States, on the relationship between the States and the Federal government, and on the distribution of power and responsibilities among the various levels of government. As discussed below in this section, the agency concludes that the preemptive effects of the final rule are consistent with E.O. 12612.

(3) Many comments, including several from legislators, expressed opposition to the 1995 proposed rule on the grounds that the rule adversely affected State sovereignty by infringing on States' rights to regulate tobacco products, to protect their citizens, and to regulate businesses within the State. Some comments from State legislators criticized the rule, interpreting it as a statement that the State are "unable to care for [their] own children," while other comments said that legislators, not FDA, should address issues affecting private citizens because legislators are elected officials who can be held

politically accountable by their constituents.

Some comments asserted that the 1995 proposed rule would prevent States from experimenting with or trying different local approaches to reduce the accessibility and appeal of cigarettes and smokeless tobacco products. Some of these comments argued that their State laws were either adequate or superior to the 1995 proposed rule, citing, for example, State vending machine restrictions, State laws prohibiting distribution of tobacco products to minors, and State proof-of-age requirements. Moreover, some comments argued that FDA has failed to show that youth access to, and use of, tobacco products is a national (rather than State) concern warranting Federal action.

In contrast, several comments from State departments of health and State attorneys general noted that tobacco regulation is not solely a State issue. Moreover, some of the comments supported the rule for its potential impact on public health and on illegal sales of tobacco products to young people.

FDA recognizes the pioneering and continuing role in the area of regulation of youth access to tobacco products that States have played, particularly certain active tobacco-control States. Federal cooperation with, and continued reliance upon, innovative and aggressive State and local enforcement efforts is essential.

As explicitly recognized in E.O. 12612, however, Federal action limiting the discretion of State and local governments is appropriate "where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope" (section 3(b) of E.O. 12612). The final rule meets both of these conditions. First, the constitutional authority for the final rule is clearly rooted in the act which was enacted by Congress under the authority of the Commerce Clause of the Constitution, art. I, section 8, cl. 3. Second, youth access to cigarettes and smokeless tobacco is a problem of national scope that necessitates the provisions established by the final rule.

As discussed in the preamble to the 1995 proposed rule, approximately 3 million children under the age of 18 are daily smokers (60 FR 41314 at 41317). Moreover, every day, approximately another 3,000 young people become regular smokers (*Id.*). Children annually consume hundreds of millions of cigarettes, with the estimates ranging

from 516 million to 947 million packages (*Id.*). Although most segments of the American adult population have decreased their use of cigarettes, smoking among young people has recently begun to rise (60 FR 41314 at 41315). With regard to smokeless tobacco, similar statistics demonstrate the extent of the problem in this area—an estimated 1 million adolescent males use smokeless tobacco (60 FR 41314). These figures clearly demonstrate a serious problem which exists at a national level. The health effects associated with cigarettes and smokeless tobacco are well established and have national social and health implications that warrant Federal attention.

As discussed in section X. of this document, FDA believes the requirements it is establishing in this final rule set an appropriate floor for regulation of youth access to tobacco products but do not, as a policy matter, reflect a judgement that more stringent State or local requirements are inappropriate. Indeed, State and local governments may apply for exemption from preemption under section 521(b) of the act with regard to State and local requirements governing the sale and distribution of cigarettes and smokeless tobacco. A State or local requirement will be exempted from preemption under section 521(b) of the act if the State or local requirement: meets the exemption requirements established under that section, and is consistent with the goals in the final rule. The availability of exemptions from preemption established under section 521(b) of the act enables State and local governments to preserve or enact more stringent requirements governing the sale and distribution of cigarettes and smokeless tobacco.

(4) Several comments asserted that States should be free to decide how to allocate their resources, including decisions as to whether any resources should be spent on tobacco control. Other comments expressed concern as to the rule's possible impact on State resources, explaining that States lacked resources to enforce the rule or predicting that FDA would lack sufficient resources to enforce the rule and, as a result, would have States handle enforcement matters.

FDA believes that these concerns are unfounded. First, because FDA is responsible for enforcing this rule, the rule should not require the expenditure of State resources for its enforcement. Second, with regard to State tobacco control, State and local governments will retain flexibility to choose the

appropriate allocation of their resources in this area through the availability of exemptions from preemption under section 521(b) of the act.

(5) Several comments also expressed strong concern regarding the rule's possible impact on the State economies, particularly with respect to farmers, manufacturers, distributors, and retailers. A detailed analysis of the rule's economic impact can be found in section XV. of this document.

Section 3(d)(3) of E.O. 12612 directs Federal departments and agencies to consult with appropriate officials and organizations representing the States in developing those standards. Similarly, section 4(d) of E.O. 12612 instructs Federal departments and agencies to consult, to the extent practicable, with State officials and organizations when the Federal department or agency "foresees the possibility of a conflict between State law and federally protected interests within its area of regulatory responsibility." Moreover, section 4(e) of E.O. 12612 requires Federal departments and agencies to "provide all affected States notice and an opportunity for appropriate participation in the proceedings" when the Federal department or agency proposes to act through rulemaking to preempt State law.

The proposed rule published in the Federal Register of August 11, 1995, notified States and local governments of the Federal interest in regulating the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents. FDA, through the comment period on the proposed rule, gave State and local governments notice and an opportunity to participate in the rulemaking process, as required by E.O. 12612. This final rule, as well as the exemption document, which appears elsewhere in this issue of the Federal Register, provide additional notice to State and local governments. Further opportunity for participation is provided by the availability of exemptions from preemption set forth in section 521(b) of the act.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with E.O. 12612.

*C. Executive Order 12630:
Governmental Actions and Interference
with Constitutionally Protected Property
Rights*

Executive Order 12630 (E. O. 12630) directs Federal agencies to "be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth

Amendment in planning and carrying out governmental actions so they do not result in the imposition of unanticipated or undue additional burdens on the public fisc" (Section 3(a)). Section 3(c) of the order states that actions taken to protect the public health and safety "should be undertaken only in response to real and substantial threats to public health and safety, be designed to advance significantly the health and safety purpose, and be no greater than is necessary to achieve the health and safety purpose." Additionally, section 4(d) of E.O. 12630 requires, as a prerequisite to any proposed action regulating private property use for the protection of public health and safety, each agency to: (1) Clearly identify the public health or safety risk created by the private property use that is the subject of the proposed action; (2) establish that the proposed action substantially advances the purpose of protecting the public health and safety against the identified risk; (3) establish, to the extent possible, that the restrictions imposed on private property are not disproportionate to the extent to which the use contributes to the overall risk; and (4) estimate, to the extent possible, the potential cost to the Government should a court later determine that the action constitutes a taking.

The agency, in the preamble to the 1995 proposed rule, considered whether the rule would result in a "taking" of private property and concluded that, while some requirements might affect private property, the rule did not result in a "taking" of that property. (See 60 FR 41314 at 41357 through 41359.) In brief, the preamble to the 1995 proposed rule noted that the proposal would prohibit the use of a nontobacco product trade name on a tobacco product, eliminate vending machines and self-service displays, restrict outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, prohibit all brand identifiable nontobacco items (such as hats and tee-shirts), and require established names and a brief statement on labels, labeling, and/or advertising. Sponsorship, under the 1995 proposed rule, would be limited to the corporate name. The preamble to the 1995 proposed rule explained that the rule did not result in a "taking" because the rule would not require the Government to physically invade or occupy private property and would not deny all economically viable uses of property. For example, the preamble to the 1995 proposed rule also

stated that some items, such as vending machines, self-service displays, and nontobacco items, could be adapted to other uses. The preamble to the 1995 proposed rule also found that the rule substantially advanced the purpose of protecting the public health and that the restrictions were not disproportionate to the extent to which the use of the private property contributed to the public health risk (60 FR 41314 at 41357 through 41359). FDA also invited interested persons to submit information to enable the agency to determine the potential cost to the Government if a court found that the actions described in the 1995 proposed rule constituted a taking.

The final rule, as amended, prohibits the use of a trade name of a nontobacco item for any tobacco product, restricts the placement of vending machines and self-service displays, restricts outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, prohibits all brand identifiable nontobacco items, such as hats and tee-shirts and requires established names on labels, labeling, and/or advertising, and places certain restrictions on sponsorship. Thus, the final rule, in many respects, is more lenient than the 1995 proposed rule. For example, the 1995 proposed rule would have eliminated the use of vending machines; the final rule permits vending machine sales to occur in locations that are inaccessible to young people. The 1995 proposed rule would have eliminated mail-order sales; the final rule permits such sales to continue. So, given that the 1995 proposed rule did not result in a "taking," the final rule, being more lenient than the 1995 proposed rule, also should not result in a "taking."

Nevertheless, FDA received several comments asserting that the rule would effect a "taking" of private property. Most comments did not assign a specific monetary value to the private property which they felt would be "taken" or, instead, gave values or figures applicable to the entire industry rather than values or figures that would apply to the market (which, in this case, would be sales to people under age 18) affected by the rule.

(6) Several comments, particularly from retailers, claimed that the 1995 proposed rule's restrictions on self-service displays constituted a "taking." A few comments explained that, for self-service displays, requiring the displays to be moved behind the counter would be analogous to a Government requiring an easement on real property and, as a

result, would violate the Fifth Amendment. FDA also received a small number of comments from firms that manufacture displays; these firms argued that the rule would essentially force them out of business and represent a "taking" of the business.

FDA disagrees with the comments. The final rule, as amended, permits self-service displays (merchandisers only) in facilities that are totally inaccessible to young people. Thus, in those facilities where merchandisers will be permitted, the rule will not require the merchandisers to be removed, and firms that manufacture merchandisers will continue to have a market for their merchandisers.

Retailers might be able to avoid or reduce the rule's impact on some merchandisers if those merchandisers could be adapted to other uses. For example, a merchandiser that consisted of bare shelves could be used to display products other than cigarettes and smokeless tobacco. Other merchandisers could be moved and, as a result, would retain their utility; for example, a counter display that stands near a cash register could be moved behind the counter and still be used for cigarettes and smokeless tobacco.

Additionally, as explained in greater detail in section XI. of this document, reductions in personal property's value, even prohibitions on all economically viable uses, and financial expenditures to comply with a regulatory requirement do not necessarily establish a taking.

(7) Several comments asserted that the rule would eliminate the use of vending machines. In the preamble to the 1995 proposed rule, FDA cited an article from a vending machine publication to suggest that vending machines could be converted to sell other products and so, while the 1995 proposed rule would prohibit the use of vending machines for cigarettes and smokeless tobacco, the ability to convert a vending machine to other uses reduced the likelihood of a "taking" (60 FR 41314 at 41358). However, FDA received several comments explaining that some cigarette vending machines, particularly older models, cannot be adapted to other uses so that the 1995 proposed rule would destroy the value of those older vending machines.

As discussed earlier in this document, the final rule permits vending machines in facilities that are totally inaccessible to young people. While this may limit the number of places where vending machines may be used, may exclude vending machines from places where they were used most profitably, or, for

those vending machines that cannot be moved, may compel the vending machine owner to convert the machine to other uses, if possible, the final rule's restrictions do not constitute a taking. Reductions in personal property's value, even prohibitions on all economically viable uses, and financial expenditures to comply with a regulatory requirement do not necessarily establish a taking.

(8) Several comments asserted that the rule would reduce sales or tax revenues, prompt companies to terminate employees, or suspend sponsorship of events, thereby depriving States of revenues associated with those sponsored events or eliminating the event itself. For example, one State legislator claimed that the rule would adversely affect automobile racing events in the State, leading to a loss of 8 million dollars in revenue and adversely affecting the State's tourism department. Another State legislator asserted that the rule's sponsorship restrictions would end rodeo events in the State.

FDA disagrees with the comments. While the rule's economic impacts may be significant, those impacts do not necessarily result in a taking. For example, the final rule does not require firms to terminate employees or to stop sponsoring events. In fact, the final rule expressly permits sponsorships in the corporate name. The concerns expressed by the comments are also speculative and, to the extent that they do occur, would result from decisions made by third parties rather than by FDA. The Fifth Amendment requires just compensation for a governmental taking of private property; it does not require compensation for the consequential damages resulting from the exercise of a lawful Government regulation on that property.

Indeed, as noted in the preamble to the 1995 proposed rule, courts have generally required either a physical invasion of the property or a denial of all economically beneficial or productive use of the property and examined the degree to which the governmental action serves the public good, the economic impact of that action, and whether the action has interfered with "reasonable investment-backed expectations" (60 FR 41314 at 41357 through 41358). The preamble to the 1995 proposed rule noted that deprivation of the most beneficial use of property does not constitute a taking and that Government regulation often involves adjustment of rights for the public good. If every Government regulation resulted in a taking, then the

Government would be effectively required to "regulate by purchase" (60 FR 41314 at 41358 (citing *Andrus v. Allard*, 444 U.S. 51, 65 (1979))). Here, the agency is not directing retailers to terminate staff, taking revenue belonging to retailers, or ending sponsored events. It is only issuing regulations to reduce illegal cigarette and smokeless tobacco to young people and the appeal of such products to young people. Retailers would still receive revenues from legal sales to adults; sponsorships in the corporate name could occur.

Other cases support the notion that lawful regulatory action does not constitute a taking merely because the Government action diminishes the value of private property, reduces profits, or prevents the most beneficial use of property (see *Carlin Communications, Inc. v. Federal Communications Comm'n*, 837 F.2d 546, 557-558 n. 5 (2d Cir.), *cert. denied*, 488 U.S. 924 (1988) (FCC regulation of "dial-a-porn" services to protect minors did not constitute a taking); *Galloway Farms, Inc. v. United States*, 834 F.2d 998 (Fed. Cir. 1987) (trade embargo, while closing off certain markets, did not eliminate all economic value so no taking occurred); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Public Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), *cert. denied*, 469 U.S. 1215 (1985) (nursing home's decision to participate in Medicaid program was voluntary and so a statute pertaining to Medicaid rates did not constitute a taking); *Carruth v. United States*, 627 F.2d 1068, 1081 (Ct. Cl. 1980) (regulation affecting contaminated peanuts, while reducing their value, did not constitute a taking); *Warner-Lambert Co. v. Federal Trade Comm'n*, 562 F.2d 749, 759 n. 45 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978) (FTC order requiring corrective advertising did not constitute a taking)).

Furthermore, courts have generally declined to require compensation for the loss of contracts that could not be completed following the enactment of a new statute or regulation or action by the Government and have not required compensation for the loss of future or anticipated profits. In *Omnia Commercial Co. v. United States*, 261 U.S. 502 (1923), the Supreme Court had to decide whether the Government's acquisition of a steel company's entire production of steel plate constituted a taking of a firm's contract for a large quantity of steel plate from the same steel company. The Court wrote that, "There are many laws and governmental

operations which injuriously affect the value of or destroy property—for example, restrictions upon the height or character of buildings, destruction of diseased cattle, trees, etc., to prevent contagion—but for which no remedy is afforded. Contracts in this respect do not differ from other kinds of property” (*Id.* at pp. 508 through 509). The Court reviewed earlier decisions and stated that:

The conclusion to be drawn * * * is, that for consequential loss or injury resulting from lawful governmental action, the law affords no remedy. The character of the power exercised is not material. * * * If, under any power, a contract or other property is taken for public use, the Government is liable; but, if injured or destroyed by lawful action, without a taking, the Government is not liable.

(*Id.* at p. 510)

The Court held that while the Government took the steel, it did not take the contract itself and that “[f]rustration and appropriation are essentially different things” (*Id.* at p. 513). (See also *Louisville & Nashville R.R. Co. v. Mottley*, 219 U.S. 467, 484 (1911); *NL Industries, Inc. v. United States*, 839 F.2d 1578, 1579 (Fed. Cir.), *cert. denied*, 488 U.S. 820 (1988) (“frustration of a business by loss of a customer was not a taking”); *Carruth*, 627 F.2d at 1081 (“[I]n cases where there has been no direct appropriation of property by governmental agencies, consequential damages resulting from the exercise of lawful regulations are not compensable takings within the purview of the Fifth Amendment”).)

Thus, FDA disagrees with the comments suggesting that the rule will result in a taking of jobs or future revenues associated with sponsored events.

(9) Several comments said that the 1995 proposed rule’s restrictions on the use of trade names constitute a taking of trade names or the goodwill associated with a tradename or asserted that one has a “right” to use a brand name in any manner.

As discussed in section XI. of this document, the agency disagrees that any provision in this rule effects a taking of trademarks and goodwill.

XIV. Environmental Impact

In the Federal Register of August 11, 1995 (60 FR 41314), the preamble to the proposed rule stated that FDA had determined under § 25.24(a)(8), (a)(11), and (e)(6) that the proposed action was of a type that does not individually or cumulatively have a significant impact on the human environment. No new information or comments have been

received that would affect the agency’s previous determination that this action has no significant impact on the human environment, and that neither an environmental assessment nor an environmental impact statement is required.

XV. Analysis of Impacts

A. Introduction and Summary

The Food and Drug Administration (FDA) has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts and equity). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of such rule on small entities. Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 (adjusted annually for inflation) in any year. Section 205 of the Unfunded Mandates Reform Act also requires that the agency identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule. The following analysis, in conjunction with the remainder of this preamble, demonstrates that this rule is consistent with the principles set forth in the Executive Order and in these two statutes.

FDA published its preliminary economic analysis in the preamble to its 1995 proposed regulation. In response, the agency received thousands of comments raising economic issues or concerns. Representatives of affected industry sectors emphasized burdens in excess of those estimated in the preliminary economic analysis. Other comments stressed the considerable economic value of the expected public health benefits. Although few comments provided quantifiable data on projected

economic impacts, whether benefits or burdens, a report prepared by the Barents Group and presented as Volume 11 of the Tobacco Institute submission provided a comprehensive critique of the methodology, assumptions, and cost estimates presented in FDA’s preliminary economic analysis and developed alternative estimates of regulatory costs. Other comments addressed selected economic issues. FDA carefully examined and evaluated the reasoning and data presented in these comments, accepted those that were persuasive, and presents this revised analysis of the final rule.

In its preliminary analysis, FDA based the benefits of the 1995 proposed rule on a finding that compliance could help to achieve the Department’s “Healthy People 2000” goal of reducing underage tobacco use by one-half. Comments received in response to the proposal have reinforced the agency’s conviction that this goal can be realized, although it will require the active support and participation of State and local governments and civic and community organizations, as well as manufacturers and retail dispensers of tobacco products. In the Federal Register of January 19, 1996 (61 FR 1492), the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a regulation governing a program of State-operated enforcement activities to restrict the sale or distribution of tobacco products to individuals under the age of 18. SAMHSA predicted that its rule would cut the rate of underage tobacco consumption by between one-tenth and one-third. FDA can not separately quantify the incremental benefits of the respective agency programs, due to the substantial interdependencies and uncertainties regarding future compliance with these rules; but finds that its final rule and the SAMHSA regulation are fully complementary and, working together, will produce results that would more than equal the sum of their independent efforts.

Each year, an estimated 1 million adolescents under the age of 18 begin to smoke cigarettes. The Centers for Disease Control and Prevention (CDC) estimate that approximately one in three of these adolescents will die of smoking-related diseases, and FDA has concluded that this projection provides the best estimate of the excess fatality rate. FDA finds that even overly conservative projections indicate that achieving the “Healthy People 2000” goal of reducing underage tobacco use by one-half would prevent well over

60,000 early deaths, gaining over 900,000 future life-years for each year's cohort of teenagers who would otherwise begin to smoke. The monetary value of these health benefits (at a 3 percent discount rate) is estimated to total \$28 to \$43 billion per year and includes \$2.6 billion in medical cost savings, \$900 million in productivity gains from reduced morbidity, and \$24.6 to \$39.7 billion per year in

willingness-to-pay values for averting premature fatalities. (Because of the long periods involved, a 7 percent discount rate reduces the total benefits to about \$9.2 to \$10.4 billion per year). If the agency's goal were exceeded, these benefits would be even larger. Moreover, if even a fraction of the goal were achieved, the benefits would substantially outweigh the costs of the rule. As shown in Table 1c, halting the

onset of smoking for only 1/20 of the 1 million adolescents who become new smokers each year would provide annual benefits valued at from \$2.8 to \$4.3 billion a year. In addition, although FDA has not quantified the benefits of reducing the number of serious illnesses attributable to the use of smokeless tobacco by youngsters under the age of 18, the agency is convinced that these benefits also will be substantial.

TABLE 1c.—ANNUAL ILLNESS-RELATED BENEFITS OF ALTERNATIVE EFFECTIVENESS RATES (UNDISCOUNTED LIVES AND LIFE-YEARS; 3% DISCOUNT RATE FOR MONETARY VALUES)¹

Fraction of Teenage Cohort Deterred	Fewer Teen-agers who will Smoke as Adults ³ (No.)	Smoking Related Deaths Averted (No.)	Life-Years Saved (No.)	Medical Savings (\$bils.)	Morbidity-Related Productivity Savings (\$bils.)	Mortality-Related Will- ingness-to-Pay		Total Benefits	
						Life-Yrs. Saved (\$bils.)	Deaths Averted (\$bils.)	Low (\$bils.)	High (\$bils.)
1/2 ²	250,000	60,200	905,300	2.6	0.9	24.6	39.7	28.1	43.2
1/3	167,000	40,100	603,600	1.8	0.6	16.4	26.4	18.7	28.8
1/5	100,000	24,100	362,100	1.1	0.4	9.8	15.9	11.2	17.3
1/10	50,000	12,000	181,100	0.5	0.2	4.9	7.9	5.6	8.6
1/20	25,000	6,000	90,500	0.3	0.1	2.5	4.0	2.8	4.3

¹ Totals may not add due to rounding.

² Estimate used in analysis.

³ Assumes 50% of adolescents who are deterred from smoking continue to refrain as adults.

In its evaluation of the economic impact on industry, FDA also includes those costs that might be attributable to the SAMHSA program, as the rules of both agencies work collectively to reduce youth access to tobacco products. As a result, the overall estimated compliance costs of the rules range from \$174 million to \$187 million in one-time costs and from \$149 million to \$185 million in annual operating

costs (see Table 2). Manufacturers of tobacco products will incur one-time costs ranging from \$78 million to \$91 million, primarily for removing prohibited point-of-sale promotional items and self-service displays, and for changing package labels. As the responsibility for removing the prohibited point-of-sale promotional and display items resides with the owner, manufacturers and retailers may

ultimately share the costs of removal and replacement. FDA's cost estimates assume that manufacturers will pay for most removal and installation activities and retailers will pay for most replacement items. (If, in fact, retailers assume most removal responsibilities, the estimated manufacturer costs fall by about \$47 million).

TABLE 2.—COSTS OF FDA AND SAMHSA REGULATIONS (\$ mils.)¹

Requirements By Sector	One-Time Costs	Annual Operating Costs
Tobacco Manufacturers	78–91	2
Point-of-Sale Advertising	30	
Self-Service Ban	40	
Label Changes	4–17	
Paperwork Requirements		1.2
Training	1.5	0.2
Readership Surveys	2	1
Retail Establishments	96	78
Training	34	20
I.D. Checks		43
Self-Service Ban	57	11
Point-of-Sale Advertising	5	
Vending Machines		3.5
Consumers		41–50
I.D. Checks		41–50
Government		28–55
States (SAMHSA)		25–50
FDA		3–5
TOTAL	174–187	149–185

¹ Assumes manufacturers remove prohibited retail display. If retailers bear full burden, manufacturer one-time costs fall by about \$47 million and retailer one-time costs rise by about \$17 million. Advertising restrictions are considered under distributional effects. Excludes costs of short-term resource dislocation and educational programs.

Retail establishments will incur an estimated \$96 million in one-time costs. About \$57 million of these costs are due to the self-service restriction, primarily for replacing display cases and other functional promotional items. (If retailers rather than manufacturers remove the prohibited point-of-sale advertising and display items, the estimated retailer costs rise by about \$17 million). The retail sector will also incur about \$78 million in annual costs. In addition to new labor costs attributable to the self-service restrictions, both the FDA and SAMHSA rules impose costs for training employees to verify customer ages, for routinely checking I.D.'s of young purchasers, and for foregoing profits due to reduced vending machine sales. Consumers will bear costs of up to \$50 million annually for incurring some delay in checkout lines. Finally, enforcement of these rules may cost the FDA from \$3 million to \$5 million per year and State governments from \$25 million to \$50 million per year for administering various SAMHSA enforcement programs.

FDA could not, however, quantify every regulatory cost. For example, the agency may require certain tobacco manufacturers to broadcast educational messages under the agency's notification process. Cost estimates for these activities will be developed in parallel with the program elements. In

addition, a number of commercial sectors will experience costs for short-term dislocations of current business activities. Neither FDA nor any of the industry comments on the agency's proposal projected the magnitude of these costs, but they would be mitigated for those businesses that anticipate the adjustments in long-term business plans.

In addition to the costs described previously, the rule will create significant distributional and transitional effects. Some industry comments asserted that FDA had neglected the cost of lost sales revenues in its preliminary economic analysis and one industry study estimated these "Illustrative Costs" at from \$1.3 billion to \$3.3 billion per year. In fact, FDA had considered these sector-specific revenue reductions, but described the impacts as distributional effects, rather than as net societal costs. For example, any lost sales experienced by suppliers of advertising were considered distributional impacts, because dollars not spent on advertising will not be lost to the U.S. economy, but will be spent on other goods and services. As acknowledged by the authors of one of the economic impact analyses commissioned by the tobacco manufacturing industry:

* * * when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The

increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies.

Similarly, the anticipated slow but persistent decline in tobacco product sales revenues are not societal costs, because the dollars not spent on tobacco-related items will be spent on other goods or services.

Nevertheless, FDA is aware that many tobacco-related industry sectors will be adversely affected by this rule. Tobacco manufacturers and suppliers will face increasingly smaller sales, because reduced tobacco consumption by youth will lead, over time, to reduced tobacco consumption by adults. The impact of this trend on industry revenues, however, will be extremely gradual, requiring over a decade to reach an annual decrease of even 4 percent. Also, if State and Federal excise tax rates on tobacco products remain at current levels, tax revenues would decrease slowly over time, falling by about \$231 million and \$196 million, respectively, by the 10th year following compliance with the regulation.

Tobacco manufacturers spent \$6.2 billion on advertising, promotional, and marketing programs in 1993, and about 30 percent may be substantially altered to reflect the various "text only"

restrictions or other prohibitions. If tobacco companies choose to reduce advertising and promotional activities due to the FDA restrictions, the sectors affected would include advertising agencies and communications media, owners of retail and outdoor advertising space, and recipients of corporate brand-name sponsorships (especially auto racing). These businesses would need to attract new revenues to maintain current levels of profitability. Similarly, vending machine operators will need to find substitute products to replace up to 3 percent of their sales revenues.

In summary, FDA finds that compliance with this rule will bring significant health benefits to the U.S. population. The rule will also exact long-term revenue losses on the tobacco industry and short-term costs on various affiliated industry sectors. With regard to small businesses, many near-term impacts will be small or transitory, but some business will be adversely affected. For a small retail convenience store not currently complying with this rule, the additional first year costs could average \$400. For those convenience stores that already check customer identification, these costs average \$137, largely to relocate tobacco product displays. Moreover, the rule will not produce significant economic problems at the national level, as the long-term displacement within tobacco-related sectors will be offset by increased output in other areas. Thus, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives and determined that the current rule is the least burdensome and most cost-effective alternative that would meet the objectives of this rule.

B. Statement of Need for Action

The need for action stems from the agency's determination to ameliorate the enormous toll on the public health that is directly attributable to the consumption by adolescents of cigarettes and smokeless tobacco. According to the nation's most knowledgeable health experts, tobacco use is the most important preventable cause of morbidity and premature mortality in the United States, accounting each year for over 400,000 deaths (approximately 20 percent of all deaths). Moreover, these morbidity and mortality burdens do not spare middle aged adults—with the average smoking-

related death responsible for the loss of up to 15 life-years.²⁶⁸

In its guidelines for the preparation of Economic Impact Analyses, OMB asks that Federal regulatory agencies determine whether a market failure exists and if so, whether that market failure could be resolved by measures other than Federal regulation. The basis for this request derives from standard economic welfare theory, which by assuming that each individual is the best judge of his/her own welfare, concludes that perfectly competitive private markets provide the most efficient use of societal resources. Accordingly, the lack of perfectly competitive private markets (market failure) is frequently used to justify the need for Government intervention. Common causes of such market failures include monopoly power, inadequate information, and market externalities or spillover effects.

While FDA agrees that various elements of market failure are relevant to the problem of teenage use and tobacco addiction, the agency also believes that this regulatory action would be justified even in the absence of a traditional market failure. As noted previously, the implications of the market failure logic are rooted in a basic premise of the standard economic welfare model—that each individual is the best judge of his/her own welfare. FDA, however, is convinced that this principle does not apply to children and adolescents. Even steadfast defenders of individual choice acknowledge the difficulty of applying the “market failure” criterion to non adults. Littlechild, for example, adds a footnote to the title of his chapter on “Smoking and Market Failure”²⁶⁹ to note that “[t]he economic analysis of market failure deals with choice by adults.” Although both Beales²⁷⁰ and Viscusi find that young persons balance risks and rewards in making decisions on whether or not to smoke, Viscusi explains that:

[n]evertheless, there are some classes of choices that have major consequences, and for that reason society may wish to reserve the privilege of making these choices until a

particular age is reached. These limits should, however, be set according to the age at which individuals are believed to be capable of making reasonable long-term decisions regarding their welfare, rather than some arbitrary date independent of the choice context. The emerging consensus of smoking restriction policies has focused age 18 as the minimum age for the purchase of cigarettes.²⁷¹

FDA concludes, therefore, that even if some children do make rational choices, the agency's regulatory determinations must reflect the societal conviction that children under the age of legal consent cannot be assumed to act in their own best interest.²⁷²

In particular, FDA finds that the pervasiveness and imagery used in industry advertising and promotional programs often obscure adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products. Section VI. of this document describes numerous studies on the shortcomings of the risk perceptions held by children. Health economist Victor R. Fuchs describes the typical sequence:

There is considerable evidence that the [time discount] rate falls as children mature. Infants and young children tend to live very much for the present; the prospect of something only a week in the future usually has little influence over their behavior. As children get older their time horizons lengthen, but once adult status is reached there seems to be little correlation between time discount and age.²⁷³

Thus, although most youngsters acknowledge the existence of tobacco-related health risks, the agency finds that the abridged time horizons of youth make them exceptionally vulnerable to the powerful imagery advanced through targeted industry advertising and promotional campaigns. In effect, these conditions constitute an implicit market failure not adequately remedied by existing government action.

Moreover, the agency does not view these results as inconsistent with the growing economic literature based on the Becker and Murphy models of “rational addiction.”²⁷⁴ Although several empirical studies have

²⁶⁸ Statement of Clyde Behney and Maria Hewitt on Smoking-Related Deaths and Financial Costs: Office of Technology Assessment Estimates for 1990 Before the Senate Finance Committee, pp. 1–2, April 28, 1994.

²⁶⁹ Littlechild, S. C., “Smoking and Market Failure,” in “Smoking and Society: Toward a More Balanced Assessment,” edited by R. D. Tollison, Lexington Books, p. 271, 1986.

²⁷⁰ Beales III, J. Howard, “Advertising and the Determinants of Teenage Smoking Behavior,” p. 44, 1993.

²⁷¹ Viscusi, W. K., “Smoking: Making the Risky Decision,” Oxford University Press, New York, p. 149, 1992.

²⁷² Goodin, R. E., “No Smoking: The Ethical Issues,” University of Chicago Press, pp. 30–32, 1989.

²⁷³ Fuchs, V. R., “How We Live,” Harvard University Press, Cambridge, MA, pp. 228–229, 1983.

²⁷⁴ Becker, G. S., and K. M. Murphy, “A Theory of Rational Addiction,” Journal of Political Economy, vol. 96, No. 4, pp. 675–700, 1988.

demonstrated that, for the general population, cigarette consumption is “rationally addictive” in the sense that current consumption is affected by both past and future consumption.²⁷⁵ Chaloupka notes that this “rationality” does not hold for younger or less educated persons, for whom past but not future consumption maintains a significant effect on current consumption. He concludes, “[t]he strong effects of past consumption and weak effects of future consumption among younger or less educated individuals support the a priori expectation that these groups behave myopically.”²⁷⁶

FDA’s justification of this regulation relies on the total costs associated with childhood addiction to tobacco, rather than on the external or spillover costs to nonusers. Nevertheless, a further market failure would exist if the use of tobacco imposed such costs on nonusers. Many studies have attempted to calculate the societal costs of smoking, but few have addressed these externalities. The most detailed research on the issue of whether smokers pay their own way is the 1991 study by Manning, et al.,²⁷⁷ which develops estimates of the present value of the lifetime external costs attributable to smoking. This study examines differences in costs of collectively financed programs for smokers and nonsmokers, while simultaneously controlling for other personal characteristics that could affect these costs (e.g., age, sex, income, education, and other health habits, etc.). The authors found that nonsmokers subsidize smokers’ medical care, but smokers (who die at earlier ages) subsidize nonsmokers’ pensions. On balance, they calculated that, before accounting for excise taxes, smoking creates net external costs of about \$0.15 per pack of cigarettes in 1986 dollars (\$0.33 per pack adjusted to 1995 dollars by the medical services price index). While acknowledging that these

estimates ignored external costs associated with lives lost due to passive smoking, perinatal deaths due to smoking during pregnancy, and deaths and injuries caused by smoking-related fires, the authors concluded that there is no net externality, because the sum of all smoking-related externalities is probably less than the added payments imposed on smokers through current Federal and State cigarette excise taxes. A Congressional Research Service Report to Congress concurred with the study’s conclusion,²⁷⁸ although many uncertainties remain regarding the potential magnitude of the omitted cost elements.

C. Regulatory Benefits

1. Prevalence-Based Studies

The benefits of the regulation include the costs that would be avoided by reducing the adverse health effects associated with the consumption of tobacco products. Most research on the costs of smoking-related illness has concentrated on the medical costs and productivity losses associated with the prevalence of death and illness in a given year. These prevalence-based studies typically measure three components: (1) The contribution of smoking to annual levels of illness and death, (2) the direct costs of providing extra medical care, and (3) the indirect costs, or earnings foregone due to smoking-related illness or death.²⁷⁹

In a recent statement, the former U.S. Office of Technology Assessment (OTA) declared that “the greatest ‘costs’ of smoking are immeasurable insofar as they are related to dying prematurely and living with debilitating smoking-related chronic illness with attendant poor quality of life.” Nonetheless, OTA calculated that in 1990 the national cost of smoking-related illness and death amounted to \$68 billion and included \$20.8 billion in direct health care costs, \$6.9 billion in indirect morbidity costs, and \$40.3 billion in lost future earnings from premature death.²⁸⁰ More recently,

the CDC estimated the 1993 smoking-attributable costs for medical care, alone, at \$50 billion.²⁸¹ Unfortunately, these prevalence-based studies do not answer many of the most important questions related to changes in regulatory policy, because they present the aggregate cost of smoking-related illness in a single year, rather than the lifetime cost of illness for an individual smoker. As noted in the 1992 Report of the Surgeon General, most prevalence-based studies fail to consider issues concerning “the economic impact of decreased prevalence of cigarette smoking, the length of time before economic effects are realized, the economic benefits of not smoking, and a comparison of the lifetime illness costs of smokers with those of nonsmokers.”²⁸² In effect, although these studies are designed to measure the smoking-related draw on societal resources, they are not well-suited for analyzing the consequences of regulation-induced changes in smoking behavior.

2. FDA’s Methodology

An alternative methodology, termed incidence-based research, compares the lifetime survival probabilities and expenditure patterns for smokers and nonsmokers. As this approach models the individual life-cycle consequences of tobacco consumption, FDA relied on these incidence-based studies for its original analysis of the proposed rule to value the beneficial effects of the rule over the lifetime of each new cohort of potential smokers. The methodology incorporates the following steps:

- A projection of the extent to which the rule will reduce the incidence, or the annual number, of new adolescent users of tobacco products;
- A projection of the extent to which the reduced rates of adolescent tobacco consumption will translate to reduced rates of lifetime tobacco consumption;
- A projection of the extent to which the reduced rates of lifetime tobacco consumption will decrease the number of premature deaths and lost life-years; and
- An exploration of various means of estimating the monetary value of the expected health improvements.

Office of Technology Assessment Estimates for 1990 Before the Senate Finance Committee, p. 2, April 28, 1994.

²⁸¹ “Medical-Care Expenditures Attributable to Cigarette Smoking—United States, 1993,” in *Morbidity and Mortality Weekly Reports (MMWR)*, CDC, DHHS, vol. 43, No. 26, pp. 469–472, July 8, 1994.

²⁸² 1992 SGR, p. 111.

²⁷⁵ Becker, G. S., M. Grossman, and K. M. Murphy, “An Empirical Analysis of Cigarette Addiction,” *The American Economic Review*, vol. 84, No. 3, pp. 396–418, June 1994; Chaloupka, F., “Rational Addictive Behavior and Cigarette Smoking,” *Journal of Political Economy*, vol. 99, No. 4, pp. 722–742, 1991; Keeler, T. E., T. W. Hu, P. G. Barnett, and W. G. Manning, “Taxation, Regulation, and Addiction: A Demand Function for Cigarettes Based on Time-Series Evidence,” *Journal of Health Economics*, vol. 12, pp. 1–18, 1993.

²⁷⁶ Chaloupka, F., “Rational Addictive Behavior and Cigarette Smoking,” *Journal of Political Economy*, vol. 99, No. 4, p. 740, 1991.

²⁷⁷ Manning, W. G., E. B. Keeler, J. P. Newhouse, E. M. Sloss, and J. Wasserman, “The Costs of Poor Health Habits, A RAND Study,” Harvard University Press, Cambridge, MA, 1991.

²⁷⁸ Gravelle, J. G., and D. Zimmerman, “CRS Report for Congress: Cigarette Taxes to Fund Health Care Reform: An Economic Analysis,” Congressional Research Service, p. 1, March 8, 1994.

²⁷⁹ See “Smoking and Health in the Americas: A 1992 Report of the Surgeon General in collaboration with the Pan American Health Organization,” Department of Health and Human Services (DHHS), Public Health Service (PHS), CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Office on Smoking and Health (OSH), pp. 105–112, 1992, (hereinafter referred to as “1992 SGR”) for a full summary of these methodologies and findings.

²⁸⁰ Statement of Clyde Behney and Maria Hewitt on Smoking-Related Deaths and Financial Costs:

The annual benefits of the 1995 proposed rule were measured as the present value of the lifetime benefits gained by those youngsters, who in the absence of the proposed regulation, would have become new smokers. Upon review of the public comments, FDA found none that would persuade the agency to revise its projections. In general, the relevant comments expressed no objection to the basic methodology or model, but some disputed the accuracy of the specific data estimates. The following paragraphs describe the FDA assumptions that underlie these benefit estimates and present the agency's response to the applicable public comments.

3. Reduced Incidence of New Young Smokers

FDA's preliminary analysis assumed that 1 million youngsters become new smokers each year. One trade association comment questioned this figure, asserting that the relevant studies included individuals over the age of 18. However, the 1985 National Health Interview Survey reported 1.08 million 20-year old smokers, and the Combined National Health Interview Surveys for 1987–1988 found that 92 percent of 20-year old smokers had started smoking by age 18. Taking 92 percent of 1.08 million yields 993,600 new underage smokers per year. This figure is supported by parallel estimates of the SAMHSA. Based on data from the 1994 National Household Survey on Drug Abuse, SAMHSA estimated that 1.29 million persons under age 20 became daily smokers in 1993, and that 1.1 million of these persons were under the age of 18. As a result, FDA retains confidence in its original estimate of 1 million new smokers per year.

The regulation targets youngsters by restricting youth access to tobacco products and by limiting advertising activities that affect adolescents. Several communities have demonstrated that access restrictions are extremely effective when vigorously applied at the local level. Woodridge, IL, for example, achieved a compliance rate of over 95 percent. Moreover, 2 years after that law was enacted, a survey of 12- to 14-year-old students indicated that overall smoking rates were down by over 50 percent (over 2/3 for regular smokers).²⁸³

²⁸³ Jason, L. A., P. Y. Ji, M. D. Anes, and S. H. Birkhead, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," *The Journal of the American Medical*

Advertising and promotional restrictions will augment these efforts to limit the attractiveness of tobacco products to underage consumers. As discussed in detail in section VI. of this document, no one study has definitively quantified the precise impact of advertising or of advertising restrictions. Nevertheless, much of the relevant research indicates that advertising restrictions will reduce consumer demand. For example, according to the 1989 report of the Surgeon General, "The most comprehensive review of both the direct and indirect mechanisms concluded that the collective empirical, experiential, and logical evidence makes it more likely than not that advertising and promotional activities do stimulate cigarette consumption."²⁸⁴ Similarly, after a careful examination of available studies, Clive Smee, Chief Economic Adviser to the United Kingdom Department of Health determined that, "the balance of evidence thus supports the conclusion that advertising does have a positive effect on consumption."²⁸⁵ A detailed evaluation of the effects of advertising on youth consumption of tobacco products is provided in section VI. of this document.

In Northern California, 24 cities and unincorporated areas in 5 counties adopted local youth tobacco access ordinances that prohibit self-service merchandising and point-of-sale tobacco promotional products in retail stores. Survey measures of the impact of these ordinances by the Stop Tobacco Access for Minor Project (STAMP) found that, on average, tobacco sales to minors dropped by 40 to 80 percent.²⁸⁶

In its analysis of the 1995 proposed rule, FDA argued that, while quantitative estimates of the effectiveness of its regulation cannot be made with certainty, comprehensive

Association (JAMA), vol. 266, No. 22, p. 3159, December 11, 1991.

²⁸⁴ DHHS, "Reducing the Health Consequences of Smoking: 25 Years of Progress," A Report of the Surgeon General, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, DHHS publication No. (CDC) 89–8411, p. 517, 1989 (the 1989 SGR).

²⁸⁵ Leaney, K., "Effect of Tobacco Advertising on Tobacco Consumption: A Discussion Document Reviewing the Evidence," Economics and Operational Research Division, Department of Health, London, p. 22, October 1992.

²⁸⁶ Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access to Minors Program (STAMP), Petaluma, CA, p. 4, November 3, 1994.

programs designed to discourage youthful tobacco consumption could reasonably achieve the "Healthy People 2000" goal of halting the onset of smoking for at least half, or 500,000, of the 1,000,000 youngsters who presently start to smoke each year. In the Federal Register of January 19, 1996 (61 FR 1492) SAMHSA published a regulation governing a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age. SAMHSA had originally estimated that its program would reduce tobacco consumption by youth and children by from one-third to two-thirds, but subsequently determined that reductions of between one-tenth and one-third would be "more realistic given the uncertainties implicit in varying levels of State enforcement and the absence of meaningful controls on tobacco advertising and promotion."²⁸⁷ While strongly supporting the objectives of the SAMHSA program, FDA finds that achieving the "Healthy People 2000" goal will demand a full arsenal of controls to complement and fortify the new State inspectional programs, including restrictions on industry advertising and promotions and quite possibly educational messages to counter the influence of ongoing marketing activities.

Numerous public comments to the 1995 proposal addressed the issue of the effectiveness of the regulation. Many argued that tobacco advertising does not increase tobacco use, or that the enforcement of existing or forthcoming State laws, alone, could accomplish reasonable goals. In contrast, many others supported a comprehensive regulation, contending that only vigorous enforcement of new restrictions would bring significant results. As outlined earlier in the preamble in this document, FDA has determined, based on a full examination of the evidence, that the combined effect of the regulations (restricting advertising and promotion, prohibiting self-service sales, providing new labeling information, and imposing age verification obligations) and educational programs will significantly diminish the allure as well as the access to tobacco products by youth. The agency acknowledges the imposing size of the required effort, but is confident that its goals are reasonable and presents regulatory benefits based on the presumption that the "Healthy People 2000" goals will be met.

²⁸⁷ 61 FR 1502, January 19, 1996.

FDA agrees, however, that these projections are uncertain and therefore also presents estimates of benefits at effectiveness levels that are considerably smaller. The agency conducted this exercise not because its estimates are excessively speculative or arbitrary, as suggested by one comment, but because sensitivity analyses are part of generally accepted "best practice" for the conduct of cost-benefit analysis and are recommended by OMB guidance. These results demonstrate that even if the rule were only modestly effective in reducing tobacco use, it yields justifiable benefits.

One comment urged the agency to demonstrate the effectiveness of tobacco marketing restrictions over and above those for access restrictions or public information campaigns. FDA is unable to forecast the independent results of each regulatory provision, due to the high degree of interdependence among the various requirements, but notes that SAMHSA concluded that its access restrictions, alone, would reduce underage tobacco consumption by one-tenth to one-third. If so, accomplishing the "Healthy People 2000" goal implies that the FDA rule would generate incremental tobacco use reductions of

between 17 and 40 percent for youngsters under 18 years of age.

4. Reduced Number of Adult Smokers

The major beneficiaries of the rule are those individuals who would otherwise begin using tobacco early in life and who, accordingly, are unlikely to start using tobacco products as an adult. Evidence suggests that this percentage will be high, as over half of adult smokers had become daily cigarette smokers before the age of 18. Moreover, the 1994 Surgeon General's Report indicates that 82 percent of persons (aged 30 to 39) who ever smoked daily began to smoke before the age of 18. That report concludes that "if adolescents can be kept tobacco-free, most will never start using tobacco."²⁸⁸ Although some comments disagreed with that conclusion, FDA believes that the Surgeon General's Report is correct. Nonetheless, to account for the possibility that some would-be smokers who are prevented from smoking until they are age 18 may eventually start smoking as adults, FDA uses the more conservative assumption that these rules will lead to a tobacco free adult life for only one-half of the estimated 500,000 youngsters who will be deterred from starting to smoke each year.

Accordingly, FDA calculates the annual benefits from the lifetime health gains associated with preventing 250,000 adolescents from ever smoking as an adult. Further, in response to comments that challenge this estimate, FDA presents sensitivity analysis showing results using a wide range of alternative rates.

5. Lives Saved

Based largely on data from Peto, et al., who found that about half of all adolescents who continue to smoke regularly throughout their lives will eventually die from a smoking-related disease,²⁸⁹ CDC estimates that about one in three adolescent smokers will die prematurely.²⁹⁰ Although the CDC projection provides the best estimate of this excess fatality rate, it does not provide a distribution of the smoking-related fatalities over time. Consequently, FDA derived this distribution by comparing age-specific differences in the probability of survival for smokers and nonsmokers. The probability of survival data for the agency's estimate are derived from the American Cancer Society's Cancer Prevention Study II, as shown in Table 3.

TABLE 3.—PROBABILITY OF SURVIVAL BY AGE, SEX, AND SMOKING STATUS
(Probabilities of a 17-year-old surviving to age shown)

Age (Years)	Male Neversmokers	Male All Smokers	Female Neversmokers	Female All Smokers
35	1	1	1	1
45	0.986	0.966	0.988	0.984
55	0.951	0.893	0.962	0.939
65	0.867	0.733	0.901	0.831
75	0.689	0.466	0.760	0.630
85	0.336	0.159	0.453	0.289

Source: Thomas Hodgson, "Cigarette Smoking and Lifetime Medical Expenditures," *The Milbank Quarterly*, vol. 70, No. 1, 1992, p. 91. Based on data from the American Cancer Society's Cancer Prevention Study II.

FDA initially multiplied differences in the probabilities of death for smokers versus nonsmokers within each 10-year period by the number of smokers remaining at the start of each 10-year period. Assuming an equal number of males and females, the excess deaths among smokers in all age groups totaled almost 28 percent of the 250,000 cohort. FDA recognizes that this methodology probably understates the current risk of

smoking, because it arbitrarily assumes that the smoking-related risks for females will continue to be smaller than for males, even though female smoking patterns are presently comparable to those of males. Nevertheless, FDA used this model to support its proposed regulation and maintains the calculation to demonstrate the robustness of the results. Moreover, because some comments suggested that these data may

not account for all potentially confounding variables, such as alcohol consumption or other lifestyle differences, FDA further adjusted the mortality estimate to 24 percent to reflect findings by Manning et al., that such nontobacco versus tobacco lifestyle factors may account for 13 percent of excess medical care expenditures. Thus, the benefits projections presented below conservatively rely on the probabilities

²⁸⁸ 1994 SGR, pp. 5 and 65.

²⁸⁹ Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, Jr., "Mortality from Smoking in Developing Countries, 1950–2000," Oxford University Press, p. A10, 1994. Indirect estimates from national vital statistics.

²⁹⁰ Memorandum from Michael P. Eriksen (CDC) to Catherine Lorraine (FDA) August 7, 1995 and CDC Fact Sheet; citing Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatzianandreu, and R. M. Davis, "Trends in Cigarette Smoking in the United States: Projections to the Year 2000," *JAMA*, vol. 261, pp. 61–65, 1989; Unpublished data from the 1986

National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, "Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from national Vital Statistics," Oxford University Press, Oxford, 1994.

shown in Table 3, corrected by the 13 percent lifestyle influence adjustment. In sum, they indicate that achieving the "Healthy People 2000" performance goal will prevent about 60,200 smoking-related fatalities among each year's cohort of potential new smokers.

The economic assessment of health-related variables requires discounting the value of future events to make them commensurate with the value of present events. For this analysis, a 3 percent discount rate is used to calculate the present value of the projections. (This rate was recommended by the Panel on Cost-Effectiveness in Health and Medicine, a nonfederal multidisciplinary group of experts in cost-effectiveness analysis, convened by the Office of the Assistant Secretary for Health in 1993.²⁹¹ Since the Office of Management and Budget (OMB) Circular A-94 recommends the use of 7 percent as a base case, FDA presents summary estimates below for discount rates of both 3 percent and 7 percent.) On the assumption that it would be roughly 20 years for each year's cohort of new adults to reach the midpoint of the 35 to 45 age bracket and 60 years to reach the 75 to 85 age bracket, these calculations indicate that the present value of these benefits equate to 15,863 lives per year.

6. Life-Years Saved

The number of life-years that will be saved by preventing each year's cohort of 250,000 adolescents from acquiring a smoking addiction was calculated from the same age-specific survival differences between smokers and nonsmokers. In each 10-year life span, the number of years lived for each cohort of persons who would have been smokers but who were deterred was compared to the number of years that would have been lived by that same cohort if they had been smokers. The difference between these two measures is the life-years saved for that 10-year period.²⁹² Deducting the 13-percent lifestyle adjustment indicates that, over the full lifetime of each cohort, the regulations will gain an estimated 905,000 life-years, which translates to almost 4 years per smoker and 15 years

per life saved.²⁹³ The present value of these additional life-years equates to 211,391 life-years annually.

7. Monetized Benefits of Reduced Tobacco Use

There is no fully appropriate means of assigning a dollar figure to represent the attendant benefits of averting thousands of tobacco-induced illnesses and fatalities. However, to quantify important components of the expected economic gains, FDA developed estimates of the value of the reduced medical costs and the increased worker productivity that will result from fewer tobacco-related illnesses. In addition, since productivity measures do not adequately address the avoidance of premature death, FDA adopted a willingness-to-pay approach to value the benefits of reduced tobacco-related fatalities.

8. Reduced Medical Costs

On average, at any given age, smokers incur higher medical costs than nonsmokers. However, nonsmokers live longer and therefore continue to incur medical costs over more years. Several analysts have reported conflicting estimates of the net outcome of these factors, but the most recent research is the incidence-based study by Hodgson,²⁹⁴ who found that lifetime medical costs for male smokers were 32 percent higher than for male never-smokers and lifetime medical costs for female smokers were 24 percent higher than for female never-smokers. Hodgson determined that the present value of the lifetime excess costs were about \$9,400 in 1990 dollars (future costs discounted at 3 percent).²⁹⁵ As noted earlier, the incidence-based study by Manning, et al., implies that about 13 percent of the excess medical costs were attributable to factors other than smoking. Accounting for this reduction and adjusting by the consumer price index for medical care raises the present value of Hodgson's excess medical cost

per new smoker to \$10,590 in 1994 dollars. Thus, those 1,000,000 young people under the age of 18, who currently become new smokers each year, are responsible for excess lifetime medical costs measured at a present value of \$10.6 billion (1,000,000 x \$10,590). Because FDA projects that achieving the "Healthy People 2000" goals will prevent 250,000 of these individuals from smoking as adults, the medical cost savings are estimated at \$2.6 billion per year.

9. Reduced Morbidity Costs

An important cost of tobacco-related illness is the value of the economic output that is lost while individuals are unable to work. Thus, any future reduction in such lost work days contributes to the economic benefits of the regulation. Several studies have calculated prevalence-based estimates of U.S. productivity losses due to smoking-related morbidity, but FDA knows of no incidence-based estimates. Hodgson, however, has shown that, in certain situations, incidence measures can be derived from available prevalence measures. For example, he demonstrates that in a steady-state model the only difference between prevalence and incidence-based costs is due to discounting.²⁹⁶ Accordingly, FDA has adopted Hodgson's method to develop a rough approximation of incidence-based costs from an available prevalence-based estimate of morbidity costs.

Rice, et al.,²⁹⁷ found that lost wages due to tobacco-related work absences in the United States amounted to \$9.3 billion in 1984. This equates to \$12.3 billion in 1994 dollars when adjusted by the percentage change in average employee earnings since 1984. Although FDA does not have a precise estimate of the life-cycle timing of these morbidity effects, the relevant latency periods would certainly be shorter than for mortality effects. Thus, to account for the deferred manifestation of smoking-related morbidity effects, FDA assumed that they would occur over a time horizon equal to 80 percent of that previously measured for mortality effects. Although one comment mistakenly assumed that FDA had made no adjustment for lifestyle differentials between smokers and nonsmokers, in fact, these estimates were further

²⁹¹ Gold, M. R., J. E. Siegel, L. B. Russell, and M. C. Weinstein, "Cost-effectiveness in Health and Medicine," Oxford University Press, p. 232, 1996.

²⁹² For each 10-year age interval, the number of life-years is calculated as the number of people in each cohort (250,000) times the probability of surviving until the end of that age interval times 10 years of life, plus the number expected to die in that interval times an assumed 5 years of life.

²⁹³ The calculation procedure probably understates total life-years saved, because it misses smoking related-fatalities that occur within the same 10-year age interval. However, because more of these misses involve fatalities that, if avoided, would add few life-years, the resulting 15-year average life-years saved may be high. FDA's benefit estimates, however, remain understated because they are based on total life-years saved, not average life-years saved.

²⁹⁴ Hodgson, T. A., "Cigarette Smoking and Lifetime Medical Expenditures," *The Milbank Quarterly*, vol. 70, No. 1, p. 97, 1992. (Based on data from the American Cancer Society's Cancer Prevention Study II).

²⁹⁵ *Id.* (Using the average of the male and female totals).

²⁹⁶ Hodgson, T. A., "Annual Costs of Illness Versus Lifetime Costs of Illness and Implications of Structural Change," *Drug Information Journal*, vol. 22, No. 3, p. 329, 1988.

²⁹⁷ Rice, D. P., et al., "The Economic Costs of the Health Effects of Smoking, 1984," *The Milbank Quarterly*, vol. 64, No. 4, p. 526, 1986.

reduced by 13 percent to reflect the Manning, et al., findings. Finally, because the long-term decline in smoking prevalence has exceeded the growth in population, FDA reduced the incidence-based costs by another 20 percent. At a 3 percent discount rate, this methodology implies that the incidence-based cost of smoking-related morbidity, or the present value of the future costs to 1 year's cohort of 1,000,000 new smokers, is about \$3.5 billion. Thus, the estimated annual morbidity-related savings associated with preventing 250,000 new youths per year from smoking as adults is estimated at about \$879 million.

10. Benefits of Reduced Mortality Rates

From a societal welfare perspective, OMB guidance advises that the best means of valuing benefits of reduced fatalities is to measure the affected group's willingness-to-pay to avoid fatal risks. Unfortunately, the specific willingness-to-pay of smokers is unknown, because institutional arrangements in the markets for medical care obscure direct measurement techniques.²⁹⁸ Nevertheless, many studies have examined the public's willingness-to-pay to avoid other kinds of life-threatening risks, especially workplace and transportation hazards. An EPA-supported study²⁹⁹ found that most empirical results support a range of \$1.6 to \$8.5 million (in 1986 dollars) per statistical life saved, which translates to \$2.2 to \$11.6 million in 1994 dollars. However, the uncertainty surrounding such estimates is substantial. Moreover, Viscusi has shown that smokers, on average, may be willing to accept greater risks than nonsmokers. For example, smokers may accept about one-half the average compensation paid to face on-the-job-injury risks.³⁰⁰ FDA therefore has conservatively used \$2.5 million per statistical life, which is towards the low end of the research findings, to estimate society's willingness-to-pay to avert a fatal smoking-related illness. Thus, the annual benefits of avoiding the discounted number of 15,863 premature fatalities would be \$39.7 billion.

An alternative method of measuring willingness-to-pay is to calculate a value for each life-year saved. This approach

is intuitively appealing because it places a greater value on the avoidance of death at a younger than at an older age and is the traditional means of assessing the cost-effectiveness of medical interventions. Nevertheless, there have been few attempts to determine the appropriate value of a life-year saved. OMB suggests several methodologies, including annualizing with an appropriate discount rate the estimated value of a statistical life over the average expected life-years remaining. For example, at a 3-percent discount rate, a \$2.5 million value per statistical life for an individual with 35 years of remaining life-expectancy converts to about \$116,500 per life year. Since achieving the agency's goals were estimated to save 211,391 discounted life-years annually, this calculation yields annual benefits of \$24.6 billion.

FDA notes that even these values understate the full value of the health impact, because they fail to quantify any reduction in either the adverse effects attributable to passive smoking or the infant and child fatalities caused by mothers' smoking. Moreover, these totals may not capture the heavy toll of psychic loss to surviving family members, or the corresponding economic losses among family members for the mental health care of grief-related depression and other conditions that often follow the premature death of middle aged adults.³⁰¹

11. Reduced Fire Costs

Every year lighted tobacco products are responsible for starting fires which cause millions of dollars in property damage and thousands of casualties. In 1992, fires started by lighted tobacco products caused 1,075 deaths and \$318 million in direct property damage.³⁰² A reduction in the number of smokers, and the corresponding number of cigarettes smoked, will result in a drop in the number of future fires. In the 1995 proposal, FDA estimated that if the number of fires falls by the same percentage as the expected reduction in cigarette sales, this implies present value savings of \$203 million for the value of lives saved and \$24 million for the value of averted property damage, totaling \$227 million annually over a 40-year period.

One comment denied the existence of any association between fires and cigarette consumption. FDA acknowledges that the relationship may be nonlinear, but finds the asserted lack of a positive correlation implausible. This comment further stated that residential fires caused by smoking and deaths from residential fires caused by smoking decreased from 1983 to 1992 by 39 percent and 40 percent, respectively, or about 5.5 percent annually. Accounting for this trend would lower FDA's fire cost estimate to a present value savings of \$145 million for the value of lives saved and \$17 million for the value of averted property damage, totaling \$162 million annually over a 40-year period. Even these estimated savings significantly underestimate the potential benefits, however, because they exclude both nonfatal injuries and the need for temporary housing.

12. Smokeless Tobacco

The Smokeless Tobacco Council, Inc., remarked that FDA had not attempted to measure the benefits that would result from the decreased use of smokeless tobacco products by underage youths. The introduction to the 1995 proposed regulation, however, explained that the use of smokeless tobacco causes severe health effects. While data are not available on age-specific differences in the probability of survival for smokeless tobacco users as compared to nonusers, the 1994 Surgeon General Report indicates that the "primary health consequences during adolescence include leukoplakia, gum recession, nicotine addiction, and increased risk of becoming a cigarette smoker. Leukoplakia and/or gum recession occur in 40 to 60 percent of smokeless tobacco users."³⁰³ Oral leukoplakias have a 5-percent chance of becoming malignancies in 5 years.³⁰⁴ Cancers of the nasal cavity, pharynx, larynx, esophagus, stomach, urinary tract and pancreas have also been linked to smokeless tobacco use.³⁰⁵ Other effects include discoloration of teeth, periodontal disease and excessive tooth wear and decay.³⁰⁶ One study of female snuff users showed that it increased one's risk of developing oral and

²⁹⁸ Schelling, T. C., "Economics and Cigarettes," *Preventive Medicine*, vol. 15, pp. 549-560, 1986.

²⁹⁹ Fisher, A., L. G. Chestnut, and D. M. Violette, "The Value of Reducing Risks of Death: A Note on New Evidence," *Journal of Policy Analysis and Management*, vol. 8, No. 1, pp. 88-100, 1989.

³⁰⁰ Viscusi, W. K., "Fatal Tradeoffs: Public and Private Responsibilities for Risk," Oxford University Press, p. 24, 1992.

³⁰¹ Harris, M., "The Loss That is Forever The Lifelong Impact of the Early Death of a Mother or Father," Penguin Books, 1995.

³⁰² Miller, A. L., "The U.S. Smoking-Material Fire Problem Through 1992: The Role of Lighted Tobacco Products in Fire," National Fire Protection Association, p. 2, 1994.

³⁰³ 1994 SGR, p.39.

³⁰⁴ *Id.*

³⁰⁵ Goolsby, M. J., "Smokeless Tobacco: The Health Consequences of Snuff and Chewing Tobacco", *Nurse Practitioner*, vol. 17, No. 1, p. 31, January 1992.

³⁰⁶ *Id.*

pharyngeal cancer between 1.5 to 4.2 times.³⁰⁷

If the provisions pertaining to smokeless tobacco are as effective as those pertaining to cigarettes, the rule will prevent about 36,500 youths from becoming adult users of smokeless tobacco. This projection assumes that the number of underage users will decrease by 50 percent and one-half of those youths will remain nonusers after reaching 18 years of age. The estimate also assumes that the ratio of new underage users to total underage users parallels that of cigarette users (i.e., approximately one-third) and that about 440,000 youths under the age of 18 are current users of smokeless tobacco products.³⁰⁸

Leukoplakia and/or gum recession are estimated to occur in 40 to 60 percent of smokeless users.³⁰⁹ If even 50 percent of these cases were caused by smokeless tobacco use, the previous assumptions imply that these regulations will prevent from 7,300 to 11,000 cases of leukoplakia and/or gum recessions per year. Although FDA can not estimate the number of oral or other cancers prevented, the realized number will be substantial.

13. Summary of Benefits

The discussion above demonstrates the formidable magnitude of the economic benefits available from smoking reduction efforts. As described, FDA forecasts annual net medical cost savings of \$2.6 billion and annual morbidity-related productivity savings of \$900 million. From a willingness-to-pay perspective, the annual benefits of reduced smoking-related disease mortality range from \$24.6 to \$39.7 billion. As a result, the value of the annual disease-related benefits of achieving the "Healthy People 2000" goal is projected to range from \$28.1 to \$43.2 billion. (Following Hodgson, this analysis uses a 3-percent discount rate. A 7-percent rate reduces these benefits to a range of \$9.2 to \$10.4 billion). These totals do not include the benefits expected from fewer fires (over \$160 million annually), reduced passive smoking, or infant death and morbidity

associated with mothers' smoking. Moreover, while FDA believes these effectiveness projections are plausible, much lower rates still yield impressive results. Table 1c of this section summarizes the disease-related health benefits and illustrates that youth deterrence rates as small as 1/20, which would prevent the adult addiction of at least 25,000 of each year's cohort of 1,000,000 new adolescent smokers, would provide annual benefit values measured in the billions of dollars. Moreover, the higher risk estimates suggested by Peto, et al., could significantly increase these values. In addition, while FDA could not quantify the benefits that will result from the projected decline in the use of smokeless tobacco, they would be considerable.

D. Regulatory Costs

A recently issued guideline for conducting economic analysis of Federal regulations, prepared under the auspices of OMB, states that:

[T]he preferred measure of cost is the "opportunity cost" of the resources used or the benefits foregone as a result of the regulatory action. Opportunity costs include, but are not limited to, private-sector compliance costs and government administrative costs. Opportunity costs also include losses in consumers' or producers' surpluses, discomfort or inconvenience, and loss of time * * *. An important, but sometimes difficult, problem in cost estimation is to distinguish between real costs and transfer payments. Transfer payments are not social costs but rather are payments that reflect a redistribution of wealth. While transfers should not be included in the [Economic Analyses'] estimates of the benefits and costs of a regulation, they may be important for describing the distributional effects of a regulation.³¹⁰

Accordingly, FDA finds that the final rule will impose new cost burdens on manufacturers, retailers, consumers, and Government regulators of tobacco products. In addition, certain industry sectors will experience lost sales and employment, but these revenue losses will be at least partly offset by gains to other sectors, as discussed in the "Distributional Effects" section of this document.³¹¹ While a number of industry comments argued that the agency's preliminary analysis was

deficient for not including these lost revenues in its cost-benefit assessment, FDA finds that the revenue losses suggested by these comments do not meet the previous definition of "opportunity cost;" because they fail to provide the changes in net costs that are necessary to estimate producer surplus, conventionally defined as sales minus variable costs. This rule will affect producer surplus in several industries and only net changes in these surplus' are social costs. Calculating such changes would require a multi-market model of economic changes over many years. Such general equilibrium models have not been used by Federal agencies for regulatory analyses, are not specifically recommended by the OMB guidance, and would be impractical to use, especially where major markets are dominated by few firms.

The most comprehensive critique of FDA's preliminary economic analysis was prepared by the Barents Group, economic consultants to the Tobacco Institute. While the Barents Group developed independent estimates of economic costs, in many instances its methodology was consistent with FDA's analysis of its 1995 proposal. Often, however, the Barents Group had access to more recent data, or to additional data provided by the affected industries. FDA's revised cost estimates rely extensively on these new data, but as described below, the agency's final cost estimates are far smaller than those presented by the Barents Group.

1. Number of Affected Retail Establishments

A critical variable underlying the agency's cost estimates is the number of retail outlets currently selling over-the-counter (OTC) tobacco products. A major confounding factor is that the U.S. Census publishes product line data only for establishments with payroll. For its original estimate of the number of retail establishments selling tobacco products, FDA relied on 1987 Census data to count the number of affected payroll establishments and very conservatively included every nonpayroll establishment in those categories that traditionally sell tobacco products (general merchandise stores, grocery stores, service stations, eating and drinking places, drug stores, and liquor stores). FDA estimated that the number of establishments selling tobacco products OTC included 275,000 payroll establishments and 215,000 nonpayroll establishments, for a total of 490,000 retail establishments. To account for all other business categories that might sell

³⁰⁷ Winn, D. M., W. J. Blot, C. M. Shy, L. W. Pickle, A. Toledo, and J. F. Fraumeni, "Snuff Dipping and Oral Cancer Among Women in the Southern United States," *The New England Journal of Medicine*, vol. 304, No. 13, pp. 745-749, Table 2, March 26, 1981.

³⁰⁸ Estimates of youth smokeless usage vary. This projection relies on a conservative estimate of total youth (ages 12-17) usage calculated from data in the Statistical Abstract of the U.S. 1995, 115th edition, Tables 16 and 218.

³⁰⁹ 1994 SGR, p.39.

³¹⁰ Economic Analysis of Federal Regulations Under Executive Order 12866, January 11, 1996. Prepared by interagency group convened by OMB and co-chaired by a Member of the Council of Economic Advisers.

³¹¹ This analysis evaluates the regulation following the Kaldor-Hicks criteria for societal welfare maximization.

OTC tobacco products, FDA estimated a total upper bound range of 600,000 establishments. FDA did not know how many locations currently served by cigarette vending machines would convert to OTC operations following implementation of the regulation, but estimated the number at 100,000, raising the upper bound total to 700,000 future establishments.

FDA still has no definitive estimate of the number of retail outlets selling tobacco products. For their economic analysis, the Barents Group used 1992 U.S. Census estimates for the number of affected retail establishments with payroll, but adopted an alternative methodology to estimate the number of affected establishments without payroll. The Barents Group subdivided retail businesses into 10 categories: General merchandise stores, supermarket/grocery stores, convenience stores without gas, convenience stores with gas, gasoline service stations, eating places, drinking places, drug and proprietary stores, specialty tobacco stores, and miscellaneous retail stores. Within each category, the Barents Group assumed that the percentage of nonpayroll establishments selling tobacco products would be the same as the percentage of payroll establishments selling tobacco products. As a result, they concluded that the number of retail payroll establishments selling tobacco products OTC is approximately 283,000, and the number of retail nonpayroll establishments selling tobacco products OTC is about 107,000, for a total of 390,000 retail outlets. The Barents Group's subsequent calculations are less

clear and not documented in their appendix on methodology. Noting that FDA had estimated an upper bound of 600,000 establishments selling OTC tobacco products, they assumed the existence of an additional 100,000 to 200,000 nonretail establishments, such as operations within manufacturing or service businesses, that sell OTC tobacco products. Finally, the Barents Group accepted FDA's estimate that about 100,000 current vending machine locations would convert to OTC sales for tobacco products and proposed total lower and upper bound estimates of from 500,000 to 700,000 establishments.

For this final economic analysis, FDA adopts the apparent mid-point of the Barents Group's forecast of the number of establishments that will sell tobacco products, or about 500,000 current establishments and a total of 600,000 future establishments. FDA estimates by business category are displayed in Table 4 and follow closely the methodology presented by the Barents Group, except for slight adjustments to eliminate nonstore outlets. Because Census data on the number of establishments without payroll were not reported separately for convenience stores, convenience stores with gas, or specialty tobacco stores, these outlets are counted with the higher level outlet categories.

2. Removing Self-Service and Other Prohibited Retail Displays

The 1995 proposed regulation restricted all point of purchase advertising to "text only" and banned the use of all self-service displays by requiring vendors to physically provide

the regulated tobacco product to purchasers. In its original analysis, FDA explained that the proposed ban on self-service displays would affect many retail stores selling tobacco products, although shoplifting concerns had already caused a large number of these stores to place tobacco products in areas not directly accessible to customers. Those retailers that discontinued self-service displays typically modified their stores by either: (1) Placing tobacco products behind or above store cashiers or in locked cases located within close reach of store cashiers, (2) placing tobacco products behind only one or two checkout lines, similar to the "cash only" or "less than 10 items" lines commonly found in supermarkets, (3) dispensing tobacco products from a controlled area of the store, where store employees also conduct other administrative or customer-service tasks, or (4) installing a signaling system, whereby assigned store clerks bring requested tobacco products to individual checkout stations. Each store's physical configuration dictates the most cost-effective approach, but at least one regional survey found that retail outlets readily complied with comparable local ordinances without architectural remodeling or substantial refitting of checkout counters or store aisles.³¹²

³¹² Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

TABLE 4.—ESTIMATED NUMBER OF ESTABLISHMENTS CURRENTLY SELLING TOBACCO PRODUCTS OVER-THE-COUNTER

Kind of Business	Number of Retail Establishments with Payroll	Percentage of Retail Establishments with Payroll Selling Tobacco Products	Number of Retail Establishments with Payroll Selling Tobacco Products	Total Number of Retail Establishments without Payroll	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products ⁽ⁱ⁾	Estimated Total of Establishments Selling Tobacco Products Over-the-Counter ^(k)
	(1)	(2)	(3)	(4)	(5)	(6)
Retail Establishments:						
General Merchandise	34,606	35.01%	12,117	28,010 ^(f)	9,807	21,924
Supermarket/Grocery	126,785 ^(a)	56.19%	71,240	97,061 ^(g)	54,538	125,778
Convenience Stores	30,748	95.62%	29,400	— ^(h)	—	29,400
Convenience Stores with Gas	57,033 ^(b)	91.02%	51,913	— ^(h)	—	51,913
Service Stations	71,336 ^(c)	53.21%	37,958	14,248	7,581	45,539
Eating Places	377,760 ^(d)	3.17%	11,992	96,538	3,065	15,057
Drinking Places	55,848	19.24%	10,745	27,733	5,336	16,081
Drug Stores	48,142	60.33%	29,046	3,031	1,829	30,875
Tobacco Stores	1,477	100.00%	1,477	— ^(h)	—	1,477
Miscellaneous Retail Stores	273,256 ^(e)	9.15%	24,995	490,633 ⁽ⁱ⁾	44,879	69,874
Other Establishments	—	—	—	—	—	100,000
Total	1,076,991		280,883	757,254	127,035	507,918

(a) Category contains food stores (SIC 54) with payroll, excluding convenience food stores (SIC 541 pt) and convenience food/gasoline stores (SIC 541 pt).

(b) Category contains convenience food/gasoline stores (SIC 541 pt) and gasoline/convenience food stores (SIC 554 pt).

(c) Category excludes gasoline/convenience food stores (SIC 554 pt).

(d) Category contains eating and drinking places (SIC 58), excluding drinking places (SIC 5813).

(e) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596) and tobacco stores and stands (SIC 5993).

(f) 1992 Nonemployer Statistics Series only provides data on variety and miscellaneous general merchandise establishments without payroll.

(g) 1992 Nonemployer Statistics Series only provides data on grocery stores, retail bakeries, and other food stores without payroll.

(h) 1992 Nonemployer Statistics Series does not provide data on establishments without payroll for these categories.

(i) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596).

(j) Column (2) times Column (4).

(k) Column (3) plus Column (5).

Source: Columns (1)–(4) from U.S. Census of Retail Trade Merchandise Line Sales and Nonemployer Statistics Series; Columns (5) and (6) projections according to Barents Group LLC Appendix I methodology.

Because prevailing business practice is for tobacco manufacturers to assist and even pay for most product display equipment,³¹³ FDA had assumed that manufacturers would share with retailers any expense of relocating displays and that the majority of the costs would be to relocate self-service displays for cartons. FDA estimated one-time costs of \$22 million to be shared by manufacturers and retailers and additional annual operating costs of \$14 million to be incurred by retailers (all in 1994 dollars). In stark contrast, the Barents Group projected one-time costs of from \$558 to \$780 million in 1996 dollars (\$520 to \$728 million in current dollars), with 62 percent attributed to the replacement of display items by retailers and the remaining 38 percent to manufacturers due to "time costs involved in removing banned display and promotional items, whether the work would be performed directly by a manufacturer's employee or subcontracted out to a display distributor." As explained below, FDA finds that many aspects of the Barents Group's estimates are seriously flawed. Nevertheless, the agency has adopted the basic framework of that analysis and its revised estimates reflect the Barents Group's methodology and data, unless specifically modified as discussed below.

a. *The Barents Group's methodology.* The Barents Group's cost projections were based on estimates of an average outlet cost for each of seven outlet categories. Each average outlet cost was multiplied by the total number of outlets of that category in the United States to produce national cost estimates. The actual outlet cost data were collected by A. T. Kearney, Inc., still another business consulting firm. The Barents Group explained that:

[O]ur estimates are based on a compliance audit study conducted especially for this purpose by A. T. Kearney, Inc. A. T. Kearney performed an in-depth study of the actions and efforts that would be required of tobacco manufacturers' representatives, of point-of-sale display item distributors, and of tobacco retailers in order to bring stores into compliance with the proposed regulations. Detailed surveys were conducted of seven categories of retail outlets in five U.S. metropolitan areas, for a total of 88 retail outlets. Surveyors performed a detailed inventory of the many types of tobacco product displays and promotional materials which are currently found in stores. The surveyors noted which items would need to be modified or replaced.

A. T. Kearney reportedly completed a comprehensive on site compliance

protocol checklist at 88 establishments randomly selected in 5 general regions of the United States. The individual display items were grouped into 41 discrete item categories and a lengthy discussion of the methodology and results are presented as a Technical Appendix to the Barents Group's comments.

b. *The Barents Group's miscalculations.* To evaluate these results, FDA carefully reviewed the A. T. Kearney survey data and the Barents Group's extrapolation procedures and attempted to replicate the aggregate estimates. In doing so, numerous computational discrepancies were identified. For example, in calculating retailer time costs, the Barents Group intended to use an estimated retail employee wage of \$9.51, but in fact used the estimated wage for a manufacturer's sales representative of \$25.70. (See Appendix Table "Initial Compliance Effort Costs per Retail Store.") Also, the Barents Group's calculations relied on incorrectly transposed data for the average number of disposable displays per store and miscalculated compliance effort costs for five of the seven types of business. Further, A. T. Kearney reported that only one-third of the lighted signs and clocks would need to be replaced by retailers, but the Barents Group's calculations assumed that all would be replaced. Finally, A. T. Kearney reported that retailers would not replace most promotional posters, signs and displays, but the Barents Group's calculations assigned each \$85 in replacement costs. Correcting these errors reduces the Barents Group's low and high cost estimates by \$77 and \$108 million, respectively.

Even more important, in aggregating the unit costs for "Compliance Activity No. 19—Remove and replace interior newsstands and shopping basket racks and baskets and shopping carts," A. T. Kearney committed a major error that dominates the aggregated cost totals. In discussing the costs for this item, A. T. Kearney focused on the need to replace shopping basket racks, which " * * * are free-standing units and contain about 20 shopping baskets, that also contain the name or logo of the cigarette manufacturer." Although it seems probable that the logos or brand names affixed to these items could be either removed or obscured, the survey data indicate that six supermarket/grocery stores, three convenience stores, two tobacco stores and one convenience store with gas would replace shopping basket racks. The detailed survey data for supermarket/grocery stores,

however, reveal that one store supposedly possessed 71 racks, two stores 50 racks, and the remaining three stores 41, 32, and 10 racks, respectively. Even a casual review of these data suggests that individual hand-held shopping baskets rather than basket racks were counted. Indeed, an FDA contractor visited the five Washington, DC area outlets in which A. T. Kearney observed the largest number of racks and found scores of plastic hand-held baskets adorned with simple advertising stickers, but only a few basket racks.³¹⁴

Although the advertising on these plastic baskets could easily be removed or covered, or new plastic baskets purchased quite inexpensively, the Barents Group's calculations inadvertently assumed that a distribution services contractor would be hired to remove each plastic hand-held shopping basket at a fee of \$45 apiece and that a retailer would spend 30 minutes plus an additional \$89 replacement fee for each plastic hand-held shopping basket in its possession. Thus, the estimated cost attributed to each hand-held basket was \$138 and the cost for just the one outlet reporting 71 shopping baskets totaled \$9,850. Extrapolating to each outlet category, the A. T. Kearney results implied that removing and replacing plastic hand-held baskets would cost, on average, over \$1,300 for each supermarket/grocery store and \$300 for each convenience store in the United States. Its projected costs for removing and replacing the hand-held shopping baskets in all supermarket/grocery stores in the United States ranged from \$163 million to \$229 million. For all outlet types, costs for these hand-held baskets were estimated at \$194 to \$271 million, or 43 percent of the national point-of-sale costs estimated by the Barents Group.

Based on site visits, FDA modified Kearney's field data for the correct number of shopping basket racks in the Washington, DC area establishments. Furthermore, FDA contractors determined that the hand-held shopping baskets could easily be modified by a marketing representative, who would take, at most, 5 minutes to affix new stickers on each basket or rack. For a rack of 20 baskets, this task was estimated to take a total of 105 minutes, plus about \$42 for stickers. These adjustments reduce the Barents Group's estimated one-time costs by \$180 to \$252 million.

³¹³ *Id.*

³¹⁴ Buck, E., "Site Visit Report," April 24, 1996.

c. The Barents Group's extrapolation procedure. The Barents Group contributed still another bias by their method of extrapolating these survey results to the assumed range of 500,000 to 700,000 retail establishments. A. T. Kearney surveyed stores in only seven business categories: General Merchandise, Supermarket/Grocery, Tobacco Specialty, Convenience Store without Gas, Convenience Store with Gas, Service Station, and Drug Store. To represent all affected outlets, the Barents Group apportioned the full upper and lower bounds for their estimated number of establishments (500,000 and 700,000) among 10 business categories "based on the fractions they represent in the Census sample of with-payroll retail stores selling tobacco products." (Eating Places, Drinking Places, and Miscellaneous Retailers were added for this outlet allocation, but were assigned no costs because they are not "the types of retail outlets where the vast majority (more than 90 percent) of tobacco product sales occur and where promotional items are most prevalent." That is, the Barents Group used a proportional adjustment to raise each establishment category count so that the lower and upper bound totals sum to 500,000 and 700,000, respectively. The estimated number of establishments in each category was then multiplied by the average cost for each business category using data from the A. T. Kearney site visits.

The implications of these inappropriate establishment number extrapolations are considerable. For example, A. T. Kearney surveyed a sample of 10 outlets from its first business category—General

Merchandise Stores. These 10 outlets, which include three K-Mart and two Wal-Mart stores, averaged over 84,000 square feet of space, with the smallest store measuring 40,000 square feet. The U.S. Census reports only 12,117 such establishments with payroll. The Barents Group's proportional adjustment automatically expanded this outlet type count to between 21,299 and 29,818. (See Barents Group's Appendix Table.) Thus, to generate a national estimate of costs, the Barents Group applied the cost per establishment for its sample of very large general merchandise stores to roughly double the number reported in the U.S. Census for such establishments with payroll. This methodology inappropriately bases the per outlet cost for thousands of small nonpayroll and nonretail outlets on the per outlet cost reported for very large general merchandise stores.

The identical problem holds for the Barents Group's projection of the A. T. Kearney survey sample of 27 Supermarket/Grocery stores. Although this sample includes a few moderately sized establishments (1 less than 1,000 square feet and 4 less than 5,000 square feet), 21 of the establishments exceed 10,000 square feet and the average sized facility is almost 35,000 square feet. Nevertheless, the Barents Group's apportionment procedure inflates the number of establishments in this category from the U.S. Census estimate of 71,240 with payroll to 125,222 and 175,311, on the dubious assumption that thousands of small nonpayroll or other nonretail establishments are best represented by the A. T. Kearney sample of mostly large supermarkets/grocery stores.

FDA's fundamental concern is not with the Barents Group's estimate of 500,000 to 700,000 affected establishments (although the upper bound of this estimate should be 600,000, because there would be no display relocation costs for the additional 100,000 outlets assumed to be established at existing vending machine locations), but with the allocation of the small establishments among the largest business categories surveyed by A. T. Kearney. To offset this bias, FDA reallocated the number of establishments in the business categories used to extrapolate the outlet cost estimates. As shown, in Table 5, FDA takes the number of establishments in the first two business categories—General Merchandise and Supermarket/Grocery stores—directly from the U.S. Census number of establishments with payroll, because there would be very few nonpayroll or nonretail establishments equivalent to those surveyed. For outlet extrapolation purposes, FDA assigns its estimated number of nonpayroll establishments in these two business categories to the Convenience Store category, on the assumption that this category is most representative of the small establishments excluded from the Census product line data. Although the Barents Group omitted all costs for Eating Places, Drinking Places, and Miscellaneous Retail Stores, FDA groups these outlets under Other Establishments and assumes certain minimal costs, as explained below. This redistribution of the establishment category groupings reduces the Barents Group's low cost estimate by \$65 million and its high cost estimate by \$170 million.

TABLE 5.—ESTIMATED NUMBER OF ESTABLISHMENTS REMOVING SELF-SERVICE AND OTHER PROHIBITED RETAIL DISPLAYS

Kind of Business	Number of Retail Establishments with Payroll Selling Tobacco Products Over-the-Counter	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products Over-the-Counter	Estimated Total Number of Establishments Selling Tobacco Products Over-the-Counter
A. T. Kearney Categories:			
General Merchandise	12,117	— (A)	12,117
Supermarket/Grocery	71,240	— (B)	71,240
Convenience Stores	29,400	64,345 (C)	93,745
Convenience Stores with Gas	51,913	— (D)	51,913
Service Stations	37,958	7,581	45,539
Drug Stores	29,046	1,829	30,875
Tobacco Stores	1,477	— (E)	1,477
Other Establishments	—	—	201,012 (F)
Total	233,151	73,755	507,918

(A) Variety and miscellaneous general merchandise stores are tallied as convenience stores.

(B) Food stores are tallied as convenience stores.

(C) This category includes food, variety, and miscellaneous general merchandise stores. The 1992 Nonemployer Statistics Series does not provide information about convenience stores without payroll.

(D) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.

(E) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.

(F) Includes retail establishments excluded from the Kearney field audit and other establishments selling tobacco products over-the-counter.

d. *Further modifications.* The Barents Group faulted FDA for not including costs for the removal of banned display items or for the replacement of banned point-of-sale promotional materials. Their estimates assumed that manufacturers alone would bear these costs, since the proposed regulation required that manufacturers remove all prohibited advertising displays. The final regulation, however, places this responsibility on the owners of the displays, which may frequently be the retail establishments. FDA cannot forecast the ultimate distribution of display ownership, but in view of current business practices, assumes that the manufacturer representatives will at least participate in the removal process. Nevertheless, this change in regulatory responsibility is likely to shift a greater share of the cost burden to retailers.

On the other hand, the Barents Group assumed that retailers alone would replace those promotional items having a utilitarian function, including display cases, signs, shopping carts or baskets, newspaper racks, ash trays, and clocks. FDA believes that this assumption is unfounded, because many retailers will modify rather than replace these items and many manufacturers will share the replacement burden with retailers. For example, one report describing the results of a local self-service ban indicated that, "tobacco distributors and tobacco company sales representatives furnished behind-the-counter shelving and locking cases for tobacco products to retailers at no charge in order to assist retailers comply with self-service/vendor-assisted regulations."³¹⁵ Again, however, the future allocation of these costs among manufacturers and retailers is unknown. For its initial estimates, except as explained below, FDA maintains the Barents Group's assumptions that removal costs are primarily borne by the manufacturer and replacement costs by the retailer. In fact, both cost categories will be shared and the implications of these assumptions are illustrated below through sensitivity analysis.

In February 1996, economic consultants to FDA attempted to replicate the A. T. Kearney field audit in Boston (the Eastern Research Group, Inc. (ERG)),³¹⁶ and in Washington, DC (an independent contractor). While most observations of the number of affected display cases were reasonably consistent with the A. T. Kearney findings, the observed number of exterior and interior promotional materials deviated significantly from the A. T. Kearney audit data. One explanation may be that the seasonal items available at the end of November had been removed by the following February. As a result, FDA has not adjusted its calculations to account for these discrepancies (except for the cost of basket racks in the Washington, DC stores), but used certain insights from these visits to revise the Barents Group's unit cost assumptions, as follows:

(i) The agency rejects the Barents Group's assumption that retailers rather than manufacturers will bear the costs of replacing promotional unattached counter displays. Because many of these items will be moved to visible locations behind counters, it is far more likely that manufacturers, not retailers, would pay for replacements. For its revised estimate, therefore, FDA assumes that manufacturers will pay replacement costs for unattached counter displays. Although total costs are unchanged, this assumption increases the costs for manufacturers by \$17 million and decreases the costs for retailers by an equal amount.

(ii) A. T. Kearney and the Barents Group contradict themselves on the cost of removing disposable display cases. A. T. Kearney describes these units as temporary displays "frequently found in association with promotional offerings, sales, or seasonal themes," but assumes that retailers will replace them with permanent self-standing retail pack cases at \$250 each. In contrast, the Barents Group calculations imply that a distribution services company will remove each display for a fee of \$150 and retailers will replace each item for \$50. FDA agrees with the Barents Group that retailers will not replace temporary units with permanent retail pack cases.

Moreover, if a marketing representative can throw away free-standing ash trays filled with sand, as noted by A. T. Kearney, then a marketing representative can also dismantle and throw away disposable displays made of cardboard and plastic. FDA estimates, therefore, that instead of hiring a distribution services company, the manufacturer's representative will take no more than 15 minutes to remove each disposable unit, install a new unattached counter display and restock any excess inventory in a nonself-service area. This assumption decreases the estimated one-time costs by \$7 million.

(iii) The A. T. Kearney cost-estimating methodology for the self-service ban implies that store modifications take place in a sequential pattern, with no allowances for economies of scale. For example, the outlet cost for hiring a distribution services contractor to relocate or replace display cases was calculated as a fixed multiple of the number of cases to be removed, even though many establishments must remove several display cases. This approach overstates costs by ignoring the significant scale economies achievable by performing all compliance activities at one time. Thus, FDA modified A. T. Kearney's distribution services costs for the removal, relocation and installation of small attached, retail pack, and carton self-service display cases by assuming that the first display unit in an outlet would be removed at a unit charge of \$90, \$150, or \$185, respectively, but that each additional unit would be removed at one-half of these costs. For those stores with different sizes of display cases, the first unit was assumed to be the most expensive to remove (e.g., a carton display would be considered the first item when there is also a retail pack display or a small attached display). Adjusting for these scale economies reduces the estimated total costs by \$15 million.

(iv) A. T. Kearney assumed that many promotional items, such as signs and clocks, would be removed by a distribution services company hired by the manufacturer. FDA's consultants, however, found that almost all of the promotional material observed could be easily removed or modified by retail personnel or marketing representatives.

³¹⁵ Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

³¹⁶ "ERG's Review of Docket Materials Concerning FDA's Proposed Regulations Covering Tobacco Products: Final Site Visit Report," Eastern Research Group, April 22, 1996.

For example, rather than needing a contractor to remove the lighted sign in one of the sampled outlets, ERG found that the front panel was easily removable and could be quickly replaced by an acceptable panel. Although a few signs may require substantial time to dismantle, most of these items will take just a few minutes to remove. To account for this range, FDA assumes that a manufacturer's representative will take 15 minutes to remove and dispose of the various exterior signs, banners, clocks and news stand displays, as well as the interior lighted signs and clocks, lowering total costs by \$27 million.

(v) A. T. Kearney assumed that many display cases located in nonself-service areas would be removed and replaced, because of improper advertising. They assumed that the manufacturer would pay for the removal of the old case and the installation of the new case, but that the retailer would purchase the new display case. Contrary to this finding, FDA consultants found no sites in the Boston or Washington, DC regions where it was necessary to replace nonself-service displays. Because in each instance, all visible advertising could be altered or obscured, retailers would almost always opt to cover impermissible advertising rather than to purchase new display cases costing up to \$300. Accordingly, FDA estimated that it would take 15 minutes and \$5 worth of stickers to cover each small attached display; 25 minutes and \$10 worth of stickers to cover each retail pack display; and 35 minutes and \$15 worth of stickers to cover each carton display. This modification decreases total costs by \$20 million.

(vi) Even though the A. T. Kearney audit identified a number of self-service display cases that did not fit in the nonself-service area but could be

retrofitted with locks, the Barents Group did not include cost estimates for these items. FDA estimates that it would take 30 minutes of retailer time and cost about \$10 for materials to add a lock to these display cases, increasing the total one-time costs by \$1.5 million.

(vii) In its analysis of the 1995 proposed regulation, FDA acknowledged that the required reconfiguration of tobacco displays may also impose added labor costs for some purchase transactions, especially for those stores that move inventory to areas located away from employee work stations. On the assumption that the ban on self-service tobacco displays would require 10 seconds of additional labor time for 75 percent of all retail transactions involving cartons, FDA had estimated costs of about \$14 million per year. Although a few comments indicated that the self-service ban would increase labor costs, the Barents Group did not include such costs in its assessment. Nevertheless, FDA believes that some establishments, particularly those selling a substantial number of cigarette cartons that could not be stored within easy reach of a checkout station, could experience increased annual labor costs. Thus, FDA recalculated its estimate based on the updated retail employee compensation rate of \$9.51 suggested by the Barents Group and the new site visit data from the A. T. Kearney study, which imply that only about 40 percent of cigarette cartons are purchased at establishments that sell cigarette cartons from self-service areas. These adjustments project additional annual labor costs of about \$10.9 million per year.³¹⁷

³¹⁷ Derived from assumption that 10 percent of carton transactions are for multiple (2) cartons, and that cartons constitute 85 percent of tobacco sales at supermarket/grocery stores, general merchandise stores, drug stores, and tobacco stores, and 10

Except for those adjustments, FDA used the information found in the A. T. Kearney field audit to develop its revised estimate. For comparison, the original Barents Group estimates of the number of establishments and one-time point-of-sale costs (corrected for miscalculations as described above) are shown in Table 6 and FDA estimates of one-time costs in Table 7. Detailed summaries of the FDA one-time cost estimates are presented in Table 8 and Table 9 and indicate that costs related to self-service display cases comprise 73 percent of the total, followed by 18 percent for promotional materials and 9 percent for nonself-service display cases. As explained above, these estimates assume that manufacturers will bear the cost of removing all promotional items and retailers will bear the cost of replacing most functional items. Because the regulation places the removal responsibility on owners of the materials, FDA does not know how these obligations will be divided. However, if retail outlets, rather than manufacturers, must remove these items, the overall cost to manufacturers falls by about \$47 million and the cost to retailers increases by about \$17 million. (Retail compensation rates are about one-third of manufacturer rates, according to the Barents Group data). The following discussion describes specific compliance costs for each outlet category.

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percent of tobacco sales at other outlets. Tobacco sales data from 1992 Census of Retail Trade, pp. 3-31. Kearney site visits found that 80 percent of general merchandise stores, 33 percent of supermarket/grocery stores, 25 percent of convenience stores, 17 percent of service stations, 30 percent of drug stores, 42 percent of tobacco stores had self-service carton display cases.

TABLE 6.—BARENTS GROUP LLC ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS¹

Kind of Business	Estimated Number of Establishments		Average Cost per Facility (\$)	Estimated Point-of-Sale Costs (Lower)			Estimated Point-of-Sale Costs (Upper)		
	Lower	Upper		Retail Costs (\$)	Manufacturer Costs (\$)	Total Costs (\$)	Retail Costs (\$)	Manufacturer Costs (\$)	Total Costs (\$)
General Merchandise	21,299	29,818	1,067	13,268,172	9,449,404	22,717,576	18,575,066	13,228,900	31,803,966
Supermarket/Grocery	125,222	175,311	2,356	182,028,407	112,960,223	294,988,630	254,840,061	158,144,493	412,984,554
Convenience Stores	51,678	72,349	925	24,408,368	23,382,610	47,790,978	34,171,621	32,735,564	66,907,185
Convenience Stores with Gas	91,250	127,750	515	21,656,668	25,294,382	46,951,050	30,319,336	35,412,134	65,731,470
Service Stations	66,721	93,409	217	4,894,902	9,616,053	14,510,955	6,852,833	13,462,416	20,315,250
Drug Stores	51,056	71,478	167	4,472,540	4,054,323	8,526,863	6,261,520	5,676,020	11,937,541
Tobacco Stores	2,596	3,635	2,940	4,486,055	3,147,456	7,633,511	6,281,514	4,407,166	10,688,680
Total	409,822	573,750		255,215,112	187,904,451	443,119,563	357,301,952	263,066,694	620,368,645

¹ Totals may not add due to rounding.

TABLE 7.—FDA ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS

Kind of Business	Estimated Number of Establishments ¹	Average Cost Per Facility (\$)	Estimated Point-of-Sale Costs ²		
			Retail Costs (\$)	Manufacturer Costs (\$)	Total Costs (\$)
General Merchandise	12,117	919	7,874,058	3,263,894	11,137,952
Supermarket/Grocery	71,240	810	32,655,560	25,067,316	57,722,876
Convenience Stores	93,745	364	12,271,061	21,879,370	34,150,431
Convenience Stores with Gas	51,913	213	1,397,066	9,644,359	11,041,425
Service Stations	45,539	122	2,560,164	2,974,000	5,534,164
Drug Stores	30,875	160	2,978,007	1,966,563	4,944,570
Tobacco Stores	1,477	2,175	2,165,591	1,046,163	3,211,753
Other Establishments	210,012	19	522,765	3,384,741	3,907,506
Total	507,918		62,424,273	69,226,404	131,650,677

¹ Number of establishments from Table 5.² Totals may not add due to rounding.

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS¹

Compliance Activities	General Merchandise	Supermarket/ Grocery	Convenience Stores	Convenience Stores with Gas	Service Stations	Drug Stores	Specialty Tobacco Stores	Other Establishments
	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)
Promotional Materials:								
No. 3 Ext. Attached Signs	*	1.19	*	*	1.07	*	*	*
No. 4 Ext. Movable Sign Board	*	0.95	0	2	3.75	*	8.57	0
No. 5 Ext. Decal/Stickers	*	0.85	0	2	2.82	*	4.02	*
No. 6 Ext. Lighted Signs/Clocks	*	0.61	0	2	0.85	*	16.34	1
No. 7 Ext. Signs, Posters & Displays	*	0.38	0	1	1.36	*	1.43	*
No. 8 Ext. Movable Window Signs	*	0.95	0	1	1.33	*	1.54	*
No. 9 Ext. Open/Closed Signs	*	0.43	0	3	2.14	*	0.98	0
No. 10 Ext. Signs on Gas Pumps	*	0.43	0	1	0.14	0	0.59	3
No. 11 Ext. News Stand Displays	*	7.42	1	*	0.14	*	*	*
No. 12 Ext. Novelty Item Displays	*	*	*	*	*	*	*	*
No. 13 Ext. Banners	*	*	*	*	*	*	*	*
No. 14 Signs, Posters & Banners	0.34	*	0.80	2	1.07	*	0.54	0
No. 15 Lighted Signs, Clocks/Mach. Dev.	19.61	1.14	0	1	1.71	0	2.14	0
No. 16 Decals/Stickers	0.26	10.29	1	5	8.17	7	28.60	1
No. 17 Shelf Marker w/Adv.	0.60	0.79	0	1	0.67	0	0.93	0
No. 18 Shopper Aids	0.04	0.44	0	1	1.49	1	0.96	0
No. 19 News Racks, Shop. Bask., Carts	*	0.42	0	0	0.31	0	0.21	0
No. 20 Fl. St. Ash Trays, Waste Basket	*	83.75	10	12	9.66	5	14.50	1
No. 21 Merch. w/ Ref. to Tobacco Prod.	*	3.30	0	*	9.89	5	24.71	1
Promotional Materials Subtotal:	20.85	112.92	14	28	23.47	19	106.39	5
Self-Service Display Cases:								
Small, Unattached								
No. 22 Space Available, Ads Removed	*	0.32	0	0	0.71	1	3.21	0
No. 23 Unit Must Be Replaced	10.60	25.52	3	15	8.83	7	141.33	6
Small, Attached								
Removal and Installation/Relocation	13.50	65.00	8	*	*	*	*	*
No. 24 Unit Must Be Replaced	10.00	55.56	7	*	*	*	*	*
No. 25 Space Available, Ads Removable	*	*	*	*	*	*	*	*
Packs								
Removal and Installation	67.50	86.11	11	*	6.25	5	193.75	9
No. 26 Space Available, No Ads	*	*	*	*	*	*	*	*
No. 27 Space Available, Ads Removable	0.79	0.29	0	*	*	*	*	*
No. 28 Unit Must Be Replaced	200.00	222.22	27	*	20.83	17	625.00	29
No. 29 Unit Modified w/Locking Doors	1.48	3.28	0	*	*	*	*	*

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS--(CONTINUED)

Compliance Activities	General Merchandise	Supermarket/ Grocery	Convenience Stores	Convenience Stores with Gas	Service Stations	Drug Stores	Specialty Tobacco Stores	Other Establishments
	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)	Avg. Outlet Cost (\$)
Cartons								
Removal and Installation	166.50	65.09	46.25	13	15.42	37.00	262.08	
No. 10 Space Available, No Ads	*	0.26	*	*	*	*	*	*
No. 41 Unit Must Be Replaced	390.00	155.56	119	0	25.00	60.00	775.00	*
No. 43 Unit Modified w/Locking Doors	35.41	3.83	112.50	31	3.69	8.85	11.07	*
No. 44 Disposable, Replaced	*	2.09	*	*	4.70	*	37.62	*
Self-Service Subtotal:	895.78	685.12	214.28	59	85.44	148.42	2,051.30	10.07
Non-Self-Service Display Cases:								
Small, Unattached								
No. 15 Advertising Removable	*	0.16	2.41	1	3.75	2.14	0.89	2.14
No. 16 Unit Must Be Replaced	*	*	26.50	7	*	*	13.25	*
Small, Attached								
No. 37 Advertising Removable	*	1.27	3.75	1	2.86	1.50	2.14	0
No. 38 Unit Must Be Replaced	*	*	8.57	2	0.95	*	*	*
Packs								
No. 39 Advertising Removable	*	0.40	1.07	0	0.36	1.71	0.18	0
No. 40 Unit Must Be Replaced	*	2.30	*	*	*	*	*	*
Cartons								
No. 41 Advertising Removable	2.57	1.43	*	*	*	0.64	0.36	0
No. 42 Unit Must Be Replaced	*	6.66	*	*	*	*	*	*
No. 43 Disposable, Replaced	*	*	7.05	2	4.70	*	*	*
Non-Self-Service Subtotal:	2.57	12.22	49.35	14	12.61	6.00	16.82	3.64
TOTAL:	919.20	810.26	364.29	100	121.53	160.15	2,174.51	19.44

Totals may not add due to rounding.

TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS¹

Compliance Activities	General Merchandise (\$000)	Supermarket/Grocery (\$000)	Convenience Stores (\$000)	Convenience Stores with Gas (\$000)	Service Stations (\$000)	Drug Stores (\$000)	Specialty Tobacco Stores (\$000)	Others (\$000)	ALL ESTABLISHMENTS (\$000)	%
Promotional Materials:										
No. 1 Ext. Attached Signs	*	85	*	*	49	*	*	*	134	0.1
No. 4 Ext. Movable Sign Board	*	68	602	148	171	*	13	*	1,002	0.8
No. 5 Ext. Decal/Stickers	*	60	565	146	39	*	6	*	816	0.6
No. 6 Ext. Lighted Signs/Clocks	*	43	383	471	62	*	24	*	984	0.7
No. 7 Ext. Signs, Posters & Displays	*	27	181	69	*	*	2	*	279	0.2
No. 8 Ext. Movable Window Signs	*	68	979	111	73	*	1	*	1,232	0.9
No. 9 Ext. Open/Closed Signs	*	31	206	*	*	18	1	118	375	0.3
No. 10 Ext. Signs on Gas Pumps	*	*	*	12	7	*	*	*	19	0
No. 11 Ext. News Stand Displays	*	529	*	*	*	*	*	*	529	0.4
No. 12 Ext. Novelty Item Displays	*	*	*	*	*	*	*	*	*	*
No. 13 Ext. Banners	*	*	75	185	49	*	1	*	310	0.2
No. 14 Signs, Posters & Banners	4	81	161	89	78	5	3	34	456	0.3
No. 15 Lighted Signs, Clocks/Mach. Dev.	238	733	1,724	848	372	101	42	657	4,715	3.6
No. 16 Decals/Stickers	3	57	221	35	33	40	1	258	647	0.5
No. 17 Shelf Marker w/Adv.	7	31	201	77	83	12	1	75	488	0.4
No. 18 Shopper Aids	1	30	18	16	1	1	0	9	75	0.1
No. 19 News Racks, Shop. Bask., Carts	*	5,967	502	502	*	*	21	*	10,566	8
No. 20 Pl. St. Ash Trays, Waste Basket	*	235	4,077	513	*	*	37	*	784	0.6
No. 21 Merch. w/ Ref. to Tobacco Prod.	*	*	45	37	54	*	3	*	139	0.1
Promotional Materials Subtotal:	253	8,044	9,437	3,261	1,069	177	157	1,151	23,549	17.9
Self Service Display Cases:										
Small, Unattached										
No. 22 Space Available, Ads Removed	*	23	125	124	33	33	5	215	557	0.4
No. 23 Unit Must Be Replaced	128	1,818	4,968	2,751	402	*	209	*	10,277	7.8
Small, Attached										
No. 24 Unit Must Be Replaced	164	4,631	*	519	*	278	*	1,809	7,400	5.6
No. 25 Space Available, Ads Removable	121	3,958	*	*	*	*	*	*	4,079	3.1
Packs										
Removal and Installation	818	6,135	*	*	285	232	286	*	7,755	5.9
No. 26 Space Available, No Ads	*	*	*	*	*	*	*	*	*	*
No. 27 Space Available, Ads Removable	10	21	*	46	*	*	1	*	77	0.1
No. 28 Unit Must Be Replaced	2,423	15,831	*	*	949	772	923	*	20,898	15.9
No. 29 Unit Modified w/Locking Doors	18	234	*	*	*	*	*	*	251	0.2
Cartons										
Removal and Installation	2,017	4,637	4,336	*	702	1,142	387	*	13,222	10
No. 30 Space Available, No Ads	*	19	*	*	*	*	*	*	19	0
No. 31 Space Available, Ads Removable	*	*	111	*	*	*	2	*	114	0.1
No. 32 Unit Must Be Replaced	4,726	11,082	10,546	*	1,138	1,853	1,145	*	30,489	23.2
No. 33 Unit Modified w/Locking Doors	429	273	168	*	168	273	16	*	1,159	0.9
No. 34 Disposable, Replaced	*	149	*	*	214	*	56	*	419	0.3

TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS-- (CONTINUED)

Compliance Activities	General Merchandise (\$000)	Supermarket/Grocery (\$000)	Convenience Stores (\$000)	Convenience Stores with Gas (\$000)	Service Stations (\$000)	Drug Stores (\$000)	Specialty Tobacco Stores (\$000)	Others (\$000)	ALL ESTABLISHMENTS (\$000)	%
Self-Service Subtotal:	10,854	48,808	20,087	3,440	3,891	4,583	3,030	2,024	96,717	73.5
Non-Self-Service Display Cases:										
No. 15 Advertising Removable Small, Unattached	*	11	226	334	171	66	1	431	1,239	0.9
No. 16 Unit Must be Replaced Small, Attached	*	*	2,484	2,446	*	*	20	*	4,949	3.8
No. 17 Advertising Removable	*	90	351	235	130	46	3	301	1,157	0.9
No. 18 Unit Must be Replaced Packs	*	*	803	*	43	*	*	*	1,847	0.6
No. 19 Advertising Removable	*	28	100	25	16	53	0	*	223	0.2
No. 40 Unit Must be Replaced Cartons	*	164	*	*	*	*	*	*	164	0.1
No. 41 Advertising Removable	31	102	*	*	*	20	1	*	153	0.1
No. 42 Unit Must be Replaced	*	475	*	*	*	*	*	*	475	0.4
No. 43 Disposable, Replaced	*	*	661	1,302	214	*	*	*	2,177	1.7
Non-Self-Service Subtotal:	31	870	4,626	4,340	574	185	25	732	11,385	8.6
TOTAL:	11,138	57,723	34,150	11,041	5,534	4,945	3,212	3,908	131,651	100

* Totals may not add due to rounding.

e. *General merchandise stores.* None of the general merchandise stores in the A. T. Kearney sample had exterior promotional materials and only a few had interior promotional materials. Eighty percent of the stores had only self-service displays, with carton displays more numerous than pack displays at these locations. The average per facility one-time costs estimated by FDA were \$919. Overall, 97 percent of the outlet costs related to the replacement of self-service display cases, although in some general merchandise stores, tobacco products were stocked on shelves rather than in special display cases, which suggests that the costs for this business category may be overstated.

f. *Supermarket/grocery.* Unlike general merchandise stores, supermarkets had significant promotional materials. While both packs and cartons were sold at most locations, over 75 percent of the stores already had nonself-service display areas. FDA estimates per facility costs at \$810. Self-service display case removal and replacement amount to 85 percent of the total cost, whereas promotional materials account for 14 percent. Commenting on the feasibility of the proposed FDA self-service ban, the Food Marketing Institute argued that most retail food stores do not have adequate space at checkout lines for tobacco products and rejected the practicability of alternative procedures. They suggested that the only option available to many food retailers would be to remodel and set-up a controlled area for the sale of tobacco products, costing up to \$50,000 per store. The A. T. Kearney audit, however, found that a majority of supermarket/grocery stores have already installed nonself-service areas for tobacco products and would not need to reconfigure their stores. While some establishments will incur costs above the average, the A. T. Kearney site visit data suggest that most stores could comply by either moving inventory to nonself-service areas or by purchasing new displays that are compatible with existing store configurations.

g. *Convenience stores.* Stores in this category exhibited numerous interior and exterior promotional items. All of the convenience stores surveyed had nonself-service display cases and 50 percent had carton displays. FDA estimates per facility costs of \$364. Costs for removing and replacing self-service display cases made up 59 percent of the total, while costs for promotional materials and nonself-

service display cases were 28 percent and 14 percent, respectively.

The National Association of Convenience Stores (NACS) faulted FDA on its assumption that the main cost of the self-service ban would be to relocate tobacco product inventory, contending that their members would incur thousands of dollars in reconfiguration costs. According to NACS:

[i]t is largely irrelevant that retailers already keep packs behind the counter. Many NACS members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales. Based on an estimate from one member with a high volume of self-service cigarette sales, NACS suggested it could cost \$4,320 and \$10,120, respectively, to reconfigure a newer and older convenience store.

Based on other evidence, however, FDA does not believe that a large number of stores will be forced to undergo extensive modifications and finds that most convenience stores can adequately adapt space either behind or above checkout counters. As noted earlier, one regional survey reported that retail outlets readily complied with local self-service restrictions without architectural remodeling or substantial refitting of checkout counters or store aisles.³¹⁸ Space above counters is typically available for display cases either by suspending a case from the ceiling or by supporting a case on beams from the counter. In its survey, A. T. Kearney found at least some tobacco products sold from nonself-service space in every convenience store. Although it is possible that stores might incur added inventory handling costs if this space were smaller than optimal, FDA concludes that major reconfiguration would rarely be required and relies on the A. T. Kearney survey data, as adjusted, to project average costs for this sector.

h. *Convenience stores with gas.* Like convenience stores without gas, these establishments had numerous interior and exterior promotional materials. About 89 percent of the stores surveyed had nonself-service display cases. FDA estimates per facility costs of \$213. Consistent with the findings of the Barents Group, the average outlet cost

for this sector is about one-half that of convenience stores without gas.

In comments to the 1995 proposed rule, the Society of Independent Gasoline Marketers of America (SIGMA) did not present specific data on the cost to their members, but indicated that many members would be required to reconfigure their stores. They stated that:

[m]any SIGMA members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales. At a minimum, these members would have to install new cabinets to accommodate tobacco products behind the counter. Many members would have to enlarge the counter area to make room for the new cabinets. In contrast, the A. T. Kearney field audit found few convenience stores with gas that have self-service displays, other than unattached promotional counter displays. Costs to remove or replace promotional counter displays will be borne primarily by manufacturers, not retailers. In sum, the costs for self-service display cases amount to about 31 percent of the total, promotional material 30 percent, and nonself-service display cases 39 percent.

i. *Service stations.* These establishments had both interior and exterior promotional material. Seventy-five percent of the locations surveyed had only nonself-service display cases and one-fourth had carton displays. FDA estimates the per facility cost at \$122.

j. *Drug stores.* Drug store outlets had few exterior and interior promotional materials. As in general merchandise stores, tobacco products were stocked on shelves in some locations. Ninety percent of the stores surveyed by A. T. Kearney already had nonself-service displays and approximately 70 percent had carton displays. FDA estimated \$160 cost per facility for this category of business. About 93 percent of the total one-time costs are for replacement of self-service display cases.

k. *Tobacco stores.* These stores had substantial promotional materials and multiple display cases. FDA estimates per facility costs of \$2,175. About 94 percent of the costs are for self-service display cases, with promotional materials and nonself-service display cases dividing the remaining 6 percent. While not reflected in the cost totals, these establishments may choose to operate as "adult only" restricted areas to avoid replacing self-service display cases.

l. *Other establishments.* This category includes eating/drinking establishments and miscellaneous retail stores, which

³¹⁸ Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

were excluded from the A. T. Kearney audit, plus the estimated 100,000 nonretail establishments that sell tobacco products OTC, such as hotels, factories and sporting facilities. Due to the low volume of tobacco product sales at these establishments, FDA assumed that only a small quantity of packs and no cartons would be sold. Lacking detailed data, FDA assigned costs of \$19 per outlet, based on the costs of removing promotional materials and relocating and replacing small attached display cases, as reported for drug stores.

3. Label Changes

The final regulation requires that the tobacco product package contain the established name of the tobacco product in a specified size. FDA estimated the compliance costs for printing new labels in its earlier analysis of the proposed regulation and has received no comments that improve those original estimates.

Approximately 933 varieties of cigarettes are currently produced in the United States.³¹⁹ FDA does not have information on the number of smokeless tobacco varieties, but assumes that the total number of cigarette and smokeless tobacco varieties is roughly 1,000. Because most varieties of cigarettes are packaged in both single packs and cartons, the total number of labels is assumed to number about 2,000.

FDA used two approaches to estimate the cost to industry of changing these labels. The first approach relied on information compiled by The Research Triangle Institute (RTI) for its report to FDA on the cost of changing food labels.³²⁰ RTI reported a cost of about \$700 for a 1-color change in a lithographic printing process. FDA multiplied this figure by 4 to account for a 2-color change on the actual warning labels and an additional 2 colors for modifications to the existing label to make room for the warning label. This calculation yielded incremental printing costs of about \$2,800 per label, or \$5.6 million for all 2,000 varieties of affected tobacco products. Adjusting this figure downward by RTI's methodology to account for the current frequency of label redesign predicts that the total one-time cost of completing these label changes within a 1-year compliance

period would be approximately \$4 million.

The second approach was to use cost information provided in the regulatory impact analysis of a roughly comparable Canadian regulation.³²¹ The Canadian Government estimated a cost of \$30 million to change labels for about 300 cigarette varieties. Most Canadian cigarettes are likewise sold in two sizes, but about 20 percent are also sold in flip top packages.³²² Canadian labels, however, are typically printed using a gravure method; which, according to RTI, is about 3.5 times as expensive as the lithography process used in the United States. Adjusting the Canadian estimate upward, to account for the larger number of cigarette and smokeless tobacco varieties in the United States; and downward, for the smaller number of packages per variety and the smaller cost of the lithography printing process, provides a \$17 million estimate for the total cost of these label changes.

4. Educational Program

FDA may issue notification orders under section 518(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.360h(a)) to require manufacturers of cigarettes and smokeless tobacco products to fund consumer educational programs. While the precise details of these orders are still under development, these orders may involve the achievement of specific performance objectives by directing manufacturers to initiate informational programs designed to transmit messages that will reach the majority of young people. The 1995 proposed regulation directed manufacturers to spend at least \$150 million annually on this program. While industry comments were critical, many other comments suggested that this figure was too low. One comment noted that \$150 million is equivalent to about one week of pro-tobacco expenditures and another that the industry gained \$221 million in profits from underage sales. Still another pointed out that the current dollar value of the informational advertising that was conducted under the Fairness Doctrine would amount to about \$300 million per year. One study appears to indicate that 75 percent of adolescents aged 12 to 17 could have been reached in 1985 to

1986 with multiple messages at a cost of about \$17 million a year.³²³ FDA is still evaluating various types of informational programs, with respect to both effectiveness and practicality. Before a final decision is reached, the agency will determine the costs of selected alternatives.

5. Restricted Advertising and Promotional Activities

a. *Tobacco industry.* The determination of the societal costs attributable to the restrictions on tobacco product advertising and promotion is complex. While there is no doubt that individual manufacturers realize enhanced goodwill asset values from advertising programs, the industry has long held that advertising prompts brand-switching, but does not increase aggregate sales. Of course, if this were true, advertising would be unprofitable from the standpoint of the industry as a whole and reduced levels would increase rather than decrease aggregate industry profits. In addition, if the primary motivation for tobacco advertising is to promote brand-switching, then, as long as all firms are equally restricted from advertising, the above mentioned loss in goodwill value will be substantially reduced.

In its comments, the tobacco industry claimed that tobacco advertising and promotion have virtually no effect on youth consumption. Although FDA does not accept this claim, the agency does not consider the expected voluntary reduction in the consumption of tobacco products to be a societal cost. Although industry sales will fall, they will reflect new consumer preferences and consumer dollars no longer used on tobacco products will be redirected to other more highly valued areas. Thus, for the most part, the resulting reduction in industry sales are not net costs and the potential magnitude of this revenue transfer is discussed below under the heading of Distributional Effects. Moreover, as shown in that discussion, any short-term frictional or relocation impacts will be significantly moderated by the gradual phase-in of the economic effects.

b. *Advertising industries.* In its original analysis, FDA argued that advertising and promotional restrictions will impose no long term net costs on society. The Barents Group's study found that the various suppliers of

³¹⁹ "Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes," Federal Trade Commission, 1994.

³²⁰ French, M. T., D. M. Neighbors, L. K. Carswell, K. B. Heller, and G. L. McDougal, "Compliance Costs of Food Labeling Regulations," Final Report, RTI Project Number 233U-3972-02 DFR, January 1991.

³²¹ Department of National Health and Welfare, "Tobacco Products Control Regulations, amendment," *Canada Gazette*, Part II, vol. 127, No. 16, pp. 3277-3294, August 11, 1993.

³²² Kaiserman, M., Department of National Health and Welfare, Canadian Government, personal communication, February 1, 1995.

³²³ Bauman, K. E., J. D. Brown, E. S. Bryan, L. A. Fisher, C. A. Padgett, and J. M. Sweeney, "Three Mass Media Campaigns to Prevent Adolescent Cigarette Smoking," *Preventive Medicine*, vol. 17, pp. 510-530, 1988.

industry advertising will incur substantial regulatory costs. It estimated that illustrative annual costs for this sector could reach \$722 million to \$2.17 billion, or up to one-half of its estimate of the total costs of the FDA proposal.

Upon review, FDA remains firmly convinced that its original position was correct. That is, from the standpoint of assessing societal costs and benefits, reduced revenues from tobacco advertising and promotional activities are not net costs and are appropriately considered a distributional impact. Indeed, FDA believes that a strong argument can be made that, even irrespective of health benefits, these advertising restrictions will decrease net societal costs by freeing productive resources for alternative uses. This does not imply that no individual business entities will be negatively impacted. Many of the companies that currently benefit from tobacco promotions (e.g., advertising agencies, publishers, sporting event promoters) will suffer lost revenues and those firms that specialize in those activities may lose a substantial part of their business. Nevertheless, from a societal perspective, these losses will be counterbalanced by an increase in demand for other consumption and investment goods, so that nontobacco-related entities will gain sales. Although overlooked in most industry comments, this result is acknowledged within the comments submitted for the Tobacco Institute by the Barents Group:

A key assumption in the simulations is that, when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies. That report also reveals the underlying distributional nature of the impacts by explaining that its modeling incorporates the assumption that:

* * * in the long run economic losses in one sector of the economy will be redistributed to other sectors of the economy, i.e., winners and losers will generally balance out for the economy as a whole. Further discussion of the impact of these revenue transfers is included below under the section on "Distributional Effects."

c. *Retail sector.* In addition to the previously estimated direct costs associated with the removal of prohibited point-of-purchase advertising, promotional restrictions

will impact the retail sector because they will lead to a long-term decline in tobacco products sales and a potential fall in promotional allowances (slotting fees) from manufacturers. Once again, these impacts are not net societal costs, since reduced tobacco product sales will be counterbalanced by increased sales for other products or services; and smaller promotional allowances, if they occur, are gains to tobacco manufacturers that would be used for other purchases. Consequently, these impacts also are examined below under "Distributional Effects."

d. *Consumers.* Advertising restrictions may impose costs on society if they disrupt the dissemination of relevant information to consumers. Firms engage in advertising to inform potential customers about their product (informative advertising) or to persuade customers that a product is desirable (persuasive advertising). According to the FTC's Bureau of Economics, the benefits of advertising derive from:

* * * its role in increasing the flow and reducing the cost of information to consumers * * * First, advertising provides information about product characteristics that enables consumers to make better choices among available goods * * * Second, theoretical arguments and empirical studies indicate that advertising increases new entry and price competition and hence reduces market power and prices in at least some industries * * *. Third, advertising facilitates the development of brand reputations. A reputation, in turn, gives a firm an incentive to provide products that are of consistently high quality, that live up to claims that are made for them, and that satisfy consumers.³²⁴

FDA has considered each of these issues. First, while agreeing that many forms of advertising offer substantial benefits to consumers, the agency nevertheless believes that consumers will lose little utility from these particular advertising restrictions. The regulation does not prohibit factual, written advertising. Thus, the rule will not impede the dissemination of important information to most consumers. In its preliminary analysis, the agency concluded that, "[w]hile imagery and promotional activities may be important determinants of consumer perceptions and sales, they typically provide little meaningful information on essential distinctions among competing tobacco products" (60 FR 41314 at 41368).

³²⁴ Recommendations of the Staff of the Federal Trade Commission, "Omnibus Petition for Regulation of Unfair and Deceptive Alcoholic Beverage Advertising and Marketing Practices," Appendix A, pp. 3-4, March 1985.

One industry comment strongly opposed this position, arguing that advertising is important for product improvement and that past restrictions on the advertising of "low tar" products retarded product innovation. The crux of the argument is that color and/or imagery are prerequisites for disseminating relevant quality information and that, in its absence, consumers could not be adequately informed about the merits of new products. FDA, however, is not persuaded that manufacturers will be unable to convey vital information. The agency finds that true product improvements in this industry are rare, but where they exist, manufacturers could rely on traditional ads in adult-oriented publications and on "text only" advertising elsewhere. Moreover, FDA and other public health agencies would likely coordinate with companies in disseminating truly important consumer safety information.

The implications of FTC's second point, which addresses the effect of advertising restrictions on market power and prices, are less certain, as various empirical studies have reached conflicting conclusions. One industry comment insisted that FDA's regulation will deprive consumers of the benefits of competition, stating that, "[u]ndoubtedly the clearest measure of consumer benefit is the effect of advertising on price." To support this view, the comment references several studies that demonstrate the ability of advertising to reduce product prices. The comment also contended that the "[e]limination of advertising will predictably consolidate the market as marginal brands are abandoned and fewer brands are introduced" and that, "[o]ver time this can also reduce the number of players, as companies with dominant brands drive out others."

FDA agrees that advertising can often lead to decreased product prices, but notes that the other industries referenced (e.g., eyeglasses and pharmaceuticals) are much more competitive than tobacco products. Moreover, economists have found that advertising can also serve as a barrier to entry in oligopolistic industries. One author, for example, determined that ready-to-eat breakfast foods companies used advertising programs to support brand proliferation strategies in order to dominate retail shelf space.³²⁵ These programs helped to keep new firms out and prices high without necessarily

³²⁵ Sutton, J., "Sunk Costs and Market Structure," The MIT Press, Cambridge, Massachusetts, pp. 229-247, 1991.

embodying improved quality. Thus, in certain circumstances, oligopolistic firms can use extensive advertising to create barriers for suppressing innovation and competition. FDA cannot determine whether tobacco advertising restrictions would ultimately increase or decrease product prices.

Finally, FTC's third point, which emphasizes the positive aspects of advertising in supporting brand reputations, is more relevant for long-lived items, such as consumer durables, where purchases are infrequent or personal experience is inadequate. Advertising is less likely to play a key role in assuring high quality levels for tobacco products, where consumer search costs are low and a brand's reputation for quality is tested by consumers every day. For these products, high quality will remain a prerequisite of commercial success irrespective of advertising strategies.

Other analysts suggest still other potential attributes of product advertising. For example, according to F. M. Scherer, author of a widely read text on industrial organization:

Advertising is art, and some of it is good art, with cultural or entertainment value in its own right. In addition, it can be argued that consumers derive pleasure from the image advertising imparts to products, above and beyond the satisfaction flowing in some organic sense from the physical attributes of the products. There is no simple case in logic for distinguishing between the utility people obtain from what they think they are getting and what they actually receive. As Galbraith observed, "The New York housewife who was forced to do without Macy's advertising would have a sense of loss second only to that from doing without Macy's."³²⁶

Similarly, Becker and Murphy have argued that advertisements should be considered "goods" if people are willing to pay for them and as "bads" if people must be paid to accept them.³²⁷ They explain that, in general, the more easily the advertisements can be ignored, the more likely it is that the ads themselves provide utility to consumers. Newspaper and magazine advertisements, for example, must provide positive consumer utility or they would be ignored by readers. This final rule allows such advertisements to continue, some in their current form, others in a text-only format. (In fact, industry outlays for newspaper and magazine advertisements have dropped

sharply in recent years and currently constitute less than 5 percent of the industry's total advertising and promotion budget).³²⁸ Conversely, the extraordinary growth in industry advertising and promotion has occurred in areas that are typically bundled with other products, or placed in prominent public settings that are difficult to ignore. Thus, there is considerable question about the contribution of these programs to consumer utility.

6. Training

a. *Retailers.* The final regulation does not explicitly require retail employees who sell tobacco products to be trained in checking customer I.D.'s. FDA understands, however, that some training is essential to effective performance. In its analysis of the proposed regulation, FDA estimated total annual costs of \$10 million for employee training at retail outlets. This estimate assumed that an average of 12 employees per store at 467,000 retail stores (assuming 1/3 of 700,000 stores already conducted training) would receive 15 minutes of training at a compensation rate of \$7.41/hour. The Barents Group commented that FDA's analysis did not account for many individual cost elements, resulting in a significant underestimate of total training costs. It estimated one-time training costs of \$184 to \$257 million and recurring annual training costs of \$48 to \$67 million.

Specifically, the Barents Group stated that FDA relied on outdated compensation data. FDA had obtained these data from a 1992 report prepared by Price Waterhouse for the Tobacco Institute, but agrees that more recent data are available and employs the suggested compensation rate of \$9.51 for its revised estimate. The Barents Group also claimed that FDA failed to consider recurring training costs due to annual employee turnover and annual updating, focusing instead on one-time training costs only. This criticism is not valid. Table 2 of the original analysis (60 FR 41314 at 41360) clearly lists training costs for retail establishments as an annual operating cost and the text (60 FR 41314 at 41367) refers to a "per year" cost. Because employees would be trained when first hired, this estimate implied a 100 percent employee turnover rate.

To refine its analysis, however, FDA has disaggregated the cost elements. Although the Barents Group accepted FDA's preliminary estimate of 12 employees per retail store, FDA now believes that this figure is accurate only for retail stores with payroll. Stores without payroll constitute a significant percentage of the stores selling tobacco products and, on average, are much smaller. As explained above, FDA estimates that about 600,000 establishments will sell over-the-counter tobacco products, including the 100,000 that replace those vending machines that are removed. Table 10 presents the data that underlie FDA's revised estimates of the number of employees who will be trained. For existing retail establishments with payroll, FDA assumes that training will be needed for all employees in the affected outlets, except in General Merchandise and Supermarket/Grocery stores, where one-third of the employees will be trained. For establishments without payroll, nonretail establishments, and new establishments replacing vending machines, Census data on the number of employees is not available, but FDA assumes that an average of six employees will be trained. As shown in Table 10, these calculations indicate that training will be required for a total of 4.2 million workers.

The Barents Group further faulted FDA for underestimating the training time that would be required to educate retail sales clerks about recognizing proper forms of identification and handling related customer service problems. It assumed that 2 hours of training would be necessary. FDA, however, reviewed the time needed to present the training materials from several corporate entities and finds that they need not exceed one hour. For example, one large convenience store corporation uses a 45 minute training videotape that covers the sale of tobacco products, but also covers the sale of alcohol and possible inhalants, including means for recognizing inebriated or drugged individuals. Moreover, many establishments, especially small stores, will provide no formal training, but will provide instruction during the work day with minimal lost time. Thus, FDA believes that average costs are reasonably based on a 1-hour training program.

³²⁶ Scherer, F. M., *Industrial Market Structure and Economic Performance*, 2nd edition, Rand McNally College Publishing Co., Chicago, IL, p. 380, 1980.

³²⁷ Becker, G. S., and K. M. Murphy, "A Simple Theory of Advertising as a Good or Bad," *Quarterly Journal of Economics*, vol. 108, p. 941, November 1993.

³²⁸ Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, issued 1995.

TABLE 10.—NUMBER OF EMPLOYEES TO BE TRAINED

Kind of Business	Payroll Establishments				Nonpayroll Establishments		Total Employees Trained
	Establishments Selling Tobacco Products	Employees Per Store	Percent Trained	No. of Employees Trained	Establishments Selling Tobacco Products	No. of Employees Trained ¹	
General Merchandise	12,117	60.1	33%	242,593	9,807	58,842	301,435
Supermarket/Grocery	71,240	20.9	33%	497,253	54,538	327,228	824,481
Convenience Store/no gas	29,400	5.6	100%	164,718	---	---	164,718
Convenience Store/gas	51,913	6.8	100%	353,868	---	---	353,868
Gas Station	37,958	6.0	100%	228,002	7,581	45,486	273,488
Eating Place	11,992	16.5	100%	198,212	3,065	18,390	216,602
Drinking Place	10,745	5.4	100%	58,498	5,336	32,016	90,514
Drug/Proprietary Store	29,046	12.2	100%	354,730	1,829	10,974	365,704
Specialty Tobacco	1,477	3.7	100%	5,530	---	---	5,530
Miscellaneous	24,995	5.2	100%	130,253	44,879	269,274	399,527
Retail Subtotal	280,883			2,233,656	127,035	762,210	2,995,867
Nonretail ²							600,000
Converted Vending Machines ²							600,000
Total							4,195,867

¹Assumes 6 employees per establishment.

²Assumes 100,000 outlets with 6 employees to be trained.

Sources: Table 4 for description of establishment data; 1992 Census of Retail Trade, Subject Series: Establishment and Firm Size (Table 1) for employment data; FDA estimates for percent trained.

Adopting FDA's original estimate that about one-third of all affected establishments already provide employee training (also assumed by the Barents Group), implies one-time employee training costs of \$26.6 million (4.2 million employees x 2/3 x \$9.51). The Barents Group suggested, however, that even employees who currently receive training would need 5 extra minutes on the new regulations, which adds about \$1.0 million to the cost estimate. Next, the Barents Group included costs for time spent by trainers, assuming that the training would be provided by an outside source. FDA believes that a more typical approach would have a store supervisor provide the training. Using \$13.64 as the compensation rate for a retail manager, as suggested by the Barents Group, and adjusting for the assumed one-third current compliance rate in existing establishments, yields a one-time cost for trainer time of \$6 million. Thus, FDA projects total one-time training costs of about \$33.5 million.

In addition, FDA estimates that employee turnover, using the Barents Group suggested rate of 42 percent, will add annually recurring training costs of about \$11.2 million. Also, new employees will receive I.D. check training as part of their initial orientation activities. Since stores may provide this to several new employees at once, using either written or video training materials, FDA estimates that retail managers, on average, would

spend about 1 additional hour per year providing this training. This adds \$6.0 million to the annual training costs. The Barents Group also recommended annual reinforcement training. An annual 10-minute reinforcement training period for employees of those establishments that do not already have a training program will cost about \$2.9 million. In sum, these annual recurring training costs total about \$20 million.

The Barents Group also assumed that retail managers would need extensive training to understand the new regulations. FDA estimated in its 1995 proposal that manufacturers' representatives would need about 8 hours of training on their new responsibilities and the Barents Group assumed that retail managers would need a similar duration of training. FDA rejects this estimate, however, as the final provisions affecting retailers are straight-forward and will be routinely communicated through traditional industry channels.

b. *Manufacturers representatives.* In its preliminary economic analysis, FDA estimated that 7,300 manufacturer representatives would be trained for 8 hours at a cost of \$25.00 per hour. After noting FDA's "undocumented" cost estimate, the Barents Group proceeded to apply the identical number of training hours to their "documented" cost estimate of \$25.70 per hour. They also suggested a 15 percent labor turnover premium, giving a total cost of \$1.5 million. As the final rule eliminates

the monitoring burden for these employees, this training cost should be correspondingly smaller. Nevertheless, these manufacturer employees will still need to determine the types of displays that remain permissible. FDA therefore accepts the \$1.5 million cost estimate.

7. Access Restrictions

a. *Manufacturers.* Although voluntary decreases in the sale of consumer products do not impose long-term net societal costs, mandatory restraints on the access of consumers to desired products may imply economic costs. Economists typically measure producer-related inefficiencies attributable to product bans by calculating lost "producers' surplus," which is a technical term for describing the difference between the amount a producer is paid for each unit of a good and the minimum amount the producer would accept to supply each unit, or the area between the price and supply curve. Data derived from Cummings, et al., indicate that youngsters under the age of 18 consume 316 million packs of cigarettes per year, leading to industry profits of \$118 million.³²⁹ On the assumption that the regulation would reduce teenage smoking by one-half, these profits would fall by about \$59

³²⁹ Cummings, K. M., T. Pechacek, and D. Shopland, "The Illegal Sale of Cigarettes to U.S. Minors: Estimates by State," *American Journal of Public Health*, vol. 84, No. 2, p. 301, February 1994, (derived by subtracting sales to 18-years-olds from the reported 516 million packs consumed).

million. However, because most of this profit stems from illegal sales to youths, FDA has not counted this figure as a societal cost.

b. *Consumers.* Consumer surplus is a concept that represents the amount by which the utility or enjoyment associated with a product exceeds the price charged for the product. Because it reflects the difference between the price the consumer is willing to pay and the actual market price, it is used by economists to measure consumer welfare losses imposed by product bans. However, FDA's rule imposes no access restrictions on adults, who will be free to consume tobacco products if they so desire. Thus, FDA has not included any value for lost consumer surplus in its estimate of the societal costs of these access restrictions.

8. I.D. Checks

a. *Retailers.* For the 1995 proposed regulation, FDA estimated that retail establishments would bear annual compliance costs of \$28 million for consumer identification checks. This figure was derived by multiplying the estimated retail employee compensation rate by the extra time that might be needed to complete purchase transactions. The estimate measured the cost to retailers for either increasing the number of working hours of existing staff or for hiring new staff to handle the added workload. The Barents Group commented on numerous aspects of this compliance cost estimation, accepting several key FDA assumptions, but rejecting others in deriving its estimate of \$142 million per year.

In its preliminary analysis, FDA estimated the number of tobacco product transactions for the 18 to 26 year-old age group based on data that reflected the tobacco consumption of cigarette smokers 5 to 6 years after high school³³⁰ and the annual per capita consumption of smokeless tobacco.³³¹ The Barents Group faulted FDA for limiting these transactions to 18 to 26 year-olds, asserting that the standard practice for alcohol sales is to request identification for anyone who appears to be 30 years old or younger. The Barents Group calculations actually estimated compliance costs on the assumption that customers up to age 34 would be asked for identification, because some

older consumers would appear to be only 30 years old.

FDA has not accepted this Barents Group assumption for several reasons. First, the legal age of purchase for alcohol in all 50 States is 21 years, whereas the rule for cigarettes and smokeless tobacco sets 18 as the legal age of purchase. This 3-year difference implies that comparable cigarette and smokeless identification checks would be expected only up through age 27. Also, the current policy and practice of many retail stores is to request identification from tobacco consumers only up to age 26. Requiring proof of age for anyone who appears younger than 26 years of age was also recommended by a working group of 26 State Attorneys General.³³² Finally, the Barents Group's use of age 34 to provide a margin of safety for identifying those under the age of 30 is illogical, since the FDA rule requires retail stores to identify consumers who are under the age of 26, not 30.

The Barents Group accepted the FDA assumption that an I.D. check would take an average of 10 seconds, but referenced a study by A. T. Kearney that found that the actual time needed to verify a photo I.D. for a tobacco product sale averaged 8.3 seconds. Because FDA has no better data, the agency adopts 8.3 seconds as the average time needed to conduct an I.D. check. The Barents Group further commented that FDA used outdated employee compensation data in its calculations. FDA's revised totals use the Barents Group's employee compensation estimate of \$9.51/hour (1994 dollars) as the time value for retail sales employees.

FDA originally assumed that only 75 percent of all retail transactions for the 18 to 26 year-old age group would be extended due to I.D. checks. The Barents Group argued that the correct percentage should be 100 percent, as the rule would apply to all sales to the relevant age group. FDA continues to believe that this assumption leads to an over-estimate of the probable costs. First, not every moment of a clerk's time is effectively utilized and a few seconds more per transaction will not always result in lost labor productivity. Second, many smokers patronize the same retail store almost daily and are well-known to clerks. I.D. checks for these customers will take little extra time. Finally, many customers will take less time to produce an I.D., once they realize that

identification checks have become routine. Nevertheless, FDA adopts the Barents Group's 100-percent assumption to assure a full accounting of the relevant costs.

One comment claimed that FDA failed to include the cost of hiring additional sales clerks. As noted above, the FDA calculation does reflect the cost of the additional labor time that might be needed. The Barents Group also inexplicably asserts that FDA failed to consider I.D. checking costs as annual costs, instead listing them as a one-time cost. Table 2 of the original analysis (60 FR 41314 at 41360), clearly lists the \$28 million identification check cost as an annual operating cost and the accompanying text (60 FR 41314 at 41367) refers to the figure as a "per year" cost. The Barents Group further faulted FDA for not taking into account the cost of checking I.D.'s for those youths under age 18, who will still attempt to buy cigarettes. While a small percentage of underage smokers may opt for this course of action, few would return to complying outlets. Thus, FDA believes that any plausible estimate of the associated costs would be less than \$1 million annually.

FDA originally estimated the number of tobacco product transactions for the 18 to 26 year-old age group at 2.2 billion, but has updated its estimate to 2.5 billion.³³³ Also, the 80-percent current noncompliance rate that had been assumed for the 1995 proposal may be too high, as the Surgeon General estimated that minors are unable to make an OTC purchase of tobacco products about one-third of the time.³³⁴ Nevertheless, FDA retains this assumption to calculate a cost to

³³³ 1994 Population data for 18 to 26 year-olds from 1995 Statistical Abstract, Table 16. Cigarettes: Number of smokers for age group calculated from Table 217 (1993 data). Average packs/yr. and total packs/yr. for smokers aged 18 to 26 calculated from data in Table 20, 1994 SGR, p. 85. (Those smoking 1 to 5 cigarettes/day assumed to smoke 3, those smoking 20+ cigarettes/day assumed to smoke 25). The resulting number of packs smoked by 18 to 26 yr.-olds totals about 2.5 billion. If even 1 percent of these transactions were for cartons, this number falls to about 2.3 billion. Smokeless: Total units of smokeless products sold calculated from data in *Spit Tobacco and Youth: Additional Analysis*, Dept. of Health and Human Services, June 1993, Excise Tax calculations, Option 4; Units consumed by youths from the Institute of Medicine Report (the IOM Report) "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths", p. 8. 1994, Usage data and total units (cans or pouches) consumed for age group for those aged 18 to 26 from "Use of Smokeless Tobacco Among Adults-U.S., 1991" in "MMWR", CDC, DHHS, volume 42, No. 14, p. 264, 1993. The number of containers sold for 18 to 26 yr. old age group totals about 0.2 billion.

³³⁴ IOM Report, p. 202.

³³⁰ 1994 SGR, p. 85.

³³¹ U.S. Department of Commerce, *Statistical Abstract of the United States 1993*, 113th edition, p. 137, 1993; DHHS, Office of Inspector General, *Spit Tobacco and Youth: Additional Analysis*, June 1993.

³³² "No Sale: Youth Tobacco and Responsible Retailing," Findings and Recommendations of Working Group of State Attorneys General, p. 28, December 1994.

retailers for I.D. checks of \$43 million per year (2.5 billion transactions x 8.3 seconds/transaction x \$9.51/hour ÷ 3600 seconds/hour x 80 percent noncompliance rate). This revised estimate exceeds FDA's original \$28 million figure, but remains far below the \$142 million estimate of the Barents Group.

b. *Consumers.* The Barents Group also criticized FDA for not quantifying the costs to consumers for the extra time needed to undergo I.D. verifications. They estimated this cost at \$282 million a year. FDA agrees that consumers would incur time costs and, for its revised estimates, adopts the analytical framework suggested by the Barents Group, which counts only the time lost by young customers. (The Barents Group suggests that older consumers also would experience delays, but FDA's estimates already account for the cost of additional clerk time that would offset longer checkout lines. Younger customers, however, must wait while their age is verified, even when additional checkout clerks are available.) To estimate the time cost, FDA applies the same methodology that was used to estimate the time cost for retail employees. That is, 2.5 billion transactions taking an extra 8.3 seconds each for the 18 to 26 year-old age group, adjusted for a 20 percent current compliance rate. The Barents Group used an average hourly private sector compensation rate (\$15.13/hour) as the basis of its consumer time cost estimate, but FDA finds this average rate too high for young consumers and estimates a range of \$9 to \$11 per hour.³³⁵ As a result, FDA's estimate of the cost to consumers for lost time cost amounts to between \$41 and \$50 million per year.

9. Vending Machines

In its comments on the costs of FDA's proposed vending machine ban, the Barents Group reports that automatic vending machine operators will lose \$403 million in annual revenues. They then subtract an estimated \$281 million offset for future over-the-counter sales (calculated by assuming an equal number of future packs sold and an \$.80

price premium for vending machine packs) to project a net \$122 million of regulatory costs to the retail sector. Although not acknowledged, this methodology implicitly assumes that a redistribution of revenues (from vending machine owners to over-the-counter sellers) does not generate added societal costs. Elsewhere, the Barents Group includes distributional impacts in cost totals. Nevertheless, even this \$122 million estimate is far too high.

The fundamental problem is that changes in revenue, as discussed above, do not measure economic costs. The relevant economic measure of regulatory costs to an industry is the change in producer surplus that a firm makes from selling a good or service. Because producer surplus' are difficult to measure, accounting profits are sometimes used as a proxy. By examining only lost revenues, the Barents Group ignores the difference in the operating costs of the alternative sales channel, despite its recognition that "[i]n general terms, the extra margin at vending machines reflects the costs to vending machine owners of operating these machines, in addition to a return on their labor effort and capital investments." In other words, the reason that cigarettes purchased from a vending machine are more expensive is that it costs more to sell a pack of cigarettes by vending machine. Consequently, if cigarette sales shift from more expensive-to-operate vending machines to OTC, the loss of industry profits is much smaller than the loss of industry revenues.

An approximate assessment of the net impact on retail profits requires a comparison of the pretax profit margins for vending machine operations as compared to OTC sales. The Barents Group cited survey results from the National Automatic Merchandising Association (NAMA) showing an average pretax profit margin of 3.8 percent in 1993 and 2.0 percent in 1992, for an average 2.9 percent for vending machine operations. Because cigarette vending machine sales have decreased in recent years, current profit margins might be even smaller. Coincidentally,

the Barents Group reports that the estimated average industry profit margin for convenience stores is also 2.9 percent. If this rate applies to cigarette sales at convenience stores and if all lost vending machine cigarette sales were transferred to convenience stores, the net pretax cost to the industry would be \$3.5 million, not \$122 million (\$403 million to \$281 million) x 2.9 percent). Moreover, NAMA reports that over 50 percent of all vending machines are located in bars and taverns and many others in business establishments frequented only by adults. The final rule permits vending machines in those places where the owner can ensure that no young people under age 18 are present at any time. FDA does not know how many vending machines will be moved to restricted areas in compliance with this rule, but the number will further reduce this annual cost.

10. Readership Surveys

The Barents Group reported that 101 leading national magazines had advertisements for tobacco products in 1994. In addition, Barents obtained youth and adult readership data for 1994 from MediaMark Research, Inc. (MediaMark), for 41 of these 101 magazines. Applying the regulatory threshold of 2 million readers or 15 percent of total readership below the age of 18, Barents projected that advertisements in 32 of the 41 magazines (78 percent) would be restricted to "text only" by the proposed regulation. In comparison, FDA examined copyrighted youth and adult readership data from the Simmons Marketing Bureau, Inc. (Simmons), another major marketing research firm, and found that only 13 of the 27 magazines with tobacco ads (48 percent) had youth readership over the threshold. A comparison of youth readership levels from MediaMark and Simmons for magazines that had tobacco advertisements in 1992 is shown in Table 11.³³⁶

³³⁵ Data from the 1995 *Statistical Abstract of the United States*, Table 677 lists weekly earnings for full time wage and salary workers for the group "16 to 24 year-olds" in 1994. Table 682 lists median hourly earnings for workers paid hourly rates for the same group in 1994. Assuming a 40 percent increase for benefits, the compensation rates for these two tables for 16 to 24 year-olds are \$9.98/hour and \$7.87/hour, respectively.

Using these figures will result in a low estimate for the 18 to 26 year-old group because 25 and 26 year-olds earn more than 16 and 17 year-olds.

Conversely, using a benefits/wage ratio of 40 percent for 18 to 26 year-olds will overstate the costs because lower paid workers (hourly and part-time workers, college students) are more likely to have less generous benefits packages (little or none of the following: paid vacation, sick leave, employer-paid health insurance). FDA increased the estimated compensation rates to \$9 to \$11/hour to assure it does not underestimate the true compensation rate.

³³⁶ Tobacco industry spending on magazine advertising was calculated using tobacco

advertising share data from Barents and advertising revenues from *Advertising Age*. Advertising revenue was unavailable for five small publications that accounted for less than one percent of tobacco magazine advertising spending in 1994. To estimate tobacco advertising expenditures in these five publications, FDA assumed total advertising revenues for each publication equal to \$14,388, which is the lowest total revenue reported in *Advertising Age* for 1994.

TABLE 11.—AVAILABLE YOUTH READERSHIP DATA FOR PUBLICATIONS
WITH TOBACCO ADVERTISEMENTS IN 1994

Publications with Youth and Adult Readership Data	Estimated Percentage of 1994 Tobacco Industry Spending on Magazine Advertisements	MediaMark Research Inc. (1994 readership data)		Simmons Market Research Bureau, Inc. (1994 readership data)	
		Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)	Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)
Sports Illustrated ^{1,2}	10.0	5,201	18.0	4,614	17.1
People ^{1,2}	9.8	3,020	7.8	2,465	8.0
TV Guide ^{1,2}	6.5	6,739	13.2	7,102	15.6
Time	4.1	1,972	7.7	n/a	n/a
Parade ²	3.7	n/a	n/a	6,059	6.9
Cosmopolitan ¹	3.1	2,279	12.8	1,410	11.4
Woman's Day	3.0	1,202	4.8	n/a	n/a
Entertainment Weekly ²	2.9	n/a	n/a	674	15.3
Better Homes & Gardens ¹	2.4	2,042	5.5	785	3.4
Newsweek	2.4	1,911	8.0	n/a	n/a
Family Circle	2.1	1,210	4.2	646	3.5
Field & Stream	2.1	1,760	11.1	815	7.9
Glamour ^{1,2}	2.0	2,216	17.1	1,540	17.4
Rolling Stone ^{1,2}	2.0	1,869	18.5	1,506	20.1
Ladies' Home Journal	1.7	838	4.4	n/a	n/a
McCall's	1.7	1,274	6.7	506	3.7
Redbook	1.7	1,153	7.8	565	5.4
Car & Driver ¹	1.6	1,465	18.3	n/a	n/a
Life ¹	1.6	2,665	12.9	n/a	n/a
Popular Mechanics	1.5	1,617	14.5	744	10.3
Outdoor Life ¹	1.3	1,579	18.0	569	8.8
Us	1.2	814	13.8	n/a	n/a
New Woman	1.1	685	14.0	n/a	n/a
Road & Track ¹	1.1	1,234	20.6	n/a	n/a
Soap Opera Digest	1.1	1,299	14.4	853	12.6
Mademoiselle ^{1,2}	1.0	1,369	19.7	959	18.5
Vogue ^{1,2}	1.0	2,237	18.0	1,300	17.4
Hot Rod ¹	0.8	2,295	28.0	n/a	n/a
Ebony ¹	0.7	2,111	15.8	1,046	9.4
Gentlemen's Quarterly ¹	0.7	1,037	15.1	n/a	n/a
Motor Trend ¹	0.7	1,393	22.1	n/a	n/a
Premiere ¹	0.7	617	25.8	n/a	n/a
Sport ^{1,2}	0.7	2,274	33.8	1,132	24.0
Elle ¹	0.6	819	17.8	409	14.4
Essence ¹	0.6	1,251	16.9	537	9.4
Sports Afield	0.6	n/a	n/a	0	0.0
True Story	0.5	740	14.8	n/a	n/a
Jet ¹	0.4	1,724	16.7	1,169	12.2
Popular Science ^{1,2}	0.4	1,906	20.8	874	16.1
Self ¹	0.4	786	16.2	n/a	n/a
Harper's Bazaar ¹	0.3	718	18.2	n/a	n/a
The Sporting News ^{1,2}	0.3	1,394	27.8	666	15.7
Cable Guide ¹	0.2	3,358	22.6	n/a	n/a
Ski ^{1,2}	0.0	827	26.4	584	24.9

¹MediaMark youth readership exceeds regulatory threshold.²Simmons youth readership exceeds regulatory threshold.Source: Barents Group LLC Tables IV-1 and A-2; Simmons Market Research Bureau, Inc.; R. Craig Endicott, "The Ad Age 300," *Advertising Age*, June 19, 1995.

The final regulation requires that specific youth and adult readership data be available for any magazine that displays a tobacco advertisement with color or imagery. Simmons currently conducts interviews with adults in approximately 20,000 households annually and subsequently returns to about 3,000 of these households to interview their youth members. In general, however, marketing research

firms collect data on youth readership only for those magazines commonly read by this age group. Thus, although 78 percent and 48 percent of the magazines in the two youth readership samples described above exceeded the regulatory readership threshold, these sample results likely overestimate the percentage of magazines with current tobacco ads that exceed the threshold.

Simmons now collects adult readership data for about 230 magazines and youth readership for about 65 magazines. Because tobacco manufacturers currently advertise in about 100 magazines, the industry could often add magazines that are currently part of an ongoing adult readership survey to a youth survey, saving approximately 60 percent of the cost of collecting both adult and youth data.

Because FDA does not know how tobacco manufacturers will adapt their marketing strategies to the new regulatory thresholds, it is difficult to predict the number of new readership surveys that may be initiated. It seems likely, however, that tobacco companies will both increase the frequency of advertising in "adult" magazines that already carry tobacco advertisements and find suitable "adult" magazines to replace many of the other magazines.

One plausible scenario is that approximately one-half, or 50, of the magazines with current tobacco ads would not qualify as "adult" publications, because they exceed the youth readership threshold; and that the tobacco industry would choose to advertise in 50 other "adult" publications that do not currently carry tobacco ads. To identify these 50 additional "adult" magazines, the industry might need to collect new youth readership data for up to 100 magazines. In addition, as noted above, of the original 100 magazines with current tobacco advertising, youth readership data is now available for at least 40. Thus, the tobacco industry may initially need to obtain new youth readership data for the remaining 60 magazines. In total, therefore, the tobacco industry might opt to obtain youth readership data for an additional 160 publications in the first year that the rule becomes effective. In subsequent years, this number might fall to about 100 surveys, as the industry would concentrate its survey efforts on publications very likely to qualify.

If a marketing research firm collects youth readership data, the cost may depend on the particular characteristics of the magazines being surveyed. The tobacco industry could choose, however, to hire a survey firm to develop and administer a questionnaire solely to gather readership data for magazines with tobacco advertising. While FDA is uncertain about which approach the industry would take, the agency estimates that such new surveys might cost approximately \$2 million in one-time costs and \$1 million in annual costs, based on an average cost of about \$650 and \$350 per sample household.

11. Records and Reports

Manufacturers will need to comply with device regulations governing submissions of representative labels and advertising, medical device reporting (MDR's), establishment registration and product listing, and current good manufacturing practices (CGMP's).

a. *Labels and advertising.* The rule requires that each manufacturer annually submit to FDA copies of representative samples of labels and advertising. While the agency expects about 1,000 product labels, FDA has no direct evidence on the number of advertisements that will be submitted. An approximate estimate, however, can be derived from the number of advertising samples submitted by the pharmaceutical industry. First, FDA calculated that of the \$6.1 billion in advertising and promotional outlays reported to the FTC by the tobacco industry, only about \$1.2 billion is spent on printed advertisements. (Derived by subtracting categories for "Coupons/Value Added," "Promotional Allowances," "Specialties Items," and "Free Samples" from the total \$6.1 billion).

The pharmaceutical industry spends an estimated 22.5 percent of sales on marketing, of which about one-quarter may be allocated to advertising ethical pharmaceuticals.³³⁷ The approximately \$50 million in annual sales of pharmaceutical manufacturers, therefore, implies a \$2.5 billion annual advertising budget. FDA estimates that it currently receives about 25,000 pieces of pharmaceutical advertising per year. As the pharmaceutical budget is roughly twice the size of the \$1.2 billion tobacco industry figure derived above, the agency might receive half as many documents. Alternatively, reduced promotional activities may prompt an increase in the number of printed advertisements prepared by tobacco companies, although the Barents Group assumed this number would decline. Therefore, FDA projects that it will receive the same number of advertisements for tobacco products as it currently receives for pharmaceutical products, or about 25,000 per year, plus about 1,000 labels.

Estimates of the time burden of these paperwork submissions ranged from 20 minutes (The Barents Group) to 1 hour and estimates of the hourly cost ranged from \$25.00 (Tobacco Institute) to \$45.26 (the Barents Group). Using the high end of both ranges provides an upper bound cost estimate of \$1.2 million. This figure is significantly lower than either the original FDA estimate, or the Barents Group estimate of \$55 to \$57 million, largely because the final rule imposes no specific

paperwork requirements on retail establishments.

b. *MDR's.* The final rule will require MDR's for serious unexpected incidents. FDA assumes that 31 manufacturing companies³³⁸ and 1,365 distributors³³⁹ will bear total one-time costs of \$21,000 and \$231,000, respectively, for establishing and documenting procedures for MDR reporting. These costs include 32 hours of effort per manufacturing firm and 8 hours per distributor. Based on estimates previously developed for the Medical Device User Facility and Manufacturer Reporting Final Rule, these activities were distributed over wage rates averaging \$21.17. Annual costs for MDR reporting requirements are more difficult to predict, because they depend on the number of adverse event reports that will be submitted. FDA projects, however, that followup investigation and reporting of a single event takes about 8 hours of labor and costs about \$218. Thus, if 50 adverse event reports were filed annually, the annual cost would be about \$11,000. In addition, if each manufacturing company submits a single baseline report and annual updates, these costs would be about \$2,100 annually, based on unit costs of \$54 and \$14 per report, respectively. Annual certification is necessary, but is typically a formality in terms of data collection and reporting and is estimated to cost about \$800 for all manufacturers and \$35,000 for all distributors assuming 1 hour of professional and clerical time at \$25.80 per hour.

c. *Registration and listing.* Registration and listing duties are estimated to take 41 manufacturing establishments 2 hours each to prepare at a unit cost of \$42, totaling about \$1,700 per year for the industry.

d. *CGMP's.* The Tobacco Institute asserted that cigarette manufacturers would need substantial time to comply with CGMP's as the industry "would need to adopt major new systems * * * [and] make major changes to their procedures just to accommodate the recordkeeping required." Conversely, the economics study prepared by the Barents Group for the Tobacco Institute showed no additional costs for this requirement. FDA agrees that these costs

³³⁸ 1992 U.S. Census of Manufactures, Industry Series, Tobacco Products, Table 1a. A few U.S. agents designated to represent foreign manufacturers would also need to file forms, but these costs should be minimal.

³³⁹ Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States (unpublished data).

³³⁷ U.S. Congress, Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks and Rewards," OTA-H-522 Washington, DC: U.S. Government Printing Office, pp. 303–304, February 1993.

should be minimal for facilities with good quality assurance programs. Its CGMP's do not specify a specific format, but encompass a wide variety of broad requirements for documenting operating procedures. Contrary to the Tobacco Institute's claim that "even a well-run cigarette manufacturing facility would need to adopt major new systems," CGMP's are, in fact, based on the activities of well-run operations. Moreover, device CGMP's are currently under revision to bring them even closer to ISO 9001, the generally recognized international standard for quality assurance systems. Thus, while FDA has little experience with day-to-day tobacco manufacturing procedures, the agency does not anticipate the need for substantial quality system redesign. Wholesalers and distributors also submitted comments contending that the CGMP's would create added paperwork burdens, but the agency has exempted these sectors from the CGMP requirements.

12. Government Enforcement

FDA estimates of internal costs for administering and enforcing this regulation are extremely uncertain, as they will depend on the working relationships to be established with State tobacco control programs. As a best estimate, however, FDA projects that between 30 to 50 full-time employees (FTE's) will be needed to implement the rule. Fully loaded employee costs vary with the type of employee (e.g., field inspectors versus administrative), but an average of \$100,000 per FTE places the dollar cost at between \$3 and \$5 million per year. SAMHSA has estimated that State

programs will need between \$25 and \$50 million annually to administer and enforce appropriate State operations.

13. Comparison of Benefits to Costs

FDA expects the net societal benefits of the rule to far exceed the regulatory costs. Based on the analysis presented above, the estimated one-time costs of the combined FDA and SAMHSA rules are \$174 to \$187 million and the estimated annual costs are \$149 to \$185 million. Taking the midpoint of the ranges and annualizing the one-time costs at 3 and 7 percent, respectively, yields total annualized costs of \$172 million and \$180 million. In contrast, the agency's best estimate of the monetized regulatory benefits that would follow a 50 percent reduction in underage tobacco use ranges from \$28.1 to \$43.2 billion at a 3 percent discount rate and from \$9.2 to \$10.4 billion at a 7 percent discount rate. Thus, as shown in Table 12, the *net* benefits (benefits minus costs) of a total effectiveness rate of 25 percent range from \$27.9 to \$43 billion at a 3 percent discount rate and from \$9.0 to \$10.2 billion at a 7 percent rate. Table 13 indicates that those figures imply a cost per life-year saved of from \$800 to \$4,700 and a cost per death avoided of from \$11,000 to \$52,000. As noted earlier, these benefits are exclusive of the substantial health improvements expected to result from the reduced consumption of smokeless tobacco.

The substantial differential between these estimated costs and benefits withstands rigorous sensitivity analysis (see Table 12). For example, SAMHSA estimated that its rule would reduce underage tobacco use by from one-third

to one-tenth. The approximate midpoint of that estimate (20 percent) constitutes about 40 percent of the regulatory benefit of reducing underage tobacco use by one-half. If, for illustrative purposes, these results, as well as a proportional fraction of the relevant costs,³⁴⁰ are attributed to SAMHSA, the *incremental* net benefits of the FDA rule still range from \$16.8 to \$25.8 billion at a 3 percent discount rate, and from \$5.4 to \$6.2 billion at a 7 percent discount rate.

Moreover, FDA assumed that reaching the "Healthy People 2000" goal would deter about one-quarter of the 1 million youth under age 18 who currently begin to smoke each year from ever smoking as an adult. Thus, this goal implies a 25 percent overall effectiveness rate. If, however, these rules prevent smoking as an adult for even 5 percent of the teenagers who would otherwise become adult smokers, they would produce estimated annual net benefits of from \$5.4 billion to \$8.5 billion at a 3 percent discount rate and from \$1.7 billion to \$1.9 billion at a 7 percent discount rate. Even if this latter scenario attributed 40 percent of the benefits and relevant costs to SAMHSA, the annual *net* benefits of the FDA rule would still range from \$3.3 billion to \$5.1 billion at a 3 percent discount rate and from \$1.0 billion to \$1.2 billion at a 7-percent discount rate. This last example implies a cost per life-year saved of \$3,500 to \$21,100 and a cost per death avoided of \$47,000 to \$234,246. These figures are well within the range of values for health interventions typically considered cost-effective.

TABLE 12.—NET BENEFITS
(\$ Billions)

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Low	High	Low	High	Low	High	Low	High	Low	High
3%	27.9	43.0	16.7	25.7	11.1	17.1	5.4	8.5	2.6	4.1
7%	9.0	10.2	5.3	6.1	3.5	4.0	1.7	1.9	0.74	0.86
Illustrative Incremental Net Benefits ¹										
3%	16.8	25.8	10.0	15.5	6.7	10.3	3.3	5.1	1.6	2.5
7%	5.4	6.2	3.2	3.7	2.1	2.4	1.0	1.2	0.45	0.53

¹ Attributes 40% of benefits and associated costs to SAMHSA

³⁴⁰ Costs include 100 percent of SAMHSA's state enforcement costs, plus 40 percent of retail training

costs, vending machine costs, and retail and consumer I.D. check costs.

TABLE 13.—COST EFFECTIVENESS

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)	Cost/Life-Year Saved (\$)	Cost/Death Avoided (\$)
3%	815	10,862	1,358	18,103	2,038	27,155	4,075	54,310	8,151	108,621
7%	4,722	52,423	7,870	87,372	11,804	131,059	23,609	262,117	47,218	524,235
Illustrative Incremental Cost-effectiveness ¹										
3%	706	9,413	1,177	15,689	1,766	23,533	3,532	47,067	7,064	94,134
7%	4,220	46,849	7,033	78,082	10,549	117,123	21,098	234,246	42,197	468,492

¹ Attributes 40% of benefits and associated costs to SAMHSA

E. Distributional Effects

These regulations will impose a variety of sector-specific distributional effects. Those sectors affiliated with tobacco and tobacco products will lose sales revenues and these losses will grow over time. Businesses engaged in the provision of tobacco product advertising may also face reduced revenues. Simultaneously, nontobacco-related industries will gain sales, because dollars not spent for tobacco products will be spent on other commodities.

1. Tobacco Manufacturers and Distributors

For its calculation of regulatory benefits, FDA estimates that implementation of the regulations may reduce the cigarette consumption of underage smokers by one-half within 7 years. As discussed earlier in this section, based on data presented in Cummings, et al., FDA finds that teenage smokers under the age of 18 consumed about 316 million packs of cigarettes in 1994. A 50-percent cut in sales would drop the number of packs sold by 158 million. Moreover, FDA has assumed that at least one-half of those 500,000 teenagers who would be deterred from starting to smoke each year would refrain from smoking as adults, decreasing the number of adult smokers by 250,000 per year. Because each adult smoker consumes about 500 packs per year, about 124 million fewer packs would be sold per year.

Thus, achieving the agency's goal would reduce cigarette consumption by 158 million packs in the first year (while only teenagers are affected), 158 million plus 124 million packs in the second year, 158 million plus 2 times 124 million packs in the third year, and so on. Since 1994 cigarette shipments

totaled 36.3 billion packs,³⁴¹ cigarette consumption would fall by about 0.4 percent in the first year, 1.8 percent in the fifth year, and 3.5 percent in the tenth year following implementation. (In fact, these reductions may take even longer, because it may be several years before the 50-percent effectiveness level is achieved, and because young adults smoke fewer packs than older adults).

Hence, annual tobacco revenues will decline slowly over time. The U.S. Bureau of the Census estimates 1994 revenues for cigarette and smokeless tobacco manufacturers at about \$25.9 billion.³⁴² Assuming comparable reductions in smokeless tobacco, these calculations imply that tobacco manufacturer revenues will fall by \$128 million in the first year (0.5 percent), \$501 million in the fifth year (1.9 percent), and \$966 million in the tenth year (3.7 percent). While these reductions are significant, the gradual phasing of the impacts will significantly dissipate any associated economic disruption.

In a 1992 report prepared for the Tobacco Institute, Price Waterhouse estimated that the tobacco manufacturing, warehousing and wholesale trade sectors employed about 107,000 full-time workers.³⁴³ Thus, a constant production-to-employment ratio projects that a 3.7-percent reduction in sales over a 10-year period

would result in the displacement of about 4,000 jobs, or 400 jobs annually among manufacturers, warehousemen, and wholesalers. Alternatively, a University of Virginia study concluded that "the Price Waterhouse study for the Tobacco Institute provides estimates of tobacco's impact that are high compared to other measures."³⁴⁴ That study referenced a recent U.S. Department of Agriculture analysis by Gale that found that manufacturing and wholesale trade activities employ only 83,000 full-time equivalent workers.³⁴⁵ If true, this finding reduces these job loss estimates to about 3,000 jobs, or 300 annually.

The smaller job loss estimate is generally confirmed by a recent study by Warner, et al., who applied a computer simulation model to forecast the regional impact of reductions in tobacco use.³⁴⁶ The authors used "a state-of-the-art macroeconomic model to simulate what would happen if consumers reduced their tobacco expenditures, with the same level of spending redistributed to other goods and services * * *." One scenario assumed that tobacco control activities would reduce the expected rate of tobacco purchases by 2.06 percent per year, or roughly 5 times the estimated effect of the FDA rule. While this scenario does not present direct impacts to the tobacco industry alone, it forecasts job losses after 8 years of 6,401 for all U.S. wholesalers and 5,957 for Southeast Tobacco Region

³⁴¹ "Tobacco Situation and Outlook Report," U.S.D.A., Economic Research Service, p. 4, April 1995.

³⁴² "1994 Annual Survey of Manufactures: Value of Product Shipments," U.S. Department of Commerce, Bureau of the Census, Table 1, p. 210. ASM does not report data below the 5-digit SIC Code Level. FDA assumed chewing tobacco represented the same percentage of SIC Code 2131 (Chewing and Smoking Tobacco) in 1994 as it did in 1992 when it was classified at a 6-digit SIC code in the Census of Manufacturers.

³⁴³ "The Economic Impact of the Tobacco Industry on the United States in 1990," Price Waterhouse, p. ES-3, October 1992.

³⁴⁴ Knapp, J. L., "Tobacco in Virginia," Weldon Cooper Center for Public Service, University of Virginia, p. 5, December 1995.

³⁴⁵ Gale, F., "What Tobacco Farming Means to Local Economies," U.S. Department of Agriculture, Economic Research Service, Agriculture Economic Report Number 694, p. 5, September 1994.

³⁴⁶ Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," JAMA, pp. 1241-1246, April 24, 1996.

manufacturers. Accounting for the multiple of 5, comparable job losses attributable to the FDA rule would total about 2,600 after 8 years, or about 325 annually.

The Barents Group did not address the long-term gradual decline in tobacco use projected by FDA. Nevertheless, it claimed that the agency underestimated the economic impact on industry by failing to account for the lost sales to adults that would result from the proposed ban on vending machines and self-service displays and the required checking of customer I.D.'s. The Barents Group argued that the added consumer inconvenience imposed by these provisions was tantamount to an increase in the effective price of tobacco products, which would rapidly decrease the consumption of tobacco by adults. Relying on "hypothetical scenarios" that assume demand declines of 5 and 10 percent, the Barents Group forecast that the tobacco manufacturing industry would lose from 1,800 to 3,700 jobs due to this increased consumer inconvenience.

FDA believes these Barents projections are substantially overstated. Impacts associated with cigarette consumption declines of 5 to 10 percent cannot possibly be attributed to the loss of vending machines, because vending machine purchases make up less than 1 percent of all cigarette purchases. Further, according to NAMA, there are only 141,000 cigarette vending machines currently in use (and that number is falling rapidly), and the cost analysis prepared by the Barents Group predicted that 100,000 of these machines would be replaced by new OTC establishments. Thus, the Barents Group's own analysis eliminates any added consumer inconvenience from three-quarters of the existing inventory of machines. Moreover, the near-term impact on adult tobacco consumption will be further moderated both because the final rule allows vending machines in "adult" facilities, and because the added inconvenience cost will be partially offset by the lower price of the OTC product. These factors together make it extremely unlikely that fewer vending machines will lead to a substantial near-term fall in tobacco industry sales revenues.

The likelihood that tobacco sales will decline significantly due to inconvenience imposed on adult customers by the self-service restriction is similarly remote. While some purchasers would need more time to complete a transaction, other purchasers would save time by no longer having to

search and retrieve a desired product. In the absence of empirical evidence, the result is indeterminate; but FDA has seen no convincing evidence or arguments to demonstrate that any delays caused by the self-service restriction will significantly curtail adult tobacco use.

Finally, although FDA calculated above that increased delays due to I.D. checking could cost young adult consumers under the age of 26 up to \$50 million per year, even this cost would not lead to significant consumption declines. As described, the increased checkout waiting time for young purchasers was estimated to average about 8.3 seconds, which translates to a cost of about 2.3 cents per transaction, or 1.35 percent of the cost of a pack of cigarettes. According to the Barents Group, representative estimates of demand elasticities for cigarettes range from -0.6 to -1.0. Young adults under the age of 26, however, purchase only about 10 percent of all tobacco products. Thus, the fall in total tobacco sales would be, at most, 0.1 percent, not the 5 to 10 percent assumed by the Barents Group. Moreover, even the 0.1 percent figure is an overestimate, because those consumers irritated by the delay will increase the volume of tobacco products purchased per transaction. As a result, the number of cartons sold will rise, but the decline in tobacco product sales revenues attributable to the inconvenience effects of I.D. checks will be negligible.

2. Tobacco Growers

As explained above, total cigarette and chewing tobacco consumption is expected to decrease by 0.5 percent in the first year, 1.9 percent by the fifth year, and 3.7 percent by the tenth year, following compliance with the regulation. Price Waterhouse estimated that, on a full-time equivalent basis, about 153,000 farmers grew tobacco in 1990. Based on these figures, constant production-to-employment ratios imply employment losses among tobacco growers of about 5,700 after 10 years, or about 570 annually. Alternatively, the Gale study for the U.S. Department of Agriculture (USDA)³⁴⁷ estimated the number of full-time equivalent tobacco farmers to be only 65,400, which would reduce the job loss estimate to about 2,500 by the tenth year, or 250 annually.

This latter figure also closely fits the findings of Warner, et al., who, as

³⁴⁷ Gale, F., "What Tobacco Farming Means to Local Economies," USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 5, September 1994.

described above, used a "state-of-the-art" macroeconomic simulation model to project the employment effects of declining tobacco consumption.³⁴⁸ Assuming domestic tobacco consumption decreases of 2.06 percent per year, Warner, et al. predicted about 7,500 job losses within an 8-year period for "Southeast Tobacco Region" farmers. As this fall in tobacco use is roughly five times that projected by FDA, the analogous job loss estimate would be about 1,500 over the 8-year period, or about 190 per year.

According to the USDA study by Gale, "[f]or most farms, tobacco growing is a part-time, seasonal enterprise, and production per farm is usually small. About two-thirds of tobacco farmers work off-farm."³⁴⁹ Citing 1987 Census of Agriculture data, Gale notes that only 65 percent of the farms growing tobacco in the United States reported earning more than half of their receipts from tobacco, and of those farms, approximately 80 percent had total farm sales under \$20,000. He explains that the availability of alternative land uses will dictate the economic results:

The key factor in adjustment to a smaller tobacco industry is the alternative uses available for land, labor, and capital used in tobacco production * * * For the most part, concern is focused on rural areas where tobacco is grown because this stage of production has the most specialized resources with fewer attractive alternative uses. In many areas, small farms that are unviable without tobacco profits would cease production and their land would be absorbed into larger neighboring farms or converted to other uses * * * In marginal farming areas * * * much of the land devoted to tobacco would be converted to residential, commercial, industrial, or forestry uses, in which case it would still generate income for the local economy * * * This land is already being converted to nonfarm uses in rapidly growing areas like southern Maryland and Raleigh-Durham, North Carolina.³⁵⁰ FDA notes that the economic consequences of these trends will be substantially mitigated by the very moderate pace of the projected changes.

3. Vending Machine Operators

The final regulation prohibits all vending machine sales of regulated tobacco products except for those machines located in a facility where

³⁴⁸ Warner, K. E., G. A. Fulton, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, pp. 1241-1246, April 24, 1996.

³⁴⁹ Gale, F., "What Tobacco Farming Means to Local Economies," USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 1, September 1994.

³⁵⁰ *Id.*, p. iii.

persons under the age of 18 are not present at any time. In recent years, cigarette vending sales have dropped precipitously, due to numerous restrictive State and local ordinances. According to the NAMA:

[t]he 1986 cigarette location survey mirrored an industry with about 700,000 cigarette vending machines on location. In 1994, the vending industry was estimated to have between 141,000 and 400,000 cigarette machines. This represents a decline in the number of cigarette vending machines on location of between 43 percent and 80 percent.

The U.S. Department of Commerce³⁵¹ reports that 1992 sales of tobacco products by automatic merchandising machine operators were about \$452 million, or 7.1 percent of that sector's total sales, but a NAMA fact sheet shows this rate continuing to fall, dropping from 8.5 percent in 1990 to 2.7 percent in 1994. One trade magazine explains that, "[c]igarette vending, once an industry mainstay, is now a niche

business increasingly conducted by specialized enterprises."³⁵²

Referring to 1992 Census data, NAMA declared that over 3,000 vending machine operators supply cigarettes, not including the bars, restaurants, hotels, and bowling alleys that own their own machines. On average, these mostly small firms receive 10 percent of their revenues from cigarette sales, although some firms are even more dependent. While some vending machines can be converted to sell other products, one large cigarette machine manufacturer maintained that more than 85 percent of the existing machines can be converted only for new products with packaging similar in dimension and form to cigarette packages.

While vending operators will need to develop new markets to replace the already dwindling sales revenues from cigarette vending machines, the overall economic impact will be mitigated somewhat by FDA's decision to exempt "adult only" locations from the ban. According to a 1995 NAMA survey, 58

percent of cigarette vending machines are located in bars and cocktail lounges, 11 percent in factory/plant locations, and 3 percent in business offices.³⁵³ Those locations that do not permit the entry of youngsters under the age of 18 will be exempted from the cigarette vending machine restriction.

4. Advertising Sector

In annual reports to FTC, manufacturers of cigarettes and smokeless tobacco reported 1993 advertising and promotional/marketing expenditures of \$6.0 billion and \$119 million, respectively (see Table 14). About \$2.6 billion (43 percent) of these outlays went to consumers as financial incentives to induce further sales (e.g., coupons, cents-off, buy-one-get one free, free samples), and \$1.6 billion (26 percent) to retailers to enhance the sale of their product. The remaining \$1.9 billion (31 percent) were related to consumer advertising activities that will be significantly modified by the "text only" restrictions.

TABLE 14.—TOBACCO ADVERTISING/PROMOTIONAL EXPENDITURES
1993 (Millions of Dollars)¹

Promotion Type	Cigarettes	Smokeless	Total
Coupons/Value Added	2,559	32	2,591
Promotional Allowances	1,558	13	1,571
Point of Sale	401	13	414
Specialties Items	756	4	760
Outdoor	231	1	232
Magazines	235	7	242
Public Entertainment	84	23	107
Free Samples	40	16	56
Transit	39	0	39
Newspapers	36	1	37
Direct Mail	31	1	32
Endorsements	0	0	0
All Others	64	7	71
Total	6,035	119	6,154

¹ Totals may not add due to rounding.
Source: U.S. Federal Trade Commission

FDA cannot project the ultimate industry response to these advertising restrictions. On the one hand, the effectiveness of many advertisements will fall. On the other hand, many alternative marketing promotional activities will be prohibited or constrained even more stringently, raising the relative desirability of the remaining advertising options. Moreover, as described above, FDA may

require new informational programs that would generate a substantial increase in advertising industry revenues. Nevertheless, if tobacco outlays fall, there will be short-term dislocations as industry resources are redirected to other uses. One firm that depends heavily on tobacco advertising warned of severe economic burdens, pointing to income and job losses for many of its employees and suppliers. Most

advertising suppliers, however, are not overly specialized with respect to particular consumer products and would redirect resources to other advertising purchasers, albeit at some revenue loss. While FDA is aware that such demand shifts cause short-term disruption, the U.S. economy creates and discards thousands of products each day. For most advertising media, the ability to respond rapidly to

³⁵¹ U.S. Department of Commerce, "Merchandise Line Sales," 1992 Census of Retail Trade, RC92-S-3RV, pp. 3-27, 3-31.

³⁵² Vending Times, Census of the Industry Issue, p. 36-D, 1995.

³⁵³ National Automatic Merchandising Association, Cigarette Vending Machine Location Study, conducted August 31, 1995.

changing markets is a mainstay of economic survival.

a. *Print media.* The final regulation requires that advertising of cigarettes or smokeless tobacco be restricted to black text on a white background in those publications where youthful readers constitute more than 15 percent of total readership or number more than 2 million. FDA cannot reasonably forecast the future marketing strategies of tobacco manufacturers, but foresees a possible fall in the \$242 million worth of magazine advertising and the \$37 million worth of newspaper advertising that tobacco manufacturers reported to the FTC in 1993. These advertising revenues comprised about 1.1 percent and 0.1 percent of the 1992 value of shipments for periodicals and newspapers, respectively.³⁵⁴ The Barents Group identified 32 leading magazines with tobacco advertising in 1994 that have youth readership levels exceeding the regulatory threshold and found that these publications received, on average, 7.3 percent of their total advertising revenues from tobacco in 1994. They also predicted, based on the sharp downward trend of these advertising outlays, a 21-percent drop in magazine advertising and a 45-percent drop in newspaper advertising for tobacco products by 1996, irrespective of the FDA regulation.

The impact of these restrictions on the various advertising media and agencies is difficult to determine. The Barents Group contended that FDA had argued in its original analysis that "regulations for print media will have little or no adverse impact." In fact, FDA made no such projection, although the agency did present several historical examples of advertising bans (e.g., the broadcast ban on tobacco products) where advertising revenues rebounded in spite of new legal restrictions. The Barents Group also faulted FDA for not comparing actual revenues after the broadcast ban to revenues "that *would have* been expected in the absence of the ban." FDA, however, does not believe that this "counterfactual" logic for estimating costs precludes the agency from suggesting that income and employment would not necessarily fall in the wake of new advertising restrictions.

Several comments declared that advertising outlays would fall sharply and subscription prices rise. According to the Barents Group, imagery is a prerequisite for effective promotion and,

in its absence, magazine and newspaper advertising revenues would fall by 25 to 75 percent. It also predicted that the reduced revenues would, in turn, force publication subscription prices to rise.

FDA agrees that there will be adverse impacts on certain publications, but notes that the tobacco industry is currently shifting its advertising budget away from print media and that only 6 of the 32 affected magazines identified by the Barents Group received over 10 percent of their revenues from tobacco products. Moreover, as noted earlier, while FDA cannot project the tobacco industry's marketing strategies, the agency suggests that restricted promotion alternatives could reestablish print advertising as a relatively attractive option for conveying product information to adult readers; thereby slowing or even reversing the recent slide in this type of tobacco advertising.

The Barents Group also asserted that the commercial printing industry, as well as other industry sectors, would be harmed by restrictions on coupons and "retail value added" promotions. These expenditures, which account for \$2.6 billion, or 42 percent of the total tobacco advertising and promotional outlays reported to FTC in 1993, include outlays associated with cents-off coupons and multiple pack promotions, such as "buy one, get one free" or "buy two, get one free;" as well as other give-away promotions, such as "buy cigarettes and get a free promotional item." The former activity will be permitted but the latter prohibited under the final regulation. Although a comment submitted by the Tobacco Institute noted that, "[a]nalytically, such spending is more akin to a price cut than to advertising,"³⁵⁵ the Barents Group, nonetheless, concluded that, "[a] considerable part of this spending would likely be eliminated by the proposed regulations." FDA, however, does not agree that the printing industry will be significantly affected by changes in "coupons and value added" outlays. Cents-off coupons and multiple pack promotions are the principal components of these promotions and will continue to be available under the final rule.

b. *Advertising agencies and other suppliers.* Advertising agency revenues are directly tied to the level of advertising expenditures by product manufacturers. If tobacco manufacturers reduce advertising outlays, these agencies will lose income. The Barents

Group found that, in 1993, tobacco companies routed almost \$1 billion through ad agencies (less than 1 percent of the reported \$131.3 billion spent on U.S. media advertising in 1992).³⁵⁶ Assuming agency fees of 10 percent (while overlooking the proposed \$150 million educational campaign), it suggested that advertising declines of 25 to 75 percent would decrease agency annual revenues by \$25 million to \$77 million. Assuming a 50 percent drop (\$140 million) in magazine and newspaper advertising, the Barents Group next applied a simulation model to predict that supplier firms among advertising agencies, government, business and professional services, and commercial printers businesses would lose revenues of from \$12 to \$23 million. While acknowledging that, " * * * there will be eventual offsetting revenue gains in other industries not shown * * *," these other sectors were not identified and the offsetting revenues not explicitly quantified. The Barents Group correctly noted that the adjustments will involve short-term costs to the affected sectors, but did not estimate the expected magnitude of these adjustment costs.

c. *Outdoor advertising industry and public transit authorities.* The final rule restricts tobacco billboards and public transit advertising to black text on a white background and bans all stationary outdoor tobacco ads within a 1,000-foot radius of any school or public playground. The Barents Group predicted that almost all urban areas would be covered by the ban and expected almost no new outdoor tobacco advertising "even in permitted areas due to the relative ineffectiveness of black-and-white text as an advertising medium." Further, explaining that the \$232 million spent on outdoor advertising in 1993 accounts for about 14 percent of all outdoor advertising in the United States, the Barents Group found it unlikely that the industry could find new means of maintaining its current revenues.

In fact, the billboard industry and public transit districts will have to find replacements irrespective of this regulation. According to the Barents Group projections, spending on outdoor advertising by tobacco companies will fall by almost 40 percent between 1988 and 1996 (Appendix Table). One billboard trade source notes that, "almost 60 percent of the industry's 1979 revenues were derived from

³⁵⁴ Statistical Abstract of the United States, p. 750, 1995.

³⁵⁵ Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," vol. 44, p. 13, 1993.

³⁵⁶ Endicott, R. C., "Top Advertisers Rebound, Spending to \$36 Billion," *Advertising Age*, vol. 64, No. 41, p. 1, September 29, 1993.

tobacco and alcohol advertisers. Today that number is down to 13 percent, replaced by retail, business and consumer services, entertainment, and travel advertisers.”³⁵⁷ Similarly, FDA’s preliminary economic analysis had recognized that Canada’s billboard industry had rapidly adjusted to a recently imposed advertising ban and “quickly replaced \$20 million in lost cigarette revenues with ads for food, soap, toothpaste and beer.”³⁵⁸

In 1993, tobacco industry spending on public transit ads (\$39.1 million) contributed less than 1 percent to total public transit revenues, having declined by 35 percent from 1990 to 1993. Acknowledging that these expenditures would continue to fall, irrespective of this rule, the Barents Group argued that since relatively few transit authorities accept tobacco ads, the impact of the regulation would be significant for those few.

d. *Specialty item suppliers.* The prohibition of nontobacco specialty items bearing the name or logo of tobacco products will affect a substantial number of specialty manufacturers. In earlier comments to FTC,³⁵⁹ the Specialty Advertising Association International noted that it “represents 4,400 firms that manufacture or sell utilitarian objects imprinted with advertising * * * predominantly small businesses.” It is likely that some of these firms would, at least initially, lose part of this \$760 million market and would experience short-term costs while exploring other business options.

The Barents Group projected that manufacturer outlays for these promotional items, in the absence of the FDA rule, would triple between 1993 and 1996, rising from \$760 million to \$2.2 billion, assumed that the rule would cause revenue decreases of 25 to 75 percent, and modeled the impacts among other affected industry sectors (e.g., miscellaneous manufacturers producing matches and matchbooks, cigarette lighters, pens and pencils, sporting goods, etc.). The revenue and employment losses, therefore, were measured from a baseline that assumed a tripling of future industry revenues. While these growth projections may be optimistic, they demonstrate the rapid swings that typify the market for many

of these industries. Indeed, the Barents Group’s forecasts imply that even if the FDA rule were to reduce the 1996 level of tobacco industry advertising on specialty items by 50 percent, these outlays would still exceed the 1995 level.

In any case, FDA believes that the Barents Group’s forecasted impacts may be overestimated, as they primarily reflect static outcomes, whereas firms supplying such products are constantly adjusting production in response to rapidly shifting patterns of demand. While these regulatory changes will impose short-term dislocation costs, these costs will be significantly mitigated in view of the extensive lead time provided. Again, the Barents Group noted that FDA had not quantified these transitory costs, but it also provided no estimate.

e. *Sponsorship recipients.* According to reports submitted to FTC, U.S. tobacco companies spent \$107 million on public entertainment, primarily sporting events, in 1993.³⁶⁰ In comparison, total spending on corporate sponsorships for sports, arts, and other entertainment by all North American companies is estimated to reach \$5.4 billion in 1996.³⁶¹ FDA received numerous public comments asserting that the loss of sponsorship revenues for sporting events would increase ticket prices and, in turn, reduce spectator attendance. In particular, comments pointed to the potential loss of jobs, employee benefits, and business revenues associated with race track events.

The Barents Group contended that a substantial part of the payments made by tobacco manufacturers would be eliminated by a ban on tobacco brand sponsorships, because few sponsors would agree to continue sponsorships under corporate names. Acknowledging the lack of reliable information on economic impacts; it, nonetheless, referenced several studies showing that lost sponsorship dollars decrease revenues and temporary jobs for local economies. The Barents Group predicted that, as tobacco companies eliminate payments, other advertisers would replace the major sponsorships, but leave reduced or no funding for the less popular events. On this basis, it

projected a 25 to 75 percent reduction in sponsorship dollars, calculated to result in revenue losses of \$27 to \$80 million.

Among the affected U.S. sporting events, the auto racing industry receives the greatest amount of tobacco sponsorship revenues. The Barents Group relied on various editions of the *IEG Intelligence Reports* (IEG) to list these sponsorships. In reviewing the IEG data and other sources, FDA found that about \$29 million worth of 1995 tobacco sponsorship revenues were designated for the National Association for Stock Car Auto Racing (NASCAR);³⁶² which amounted to about 8.3 percent of estimated NASCAR sponsorship revenues³⁶³ and about 1.4 percent of estimated NASCAR total revenues.³⁶⁴ The IEG data listed Indy Car tobacco sponsorships totaling only about \$13 million, although these data did not cover all events.

As the majority of the NASCAR tobacco sponsorship revenues were directed to the Winston Cup or other lead series, FDA agrees that a major effect of the ban will be to decrease the price of sponsorships, permitting smaller sponsors to “trade up” to the more prestigious sponsorships left vacant by tobacco companies. Although new company sponsors will be attracted by the lower overall sponsorship costs, this “ripple effect” will impose shortfalls for some smaller or lower profile events. This economic impact will be somewhat mitigated, however, by the rapid growth in nontobacco sponsorships. According to IEG estimates, over the past year, motorsport sponsorship spending rose by about 17 percent³⁶⁵ and total North American corporate sponsorship spending by about 15 percent.³⁶⁶

³⁶² 1995 IEG Intelligence Report lists \$26.7 million in tobacco sponsorships of NASCAR. Two tobacco-sponsored events did not list the sponsorship fees, which FDA estimates at about \$1 million apiece.

³⁶³ Koenig, B., “NASCAR takes Lead in Race for Sponsors: Stock-car Racing Gains Corporate Funds as CART and IRL Lag in Money and Ratings”, *The Indianapolis Star*, March 8, 1996, *Business* p. F01.; MacCrae, M., “Ricky Craven Collectibles Boost Intensive Fan Interest in Driver”, *Bangor Daily News*, May 2, 1996.

³⁶⁴ Oliver, S., “A Fan-Friendly Sport,” *Forbes*, p. 70, July 3, 1995; Horovitz, B., “Fine-Tuning an Image-New Sponsors Race to NASCAR,” *USA Today*, Final Edition, p. 1B, April 5, 1996.

³⁶⁵ MacCrae, M., “Ricky Craven Collectibles Boost Intensive Fan Interest in Driver,” *Bangor Daily News*, May 2, 1996.

³⁶⁶ IEG’s *Complete Guide to Sponsorship*, p. 3, 1995.

³⁵⁷ Burns, K., “Driving Into the Future with New Technology,” *Outdoor Advertising Magazine*, p. 5, January/February 1995.

³⁵⁸ Wolfson, A., “Canada’s Ad Ban Puts Cigarettes Out of Sight,” *The Courier-Journal*, pp. A1, A4, August 1, 1994.

³⁵⁹ 56 FR 11661 (March 20, 1991).

³⁶⁰ Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, p. 18, 1995; Federal Trade Commission Report to Congress: Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986, p. 24, 1995.

³⁶¹ EPM Communications, Inc. “Entertainment Marketing Letter,” February 1, 1996. Based on IEG Sponsorship Report.

5. Retail Sector

In addition to incurring the economic costs described earlier, certain segments of the retail industry will experience adverse distributional impacts to the extent that they receive smaller promotional allowances (slotting fees) from manufacturers. In 1993, industry promotional allowances totaled \$1.6 billion dollars. According to FTC:

Promotional allowances are designed to encourage wholesalers and retailers to stock and promote a company's products, including such things as trade allowances and slotting allowances. Trade allowances provide deals to cigarette wholesalers, dealers and merchants in the form of free goods or price reductions in return for the purchase of specific quantities of goods. Slotting allowances include fees that the cigarette manufacturers pay retailers to encourage them to carry a new product or to allocate premium shelf space to a product. Trade contests and incentives, training programs, and trade shows may also be counted as promotional allowances. One major convenience store association, estimating that its members currently receive about \$5,000 per store, remarked that convenience stores would "bear a disproportionate burden should such allowances be eliminated as a result of the ban on self-service displays." Other retailers expressed similar concerns over the prohibition of self-service displays and promotional advertising, fearing it would lead to the elimination of these revenues.

The Barents Group argued that there were strong reasons to believe that promotional allowances would fall sharply as "tobacco products are withdrawn to inaccessible areas of the store, [and] the products taking their place will offer lower allowances." While acknowledging that, "[t]he possibility of promotional payments continuing may depend on whether the proposed regulations would allow the tobacco packages and cartons to be displayed from behind the check-out counter or from some other secured location in the stores," they nonetheless presented "illustrative" revenue reductions of from 25 to 50 percent and projected total revenue losses to the retail sector of \$556 to \$1,112 million. Using the higher percentage, their analysis implies that pretax profit margins would fall 12.4 percent for the average sized convenience store and even more for smaller stores. Moreover, they predicted that about 2 percent of currently profitable convenience stores would thereafter incur losses.

FDA suspects that many of these concerns are unwarranted as tobacco manufacturers will continue to place

significant value on having their products situated in highly visible locations. Although desirable locations behind counters or in locked display cases will be more limited, there is little reason to believe that manufacturers would stop competing for the best display space available. One comment indicated that following a self-service ban in a local area of Northern California, some retailers:

* * * reported losses of tobacco industry-paid slotting fees * * * because of the removal of self-service promotional tobacco displays, racks and kiosks; * * * other retailers reported they did not lose [sic] tobacco industry-paid slotting fees if tobacco displays, racks or kiosks are relocated behind the counter or if they are replaced by locking cases * * * [There were] no reported losses of other tobacco industry-paid advertising fees, promotional allowances or other financial incentives paid to retailers for advertising, promoting and marketing tobacco products in their stores.³⁶⁷ Because of the regional aspects of this ban, it was a "worst case" situation for retail stores. If self-service displays were a prerequisite for promotional allowances, tobacco manufacturers would have quickly transferred them to other near-by localities, where self-service was permitted. The fact that this did not generally occur demonstrates that factors other than self-service displays can support manufacturer promotional payments to retailers.

Another comment noted that, "[i]n at least some areas, cigarette companies have continued payments to retailers for favored display space. For instance, Philip Morris has provided clear, plastic cases for the display of cigarette packs and cartons in some stores. These cases are placed on a checkout counter but only accessed from the clerk's side. This arrangement permits prominent display of cigarette packs to customers who are thereby offered cigarettes at close range while being unable to pick up packs or cartons themselves." In discussing the effects of the Canadian advertising ban, a Canadian study³⁶⁸ suggested that, "[i]n the absence of advertising and promotion outlets * * * the cigarette industry may be expected to provide greater incentives to retailers to provide

more and better shelf space for their brands in order to provide availability to the buyer in the store." Moreover, because FDA has not banned all point-of-purchase tobacco advertising, "text only" advertising at retail stores will be extremely important to tobacco product marketers.

In addition, alternative opportunities for point of purchase (POP) advertising have climbed briskly, as POP experts "cite in-store advertising as the fastest growing segment of the media industry."³⁶⁹ That same Northern California study expressly noted the "[r]eplacement of self-service tobacco displays, racks and kiosks with * * * non-tobacco products such as candy, gum and soft drinks for which the retailer receives slotting fees from the manufacturers of these products."³⁷⁰

In sum, FDA cannot predict with certainty the direction of future payments by product manufacturers to retailers. The agency points out, however, that this rule would affect neither the trade allowances that are commonly paid to both wholesalers and retailers, nor the slotting allowances paid to retailers to encourage them to carry a new product or to assure the availability of a particular brand in a retail outlet. Further, while many current promotional activities will be prohibited, a substantial number will remain available. As the competitive pressures that drive promotional allowances are unlikely to abate, manufacturers will continue to compete vigorously through programs involving both "text only" promotions and select product placements.

6. Other Private Sectors

FDA is aware of several recent studies that address the contribution of tobacco to the U.S. economy; or alternatively, the losses to the U.S. economy that would follow a decline in tobacco-related expenditures. The Tobacco Institute's Price Waterhouse report³⁷¹ purports to measure the induced effect on the national economy of spending by the tobacco core and supplier sector employees and their families. That

³⁶⁹ "P-O-P Scores with Marketers," *Advertising Age*, p. 2, September 26, 1994.

³⁷⁰ Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Program (STAMP), Petaluma, CA, pp. 2-3, November 3, 1994.

³⁷¹ "The Economic Impact of the Tobacco Industry on the United States in 1990," Price Waterhouse, October 1992.

³⁶⁷ Kropp, R., "A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales," North Bay Health Resources Center, Stop Tobacco Access for Minors Program (STAMP), Petaluma, CA, pp. 2-3, November 3, 1994.

³⁶⁸ "When Packages Can't Speak: Possible impacts of plain and generic packaging of tobacco products," Expert Panel Report, Prepared at the request of Health Canada, p. 140, March 1995.

report concluded that the induced or multiplier effects support 2.4 jobs for every 1 job in the core and supplier sectors combined, and over \$3 in compensation for every \$1 in the other two sectors. However, a review of that report, by Arthur Andersen Economic Consulting, explained that such multipliers lead to "massive and unrealistic estimates."³⁷² That review further emphasized that "money now being spent on tobacco would not disappear if demand for tobacco were to fall," though the Price Waterhouse report implicitly made that assumption. The Arthur Andersen review concluded that these multipliers "provide no basis by themselves for predicting how many jobs would be lost by a reduction in tobacco spending." FDA strongly supports this latter view.

The American Economics Group (AEG), in a new study submitted by the Tobacco Institute, employed a national input-output model to project broad sectoral and regional estimates of "the induced impact of the FDA proposed regulations nationwide." Applying the low and high illustrative costs estimated by the Barents Group, AEG predicted job losses of between 32,000 and 92,500. In addition to the printing and publishing industries, significant employment cutbacks were found for food, apparel and textiles, paper, metals, motor vehicles, and other miscellaneous manufacturers.

FDA is skeptical of the results of this AEG study. First, the input-output methodology employs an inherently static approach for estimating economic impacts. Indeed, the Barents Group, in its second report for the Tobacco Institute, explained that input-output models will not capture changing economic conditions, because they fail to account for changing market prices. Thus, "the input-output approach fails to measure the effects of reallocating displaced workers and resources to other parts of the economy." Furthermore, the AEG study suffers from the same fundamental problem as the earlier Price Waterhouse analysis: It assumes that all reduced industry revenues are lost to the economy. This methodology is simply inappropriate. Finally, the AEG study is based upon the illustrative cost estimates of the Barents Group. As described in detail above, these cost estimates are unreasonably high. Although some

tobacco advertising may decrease, a significant portion will be redirected towards the remaining permissible promotional activities.

In a second report, the Barents Group presented the results of using its own cost estimates in a general equilibrium model to simulate the impacts of the estimated reductions in advertising and promotional spending on revenue and employment for 56 sectors of the U.S. economy. This model predicted 21,000 to 44,000 U.S. job losses, largely among wholesale and retail businesses, but also within advertising, printing, apparel and miscellaneous manufacturing industries. FDA finds, however, that this study also is subject to several serious deficiencies. In particular, the Barents Group relies on its own illustrative cost estimates as model inputs. As noted above, FDA believes these estimates are far too high. Next, the study focuses solely on those industry sectors predicted to lose jobs, while ignoring those sectors expected to gain jobs. In fact, the study explicitly acknowledges that the underlying model assumes that:

the aggregate level of employment is not changed in the long run as a result of implementing the new regulations. In other words, though particular jobs in particular industries are expected to disappear permanently, the number of man-hours worked per year in the economy as a whole is assumed not to change in the long run
* * *

The Barents Group selectively shows changes in revenue and employment for the losers only.

Other analysts concluded that such models should not be used to assess longer term national economic impacts, because resources diverted from one use would be reallocated to the production of other goods and services. As one economist explained "[i]f the focus is longer term, involving a period of, say, more than 2 years, then the induced effect should not be included in the measure because money not spent in one industry would find another outlet with equal (undistinguishable) induced effects."³⁷³

Some comments addressed regional issues, pointing to the importance of tobacco products to the economies of several states. Comments noted, for example, that about 177,000 North Carolinians were employed by tobacco and that Price Waterhouse estimated that the economic activity of these

workers supported total State employment of 260,000. FDA is aware that tobacco growing states will experience some adverse economic effects. Nevertheless, as discussed above, the agency finds that the income and employment impacts associated with reduced tobacco consumption will be extremely gradual. Moreover, reduced tobacco consumption will minimally affect or even boost the economies of nontobacco states. For example, a recent economic simulation of the regional impacts of spending on tobacco products by Warner, et al., found that after 8 years, a 2 percent per year fall in tobacco consumption (which substantially exceeds the FDA forecast for this regulation) would cause the loss of 36,600 jobs for the Southeast Tobacco region of the United States (0.2 percent of regional employment); whereas the nontobacco regions of the United States would gain 56,300 jobs.³⁷⁴ That study concluded that "[t]he primary concern about tobacco should be the enormity of its toll on health and not its impact on employment."

7. Excise Tax Revenues

The rule will decrease State and Federal tobacco tax revenues as fewer youths will become addicted to tobacco products. These excise tax losses will increase as more youths become nonsmoking adults. According to the Tobacco Institute, State cigarette excise taxes totaled \$6.2 billion for the year ending June 30, 1993.³⁷⁵ As State excise taxes on other tobacco products (including smokeless tobacco) are reported at \$226 million, FDA assumes that the value of all State excise taxes affected by this regulation is about \$6.4 billion annually. Federal excise taxes on cigarettes totaled \$5.5 billion for the year ending June 30, 1993. Federal excise taxes on smokeless tobacco are expected to be about \$27 million, according to the Smokeless Tobacco Council. As described above, FDA estimates that compliance will reduce tobacco product sales by a gradually increasing rate over time; tobacco sales will fall by 0.5 percent in the 1st year, 1.9 percent in the 5th year, and 3.7 percent in the 10th year. Thus, the rule will decrease State excise taxes on affected tobacco products by from \$30 million in the 1st year to \$231 million in the 10th year and Federal tobacco

³⁷² "A Review of the Price Waterhouse Economic Impact Report and Tobacco Institute Estimates of 'Economic Losses from Increasing the Federal Excise Tax,'" Arthur Andersen Economic Consulting, p. 93, October 6, 1993.

³⁷³ Gray, H. P., and I. Walter, "The Economic Contribution of the Tobacco Industry," in *Smoking and Society: Toward a More Balanced Assessment*, edited by R. D. Tollison, Lexington Books, p. 248, 1986.

³⁷⁴ Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, April 24, 1996.

³⁷⁵ The Tobacco Institute, "The Tax Burden on Tobacco," vol. 28, p. 4, 1993.

taxes by from \$25 million in the 1st year to \$196 million in the 10th year.

Since tobacco taxes represented less than 1 percent of total revenues on both the State and Federal level in 1992,³⁷⁶ even the estimated tenth year impact measures only 0.03 percent of all State tax revenues and less than 0.02 percent of all Federal revenues. Nonetheless, if necessary, governments could raise tobacco product excise rates to offset these revenue losses. A full evaluation of the fiscal consequences, however, would involve a variety of public health ramifications. For example, State Medicaid programs will benefit from reduced tobacco-related medical care expenditures, but will need to finance additional nursing home expenditures associated with increased life expectancy.

F. Small Business Impacts

The Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis if a rule will have a significant economic impact on a substantial number of small entities. Analyses in this section, as well as in other sections of this preamble, constitute the agency's compliance with this requirement. According to the Regulatory Flexibility Act, the final regulatory flexibility analysis must contain "a succinct statement of the need for, and objectives of, the rule." Section XV.B. of this document explains that the need for action stems from the enormous toll on the public health that is directly attributable to the consumption of tobacco by children and adolescents under the age of 18. As described, the primary objective of the regulation is to achieve the "Healthy People 2000" goal of reducing by one-half the number of youngsters who use tobacco.

The final regulatory flexibility analysis must also provide "a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a

summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments." The analyses presented previously in this section addressed the first two of these elements.

With respect to the changes made in the proposed rule as a result of public comments, the agency has reconsidered several of its earlier decisions, at least partly due to their projected effect on small businesses. The preamble above describes these changes and presents the agency's rationale for each modification. For example, the proposed regulation banned all vending machine sales of tobacco products. In response to public comment, the final regulation exempts from the ban those vending machines in "adult only" locations. FDA does not know how many small businesses will be able to take advantage of this exemption, but it will maintain at least one line of sales for small vending machine operators without jeopardizing the protection of young people.

In addition, the proposed regulation prohibited direct mail-order sales of tobacco products. The public comments, however, indicated that many adults, especially those who are elderly or who have limited mobility, would be substantially inconvenienced and several small businesses would be adversely affected by this ban. Even more importantly, studies suggest that teenagers purchase cigarettes from vending machines or retail merchants rather than from nonretail channels. FDA took these considerations into account and the final regulation does not prohibit mail-order sales of cigarettes.

The final regulatory flexibility analysis must also include "a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available." U.S. Census data for 1993 indicate that most

cigarette manufacturers are large businesses, with only 4 employing fewer than 500 employees.³⁷⁷ The small business size standard established by the U.S. Small Business Administration (SBA) for this industry is 1,000 employees.³⁷⁸ The Federal Trade Commission (FTC) provided a list of 52 cigarette importers and small cigarette manufacturers filing plans with that agency, but could not distinguish manufacturers from importers.³⁷⁹ The 1993 Census data show that 14 of the 20 firms manufacturing chewing and smoking tobacco employ fewer than 500 employees, the SBA size standard for this sector.³⁸⁰ Also, most of the nation's 124,000 tobacco farms are small; almost 99 percent of the farms growing tobacco in 1992 had total farm sales under the SBA small business size standard of \$500,000, and almost 91 percent had total farm sales under \$50,000.³⁸¹ Further, 1993 Census data show that 1,332 of 1,365 tobacco wholesale trade firms (98 percent) employ fewer than the 100-employee threshold that constitutes a small business according to the SBA.³⁸² As noted above, the effect of the regulation on tobacco manufacturing, growing, and wholesale trade operations will be very gradual, taking over 10 years to reach a 4 percent reduction.

The regulation will affect numerous retail establishments, including food stores, small general merchandise stores, small tobacco stores and small gasoline stations. Table 15 displays the relative share of the tobacco market for the major types of tobacco-dispensing outlets with payroll in 1992. As shown, food stores and service stations received about 75 percent of all tobacco sales revenue and tobacco products comprised 5 to 7 percent of the total sales of many of these establishments. Table 16 indicates that the great majority of all retail outlets in these sectors are small businesses.

³⁷⁶ U.S. Department of Commerce, *Statistical Abstract of the United States 1994*, 114th edition, No. 464, p. 298, 1994.

³⁷⁷ Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 68.

³⁷⁸ U.S. Small Business Administration, "Table of Size Standards," March 1, 1996.

³⁷⁹ Federal Trade Commission, "Cigarette Importers and Small Manufacturers Plans Filed, May 26, 1993–October 14, 1994."

³⁸⁰ Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 69.

³⁸¹ 1992 Census of Agriculture, U.S., vol. 1, excerpts from pp. 109–110, 125–126.

³⁸² Special Census Tabulation prepared by U. S. Bureau of Census for U.S. Small Business Administration, Table 3—United States.

TABLE 15.—SALES OF TOBACCO PRODUCTS AS A PERCENTAGE OF TOTAL SALES—1992
(Establishments with Payroll Only)

Establishment Type	Tobacco Sales		% of Total Sales	
	(\$ Mils)	(%)	Establishments Handling Tobacco	All Establishments
All	30,559	100	4.5	2.9
Food Stores	16,132	52	4.5	4.4
Service Stations	7,136	23	7.1	5.3
Drug and Proprietary	2,235	7	3.7	2.9
General Merchandise	3,182	10	2.4	1.3
Liquor Stores	1,045	3	8.0	5.1
Eating and Drinking	219	1	3.0	0.1
Tobacco Stores & Stands	610	2	78.1	78.1

Source: 1992 Census of Retail Trade, Merchandise Line Sales

TABLE 16.—NUMBER OF SMALL RETAIL BUSINESSES

Establishment Type	Firms With Payroll		Establishments Without Payroll
	Total	Small ¹	
All	588,505	473,668	275,432
Food Stores	127,575	104,541 ²	97,061
Service Stations	62,585	53,288 ³	14,248
Drug and Proprietary	28,606	25,396	3,031
General Merchandise	10,264	8,176	28,010
Liquor Stores	26,565	22,859	8,811
Eating and Drinking	331,703	258,381	124,271
Tobacco Stores & Stands	1,207	1,027	n.a.

¹ Assumes Small Business Administration size standard of \$20 million in annual sales for food stores, \$6.5 million for service stations and \$5 million for all others.

² Due to data limitations, includes firms with annual sales up to \$25 million.

³ Due to data limitations, includes firms with annual sales up to \$10 million.

Source: 1992 Census of Retail Trade, Establishment and Firm Size, 1992 Census of Retail Trade, Summary.

To illustrate the effects of this proposal on a typical small retail store, FDA separately utilized Census data to estimate that the average-sized convenience store sells 177 packages of tobacco products daily, of which about 25 might be purchased by young adults aged 18 to 26.³⁸³ Based on the cost assumptions described previously, the outlet's first year costs would total about \$400, with the largest single cost, \$199, the labor cost for checking identification. For those stores that already verify the age of young customers of tobacco products, the additional costs fall to \$137.

This estimate does not account for the possible reduction in promotional allowances, as FDA believes that competitive pressures will continue to lead manufacturers to rely on promotional allowances to compete for the best shelf space available for their products. Because FDA rejected the idea of prohibiting any visible display of tobacco products, retailers can retain slotting fees by choosing to display tobacco products either behind counters or in transparent locked display cases. Nevertheless, some small establishments might experience reduced promotional payments following a ban on self-service marketing.

Census data for 1992 indicate that almost 4,000 of 4,800 merchandising machine operator businesses (83 percent) reported annual receipts below the SBA size standard of \$5 million.³⁸⁴ One trade association noted that almost three quarters of all vending machine operators had annual sales of less than \$1 million.³⁸⁵ As explained earlier, prohibiting all cigarette vending machines would initially reduce the revenues of vending machine operators by an average of 2.8 percent. Because only about one-half of the merchandising machine establishments

sell cigarettes, some businesses specializing in cigarette sales would experience greater revenue declines; although this effect will be moderated to the extent that cigarette vending machines are placed in areas restricted to adults, which would not be prohibited by the final rule.

The rule would also affect the distribution of specialty items showing a tobacco product logo or name. Industry comments do not provide precise data on the size distribution of these firms, but as noted above, the Specialty Advertising Association International indicates that 80 percent of the manufacturers and 95 percent of the distributors in this industry have annual sales below \$2 million. While the marketplace in which these firms traditionally compete demands a quick response to shifting consumer trends, this rule would have at least short-term impact on some small firms.

FDA has received no data that would allow it to estimate the number of small firms that are currently involved with some aspect of tobacco advertising or the fraction of these firms that will be affected. In 1992, 861 of 904 year-round outdoor advertising firms (95 percent) reported sales revenues of less than the SBA size standard of \$5 million.³⁸⁶ The impact of this rule, however, is difficult to assess without knowing how the tobacco industry will alter its advertising strategies. Indeed, one of the largest outdoor advertising firms recently decided to reject all tobacco business, potentially increasing sales to the smaller firms.³⁸⁷

The regulation restricts tobacco advertising to "text only" in magazines with youth readership above the regulatory threshold. Of the identified 101 magazines with tobacco ads in 1994, 79 were published by large firms (over 500 employees). Less than 3 percent of the total revenue of the remaining 22 publications (which include, Inc., Rolling Stone and Penthouse) was derived from tobacco ads.³⁸⁸ It is likely, moreover, that many of these magazines could avoid the "text only" restriction for tobacco advertising by demonstrating a low youth readership.

The regulation will also affect a substantial number of small race tracks,

although FDA does not know how many small tracks currently receive significant revenues from tobacco sponsors. As discussed previously, some small operations will likely lose promotional revenues from tobacco companies, but the sport is growing rapidly and other product manufacturers should make up a substantial part of the shortfall.

The final regulatory flexibility analysis must include "a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record." A full description of the requirements and classes of affected small entities has been provided earlier in this section and a quantitative review of the paperwork burdens imposed by the rule is provided in section XVI. of this document. No special professional skills will be required to prepare the reports or records required by the regulation.

The final regulatory flexibility analysis must also include "a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

The earlier sections of this document provide a full explanation of the agency's basis for selecting each provision of the final rule. In each instance, FDA evaluated the implications of each reasonable regulatory alternative and selected only those requirements that were absolutely necessary to satisfy the agency's statutory goals. As described, FDA found that its objectives for reducing the use of tobacco by young people could not be achieved with a partial or one-dimensional approach, but required a comprehensive set of regulatory restrictions. Thus, the final set of selected provisions reflect a careful examination of the relevant facts presented to the rulemaking record, the agency's objective of curtailing the use of tobacco by youngsters without creating unnecessary economic burdens, and a full assessment of the agency's legal authorities. Because the rejected alternatives would either provide less protection of public health, or achieve

³⁸³ Based on data from the 1994 SGR, p. 85, and the "Tobacco Situation and Outlook Report" April, 1995, p. 4, FDA estimates that smokers aged 18 to 26 account for about 10 percent of all cigarettes smoked. Alternatively, data from the Statistical Abstract, tables 16 and 218, show that smokers aged 18 to 26 comprise 18 percent of all smokers. FDA used the midpoint of the 10 to 18 percent range to avoid underestimating the cost to small retailers. In addition, data from the 1996 Census of Retail Trade, Subject Series-Merchandise Line Sales, pp. 3-9 on the number of convenience stores with payroll and their total tobacco sales, and the average price per pack, were used to estimate the average number of packs sold daily at convenience stores to smokers aged 18 to 26.

³⁸⁴ 1992 Census of Retail Trade, "Establishment and Firm Size," Table 4 p. 1-99.

³⁸⁵ "1993: Industry Posts Best Growth in Four Years," *Automatic Merchandiser*, p. A2, August 1994.

³⁸⁶ 1992 Census of Service Industries, pp. 1-145 and 1-195.

³⁸⁷ Collins, G., "Major Advertising Company to Bar Billboard Ads for Tobacco," *New York Times*, A15, May 3, 1996.

³⁸⁸ 1996 *Directory of Corporate Affiliations U.S. Private Companies*, New Providence, NJ; Reed Elsevier, Inc.; "Company Profiles" database, Information Access Co., Foster City, CA.

only minimal improvements at unwarranted cost, the agency found that the approach selected for the final rule best fit its statutory mandate.

As noted, earlier sections of the preamble fully describe the agency's rationale for selecting each provision of the final rule and for rejecting each alternative approach. Although many alternatives were considered, specific exemptions based solely on business size were not adopted, because FDA believes that children would too frequently exploit such opportunities. Unlike certain other regulations where restrictions on large firms alone might be acceptable, tobacco products are purchased easily from small, as well as large firms. An exemption for small retailers, for instance, would shift underage sales to those locations, lessening or eliminating the benefits of the remaining access restrictions. The following discussion summarizes the agency's consideration of several other regulatory alternatives.

G. Other Alternatives

One regulatory alternative would have banned all tobacco advertising; or alternatively, all tobacco advertising in selected media, such as all written publications, or all outdoor billboards. FDA rejected this approach in order to focus on those media and aspects of advertising that children are routinely exposed to and that have the greatest effect on youngsters. For example, the final rule permits black and white "text only" tobacco advertising in all written publications and color and imagery in magazines with fewer than 2 million youthful readers if youth constitute less than 15 percent of the publication's readership. Billboards are permitted to show black and white "text only" ads if located at least 1,000 feet from schools or public playgrounds. Thus, the rule leaves the informational aspects of advertising largely untouched.

Another suggested alternative was to combat underage tobacco use by relying on either voluntary compliance or on better enforcement of laws prohibiting sales to minors. As discussed earlier in this document, the tobacco industry's voluntary advertising code has failed to stop illegal sales to underage buyers. FDA agrees that these approaches can be partially effective, but finds that they inadequately counter the appeal of tobacco products for young people that is created by advertising and promotions. Thus, the agency concludes that there is no less burdensome alternative for achieving its goals that

would exclude appropriately tailored restrictions on tobacco advertising.

One alternative considered by the agency was a far more prescriptive monitoring requirement for tobacco manufacturers. Under this rule, each manufacturer of tobacco products would have been required to adopt a system for monitoring the sales and distributions of retail establishments. These monitoring systems were to: (1) Include signed written agreements with each retailer, (2) contain adequate organizational structure and personnel to monitor the labeling, advertising, and sale of tobacco products at each retail distribution point, and (3) establish, implement, and maintain procedures for receiving and investigating reports regarding any improper labeling, advertising, or distribution. The additional costs for this monitoring were estimated at about \$85 million per year. FDA rejected this alternative, because it decided that the industry might employ its resources more efficiently if permitted to choose among alternative compliance modes.

Another suggested alternative would have required package inserts containing educational information in cigarette and smokeless tobacco. FDA had incomplete data to estimate the additional cost of this requirement, but based on comments submitted by industry in response to a Canadian proposal, tentatively projected one-time costs of about \$490 million and annual operating costs of about \$54 million. This alternative was not selected because the agency was not certain that the benefits of this provision would justify the compliance costs.

FDA also considered setting the permissible age for purchase at 19 rather than 18, because many 18-year-old adolescents are still in high school and can easily purchase tobacco products for younger classmates. This alternative would have added costs of about \$34 million annually, mostly due to lost producer profits. The final regulation restricts access to regulated tobacco products for persons under the age of 18, because most adult smokers have already become smokers by the age of 18, and because that age limit is already consistent with most State and local laws.

H. Unfunded Mandates Reform Act of 1995

On the basis of the preceding discussion, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In

addition, the agency has considered other alternatives as discussed in section XV.G. of this document and determined that the current rule is the least burdensome and the most cost effective alternative that would meet the objectives of this rule.

XVI. Paperwork Reduction Act of 1995

The 1995 proposed rule would have collected information from manufacturers, distributors, and retailers of cigarettes and smokeless tobacco. Proposed § 897.24 would have required such persons to use established names for cigarettes and smokeless tobacco. Proposed § 897.29 would have required manufacturers to establish and maintain educational programs. Proposed § 897.32 would have required manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising. Proposed § 897.40 would have required manufacturers to submit labels, labeling, and advertising to FDA.

The preamble to the 1995 proposed rule, in discussing the Paperwork Reduction Act, also invited comments on four questions: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden (60 FR 41314 at 41356).

A. Comments on the Paperwork Reduction Act Statement

A small number of comments, primarily from a trade association representing cigarette manufacturers and from distributors, addressed FDA's Paperwork Reduction Act statement. In general, these comments asserted that FDA's figures were incorrect or that the rule would duplicate existing reporting requirements. Few comments provided any figures or evidence to justify using different estimates.

(1) One comment, submitted by a trade association representing major cigarette manufacturers, said FDA's Paperwork Reduction Act statement underestimated the paperwork burden due to the exclusion of burden on retailers. The comment asserted that FDA did not explain how it calculated the number of respondents and burden hours for these sections and that the absence of an explanation made it difficult to assess the agency's estimate.

The comment explained that the agency's Paperwork Reduction Act estimate said there would be 200,000 respondents for proposed § 897.40, but that the agency's analysis of impacts estimated that 700,000 retail stores sell tobacco products. The comment also asserted that the average burden per response, under proposed §§ 897.32 and 897.40, should be 1 hour instead of 20 minutes. Thus, the comment concluded that if all 700,000 outlets spend only 60 minutes annually to comply with all recordkeeping requirements, at a cost of \$10 per hour, retailers, alone, would spend 700,000 hours and \$7 million to comply with the recordkeeping requirements in §§ 897.32 and 897.40.

The agency believes that the comment misinterprets the figures in the proposed rule's Paperwork Reduction Act statement. To begin with, the comment mistakenly equates the Paperwork Reduction Act statement's reference to "annual number of responses" with the annual numbers of people or firms that might be affected. The annual number of responses simply refers to the annual number of things, whether those things are pieces of labeling, labels, advertisements, or other items, that the agency might receive under that particular regulatory requirement. So, for example, if the agency expected to receive only 500 labels, the "annual number of responses" would be 500, regardless of whether the number of firms who might be affected by the rule was greater or less than 500.

Focusing on §§ 897.32 and 897.40 (the provisions cited by the comment), proposed § 897.32 would have established specific format and content requirements for labeling and advertising. For example, proposed § 897.32(a) would have required labeling and advertising to use only black text on a white background; the only exception would be advertising appearing in "adult" periodicals. Proposed § 897.32(b) would have required advertising to carry the product's established name and a statement of intended use, and specified those names and the statement of intended use. Proposed § 897.32(c) would have required advertising to carry a specific brief statement. The agency believed that these proposed requirements and specific statements were so precise that manufacturers, distributors, or retailers could determine their regulatory obligations quickly. For example, it should be quite simple to determine whether an advertisement uses black text on a white background.

Proposed § 897.40(a) would have required manufacturers to provide copies of labels, labeling, and a representative sampling of advertising to FDA. This, too, would not appear to be an extremely time-consuming task, particularly when the rule permits manufacturers to provide a representative sampling of advertising.

To estimate the time required to comply with proposed §§ 897.32 and 897.40, the agency tried to examine other large-scale labeling and reporting programs. FDA found that one Federal department conducts a large-scale labeling program that receives approximately 200,000 labels annually and that each label requires a maximum of 20 minutes to review. Consequently, the 1995 proposed rule adopted the 200,000 figure as the estimated number of responses. In the absence of better data, the proposed rule assigned the maximum review time (20 minutes) to its estimates for average burden per response.

FDA, however, has revised the 200,000 figure and now estimates that approximately 25,000 pieces of labeling or advertising will be affected by § 897.32. (The agency has deleted § 897.40 from the rule in favor of other, preexisting regulations.) As described in greater detail elsewhere in this document, the agency derived these figures by using advertising expenditures by the cigarette and smokeless tobacco industries and by the pharmaceutical industry, applying the ratio of such expenditures against the 25,000 pieces of advertising that the agency receives from the pharmaceutical industry, and projecting that printed advertisements may increase due to the rule's effect on promotional activities. Consequently, FDA now estimates that 25,000 pieces of labeling and advertising will be affected.

Thus, the agency does not agree that the estimated number of responses should be 700,000 or more because the response rate is not determined by the number of retailers. However, because the comment estimated that firms would require 1 hour to comply, the agency will use the 1 hour figure and has adjusted its paperwork estimates accordingly.

(2) The same comment also asserted that FDA's recordkeeping estimate was incorrect for manufacturers. The comment stated that FDA did not explain how it calculated the burden hour response for manufacturers under proposed § 897.40 and asserted that manufacturers would need 40 hours to document compliance with the

educational program requirements in proposed § 897.29 alone. The comment estimated that the recordkeeping costs for the manufacturers' educational programs would be \$25 per hour, for a total cost between \$55 and 57 million annually. The comment explained that the costs may be even higher because highly skilled persons would be needed to comply with the rule.

The comment misinterprets the agency's Paperwork Reduction Act burden estimate. For § 897.29, FDA estimated that 1,000 hours would be needed to comply with the educational program requirements; this estimate included all functions related to the development of an educational program, including recordkeeping. Section 897.40(b), would have required manufacturers, distributors, and retailers to make records (including records on a manufacturer's educational program efforts) available to FDA on inspection. Because the estimate for proposed § 897.29 included time spent on recordkeeping associated with the educational program, the agency's estimates for proposed § 897.40 properly excluded time spent on maintaining educational program records. Otherwise, this time would have been counted twice. In any event, the comment is moot because FDA has deleted § 897.29 and § 897.40 from the final rule.

(3) FDA received several comments from distributors, claiming that the 1995 proposed rule would result in substantial paperwork and provide duplicative information. The comments stated that the device listing provisions of part 807 require each medical device wholesaler to prepare and file reports of all regulated products. If each brand and package style of cigarettes and smokeless tobacco are considered a separate device, this would substantially increase paperwork and duplicative reporting.

The comment correctly notes that part 807, as currently written, requires distributors to register and list devices (21 CFR 807.20). However, FDA has amended part 807 to exempt distributors of cigarettes and smokeless tobacco. Thus, distributors do not have to comply with part 807, nor do they have to comply with § 897.40 because FDA has deleted § 897.40 from the final rule.

(4) Several comments, primarily from small businesses and convenience stores, said that the 1995 proposed rule would have no impact and that adding paperwork would not curb underage smoking.

The agency disagrees with the comments. The final rule restricts young people's access to cigarettes and smokeless tobacco and reduces their appeal to young people. FDA believes that the final rule, in conjunction with State and local government efforts, will prevent large numbers of young people from using or experimenting with these products. Yet, insofar as any information collection burden is concerned, FDA points out that the rule's paperwork requirements are a function of the act and are being imposed to further the purposes of the act and of this final rule, not in any attempt to curb underage smoking by simply adding paperwork for paperwork's sake.

(5) One comment said that FDA could reduce the information collection burden in proposed § 897.29 (the educational program) by requiring manufacturers to contribute to an educational fund that an independent agency, such as FDA, CDC, or NIH, could use. The comment said that this would create a positive incentive for companies to change their marketing practices and would reduce the need for extensive recordkeeping and regulatory oversight of manufacturers.

The agency has deleted the educational program provision from the final rule. Consequently, the information collection burden associated with proposed § 897.29 no longer exists.

(6) In response to comments, FDA has amended the final rule to include a medical device reporting requirement for manufacturers and distributors at

§§ 803.19 and 804.25. For manufacturers, these reports are limited to adverse events (resulting from product contamination, a change in ingredient or in any manufacturing process, or serious adverse events that are not well-known or well-documented by the scientific community. For distributors, these reports are limited to adverse events related to contamination. FDA estimates that it will receive 50 reports and each report will require 8 hours to prepare. The agency has amended the information collection burden to reflect these changes to the rule.

(7) FDA has also revised the information collection figures for § 897.24 which requires an established name on labels. The revision changes the number of respondents from 1,000 to 2,000 to reflect the agency's position that there are 1,000 varieties of cigarettes and smokeless tobacco products and that each variety has 2 labels, thus resulting in 2,000 affected labels.

(8) FDA has also revised the information collection figures for § 897.32 to account for the survey evidence that is needed to establish that a magazine, newspaper, or other periodical is an "adult" publication that is exempt from the requirement of black text on a white background. The agency estimates that such surveys will result in a capital cost of \$2 million, with annual costs of \$1 million. FDA estimates that 31 recordkeepers would be affected at a total burden hour figure of 100,000 hours.

B. Information Collection Provisions in the Final Rule

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with the estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents.

Description: The final rule requires the collection of information regarding cigarettes and smokeless tobacco. The final rule requires manufacturers, importers, and distributors to report certain adverse events to FDA and requires manufacturers to use established names for cigarettes and smokeless tobacco. The final rule also requires manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising, and requires manufacturers, distributors, and retailers to notify FDA if they intend to use an advertising medium that is not listed in the regulations.

Description of Respondents: Businesses.

Table 17.—Estimated Annual Reporting and Disclosure Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
803.19	49	1	49	8	392	21,000	13,680
804.25	1	1	1	8	8	231,000	35,220
897.24	2,000	1	2,000	40	80,000	17,000,000	0
897.30	1	1	1	1	1	0	0
897.32	25,000	1	25,000	1	25,000	0	0
Total Burden					105,401	17,250,000	48,900

TABLE 18.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record- keeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
897.32	31	1	31	3,226	100,000	2,000,000	1,000,000
Total Burden					100,000	2,000,000	1,000,000

The 1995 proposed rule provided a 90-day comment period (extended to 144 days in the Federal Register of October 16, 1995, 60 FR 53560). As discussed previously, the revised burden hour estimates in the final rule are based partially on comments received.

The information collection provisions in the proposed rule were approved under OMB no. 0910-0312. Because of changes made since the proposed rule, FDA has submitted the information collection provisions of the final rule to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

XVII. Congressional Review

This final rule has been determined to be a major rule for purposes of 5 U.S.C. 801 *et seq.*, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121). FDA is submitting the information and reports as required by that statute.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 804

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 897

Advertising, Cigarettes, Labeling, Sale and distribution, Smokeless tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801, 803, 804, 807, and 820 are amended and a new part 897 is added as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.126 is added to subpart D to read as follows:

§ 801.126 Exemptions for cigarettes and smokeless tobacco.

Cigarettes and smokeless tobacco as defined in part 897 of this chapter are exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act.

PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

4. Section 803.19 is amended by adding new paragraphs (f) and (g) to read as follows:

§ 803.19 Exemptions, variances, and alternative reporting requirements.

* * * * *

(f) Manufacturers as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for serious adverse events that are not well-known or well-documented by the scientific community, including events related to contamination, or a change in any ingredient or any manufacturing process.

(g) User facilities are exempt from submitting medical device reports concerning cigarettes and smokeless tobacco under this part.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

5. The authority citation for 21 CFR part 804 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

6. Section 804.25 is amended by adding a new paragraph (c) to read as follows:

§ 804.25 Reports by distributors.

* * * * *

(c) Distributors as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for adverse events related to contamination.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

7. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

8. Section 807.65 is amended by adding a new paragraph (j) to read as follows:

§ 807.65 Exemptions for device establishments.

* * * * *

(j) Distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

PART 820—GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES: GENERAL

9. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: Secs. 501, 502, 515, 518, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360e, 360h, 360i, 360j, 371, 374).

10. Section 820.1 is amended by adding and reserving new paragraph (e) and adding new paragraph (f) to read as follows:

§ 820.1 Scope.

* * * * *

(e) [Reserved]

(f) This part does not apply to distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

11. New part 897 is added to read as follows:

PART 897—CIGARETTES AND SMOKELESS TOBACCO

Subpart A—General Provisions

Sec.

897.1 Scope.

897.2 Purpose.

897.3 Definitions.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

897.10 General responsibilities of manufacturers, distributors, and retailers.

897.12 Additional responsibilities of manufacturers.

897.14 Additional responsibilities of retailers.

897.16 Conditions of manufacture, sale, and distribution.

Subpart C—Labels

- 897.24 Established names for cigarettes and smokeless tobacco.
- 897.25 Statement of intended use and age restriction.

Subpart D—Labeling and Advertising

- 897.30 Scope of permissible forms of labeling and advertising.
- 897.32 Format and content requirements for labeling and advertising.
- 897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

Authority: Secs. 502, 510, 518, 519, 520, 701, 704, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360h, 360i, 360j, 371, 374, 393).

Subpart A—General Provisions**§ 897.1 Scope.**

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of Title 21, unless otherwise noted.

§ 897.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

§ 897.3 Definitions.

(a) *Cigarette* means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

(b) *Cigarette tobacco* means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the

requirements pertaining to cigarettes shall also apply to cigarette tobacco.

(c) *Distributor* means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

(d) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) *Nicotine* means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or $C_{10}H_{14}N_2$, including any salt or complex of nicotine.

(f) *Package* means a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers.

(g) *Point of sale* means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) *Retailer* means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) *Smokeless tobacco* means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age**§ 897.10 General responsibilities of manufacturers, distributors, and retailers.**

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

§ 897.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the requirements under this part.

§ 897.14 Additional responsibilities of retailers.

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b)(1) Except as otherwise provided in § 897.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in § 897.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

§ 897.16 Conditions of manufacture, sale, and distribution.

(a) *Restriction on product names.* A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) *Minimum cigarette package size.* Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale.* (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d) *Free samples.* No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco.

(e) *Restrictions on labels, labeling, and advertising.* No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subparts C and D of this part, and other applicable requirements.

Subpart C—Labels

§ 897.24 Established names for cigarettes and smokeless tobacco.

Each cigarette or smokeless tobacco package shall bear, as provided in section 502 of the act, the following established name: "Cigarettes", "Cigarette Tobacco", "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff", or "Dry Snuff", whichever name is appropriate.

§ 897.25 Statement of intended use and age restriction.

Each cigarette or smokeless tobacco package, that is offered for sale, sold, or otherwise distributed shall bear the following statement: "Nicotine-Delivery Device for Persons 18 or Older".

Subpart D—Labeling and Advertising

§ 897.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be

disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane (HFD-40), rm. 17B-20, Rockville, MD 20857.

(b) No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

§ 897.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer,

distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

(c) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, advertising permitted under this subpart D, shall include, as provided in section 502 of the act, the product's established name and a statement of its intended use as follows: "Cigarettes—A Nicotine-Delivery Device for Persons 18 or Older", "Cigarette Tobacco—A Nicotine-Delivery Device for Persons 18 or Older", or "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff" or "Dry Snuff", whichever is appropriate for the product, followed by the words "A Nicotine-Delivery Device for Persons 18 or Older".

§ 897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person

purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any

brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors,

or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Dated: August 22, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

NOTE: The following Annex will not appear in the Code of Federal Regulations.

BILLING CODE 4160-01-F

Annex

**Nicotine in Cigarettes and Smokeless Tobacco
Is a Drug and These Products Are Nicotine Delivery Devices
Under the Federal Food, Drug, and Cosmetic Act:
Jurisdictional Determination**

August 1996



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. Food and Drug Administration**

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EXECUTIVE SUMMARY

This document explains the basis for the Food and Drug Administration's assertion of jurisdiction over cigarettes and smokeless tobacco under the Federal Food, Drug, and Cosmetic Act (the Act). FDA regulates a diverse range of products under the Act, including foods, drugs, medical devices, and cosmetics. The distinguishing feature that characterizes these products is their intimate and potentially harmful relationship with the human body. The products that FDA regulates include those that are ingested, inhaled, implanted, or otherwise used in close contact with the human body.

Cigarettes, which deliver a pharmacologically active dose of nicotine to the body through inhalation, and smokeless tobacco, which delivers a pharmacologically active dose of nicotine to the body through buccal absorption, share this distinguishing feature. Like the products that FDA traditionally regulates, cigarettes and smokeless tobacco are inhaled or placed within the human body; like many of these products, they deliver a pharmacologically active substance to the bloodstream; and like these products, they have potentially dangerous effects. Indeed, no products cause more death and disease than cigarettes and smokeless tobacco.

FDA is asserting jurisdiction over cigarettes and smokeless tobacco under the drug and device provisions of the Act. Specifically, FDA has concluded that cigarettes and smokeless tobacco are combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body. FDA last considered whether cigarettes were drugs or devices in the late 1970's. *See Action on Smoking and Health v. Harris*,

655 F.2d 236 (D.C. Cir. 1980). Since that time, substantial new evidence has become available to FDA. This evidence includes the emergence of a scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine and the disclosure of thousands of pages of internal tobacco company documents detailing that these products are intended by the manufacturers to affect the structure and function of the human body. This new evidence justifies the Agency's determination that cigarettes and smokeless tobacco are delivery systems for the drug nicotine.

Under the Act, a product is a drug or device if it is an article (other than food) "intended to affect the structure or any function of the body." Sections 201(g)(1)(C), 201(h)(3). The statutory definition is "intended to define 'drug' far more broadly than does the medical profession." *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 793, 798 (1969). The legal question of whether cigarettes and smokeless tobacco are subject to FDA jurisdiction is one that "FDA has jurisdiction to decide with administrative finality." *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973).

After intensive investigation and careful consideration of the public comments, FDA concludes that cigarettes and smokeless tobacco meet the statutory definition of a drug and a device. This conclusion is based on two determinations: (1) nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body," and (2) these effects on the structure and function of the body are "intended" by the manufacturers.

The Agency's determination that nicotine in cigarettes and smokeless tobacco does

"affect the structure or any function of the body" is based on three central findings:

1. Nicotine in cigarettes and smokeless tobacco causes and sustains addiction.
2. Nicotine in cigarettes and smokeless tobacco causes other psychoactive (mood-altering) effects, including tranquilization and stimulation.
3. Nicotine in cigarettes and smokeless tobacco controls weight.

The Agency's determination that the manufacturers of cigarettes and smokeless

tobacco "intend" these effects is based on five central findings:

1. The addictive and other pharmacological effects of nicotine are so widely known and accepted that it is foreseeable to a reasonable manufacturer that cigarettes and smokeless tobacco will cause addiction to nicotine and other significant pharmacological effects and will be used by consumers for pharmacological purposes, including sustaining their addiction to nicotine.
2. Consumers use cigarettes and smokeless tobacco predominantly for pharmacological purposes, including sustaining their addiction to nicotine, mood alteration, and weight loss.
3. Manufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine and mood alteration, and that consumers use their products primarily to obtain the pharmacological effects of nicotine.
4. Manufacturers of cigarettes and smokeless tobacco design their products to provide consumers with a pharmacologically active dose of nicotine.
5. An inevitable consequence of the design of cigarettes and smokeless tobacco to provide consumers with a pharmacologically active dose of nicotine is to keep

consumers using cigarettes and smokeless tobacco by sustaining their addiction to nicotine.

This document is divided into six sections. Section I describes the evidence and legal basis supporting the Agency's finding that cigarettes and smokeless tobacco "affect the structure or any function of the body." Section II describes the evidence and legal basis supporting the Agency's finding that the manufacturers "intend" these effects on the structure and function of the body. Section III explains the Agency's conclusion that cigarettes and smokeless tobacco are combination products that contain a "drug" and a "device." Section IV explains why the Agency's decision to assert jurisdiction over cigarettes and smokeless tobacco is justified by the new evidence now available to the Agency. Section V demonstrates that Congress has not precluded or preempted the Agency's assertion of jurisdiction over cigarettes and smokeless tobacco. Section VI addresses procedural issues relating to the Agency's assertion of jurisdiction over cigarettes and smokeless tobacco. These sections are summarized below.

I. Cigarettes and Smokeless Tobacco "Affect the Structure or any Function of the Body" Within the Meaning of the Act

The nicotine delivered by cigarettes and smokeless tobacco has significant pharmacological effects on the structure and function of the body.

First, the nicotine in cigarettes and smokeless tobacco causes and sustains addiction. Nicotine exerts psychoactive, or mood-altering, effects on the brain that motivate repeated, compulsive use of the substance. These pharmacological effects create dependence in the user. The pharmacological processes that cause this addiction to nicotine are similar to those that cause addiction to heroin and cocaine.

Second, the nicotine in cigarettes and smokeless tobacco produces other important pharmacological effects on the central nervous system. Under some circumstances and doses, the nicotine has a sedating or tranquilizing effect on mood and brain activity. Under other circumstances and doses, the nicotine has a stimulant or arousal-inducing effect on mood and brain activity.

Third, the nicotine in cigarettes and smokeless tobacco affects body weight.

These effects on the structure and function of the body are significant and quintessentially drug-like. Moreover, these effects are the same as the effects of other drugs that FDA has traditionally regulated, including stimulants, tranquilizers, appetite suppressants, and products, such as methadone, used in the maintenance of addiction. For these reasons, the Agency finds that cigarettes and smokeless tobacco “affect the structure or any function of the body” within the meaning of the Act.

II. Cigarettes and Smokeless Tobacco Are “Intended” to Affect the Structure and Function of the Body Within the Meaning of the Act

To determine whether effects on the structure or function of the body are “intended” by the manufacturer, the Agency must objectively evaluate all the relevant evidence of intent in the record before it. “The FDA is not bound by the manufacturer’s subjective claims of intent,” but rather can find actual intent “on the basis of objective evidence.” *National Nutritional Foods Ass’n v. Matthews*, 557 F.2d 325, 334 (2d Cir. 1977). In the case of cigarettes and smokeless tobacco, the Agency finds that three types of objective evidence provide independent bases for finding that the manufacturers intend to affect the structure and function of the body: (1) the evidence of the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco; (2) the evidence of

the actual consumer use of cigarettes and smokeless tobacco for pharmacological purposes; and (3) the evidence of the statements, research, and actions of the manufacturers themselves. Considered independently or cumulatively, this evidence convincingly demonstrates that cigarettes and smokeless tobacco are intended to be used for pharmacological purposes.

A. A Reasonable Manufacturer Would Foresee that Tobacco Products Will Cause Addiction and Other Pharmacological Effects and Will Be Used by Consumers for Pharmacological Purposes

When Congress enacted the current definition of “drug” in 1938, it was well understood that “[t]he law presumes that every man *intends* the legitimate consequences of his own acts.” *Agnew v. United States*, 165 U.S. 36, 53 (1897). Consistent with this common understanding, FDA’s regulations provide that a product’s intended pharmacological use may be established by evidence that the manufacturer “knows, or has knowledge of facts that would give him notice,” that the product is being widely used for a pharmacological purpose, even if the product is not being promoted for this purpose. 21 CFR 201.128, 801.4. Thus, FDA may find that a manufacturer intends its product to affect the structure or function of the body when it would be foreseeable to a reasonable manufacturer that the product will (1) affect the structure or function of the body and (2) be used by a substantial proportion of consumers to obtain these effects. For example, when it is foreseeable to a reasonable manufacturer that a product will produce drug effects in consumers and be purchased by a substantial proportion of consumers for drug purposes, FDA may consider the product a “drug.”

In the case of cigarettes and smokeless tobacco, no reasonable manufacturer could fail to foresee that these products will have significant pharmacological effects on consumers and be widely used by consumers for pharmacological purposes. All major public health organizations in the United States and abroad with expertise in tobacco or drug addiction now recognize that the nicotine delivered by cigarettes and smokeless tobacco is addictive. The first major organization to do so was the American Psychiatric Association, which in 1980 defined the “tobacco dependence disorder” and the “tobacco withdrawal syndrome.” Since 1980, nicotine in tobacco products has also been recognized as addictive by the U.S. Surgeon General (1986 and 1988), the American Psychological Association (1988), the Royal Society of Canada (1989), the World Health Organization (1992), the American Medical Association (1993), and the Medical Research Council in the United Kingdom (1994). Every expert medical organization that submitted comments to FDA on whether nicotine is addictive concluded that it is. The tobacco industry’s public position that nicotine is not addictive is simply not credible in light of this overwhelming scientific consensus.

The scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine makes it foreseeable to a reasonable manufacturer that these products will affect the structure and function of the body. This scientific consensus also makes it foreseeable that cigarettes and smokeless tobacco will be used by a substantial proportion of consumers for a pharmacological purpose—namely, to satisfy their addiction.

It is also foreseeable that the nicotine in cigarettes and smokeless tobacco will cause, and be used for, other significant pharmacological effects. It is well established that

the nicotine in cigarettes and smokeless tobacco has psychoactive or mood-altering effects in the brain. Under some circumstances, nicotine can have a sedative or tranquilizing effect on the brain; under other circumstances, nicotine can have a stimulating or arousal-inducing effect. In this regard, nicotine is similar to other addictive drugs such as opiates, which can have both stimulating and sedating effects. In addition, nicotine plays a role in weight regulation, with substantial evidence demonstrating that cigarette smoking leads to weight loss.

Because a reasonable manufacturer would foresee that cigarettes and smokeless tobacco will cause and be used for these well-established pharmacological effects in a substantial proportion of consumers, the Agency finds that these drug effects and drug uses are intended by the manufacturers.

B. Consumers Use Tobacco Products to Obtain the Pharmacological Effects of Nicotine and to Satisfy Their Addiction

A second basis for establishing that a product is intended to affect the structure or function of the body is evidence showing that consumers actually use the product for pharmacological purposes. In fact, courts have recognized that even in the absence of any other evidence of intent to affect the structure or function of the body, such an intent may be established by evidence showing that consumers use the product “predominantly” for pharmacological purposes. *ASH*, 655 F.2d at 239-240.

In the case of cigarettes and smokeless tobacco, the evidence establishes that consumers do use these products “predominantly” for pharmacological purposes. Major recent studies have concluded that 77% to 92% of smokers are addicted to nicotine in cigarettes. The U.S. Department of Health and Human Services estimates that 75% of

young regular users of smokeless tobacco are addicted to nicotine in these products. The comments from the American Heart Association, the American Lung Association, and the American Cancer Society, whose member physicians provide health care for tobacco users in the United States, confirm that “the vast majority of people who use nicotine containing cigarettes and smokeless tobacco do so to satisfy their craving for the pharmacological effects of nicotine; that is, to satisfy their drug dependence or addiction.”

In addition, a large proportion of consumers also use cigarettes and smokeless tobacco for other pharmacological purposes. A recent survey found that over 70% of young people 10 to 22 years old who are daily smokers reported that they use cigarettes for relaxation. The same survey found that over 50% of young people who are daily users of smokeless tobacco reported that they use smokeless tobacco for relaxation. Other surveys show that between one-third and one-half of young smokers report that weight control is a reason for their smoking.

This evidence that consumers actually use cigarettes and smokeless tobacco predominantly to obtain the pharmacological effects of nicotine leads FDA to find that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

C. The Statements, Research, and Actions of the Cigarette Manufacturers Show that the Manufacturers Intend to Affect the Structure and Function of the Body

A third basis for establishing that a manufacturer intends to affect the structure or function of the body is evidence from the statements, research, and actions of the manufacturer that reveals that the manufacturer knows that its product will, or designs its

product to, affect the structure or function of the body. It is a canon of statutory construction that words used by Congress should ordinarily be interpreted in accordance with their plain meaning. The plain meaning of “intend” includes “to have in mind” or “to design” for a particular use. The *American Heritage Dictionary*, for instance, defines “intend” as: “1. To have in mind; plan. 2.a. To design for a specific purpose. b. To have in mind for a particular use.” Consistent with the plain meaning of “intend,” FDA may consider whether the statements, research, and actions of the manufacturer show that the manufacturer “has in mind” that its product will, or “designs” its product to, affect the structure or function of the body.

The administrative record contains three decades of documents and other evidence from the major cigarette manufacturers. This evidence, most of which has only recently become available, establishes that the manufacturers do “have in mind” that their products will have and be used for pharmacological effects. First, the evidence shows that the cigarette manufacturers know that nicotine is a pharmacologically active drug. In internal documents, for instance, researchers for Philip Morris Inc. call nicotine “a powerful pharmacological agent with multiple sites of action” and “a physiologically active . . . substance . . . [which] alters the state of the smoker by becoming a neurotransmitter and a stimulant”; a researcher for R.J. Reynolds Tobacco Co. (RJR) calls nicotine “a potent drug with a variety of physiological effects”; and researchers for Brown & Williamson Tobacco Corp. and its parent company, BAT Industries PLC (formerly the British-American Tobacco Co.) (BATCO), call nicotine “pharmacologically active in the brain”

and “an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical, and physiological responses.”

Second, the evidence establishes that the cigarette manufacturers have conducted extensive research to understand precisely how nicotine affects the structure and function of the body. In one year alone, Philip Morris conducted 16 different studies on the effects of nicotine, including 5 experiments to determine the pharmacological effects of nicotine on the human brain. RJR’s similarly extensive research found that the nicotine in cigarettes produces measurable changes in brain wave activity, such as “a significant increase in beta2 magnitude” (an effect associated with anxiety relief) and “a significant decrease in delta magnitude” (an effect associated with improved mental condition). Through the Council for Tobacco Research, an organization formed by the major tobacco companies, the manufacturers funded dozens of sophisticated investigations concerning nicotine, including numerous studies that demonstrate nicotine’s ability to alter the function of the human brain.

Third, the evidence shows that the manufacturers know that one of the pharmacological effects of nicotine is to cause and sustain addiction. Researchers and senior officials of Brown & Williamson and BATCO expressly acknowledge this fact in their internal documents, stating that “smoking is a habit of addiction” and that “nicotine is addictive.” Philip Morris scientists also know of nicotine’s addiction potential. They conducted a series of nicotine “self-administration” experiments using the tests used by the National Institute on Drug Abuse to determine whether a substance has addiction potential. These studies found that rats would self-administer nicotine, which is one of the

hallmark characteristics of an addictive drug. Moreover, through the Council for Tobacco Research, the cigarette manufacturers funded research that reported that “smoking is a form of dependence no less binding than that of other addictive drugs.”

Fourth, the evidence shows that the manufacturers know that consumers smoke cigarettes primarily to obtain the pharmacological effects of nicotine. This point is repeatedly acknowledged in internal company documents. For example, researchers for Philip Morris have stated that nicotine is “the primary reason why people smoke” and that nicotine is “the physiologically active component of smoke having the greatest consequence to the consumer”; researchers for RJR have stated that “the confirmed user of tobacco is primarily seeking the physiological ‘satisfaction’ derived from nicotine” and that “[w]ithout any question, the desire to smoke is based upon the effect of nicotine on the body”; and BATCO’s director of research has stated that “[t]he tobacco smoking habit is reinforced or dependent upon the psycho-pharmacological effects mainly of nicotine.” This knowledge of the central role of nicotine in cigarette smoking was communicated to the highest levels of the companies. In 1969, for instance, Philip Morris’ vice president for research and development told the Philip Morris board of directors that “the ultimate explanation for the perpetuated cigarette habit resides in the pharmacological effect of smoke upon the body of the smoker.”

Fifth, the evidence shows that in their internal documents, the cigarette manufacturers expressly refer to cigarettes as devices for the delivery of nicotine. For instance, researchers for Philip Morris have described cigarettes as a “dispenser for a dose unit of nicotine” and as a “nicotine delivery device”; a senior researcher for RJR has

described cigarettes as a “vehicle for delivering nicotine”; and researchers for BATCO have described cigarettes as the “means of providing nicotine dose in a metered fashion” and as a device that provides the smoker “very flexible control over titrating his desired dose of nicotine.”

This evidence establishes that cigarettes are intended by the manufacturers to affect the structure and function of the body. It demonstrates that the manufacturers know that nicotine is pharmacologically active; that consumers smoke primarily to obtain the pharmacological effects of nicotine; and that cigarettes function as devices for the delivery of nicotine. The evidence thus shows that when the manufacturers offer cigarettes for sale, they “have in mind” that their products will be used for the particular purpose of affecting the structure and function of the body.

In addition to the evidence showing that cigarette manufacturers “have in mind” the use of cigarettes for pharmacological purposes, the record shows that the manufacturers “design” cigarettes to ensure the delivery of a pharmacologically active dose of nicotine to the smoker. The evidence in the record shows that the manufacturers have conducted extensive product research and development to find ways to maintain adequate nicotine levels in low-tar cigarettes. According to one former senior official at Philip Morris, “a key objective of the cigarette industry over the last 20-30 years” was “maintaining an acceptable and pharmacologically active nicotine level” in low-tar cigarettes. Internal industry documents in the record disclose research to determine the dose of nicotine that must be delivered to provide “pharmacological satisfaction” to the

smoker, as well as estimates by industry scientists of the minimum and optimum doses of nicotine that cigarettes must deliver.

Among the many examples in the record of product research and development to enhance relative nicotine deliveries, Philip Morris conducted extensive research to identify “the optimal nicotine/tar ratios for cigarette acceptability of relatively low-delivery cigarettes”; RJR developed alternative tobacco products that provide a “more efficient and direct way to provide the desired nicotine dosage than the present system involving combustion of tobacco”; and Brown & Williamson investigated chemical manipulation to raise smoke pH, thereby increasing “free” nicotine delivery, and used genetic engineering to breed a high-nicotine tobacco plant called Y-1.

The record before the Agency shows that several methods of enhancing nicotine deliveries are used in the manufacture of commercial cigarettes. Tobacco blending to raise the nicotine concentration in low-tar cigarettes is common. As the vice chairman and chief operating officer of Lorillard Tobacco Co. has stated, “the lowest tar segment is composed of cigarettes utilizing a tobacco blend which is significantly higher in nicotine.” Another common technique for enhancing nicotine deliveries in low-tar cigarettes is the use of filter and ventilation systems that by design remove a higher percentage of tar than nicotine. Yet a third type of nicotine manipulation is the addition of ammonia compounds that increase the delivery of “free” nicotine to smokers by raising the alkalinity or pH of tobacco smoke. These ammonia technologies are widely used within the industry.

The record establishes that an important reason why the manufacturers design cigarettes that provide pharmacologically active doses of nicotine is to satisfy the demands

of users. The manufacturers concede in their comments that their “intent is to design, manufacture and market . . . cigarettes to meet the preferences of adult smokers.” The preferences of most smokers, however, include obtaining sufficient nicotine to sustain their addiction and to experience nicotine’s mood-altering effects. What the cigarette manufacturers describe as producing cigarettes that satisfy consumer preferences is, in reality, producing cigarettes that provide the pharmacological effects of nicotine sought by consumers. The effect of maintaining a pharmacologically active dose of nicotine in cigarettes is to keep consumers smoking by sustaining their addiction.

The evidence that the manufacturers “design” cigarettes to provide a pharmacologically active dose of nicotine is further proof that the manufacturers intend cigarettes to affect the structure and function of the body. Taken together, the evidence shows that the cigarette manufacturers: (1) “have in mind” the use of cigarettes for the particular purpose of delivering the pharmacological effects of nicotine, and (2) “design” their products to provide these effects. This evidence convincingly demonstrates that the pharmacological effects of cigarettes are “intended” by the manufacturers.

D. The Statements, Research, and Actions of the Smokeless Tobacco Manufacturers Show that the Manufacturers Intend their Products to Affect the Structure and Function of the Body

The administrative record also contains evidence of the statements, research, and actions of the smokeless tobacco manufacturers. Like the evidence of the statements, research, and actions of the cigarette manufacturers, this evidence establishes that the smokeless tobacco manufacturers intend to affect the structure and function of the body.

First, the evidence in the record shows that the smokeless tobacco manufacturers know that nicotine is a pharmacologically active drug and that consumers use smokeless tobacco to obtain the pharmacological effects of nicotine. As a senior vice president for United States Tobacco Co. (UST) stated, “virtually all tobacco usage is based upon nicotine, ‘the kick,’ satisfaction.” Researchers affiliated with Brown & Williamson acknowledge that “nicotine . . . absorbed through . . . the lining of the nose or mouth . . . will quickly enter a direct route, in the blood, to the brain.”

Second, the evidence shows that the smokeless tobacco manufacturers manipulate the nicotine delivery of their products in a manner that promotes tolerance and addiction to nicotine. This manipulation is accomplished through the use of chemicals that alter the pH of the smokeless tobacco. Moist snuff brands that are marketed as “starter” brands have a low pH and consequently deliver a low level of “free” nicotine to the user, limiting the absorption of nicotine in the mouth. The low nicotine deliveries allow the new user to develop a tolerance to nicotine without experiencing adverse reactions such as nausea and vomiting. In contrast, moist snuff brands that are marketed to experienced users have a high pH and consequently deliver a high level of “free” nicotine to the user, increasing the amount of nicotine available for absorption. The increased nicotine deliveries provide sufficient nicotine to sustain the user’s addiction.

Third, the evidence shows that smokeless tobacco use and addiction to nicotine has substantially increased among teenagers since the manufacturers began to manipulate nicotine deliveries. Before the introduction of starter brands with low levels of nicotine delivery, virtually no teenagers and young adults used smokeless tobacco. After the

smokeless tobacco manufacturers began to market low-nicotine “starter” brands in the 1970’s, however, use of smokeless tobacco by teenagers rose dramatically. Use of smokeless tobacco by adolescent males aged 18 to 19, for instance, increased almost 1,500% between 1971 and 1991. Most of the regular teenage users of smokeless tobacco graduate to higher nicotine brands. An analysis by the Centers for Disease Control and Prevention found that the pattern of smokeless tobacco use by teenagers “support[s] the hypothesis that snuff users in earlier stages of tobacco use and nicotine addiction use brands with low levels of free nicotine and then ‘graduate’ to brands with high levels.”

This evidence of: (1) knowledge of nicotine pharmacology, (2) manipulation of nicotine deliveries, and (3) graduation to higher nicotine brands among young users is a sufficient basis to establish that the smokeless tobacco manufacturers intend to affect the structure and function of the body.

In addition to this industry-wide evidence of intended use, the record contains numerous documents from the nation’s largest smokeless tobacco manufacturer, UST.

The UST documents in the record show that:

- UST officials in the early 1970’s recommended the development of products with “three different . . . strengths of nicotine[:] . . . a. High nicotine, strong tobacco flavor . . . b. Medium strength of nicotine . . . c. Low nicotine, sweet product.” In particular, UST officials recommended the development of a product that provided “mild” nicotine satisfaction targeted at “new users . . . age group 15-35.”
- Shortly after these recommendations, UST began aggressively to market low-nicotine products, targeted “for you guys just starting out.” Marketing techniques included free sampling on college campuses and at sports events. Advertisements included instructions on use for new users.
- Numerous UST documents and statements refer to an explicit “graduation process” in which users of smokeless tobacco are encouraged to start with low-nicotine starter brands and then progress to higher nicotine brands. For

instance, a UST vice president has stated that Skoal Bandits, one of UST's low-nicotine brands, "is the introductory product, and we look towards establishing a normal graduation process."

These UST documents confirm that smokeless tobacco manufacturers deliberately produce brands with a range of nicotine deliveries in order to allow users to progress (or "graduate") from low-delivery products to high-delivery products. They thus corroborate the Agency's finding that smokeless tobacco is intended to affect the structure and function of the body.

E. The "Intended Use" of a Product Is Not Determined Only on the Basis of Promotional Claims

The principal legal argument of the tobacco industry is that the intended use of a product must be determined exclusively on the basis of the promotional claims made by the manufacturer. Under the industry's legal theory, the Agency must disregard the voluminous internal tobacco industry documents showing that the manufacturers have in mind, and design their products to provide, the pharmacological effects of nicotine. The tobacco industry also urges the Agency to disregard the evidence of the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco, as well as the evidence of the actual consumer use of these products for pharmacological purposes.

The Agency rejects the industry's legal argument. First, the industry's position is contrary to the plain language of the Act. The Act does not say that only products "promoted" to affect the structure or function of the body are drugs or devices. Rather, the Act says that products "intended" to affect the structure or function of the body are drugs or devices. The plain meaning of "intend" is significantly broader than the meaning of "promote." As summarized above, the plain meaning of "intend" includes "to have in

mind” and “to design” for a particular use. The evidence that is relevant to determining the uses that a manufacturer “has in mind” or “designs” includes not just the promotional claims of the manufacturer, but also the internal statements of the manufacturer, as well as the manufacturer’s research and actions. Moreover, the ordinary meaning of “intend” also encompasses the reasonably foreseeable consequences of the manufacturer’s actions, thereby making consideration of the foreseeable pharmacological effects and uses of a product relevant to its intended use.

Second, the industry’s position is contrary to FDA’s regulations. These regulations provide that the term “intended use” refers to the “objective intent” of the manufacturer. Under these regulations, the Agency determines the intent of the manufacturer objectively by evaluating all of the relevant evidence in the record from the perspective of a reasonable fact-finder. FDA’s regulations expressly direct the Agency to consider the manufacturer’s “knowledge” of the use of the product; the manufacturer’s “expressions” and “oral or written statements”; and the “circumstances surrounding the distribution of the article.” 21 CFR 201.128, 801.4. Thus, the regulations expressly provide that the Agency should consider a broad range of evidence in determining intended use, not merely the manufacturer’s promotional claims.

Third, the industry’s position is contrary to judicial decisions interpreting the Act. These decisions have applied the Act’s definitions of drug and device to two different types of products. The first type of product is one that contains no known drug ingredients and has no known pharmacological effects or uses. In cases involving such products, the courts recognize that a manufacturer’s promotional claims have a crucial

role in establishing intended use. Even a product like mineral water can be brought within FDA's jurisdiction by advertisements that make pharmacological claims. See *Bradley v. United States*, 264 F. 79 (5th Cir. 1920).

The situation is fundamentally different, however, when the product contains a known drug ingredient like nicotine that has known pharmacological effects and uses. When a product is pharmacologically active, the courts have recognized that "a fact finder should be free to pierce . . . a manufacturer's misleading . . . labels to find actual therapeutic intent on the basis of objective evidence." *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir. 1974). Thus, contrary to the industry's contention, the courts have recognized that in determining intended use, FDA may consider a wide range of evidence beyond the manufacturer's promotional claims, including evidence of the pharmacological effects of the product, *e.g.*, *United States v. Undetermined Quantities . . . "Pets Smellfree,"* 22 F.3d 235, 240 (10th Cir. 1994); the purposes for which consumers actually use the product, *e.g.*, *ASH*, 655 F.2d at 239-240; the medical use of the product, *e.g.*, *United States v. An Article of Device . . . Toftness Radiation Detector*, 731 F.2d 1253, 1257 (7th Cir. 1984); and how the product was formulated, *e.g.*, *American Health Products Co. v. Hayes*, 574 F. Supp. 1498, 1508 (S.D.N.Y. 1983).

Fourth, the industry's position is contrary to FDA's administrative precedent. In a broad range of instances, FDA has asserted jurisdiction over products based on the likely pharmacological effects and uses of the product—not express promotional claims. Indeed, in many of these instances, the manufacturer's promotional claims were designed to disguise the actual intended use of the product.

Fifth, the industry's position is contrary to the public health objectives of the Act.

If promotional claims alone determined the intended use of a product, virtually any manufacturer of drugs or devices could avoid the Act's reach by simply refraining from making pharmacological claims for the product. For instance, under the industry's interpretation, a company could market a potent tranquilizer or amphetamine for its "pleasurable" effect and escape FDA regulation. To protect the public from the unregulated distribution of products with pharmacologically active ingredients, the Agency must be able to look beyond a manufacturer's promotional claims when determining whether to regulate such products.

For these reasons, the Agency rejects the tobacco industry's legal theory that intended use is determined exclusively on the basis of promotional claims. The Agency also rejects the premise of the industry's position—namely, that their promotional claims demonstrate that cigarettes and smokeless tobacco are not intended to affect the structure and function of the body. To the contrary, as internal tobacco company documents indicate, promises of "satisfaction" in tobacco advertisements imply that cigarettes and smokeless tobacco will provide consumers with desired pharmacological effects of nicotine. These implied drug claims lend support to the Agency's finding that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

F. Response to Additional Comments

This section responds to additional comments regarding the evidence of the intended use of cigarettes and smokeless tobacco and the Agency's use of this evidence.

G. Considered Cumulatively, the Evidence Overwhelmingly Demonstrates that Cigarettes and Smokeless Tobacco Are Intended to Affect the Structure and Function of the Body

As summarized above, the evidence in the record provides several independent bases for the Agency's finding that cigarettes and smokeless tobacco are "intended" to affect the structure and function of the body. Independently, each of these distinct categories of evidence is a strong and sufficient basis for the Agency's conclusion that the manufacturers of cigarettes and smokeless tobacco intend the pharmacological effects and uses of their products. Considered together, they are mutually corroborating. Both independently and taken as a whole, therefore, the evidence in the administrative record overwhelmingly establishes that cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body" within the meaning of the Act.

III. Cigarettes and Smokeless Tobacco Are Combination Products Consisting of "Drug" and "Device" Components

The Agency's findings in sections I and II establish that the nicotine in cigarettes and smokeless tobacco is a "drug" under section 201(g)(1)(C) of the Act. These findings show that the nicotine in cigarettes and smokeless tobacco "affect[s] the structure or any function of the body" and that these effects are "intended." These findings thus demonstrate that the nicotine in cigarettes and smokeless tobacco meets the statutory definition of a "drug."

Cigarettes and smokeless tobacco are not simply packaged nicotine, however. They also include delivery devices that deliver nicotine to the body. Section 201(h)(3), 21 U.S.C. 321(h)(3). In the case of cigarettes, the device components work together upon combustion outside the body to form a nicotine-containing aerosol, which then delivers

nicotine to the body when inhaled by the smoker. In the case of smokeless tobacco, the device components function by presenting nicotine to the consumer in a form that is palatable and absorbable by the buccal mucosa. Unlike the drug nicotine, these device components achieve their primary intended purpose without chemical action in or on the body and without being metabolized.

The presence of both drug and device components in cigarettes and smokeless tobacco make these products “combination products” under section 503(g) the Act, 21 U.S.C. 353(g)(1).

IV. FDA’s Assertion of Jurisdiction Over Cigarettes and Smokeless Tobacco at This Time Is Justified

FDA has always exercised jurisdiction over tobacco products when there is sufficient evidence in the record to establish that these products are “intended” to treat or prevent disease or to affect the structure or function of the body. Over thirty years ago, for instance, the Agency asserted jurisdiction over a brand of cigarettes when the evidence established that the brand was intended to reduce body weight. *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959).

The Agency last considered whether to regulate cigarettes in the late 1970’s, when the Agency rejected petitions by Action on Smoking and Health (ASH) urging the Agency to regulate cigarettes as drugs or devices. The Agency agreed with ASH that “objective evidence other than manufacturers’ claims can be material to a determination of intended use” and that “evidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act.” However, the Agency concluded that the evidence presented by ASH in the

petition was insufficient to establish that cigarettes and smokeless tobacco were in fact intended to affect the structure and function of the body. The court deferred to the Agency's determination not to regulate cigarettes as drugs but expressly left open the possibility that FDA might, at a later date, revisit its decision and determine that it did indeed have jurisdiction over cigarettes. *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

The evidence regarding the intended use of cigarettes and smokeless tobacco has changed dramatically since *ASH*. First, a scientific consensus has emerged since 1980 that nicotine is addictive and has other significant pharmacological effects and that cigarettes and smokeless tobacco are used by consumers to obtain pharmacological effects. As summarized above, no major public health organization had determined that nicotine was an addictive drug before 1980. Between 1980 and 1994, however, every leading scientific organization with expertise in addiction concluded that nicotine is addictive. This new evidence thus shows that the pharmacological effects and uses of cigarettes and smokeless tobacco have become foreseeable.

Second, scientific evidence accumulated since 1980 has shown that the vast majority of people who use cigarettes and smokeless tobacco use these products to satisfy addiction or to obtain other pharmacological effects. As summarized above, this new evidence now shows that 77% to 92% of smokers are addicted to nicotine and provides a basis for estimating that 75% of young regular smokeless tobacco users are addicted to nicotine. This new evidence establishes that consumers use cigarettes and smokeless tobacco predominantly for pharmacological purposes.

Third, FDA, congressional, and other investigations have recently uncovered a wealth of documents from a wide range of tobacco companies that show that the manufacturers have long known of the pharmacological effects and uses of nicotine and have designed their products to provide pharmacologically active doses of nicotine to consumers. Virtually none of this information was available to FDA in 1980.

Information developed since 1980 also demonstrates that the Agency has a unique public health opportunity to reduce substantially the more than 400,000 deaths from tobacco use each year in the United States. This information shows that for most people tobacco use and nicotine addiction begin in childhood and adolescence, and that an increasing number of American children and adolescents are using cigarettes and smokeless tobacco. The data now suggest that if children and adolescents can be prevented from initiating tobacco use during their teenage years, they are unlikely to begin tobacco use later in life, thereby preventing the onset of tobacco-related disease and premature death.

Before the importance of youth-centered interventions was identified, most of the regulatory approaches available under the Federal Food, Drug, and Cosmetic Act to address tobacco-related disease and death, such as removal of the products from the market, were not believed to be feasible solutions. It is now apparent, however, that FDA's authority to restrict the sale, distribution, and use of cigarettes and smokeless tobacco to people under the age of eighteen is an effective tool to reduce the adverse health consequences of tobacco use. Thus, asserting jurisdiction over cigarettes and

smokeless tobacco now presents an opportunity to use the Agency's resources effectively for substantial public health gains.

The court in *ASH* specifically recognized that FDA was permitted to modify its position and that any new FDA position would be accorded deference by the courts. *Id.* at 242 n.10. In light of the substantial new information, FDA has reviewed its earlier determination not to assert jurisdiction over tobacco products. The new evidence persuades the Agency to conclude that its previous position is no longer consistent with the relevant facts and should be changed. The evidence before the Agency is now sufficient to establish that cigarettes and smokeless tobacco are in fact intended to affect the structure and function of the body.

V. *Congress Has Not Precluded or Preempted FDA from Regulating Cigarettes and Smokeless Tobacco*

FDA disagrees with the comments of the tobacco industry that assert that Congress has precluded or preempted FDA from regulating cigarettes and smokeless tobacco. The plain language of the Act does not exclude cigarettes or smokeless tobacco from FDA jurisdiction. Tobacco products are expressly excluded from the jurisdiction of the Consumer Product Safety Commission under the Federal Hazardous Substances Act and from the jurisdiction of the Environmental Protection Agency under the Toxic Substances Control Act. The absence of any similar exclusion in the Federal Food, Drug, and Cosmetic Act demonstrates that Congress has not chosen to exclude cigarettes and smokeless tobacco from FDA jurisdiction.

The legislative history of the Act confirms that the Act should not be interpreted to preclude FDA jurisdiction over tobacco products. Congress has long known that FDA

will assert jurisdiction over cigarettes when the evidence establishes that the cigarettes are intended to affect the structure or function of the body. For instance, FDA asserted jurisdiction more than 30 years ago over cigarettes that were intended to reduce weight. This demonstrates that Congress has not “ratified” or “acquiesced in” an interpretation of the Act that would preclude FDA from regulating tobacco products intended to affect the structure or function of the body.

Moreover, even if Congress had acquiesced in such an interpretation of the Act, congressional acquiescence in a prior agency interpretation does not prevent an agency from changing its interpretation. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 45 (1983). In the case of cigarettes and smokeless tobacco, a change in interpretation would be justified by the new evidence in the record—evidence never previously before either the Agency or Congress.

The Agency also disagrees that other federal statutes preempt FDA jurisdiction over cigarettes and smokeless tobacco. Both the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act have provisions that expressly specify the limited extent to which these laws preempt FDA and other federal agencies from regulating cigarettes or smokeless tobacco. In the Federal Cigarette Labeling and Advertising Act, for instance, federal agencies are preempted only from requiring “statement[s] relating to smoking and health . . . on any cigarette package.” 15 U.S.C. 1334(a). The narrow preemption provisions that Congress expressly included in these statutes do not apply to FDA’s assertion of jurisdiction over cigarettes and smokeless tobacco.

No other federal statutes contain provisions preempting FDA regulation of tobacco products. In the absence of an express preemption provision, one federal statute preempts another federal statute only where there is an irreconcilable conflict between the two laws. *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253 (1992). There is no irreconcilable conflict between FDA jurisdiction and other federal statutes.

VI. *FDA Employed Procedures That Provided an Opportunity for Full Public Participation and Exceeded All Legal Requirements*

FDA went to great lengths to involve the public in the process by which the Agency made its final jurisdictional determination. The Commissioner made public his intention to investigate the role of nicotine in tobacco products, testified twice before Congress on the Agency's findings, wrote to all the major cigarette and tobacco companies requesting information on the role of nicotine in their products, and held a public advisory committee meeting on the abuse potential of nicotine. Although the Agency is not required to undertake rulemaking to establish jurisdiction over new products, the Agency published in the *Federal Register* its initial jurisdictional findings and comprehensive legal analysis in a 325-page document, supported by over 600 footnotes, and sought public comment on those findings. The Agency placed over 210,000 pages of supporting documents in a public docket. FDA received over 700,000 comments on the Jurisdictional Analysis and the accompanying proposed rule. The Agency has responded to substantive comments in this Annex and in the preamble to the Final Rule.

FDA disagrees with the comments of the tobacco industry that the record supporting the Jurisdictional Analysis or the procedures the Agency followed were inadequate. The procedures the Agency employed in reaching its final determination

exceeded the requirements of the Administrative Procedures Act (APA) and the Agency's own procedural requirements.

INTRODUCTION

On August 11, 1995, the Food and Drug Administration (hereinafter FDA or the Agency) announced the results of its extensive investigation and comprehensive legal analysis regarding the Agency's jurisdiction over cigarettes and smokeless tobacco in a document entitled, "Nicotine in Cigarettes and Smokeless Tobacco Products Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act" (hereinafter referred to as the "Jurisdictional Analysis"). 60 FR 41453-41787 (Aug. 11, 1995). The Agency reported that its investigation and analysis supported a finding at that time that nicotine in cigarettes and smokeless tobacco is a drug and that these products are drug delivery devices within the meaning of the Federal Food, Drug, and Cosmetic Act (hereinafter the Act). Because of the unique importance of the jurisdictional issue, the Agency invited comment on this finding.

The public comment period closed on January 2, 1996. 60 FR 53620 (Oct. 16, 1995). On March 20, 1996, the Agency published in the *Federal Register* notice of an additional 30 day comment period, until April 19, 1996, limited to specific documents the Agency added to the docket in support of the Agency's analysis of jurisdiction. 61 FR 11419 (Mar. 20, 1996). The Agency received over 700,000 comments on its Jurisdictional Analysis and its Proposed Rule restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. The Agency has carefully considered these comments.

This final jurisdictional determination responds to the public comments and reports the Agency's conclusion that the nicotine in cigarettes and smokeless tobacco is a drug and that cigarettes and smokeless tobacco are drug delivery devices whose purpose is to

deliver nicotine to the body in a manner in which it can be readily absorbed. These products, therefore, are subject to FDA regulation under the Act.

The legal question of whether cigarettes and smokeless tobacco are drugs and devices subject to FDA regulation is one that “FDA has jurisdiction to decide with administrative finality.” *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973). The Act defines a “drug” as (1) an article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,” or (2) an article (other than food) “*intended to affect the structure or any function of the body of man or other animals.*” Section 201(g)(1)(B) and (C), 21 U.S.C. 321(g)(1)(B) and (C) (emphasis added). The Act’s device definition parallels the drug definition and provides that an instrument, apparatus, or other similar article is a “device” if it is (1) “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals,” or (2) “*intended to affect the structure or any function of the body of man or other animals.*” Section 201(h)(2) and (3), 21 U.S.C. 321(h)(2) and (3) (emphasis added). These definitions are intended to be broad in scope and to encompass products that are not within the ordinary medical definitions of drugs and devices. *See United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 793 (1969) (“we think it plain that Congress intended to define ‘drug’ far more broadly than does the medical profession”).

In applying these legal standards to cigarettes and smokeless tobacco, the Agency has focused on the second prong of the definition of drug and device: whether cigarettes and smokeless tobacco are “intended to affect the structure or any function of the body.” Historically, the Agency has regulated tobacco products whenever the evidence before the

Agency was sufficient to establish that the products were intended to affect the structure or function of the body. FDA last considered whether cigarettes were drugs or devices in the late 1970's, determining that the limited evidence then before the Agency was insufficient to demonstrate that these products were intended to affect the structure or function of the body. *See Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). Since that time, substantial new evidence has become available to FDA. This evidence includes the emergence of a scientific consensus that cigarettes and smokeless tobacco cause addiction to nicotine and the disclosure of thousands of pages of internal tobacco company documents detailing that the manufacturers intend to affect the structure and function of the human body.

The determination whether a product is subject to FDA jurisdiction often requires the Agency to make difficult factual judgments, including judgments regarding the intended use of the product. The Agency must have enough evidence to show that these factual judgments are rational and not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. 706(2)(A); *see National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 700-701 (2d Cir. 1975), *cert. denied*, 423 U.S. 827 (1975). The Agency must provide some evidentiary support for its factual judgments, and there must be a rational connection between these judgments and the conclusions reached. *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983). The Agency should also have considered all the relevant data and the relevant aspects of the issue. *Id.*; *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). An agency's factual judgments made in the context of an informal agency action ordinarily need only be supported by a record that

shows a “rational basis” for the agency’s decision, *Natural Resources Defense Council, Inc. v. EPA*, 16 F.3d 1395, 1401 (4th Cir. 1993), or by a record consisting of “some evidence” in support of the agency’s decision. *Aman v. FAA*, 856 F.2d 946, 950 n.3 (7th Cir. 1988) (while an agency determination need only have “some evidentiary basis to avoid being held ‘arbitrary and capricious,’ [t]he difference between ‘some’ and ‘substantial’ probably cannot be precisely stated except in the context of particular cases. . . .”). Several courts, however, have held that an agency’s factual judgments must always be supported by “substantial evidence,” even though that standard is intended to be applied only to formal “on the record” agency actions, *see* 5 U.S.C. 706(2)(E).¹

In this case, the Agency’s evidentiary record exceeds these standards. That is, FDA has concluded that the evidence now before the Agency supports a finding of jurisdiction over these products. In assessing the new evidence, FDA has used a two-step approach, evaluating first whether the nicotine in these products “affects the structure or

¹ *See, e.g., Ass’n of Data Processing Service Organizations, Inc. v. Board of Governors*, 745 F.2d 677, 683-684 (D.C. Cir. 1984) (Scalia, J) (“When the arbitrary or capricious standard is performing that function of assuring factual support, there is no substantive difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a ‘nonarbitrary’ factual judgment supported only by evidence that is not substantial in the APA sense”). *Contra Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1213-1214 and n.17 (5th Cir. 1991) (declining to find that the substantial evidence standard and the arbitrary and capricious standard “are in fact one and the same”); *Am. Paper Inst. v. Am. Elec. Power Serv. Corp.*, 461 U.S. 402, 412 n.7 (1983) (in the absence of a specific command in the statute to employ a particular standard of review, the Court of Appeals should have applied the more lenient arbitrary and capricious standard in evaluating the factual basis supporting an agency’s informal rulemaking).

The difference in the case law, however, is of no consequence here because FDA’s evidentiary record exceeds the “substantial evidence” standard—the more stringent of the two standards. Substantial evidence is “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,” *Consolo v. Federal Maritime Commission*, 383 U.S. 607, 619-620 (1966) (quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)), even if two inconsistent conclusions might be inferred from the same evidence. *See Consolo*, 383 U.S. at 620; *NLRB v. Nevada Consolidated Copper Corp.*, 316 U.S. 105, 106 (1942). Under the substantial evidence standard, an agency’s factual determinations are conclusive even if supported by “something less than the weight of the evidence” *Consolo*, 383 U.S. at 620 (emphasis added).

any function of the body” and second whether these effects are “intended.” FDA has determined that the evidence overwhelmingly demonstrates that (1) nicotine in cigarettes and smokeless tobacco has significant effects on the structure and function of the body and (2) these effects are intended by the manufacturers of these products.

The Agency’s determination that nicotine in cigarettes and smokeless tobacco “affect[s] the structure or any function of the body” is based on three central findings:

1. Nicotine in cigarettes and smokeless tobacco causes and sustains addiction.
2. Nicotine in cigarettes and smokeless tobacco causes other psychoactive (mood-altering) effects, including tranquilization and stimulation.
3. Nicotine in cigarettes and smokeless tobacco controls weight.

These findings demonstrate that nicotine in cigarettes and smokeless tobacco has the same pharmacological effects as other drugs that FDA has traditionally regulated, including tranquilizers, stimulants, appetite suppressants, and products used in the maintenance of addiction such as methadone. Thus, the effects of nicotine in cigarettes and smokeless tobacco on the structure and function of the body are within FDA’s jurisdiction.

FDA’s determination that the manufacturers of cigarettes and smokeless tobacco “intend” the effects of nicotine on the structure and function of the body is based on five central findings:

1. The addictive and other pharmacological effects of nicotine are so widely known and accepted that it is foreseeable to a reasonable manufacturer that cigarettes and smokeless tobacco will cause addiction to nicotine and other significant pharmacological effects and will be used by

consumers for pharmacological purposes, including sustaining their addiction to nicotine.

2. Consumers use cigarettes and smokeless tobacco predominantly for pharmacological purposes, including sustaining their addiction to nicotine, mood alteration, and weight loss.
3. Manufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine and mood alteration, and that consumers use their products primarily to obtain the pharmacological effects of nicotine.
4. Manufacturers of cigarettes and smokeless tobacco design their products to provide consumers with a pharmacologically active dose of nicotine.
5. An inevitable consequence of the design of cigarettes and smokeless tobacco to provide pharmacologically active doses of nicotine is to keep consumers using cigarettes and smokeless tobacco by sustaining their addiction to nicotine.

Each of these findings provides an independent basis for establishing that the manufacturers of cigarettes and smokeless tobacco “intend” to affect the structure and function of the body. Taken together, the cumulative weight of the evidence convincingly supports the determination that the effects of nicotine on the structure and function of the body are “intended” by the manufacturers.

FDA’s assertion of jurisdiction over cigarettes and smokeless tobacco is consistent with the Agency’s assertion of jurisdiction over other similar products. FDA regulates a diverse range of products under the Act. These products—foods, drugs, devices, cosmetics, and radiation-emitting electronic products—all “affect the health and well-being of the public.” *United States v. Park*, 421 U.S. 658, 672 (1975). The common feature that distinguishes these products is their intimate and potentially harmful contact

with the human body. *See id.* at 668. FDA-regulated products include those that are intended to be ingested, inhaled, applied to the skin, implanted, or otherwise used in close contact with the body. Cigarettes, which deliver a pharmacologically active dose of nicotine to the body through inhalation, and smokeless tobacco, which delivers a pharmacologically active dose of nicotine through buccal absorption, share this distinguishing feature and thus are properly subject to FDA jurisdiction.

The determinations that (1) the nicotine in cigarettes and smokeless tobacco “affects the structure or any function of the body” and (2) these effects are “intended” by the manufacturers satisfy the legal requirements under the Act for FDA jurisdiction. FDA has also determined that cigarettes and smokeless tobacco contain both a “drug” and a “device” and are thus combination products within the meaning of the Act. Accordingly, the Agency has concluded that the nicotine in cigarettes and smokeless tobacco is a drug and that cigarettes and smokeless tobacco are drug delivery devices under the Federal Food, Drug, and Cosmetic Act.

I.

I. CIGARETTES AND SMOKELESS TOBACCO “AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY” WITHIN THE MEANING OF THE ACT

In the Jurisdictional Analysis, FDA found, based on the evidence available to it at the time, that nicotine in cigarettes and smokeless tobacco is “highly addictive, causes other psychoactive effects, such as relaxation and stimulation, and affects weight regulation.” See Jurisdictional Analysis, 60 FR 41464 (Aug. 11, 1995). The Agency found that the nicotine in these products “has pharmacological effects on both the structure and function of the central nervous system, particularly the brain,” and that “[a]ddiction is a direct result of nicotine’s effects on the structure and function of the body.” *Id.* at 41470. Based on these findings of pharmacological effects, the Agency found that cigarettes and smokeless tobacco “*affect the structure or any function of the body.*” *Id.* (emphasis added).

As described more fully below, the Agency received comments that agreed and disagreed with the Agency’s position.² After considering the evidence in the administrative record,³ including the public comments, the Agency finds that cigarettes and

² The Agency received a consolidated comment of the cigarette industry (Brown & Williamson Tobacco Corp., Liggett Group Inc., Lorillard Tobacco Co., Philip Morris Inc., R.J. Reynolds Tobacco Co., Tobacco Institute Inc.) (Jan. 2, 1996) (hereinafter Joint Comments of the Cigarette Manufacturers). See AR (Vol. 535 Ref. 96). The Agency also received a consolidated comment of the smokeless tobacco industry (Smokeless Tobacco Council Inc., Brown & Williamson Tobacco Corp., Conwood Co., L.P., National Tobacco Co., L.P., the Pinkerton Tobacco Co., R.C. Owen Co., Swisher International, Inc., United States Tobacco Co.) (Jan. 2, 1996) (hereinafter Joint Comments of the Smokeless Tobacco Manufacturers). See AR (Vol. 526 Ref. 95).

³ In the footnotes of this document, cites to the administrative record (AR) specify both the number of the reference and the volume of the AR in which the reference is found. The reference may contain the full document or a partial document. Where the reference contains a partial document, the full document may be found elsewhere in the AR. In a small number of cases, a reference will occupy several volumes of the AR, for example, the Joint Comments of the Cigarette Manufacturers. In these cases, the cite will specify the volume of the AR in which the reference begins.

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smokeless tobacco do indeed “affect the structure or any function of the body” within the meaning of sections 201(g)(1)(C) and 201(h)(3) of the Act, 21 U.S.C. 321(g)(1)(C), 321(h)(3).

To interpret the Federal Food, Drug, and Cosmetic Act in a manner that excludes the effects of these products from the scope of the structure-function prong of the drug and device definitions would be inconsistent with the plain meaning of the Act, its legislative history, case law interpreting the structure-function prong, and the Agency’s past applications of that provision. The Agency’s conclusions are summarized in section I.A., followed by a detailed discussion of the comments and the Agency’s responses to them in section I.B.

A. THE PHARMACOLOGICAL EFFECTS OF THE NICOTINE IN CIGARETTES AND SMOKELESS TOBACCO ON THE BODY ARE SIGNIFICANT

Cigarettes and smokeless tobacco contain nicotine, an addictive and pharmacologically active drug. *See* section II.A., below. Nicotine is the active ingredient in several products regulated as drugs by the Agency, including nicotine transdermal patches, nicotine chewing gums, nicotine nasal spray, and Favor, a hollow paper tube with nicotine impregnated in the mouthpiece. *See* Jurisdictional Analysis, 60 FR 41482, 41549-41550. The effects of the nicotine in cigarettes and smokeless tobacco greatly exceed those exerted by the nicotine-containing products already regulated by the Agency.⁴

Nicotine in cigarettes and smokeless tobacco produces significant pharmacological effects on the human body. First, nicotine causes and sustains addiction. The processes

⁴ Nicotine-use cessation products are discussed in section II.A.5., below.

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that lead to addiction to nicotine in cigarettes and smokeless tobacco are similar to those that lead to addiction to products such as morphine and opium. *See* section II.A.2., below. Like other addictive substances, nicotine in cigarettes and smokeless tobacco achieves its addictive effects by exerting psychoactive, or mood-altering, effects on the brain and by producing chemical reactions in the brain that motivate repeated, compulsive use of the substance. *See* section II.A.3., below. These pharmacological effects create dependence in the user. *Id.*

In addition to creating and sustaining addiction, cigarettes and smokeless tobacco produce other significant pharmacological effects. For example, under some circumstances, nicotine in cigarettes and smokeless tobacco has a sedating or tranquilizing effect on mood and brain activity. *See* section II.A.4., below. Under other circumstances, nicotine in cigarettes and smokeless tobacco has a stimulant or arousal-increasing effect on the body. *Id.*

Nicotine in cigarettes and smokeless tobacco also controls body weight. *Id.* Clinical and animal studies indicate that nicotine administration causes weight loss and that cessation of nicotine administration results in weight gain. *Id.*

These effects on the structure and function of the body are significant and quintessentially drug-like. They produce immediate pharmacological changes in the function of the brain (depressing or stimulating arousal); they change the physical structure of the body (increased growth of nicotine receptors in the brain, weight loss); and they cause drug dependence (addiction). *Id.*

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The tobacco industry comments argue that “remote” or “insignificant” pharmacological effects are not subject to FDA jurisdiction. Although “remote physical effect[s] upon the body” may not be covered by the structure-function provision, *see E.R. Squibb & Sons, Inc. v. Bowen*, 870 F.2d 678, 682 (D.C. Cir. 1989), the pharmacological effects of cigarettes and smokeless tobacco are not “remote” or insignificant. Indeed, they are powerful and immediate pharmacological effects that are not qualitatively or quantitatively different from the effects of other drugs subject to FDA jurisdiction.

In fact, the effects of cigarettes and smokeless tobacco—addiction, sedation, stimulation, and weight loss—are precisely the types of effects the Agency traditionally regulates. It is well established that the Agency has the authority to regulate, and has regulated, products that sedate, tranquilize, or reduce anxiety (e.g., Valium and other benzodiazepines); products that stimulate or restore mental alertness (e.g., caffeine-containing pills such as NoDoz, *see Stimulant Drug Products for Over-the-Counter Human Use, Final Monograph*, 53 FR 6100 (February 29, 1988); 21 CFR Part 340);⁵ products that cause weight loss (*see Weight Control Products for Over-the-Counter Human Use, Certain Active Ingredients*, 56 FR 37792 (August 8, 1991); 21 CFR 310.545(a)(20); *see also United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959)); and products that are used for maintenance treatment of addiction (e.g., methadone and other “narcotic drugs [used] in the medical treatment of narcotic addiction,” 21 CFR 291.501). The approved uses of these products include uses to “affect the structure or any function of the body” under

⁵ A more detailed discussion of the Agency’s regulation of caffeine and caffeine-containing products is contained in section I.B., below.

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section 201(g)(1)(C) of the Act. Thus, cigarettes and smokeless tobacco have the same effects as products that are undeniably within FDA's jurisdiction.

Indeed, internal tobacco company documents reveal that tobacco industry scientists understand that the nicotine in tobacco produces pharmacological effects no different from those produced by approved drugs. These industry scientists viewed prescription drugs as competing products.⁶ Over three decades ago, the British American Tobacco Company (BATCO), the parent of Brown & Williamson Tobacco Corporation, commissioned a study to compare the effects of nicotine with those of tranquilizers, "which might supersede tobacco habits in the near future."⁷ The study concluded that nicotine was "more beneficial or less noxious—than the new tranquilizers" because it reduced stress and regulated weight.⁸

Philip Morris and R.J. Reynolds Tobacco Company (RJR) also have repeatedly compared the effects of nicotine from tobacco to the effects of drugs regulated by FDA. For example, Philip Morris researchers and officials have concluded that smokers use cigarettes as "a narcotic, tranquilizer, or sedative"⁹ and that "[nicotine] is a physiologically active, nitrogen containing substance. *Similar organic chemicals include . . . quinine,*

⁶ These documents, and the conclusions the Agency has drawn from them, are described in detail in sections II.C. and II.D., below.

⁷ Haselbach CH, Libert O, *Final Report on Project HIPPO II* (Geneva: Battelle Memorial Institute, International Division, Mar. 1963), at 1. See AR (Vol. 64 Ref. 321).

⁸ *Id.* at 2.

⁹ Udow A, *Why People Start to Smoke* (Jun. 2, 1976), in 141 Cong. Rec. H7664 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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cocaine, atropine and morphine. While each of these substances can be used to affect human physiology, *nicotine has a particularly broad range of influence.*"¹⁰

Similarly, RJR scientists have reported that smokers who inhale lightly appear to use tobacco to achieve "mental activation and performance enhancement" whereas those who inhale more deeply show brain effects that "may reflect the anxiolytic properties of benzodiazepines,"¹¹ prescription drugs used to alleviate anxiety. Another RJR researcher has stated:

[I]n different situations and at different dose levels, *nicotine appears to act as a stimulant, depressant, tranquilizer, psychic energizer, appetite reducer, anti-fatigue agent, or energizer.* . . . Therefore, in addition to competing with products of the tobacco industry, *our products may, in a sense, compete with a variety of other products with certain types of drug action.*¹²

Thus, the industry's own documents acknowledge that the pharmacological effects of their products are the same as the effects the Agency has considered to be structure-function effects within the meaning of section 201(g)(1)(C). Notwithstanding the views of their own scientists, the tobacco industry comments publicly assert that cigarettes and smokeless tobacco do not affect the structure or any function of the body within the meaning of the Act because their effects are too "remote" or not therapeutic or beneficial.

The ramifications of the tobacco industry's position are far-reaching. If the Agency were to determine that the pharmacological effects of cigarettes and smokeless

¹⁰ Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table* (emphasis added). See AR (Vol. 531 Ref. 122).

¹¹ Pritchard WS, R.J. Reynolds Tobacco Co., Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485, at 488. See AR (Vol. 3 Ref. 23-2).

¹² Teague CE, R.J. Reynolds Tobacco Co., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1-2 (emphasis added). See AR (Vol. 531 Ref. 125).

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tobacco are not effects on the structure and function of the body, or are not significant effects, the Agency's authority to regulate other products with like pharmacological effects—sedation, stimulation, weight loss, and satisfaction of addiction—would be called into question. Under the industry's characterization of the effects of their products, even if the pharmacological effects of sedation, stimulation, weight loss, or satisfaction of addiction were expressly promoted or otherwise intended, products producing the same effects could not be regulated under section 201(g)(1)(C) or 201(h)(3) because, by the industry's definition, these products would not "affect the structure or any function of the body." This view, if accepted, could undermine the Agency's ability to regulate drugs and devices that are not used in the diagnosis or treatment of disease, but significantly affect the structure or any function of the body. Further, such an interpretation would be inconsistent with over 50 years of Agency practice since passage of the Act in 1938.

In sum, cigarettes and smokeless tobacco do affect the structure and function of the body within the meaning of the Act. The pharmacological effects of nicotine-containing tobacco products are significant and the same as the effects of other products traditionally regulated by FDA. Because these effects are "intended" within the meaning of the Act—the issue discussed in section II., below—cigarettes and smokeless tobacco fall within the jurisdiction of the Agency under the Act.

B. RESPONSE TO COMMENTS

1. As noted in section I.A., above, tobacco industry comments and others argue that the effects of nicotine delivered from cigarettes and smokeless tobacco are too remote or insignificant to be subject to the Act. These comments minimize nicotine's

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effects and argue that nicotine-containing tobacco products “stimulate the senses” and “calm[] feelings of stress,” more like the effects of “hammocks [and] gardening tools” than those of products within FDA’s jurisdiction.¹³ The industry comments urge the Agency to follow the holding of *FTC v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D.N.Y. 1952), *aff’d*, 203 F.2d 955 (1953), where the court concluded that the “soothing” effects of cigarettes do not affect the structure and function of the body.

FDA disagrees with these comments. As described earlier in this section, nicotine’s effects on the structure and function of the body are comparable both in quality and quantity to those of tranquilizers, stimulants, weight control products, and products for long-term maintenance of addiction. These effects have long been recognized as effects on the structure or function of the body that are within FDA’s jurisdiction. In addition, the Act’s legislative history and case law interpreting the Act provide ample support for the conclusion that nicotine’s effects are significant and within the scope of the Act. While “remote physical effect[s] on the body” may not be sufficient to invoke the Act’s jurisdiction, *see Squibb*, 870 F.2d at 682, nicotine produces significant pharmacological and physiological effects on the structure and function of the body, and these effects clearly fall within sections 201(g)(1)(C) and 201(h)(3).

The courts have held that effects much less significant than those of nicotine are effects on the structure or function of the body and are within FDA’s jurisdiction.

¹³ Joint Comments of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 241. *See* AR (Vol. 526 Ref. 95).

Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), vol. II, at 65-66. *See* AR (Vol. 535 Ref. 96).

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Products whose effects have been found sufficient to fall within the scope of sections 201(g)(1)(c) and 201(h)(3) include those for temporary smoothing of wrinkles, *United States v. . . . "Line Away, Temporary Wrinkle Smoother,"* 284 F. Supp. 107 (D. Del. 1968), *aff'd*, 415 F.2d 369 (3d Cir. 1969); *United States v. . . . "Sudden Change,"* 409 F.2d 734 (2d Cir. 1969); and products that deliver low levels of oxygen for recreational use to enhance athletic performance, *United States v. . . . "Sports Oxygen,"* Civ. No. 89-2085 (D.N.J. Oct. 27, 1992), *reprinted in Federal Food, Drug, and Cosmetic Act: A Judicial Record, 1991-92*, 110-119. These effects are plainly less significant than the potent psychoactive, addictive, and weight-regulating effects of nicotine.

Weight loss is one of the effects of cigarettes and smokeless tobacco. *See* section II.A.4., below. Courts have held that this type of effect alone is sufficient to make cigarettes a drug when the product is "intended to affect the structure and functions of the human body by . . . achieving a reduction in the body's weight." *United States v. 354 Bulk Cartons . . . "Trim Reducing-Aid Cigarettes,"* 178 F. Supp. 847, 851 (D.N.J. 1959). Similarly, the legislative history of section 201(g)(1)(C) also demonstrates that weight loss alone is an effect on the structure and function of the body within the meaning of the Act. Indeed, one of the principal reasons cited by Congress for broadening the definition of "drug" to include products that affect the structure or function of the body was to bring weight control products within FDA's jurisdiction. *See* 78 Cong. Rec. 8960, 73d Cong., 2d Sess. (May 16, 1934) (statement of Senator Copeland), *reprinted in A Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments* (hereinafter *Legislative History*), vol. 2, at 831.

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The Agency disagrees that the effects of nicotine in cigarettes and smokeless tobacco are comparable to those produced by hammocks, gardening tools, or other similar articles. First, such articles do not introduce chemical ingredients into the body. By contrast, cigarettes and smokeless tobacco deliver a potent chemical ingredient, nicotine, whose significant pharmacological effects on the human body are widely recognized in the scientific community. Second, the powerful psychoactive effects produced by nicotine in cigarettes and smokeless tobacco are comparable to those produced by tranquilizers, stimulants, weight management agents, and drugs used for long-term maintenance of addiction, all of which are indisputably within FDA's jurisdiction. Third, as described in section I.A., above, tobacco industry officials have acknowledged that nicotine's effects are comparable to those of prescription drug products.

FDA also disagrees that the 1952 decision, *Liggett & Myers*, 108 F. Supp. 573, represents a controlling determination that cigarettes do not affect the structure or function of the body within the Act's meaning. Much less was known about the addictive, psychoactive, and weight-regulating effects of nicotine when the court decided *Liggett* in 1952 than is known today. The kinds of effects that were alleged in *Liggett* (lack of irritation to the respiratory system and "soothing" effects) are far different from the addicting and other psychoactive and weight-regulating effects now known to be caused by nicotine in cigarettes. See sections II.A.1. and IV., below. Moreover, *Liggett* was decided before FDA regulated nicotine. The Agency now regulates nicotine-containing products such as nicotine transdermal patches and nicotine nasal spray intended to treat nicotine addiction. If nicotine were not a powerful pharmacological agent with addictive

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properties, nicotine cessation products would be unnecessary. Further, the *Liggett* opinion does not suggest that the definition of “drug” would preclude treating cigarettes as drugs if new evidence concerning cigarettes’ effects became known. *See* section IV., below.

Accordingly, FDA concludes that nicotine’s significant pharmacological effects are effects on the structure or function of the body within the Act’s meaning.

2. Tobacco industry comments contend that Congress intended to limit the drugs and devices covered by sections 201(g)(1)(C) and 201(h)(3) (products “intended to affect the structure or any function of the body”) to products with “therapeutic” or “medical” uses. One industry comment further elaborates that the structure-function provision was added to the Federal Food, Drug, and Cosmetic Act in 1938 only as a result of concern that certain “therapeutic” products used for weight management purposes had escaped regulation under the 1906 Pure Food and Drug Act because obesity and leanness were not considered to be diseases. Consequently, this comment argues, the structure-function provision encompasses only products intended for “therapeutic” or “medical” use in “disease-treatment” conditions.¹⁴

This industry comment also makes a related argument that effects on the structure or function of the body must be “beneficial,” or “drug-like,” and not “destructive or toxic.” According to this comment, “FDA views ‘addictiveness’ as an undesirable characteristic, not as a beneficial effect, and therefore more as a form of toxicity.”¹⁵ This

¹⁴ Joint Comments of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 145-146. *See* AR (Vol. 526 Ref. 95).

¹⁵ *Id.* at 151.

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comment argues that the effects of cigarettes and smokeless tobacco are therefore outside the scope of the Act.

Conversely, one public interest group comment argues that construing sections 201(g)(1)(C) and 201(h)(3) as requiring a “therapeutic” effect would make these sections redundant of sections 201(g)(1)(B) and 201(h)(2), which define drugs and devices as products “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.” According to this comment, such an interpretation would violate basic rules of statutory construction.

The Agency disagrees with the tobacco industry’s narrow reading of the structure-function provision. Neither the language of the statute, its legislative history, nor the case law supports the position that drugs and devices must have “therapeutic,” “medical,” or “beneficial” effects or purposes in order to “affect the structure or any function of the body.”

The plain language of the statute provides no support for the tobacco industry’s position. The terms, “therapeutic,” “medical,” and “beneficial,” or words of similar import, do not appear anywhere in section 201(g)(1)(C) or 201(h)(3). FDA agrees with the comments that assert that construing the “structure or any function” language to require a therapeutic or medical effect would make these provisions essentially identical in scope and meaning to sections 201(g)(1)(B) and 201(h)(2). To do so would violate the well-accepted principle that “a legislature is presumed to have used no superfluous words.” *Bailey v. United States*, 116 S.Ct. 501, 507 (1995).

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The legislative history is also inconsistent with the tobacco industry's position.

Congress added sections 201(g)(1)(C) and 201(h)(3) to broaden the coverage of the Act to include a "comprehensive class of preparations which were intended to affect the structure or function of the body." "*Line Away*," 284 F. Supp. at 110 (citations omitted).

The Act's legislative history makes clear that Congress intended to *expand* the Act's jurisdiction, rather than merely "close a loop-hole" in subsection 201(g)(1)(B). *See, e.g.*, H.R. Rep. No. 2139, 75th Cong., 3d Sess. 2 (1938), *reprinted in* 6 Legislative History 301 ("Drugs intended . . . for remedying underweight or overweight or for *otherwise* affecting bodily structure or function are subject to regulation") (emphasis added); *see also American Health Products Co. v. Hayes*, 574 F. Supp. 1498, 1506 (S.D.N.Y. 1983) (The structure-function provision was enacted to "reach those products . . . which evaded regulation altogether because they were neither foods *nor therapeutic agents*") (emphasis added).

The inclusive nature of the structure-function provision was raised several times during the hearings that led to enactment of the 1938 Act. *See Hearings on S. 1944, Senate Subcomm. of the Comm. on Commerce*, 73d Cong., 2d Sess. 15 (1933), *reprinted in* 1 Legislative History 107 ("The definition of the term 'drug' has been widened"); *Hearings on S. 2800, Senate Comm. on Commerce*, 73d Cong., 2d Sess. 516 (1934), *reprinted in* 2 Legislative History 519 ("This definition of 'drugs' is all-inclusive"); *Hearings on S. 5, Senate Comm. on Commerce*, 74th Cong., 1st Sess. 352 (1935), *reprinted in* 3 Legislative History 546 ("There is a universal recognition that the definition of the term 'drug' in the third subdivision is inclusive"). Congress consistently rejected

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suggestions to limit the drug definition to products with medical or medicinal purposes.

See, e.g., Hearings on S. 2800, Senate Comm. on Commerce, 73d Cong., 2d Sess. 515-516 (1934), reprinted in 2 Legislative History 518-519.

Judicial decisions and Agency practice also conflict with the narrow interpretation urged by the manufacturers. As the Supreme Court has stated:

Viewing the structure, the legislative history, and the remedial nature of the Act, . . . it [is] plain that Congress intended to define “drug” far more broadly than does the medical profession. . . .

. . . the word “drug” is a term of art for the purposes of the Act, encompassing far more than the strict medical definition of that word. If Congress had intended to limit the statutory definition to the medical one, it could have so stated explicitly.

United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 793 (1969).

The structure-function provision has been applied since 1938 to a wide assortment of products with a range of uses and effects, many of which cannot be considered “therapeutic.” For example, products that have been found to be within this provision include those with cosmetic, recreational, economic, or other nontherapeutic purposes. These products include tanning booths; sunscreens; breast implants; injectable collagen; birth control pills; products purporting to remove wrinkles temporarily, *e.g., “Line Away,” “Sudden Change”*; products intended to eliminate pet odors, *e.g., United States v. Undetermined Quantities . . . “Pets Smellfree,”* 22 F.3d 235, 240 (10th Cir. 1994); products intended to grow hair, *e.g., United States v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 540 (D.R.I.), *modified on other grounds*, 862 F. Supp. 717 (D.R.I. 1994); products intended as aphrodisiacs, *see* 54 FR 28780 (July 7, 1989), 21 CFR 310.528; products intended to enhance athletic performance by delivering a low, non-therapeutic level of

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oxygen, *e.g.*, “*Sports Oxygen*”; and veterinary products intended to increase milk production, *e.g.*, *United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219 (D. Minn. 1991), *aff’d*, 968 F.2d 681 (8th Cir. 1992).

In the case of tanning booths, the Agency considers the product to be a “device” intended to affect the structure or any function of the body despite the fact that the American Academy of Dermatology considers tanning booths to be a potential health hazard and discourages their use.¹⁶ FDA even regulates veterinary products intended to induce death in animals by humane means—an intended use that is indisputably not therapeutic. *See United States v. Articles of Drug . . . “Beuthanasia-D Regular,”* Civ. No. 77-0-396 (D. Neb. August 1, 1979), *reprinted in Federal Food, Drug, and Cosmetic Act: A Judicial Record, 1978-80*, 83-89.

The nature of a product’s effect on the structure or function of the body—therapeutic or non-therapeutic, beneficial or adverse—thus does not determine FDA’s jurisdiction. The relevant inquiry is simply whether a product has an effect on the structure or any function of the body. Cigarettes and smokeless tobacco do have such effects and, moreover, the effects are achieved through pharmacological means. The tobacco industry comments admit that products with “drug-type characteristics” (*i.e.*, pharmacological action) are within the Act’s jurisdiction.

¹⁶ Photobiology Task Force of the American Academy of Dermatology, Risks and benefits from high-intensity ultraviolet A sources used for cosmetic purposes: special report, *Journal of the American Academy of Dermatology* 1985;12:380-381. *See* AR (Vol. 711 Ref. 17).

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The argument that a product's effects must be therapeutic or medical is also inconsistent with FDA's assertion of jurisdiction over products with cosmetic, recreational, and economic uses. Notably, the comments that contend that effects on the structure or function of the body must be therapeutic or medical and also beneficial do not claim that FDA incorrectly applied the structure-function provision to products with cosmetic, recreational, or economic uses. Instead, these comments attempt to avoid the inconsistency between their arguments and these precedents by expansively interpreting "therapeutic" and "medical" to encompass products with cosmetic, recreational, economic, and other apparently non-therapeutic purposes or effects. Moreover, these comments do not provide any rationale to support the position that products regulating weight are subject to the Act, but that nicotine-containing cigarettes and smokeless tobacco, which also affect weight regulation, are not. Instead, the comments assert that the weight control effects of cigarettes and smokeless tobacco are too minor to be subject to the Act's jurisdiction. This argument is refuted in section II.A.4., below.

The Agency rejects the legal premise that effects on the structure or function of the body must be therapeutic or beneficial. However, even if the Agency were to accept the manufacturers' legal premise, this would not change the Agency's decision with respect to cigarettes and smokeless tobacco. As noted previously, cigarettes and smokeless tobacco produce pharmacological effects on the structure and function of the body that are indistinguishable from the effects of a wide range of products regulated by FDA, including sedation, stimulation, weight loss, and sustaining addiction. These pharmacological effects are as "therapeutic" or "beneficial" as many effects currently regulated under the

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Act, and would be sufficient to satisfy a requirement that products regulated as drug delivery devices have beneficial or therapeutic effects. Tobacco industry scientists have themselves argued that tobacco products provide “needed psychological benefits (increased mental alertness; anxiety reduction, coping with stress)”¹⁷ and that “nicotine is a very remarkable beneficent drug.”¹⁸

Indeed, if a new product with the powerful pharmacological effects of cigarettes and smokeless tobacco—sedation, stimulation, weight loss, and sustaining addiction—suddenly began to be distributed in the United States, there would be no question that the product would be subject to regulation under the Act because it “affect[s] the structure or any function of the body” within the Act’s meaning. For example, the Agency has regulated gamma hydroxybutyrate and gamma hydroxybutyric acid (collectively, GHB), a product intended to affect the structure or function of the body by promoting weight loss and muscle gain. The product is also used as a relaxant and sleep aid. GHB emerged as a steroid alternative after anabolic steroids became controlled substances. Very little was known about the product when GHB first entered the market because it was manufactured in clandestine laboratories (e.g., basements and kitchens), obtained from other black market sources, and usually distributed at health and sporting stores and clubs without labeling. The use of GHB as a steroid alternative and body-building aid is not “therapeutic”; nonetheless, the Agency successfully undertook regulatory actions against

¹⁷ Robinson JH, Pritchard WS, The role of nicotine in tobacco use, *Psychopharmacology* 1992;108:397-407, at 398. See AR (Vol. 66 Ref. 31-1).

¹⁸ Ellis C. Science Advisor to the BATCO Board, *The Smoking and Health Problem*, presented at the BATCO Research Conference, Southampton, England (1962), at 15. See AR (Vol. 15 Ref. 190).

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GHB pursuant to the Act's drug authorities. See *United States v. Wood*, Nos. 92-50512, 92-50514 (9th Cir. Oct. 21, 1993); 58 FR 33690, 33699 (Jun. 18, 1993); FDA Quarterly Activities Report, First Quarter, FY 1991 (Oct.-Dec. 1990).

3. One comment contends that the structure-function provision is limited to products that "purport to *change* the physical structure of the body."¹⁹ The Agency disagrees. Although the provision covers products that change a structure or function of the body, it is not limited to such effects. Courts have rejected the view that section 201(g)(1)(C) requires an actual "change [in] the physical structure or function of the [] body." *Pets Smellfree*, 22 F.3d at 237. Moreover, cigarettes and smokeless tobacco do in fact change the physical structure of the body by, for example, affecting brain chemistry and electrical activity in the brain, reducing weight, and increasing the growth of nicotine receptors in the central nervous system.

4. One comment asserts that the structure-function provision "is not intended to authorize the regulation of products solely because FDA believes their use is harmful and undesirable."²⁰ The Agency agrees. However, if a particular product meets the statutory definition of drug or device, the fact that it is also associated with harms to health is a reasonable consideration for the Agency in deciding to regulate the product. The Act's legislative history supports this view. As noted, concern about weight loss products that escaped regulation in the 1906 Pure Food and Drug Act was an impetus for

¹⁹ Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), vol. II, at 83 (emphasis added). See AR (Vol. 535 Ref. 96).

²⁰ Joint Comments of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 152. See AR (Vol. 526 Ref. 95).

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broadening the definition of “drug” to include products that affect the structure or function of the body. Congress was concerned not so much with the weight-reduction effects of weight loss products but with the serious and undesirable harms to health that resulted from their use. *See, e.g., Hearing on H.R. 6906, H.R. 8805, H.R. 8941, and S. 5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce, 74th Cong., 1st Sess. 55 (1935) (statement of FDA Chief Walter Campbell), reprinted in 4 Legislative History 370.*

5. Some comments state that FDA’s determination that cigarettes and smokeless tobacco are “drugs” and “devices” would obligate the Agency to regulate caffeine and caffeine-containing products as drugs or drug delivery devices. These comments assert that for this reason the Agency should not regulate tobacco products as drugs or devices. The Agency disagrees that a comparison to caffeine provides a reason not to regulate nicotine-containing cigarettes and smokeless tobacco.

Caffeine is the active ingredient in several products regulated as drugs by the Agency. For instance, caffeine is the active ingredient in NoDoz, an over-the-counter stimulant that is regulated for its effects on the structure and function of the body. Caffeine is also an ingredient in internal analgesics and menstrual discomfort relief products.

Although these products are regulated as drugs, the effects of these caffeine-containing products on the structure and function of the body are significantly less than those of nicotine. *See* section II.A.3.c.i., below. For instance, unlike nicotine, caffeine is not recognized at this time as an addictive drug by health organizations such as the

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American Psychiatric Association or the World Health Organization. Indeed, even an internal Philip Morris report comparing smoking and caffeine found that nicotine has a stronger stimulant effect than caffeine and that the stimulant effects of caffeine are “more like those of . . . placebo” than of nicotine.²¹ The implication for nicotine-containing cigarettes and smokeless tobacco is clear: if caffeine in products such as NoDoz “affect[s] the structure or any function of the body within the meaning of the Act,” then *a fortiori* nicotine-containing cigarettes and smokeless tobacco “affect the structure or any function of the body” as well.

Caffeine naturally occurs in coffee, tea, and other foods, and is used as an ingredient in soft drinks. The Act defines “food” as “articles used for food or drink for man or other animals.” See section 201(f)(1) of the Act, 21 U.S.C. 321(f)(1). The statutory definition “includes articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value.” *Nutrilab v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983). When caffeine is used in soft drink products in accordance with section 402 of the Act, 21 U.S.C. 342, and when it naturally occurs in other products that are foods, such as coffee, the product is a “food” under section 201(f)(1) of the Act, 21 U.S.C. 321(f)(1), and is explicitly excepted from the definition of drug in section 201(g)(1)(C), 21 U.S.C. 321(g)(1)(C) (“articles, *other than food*, intended to affect the structure or any function of the body”) (emphasis added). The Agency’s treatment of caffeine in beverages consequently has no bearing on how cigarettes and smokeless tobacco should be regulated.

²¹ Memorandum from Schori TR to Dunn WL, *Smoking and Caffeine: A Comparison of Physiological Arousal Effects* (May 17, 1972), at 1-2. See AR (Vol. 15 Ref. 189-7).

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6. Several comments assert that if FDA regulates nicotine-containing cigarettes and smokeless tobacco, it must also regulate the nicotine that occurs naturally in food products such as tomatoes, potatoes, eggplant, and cauliflower. The Agency disagrees. As noted above in response 5, section 201(g)(1)(C) specifically excludes from its coverage products that are “foods” under the Act. Tomatoes, potatoes, eggplant, and cauliflower are “foods” within the meaning of the Act because they are “articles used for food . . . for man.” *See* section 201(f)(1), 21 U.S.C. 321(f)(1). While these vegetables do contain trace amounts of nicotine, a person would have to consume 206 pounds of tomatoes, 309 pounds of potatoes, 22 pounds of eggplant, or 355 pounds of cauliflower to obtain the same amount of nicotine as in one cigarette.²² Thus, these products are appropriately regulated as foods.

7. Some comments question whether applying the structure-function provision to nicotine-containing cigarettes and smokeless tobacco might provide precedent for applying the provision to a wide range of products that have effects on the structure or function of the body—including guns and other weapons, products that prevent injury, such as airbags, and chemical sprays used for self-defense or law enforcement purposes.

The Agency has never construed the structure-function provision to include products such as guns, airbags, and chemical sprays, and applying the structure-function provision to nicotine-delivering tobacco products will not provide any precedent for doing

²² Chart Y, prepared in conjunction with the testimony of David Kessler before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (Mar. 25, 1994). *See* AR (Vol. 296 Ref. 4175).

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so. Moreover, there are fundamental distinctions between these products and nicotine-delivering tobacco products. Cigarettes deliver a pharmacologically active dose of the drug nicotine to the body through inhalation. Smokeless tobacco delivers a pharmacologically active dose of the same drug through buccal absorption. Collectively, tobacco products achieve their effects on the structure and function of the body through nicotine's pharmacological effects. These include sedation, stimulation, weight control, and maintenance of addiction. Tobacco products are thus indistinguishable from products that the Agency has traditionally regulated as drugs and devices. In contrast, guns, airbags, and chemical sprays are markedly different and distinguishable from such products.

II.

II. CIGARETTES AND SMOKELESS TOBACCO ARE “INTENDED” TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY WITHIN THE MEANING OF THE ACT

Cigarettes and smokeless tobacco clearly “affect the structure or any function of the body.” The principal issue before the Food and Drug Administration (FDA) is thus whether these effects are “intended” within the meaning of the Federal Food, Drug, and Cosmetic Act (the Act).

The Act’s drug and device definitions provide in pertinent part that an article is a drug or device if it is “*intended* to affect the structure or any function of the body.” Sections 201(g)(1)(C) and 201(h)(3), 21 U.S.C. 321(g)(1)(C) and (h)(3) (emphasis added). In determining whether an article is “intended” to affect the structure or function of the body, “the FDA is not bound by the manufacturer’s subjective claims of intent,” but rather can find actual intent “on the basis of objective evidence.” *National Nutritional Foods Ass’n (NNFA) v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). That is, the Agency determines the intent of the manufacturers objectively by evaluating all of the relevant evidence in the record from the perspective of a reasonable fact finder. *See* 21 CFR 201.128, 801.4. In determining intended use, the Agency may “examine a wide range of evidence.” *United States v. Two Plastic Drums . . . Black Currant Oil*, 761 F. Supp. 70, 72 (C. D. Ill. 1991), *aff’d*, 984 F.2d 814 (7th Cir. 1993).

In the Jurisdictional Analysis, 60 FR 41453–41787, the Agency determined, based on the evidence then available to it, that cigarettes and smokeless tobacco are “intended” to affect the structure and function of the body. This determination was based on three grounds:

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- (1) The addictive, psychoactive, and other significant pharmacological effects of cigarettes and smokeless tobacco are so widely known and foreseeable that these effects may be deemed to have been intended by the manufacturers, *see* Jurisdictional Analysis, 60 FR 41483–41490;
- (2) Such a large percentage of consumers use cigarettes and smokeless tobacco to satisfy their addiction or to obtain other pharmacological effects that the manufacturers may be deemed to intend that their products will be used for such purposes, *see* Jurisdictional Analysis, 60 FR 41490–41491; and
- (3) The statements, research, and actions of the tobacco manufacturers show that the manufacturers actually intend their products to affect the structure or any function of the body, *see* Jurisdictional Analysis, 60 FR 41491–41520.

FDA received comments on its findings from the tobacco industry, public health organizations, and other interest groups and members of the public.

In this section, the Agency considers, in light of the public comments, the objective evidence in the administrative record relevant to whether cigarette and smokeless tobacco manufacturers intend their products to affect the structure or any function of the body, including new evidence that has become available since the issuance of the Jurisdictional Analysis. The Agency also discusses the legal standard for establishing the intended use of cigarettes and smokeless tobacco, and responds to the substantive comments received by the Agency on the evidence and the legal standard. Specifically:

- Section II.A. discusses the evidence supporting FDA's finding that it is foreseeable to a reasonable tobacco manufacturer that the nicotine in cigarettes and smokeless tobacco will cause pharmacological effects and will be used by consumers for those effects and responds to comments on this issue;

II.

- Section II.B. discusses the evidence supporting FDA's finding that consumers use cigarettes and smokeless tobacco predominantly to obtain the pharmacological effects of nicotine and responds to comments on this issue;
- Section II.C. discusses the evidence supporting FDA's finding that cigarette manufacturers' statements, research, and actions show that they intend their products to be used for the pharmacological effects of nicotine and responds to comments on this issue;
- Section II.D. discusses the evidence supporting FDA's finding that smokeless tobacco manufacturers' statements, research, and actions show that they intend their products to be used for the pharmacological effects of nicotine and responds to comments on this issue;
- Sections II.E. and F. respond to comments, not already addressed in the foregoing sections, on the legal standard for evaluating intended use; and
- Section II.G. discusses the cumulative evidence of intended use.

Except as modified below, FDA confirms its prior findings and incorporates them by reference. FDA concludes that the evidence on the foreseeability of nicotine's effects, actual consumer use of tobacco for those effects, and evidence of intended use based on industry statements, research, and actions each provides an independent basis for the determination that the manufacturers of cigarettes and smokeless tobacco intend their products to affect the structure of function of the body.

Although the evidence thus provides several independent bases for establishing that cigarettes and smokeless tobacco are intended to affect the structure and function of the body, the Agency also looks at the objective evidence of intent as a whole. The

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Agency finds that, both independently and cumulatively, the evidence of foreseeable pharmacological effects and uses, actual consumer use for pharmacological purposes, and manufacturer intent as revealed through the statements, research, and actions of the manufacturers convincingly supports the Agency's determination that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

II.A.

**A. A REASONABLE MANUFACTURER WOULD FORESEE
THAT CIGARETTES AND SMOKELESS TOBACCO WILL
CAUSE ADDICTION AND OTHER PHARMACOLOGICAL
EFFECTS AND WILL BE USED BY CONSUMERS FOR
PHARMACOLOGICAL PURPOSES**

FDA may conclude that a product is intended to affect the structure or function of the body if a reasonable person in the position of the manufacturer would foresee that the product will have pharmacological effects and that a substantial proportion of consumers will use the product for those effects. In the Jurisdictional Analysis, the Agency made extensive findings, based on the evidence then available, regarding the pharmacological effects of tobacco on the human body. *See* Jurisdictional Analysis, 60 FR 41534–41575. FDA received comments on these findings from the tobacco industry, many medical and public health organizations and medical practitioners, and from other members of the public. The administrative record includes extensive, publicly disseminated evidence from scientific studies and expert panels on the subject of tobacco's pharmacological effects on the human body.

After considering the administrative record and reviewing public comments, the Agency finds that the evidence clearly demonstrates that a reasonable tobacco manufacturer would foresee that cigarettes and smokeless tobacco will cause and sustain addiction, produce other psychoactive effects, and control weight and be used by consumers for these effects. This finding provides an independent basis for the Agency's conclusion that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

II.A.1.

In section II.A.1., below, FDA describes the legal basis for considering evidence of the foreseeable effects and uses of a product. FDA presents its major findings and responds to significant comments in sections II.A.2. through II.A.6. In section II.A.7., FDA responds to the remaining relevant substantive comments.

1. “Intended Use” May Be Established on the Basis of Foreseeable Pharmacological Effects and Uses

The Agency’s legal authority to establish intended use based on the foreseeable effects and the foreseeable uses of a product comes from the plain language of the Act, as well as from FDA’s regulations, case law, administrative precedent, and the public health purposes of the Act.

The plain language of the Act provides that a drug or device is an article “*intended* to affect the structure or any function of the body.” Sections 201(g)(1)(c) and 201(h)(3) of the Act, 21 U.S.C. 321(g)(1)(C), 321(h)(3) (emphasis added). It is a widely accepted legal principle that persons can be held to “intend” the reasonably foreseeable consequences of their actions. In 1938, when Congress defined drugs and devices as articles “intended” to affect the structure or any function of the body of man, it was well established that “[t]he law presumes that every man *intends* the legitimate consequences of his own acts.” *Agnew v. United States*, 165 U.S. 36, 53 (1897); *accord Fanning v. United States*, 72 F.2d 929, 932 (4th Cir. 1934) (“the law imputes an intent to accomplish the natural results of one’s own act”) (citations omitted); *Eastern Drug Co. v. Bieringer-Hanauer Co.*, 8 F.2d 838, 839 (1st Cir. 1925) (“presumption that one intends the natural and probable consequences of his acts”); *see also 4 Wigmore on Evidence* 3388-3390

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(1904-1905) (intent is “a volition having consequences which ought reasonably to have been foreseen”), *quoted in Rushmore v. Saxon*, 158 F. 499, 506 (C.C.S.D.N.Y. 1908).

In accordance with this well-accepted legal principle, FDA may establish that a manufacturer “intends” that its product affect the structure or function of the body when it is foreseeable that the product will in fact affect the structure or function of the body in a drug-like manner. The case for establishing intent through foreseeability is especially strong when a reasonable manufacturer would foresee that a product will *both* act like a drug *and* be commonly used like a drug. Where it is foreseeable that a product will have pharmacological effects on a significant proportion of consumers and will be used by these consumers to obtain these pharmacological effects, the statute allows FDA to recognize reality and find that the manufacturer “intends” its product to be used as a drug.

Consistent with this well-established understanding of “intent,” FDA’s regulations defining “intended use” contemplate that foreseeability can be a basis for establishing the objective intent of the manufacturer. These regulations require product labeling to include adequate directions for all “intended uses.” 21 CFR 201.5 (drugs); 21 CFR 801.5 (devices). The intended uses of a drug or device that must be included on the label are defined to include those that are, or that reasonably can be, anticipated by the manufacturer.

The definition of “intended uses” for drugs establishes an “objective intent” standard. Specifically, the regulations provides:

The words “intended use” or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example,

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be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. *But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.*

21 CFR 201.128 (emphasis added). The definition of "intended uses" for devices is essentially identical. 21 CFR 801.4. Thus, under these regulatory provisions, objective intent can be established by evidence showing that the manufacturer "knows" or "has knowledge of facts that would give him notice," i.e., that a reasonable manufacturer would foresee that consumers will use a product for drug or device uses.²³

Other parts of the regulations also provide that foreseeable pharmacological uses should be considered to be intended by the manufacturer. Section 201.128, for instance,

²³ The Agency disagrees with the tobacco industry's suggestion that this foreseeability test must be interpreted to apply only to products that are already classified as "drugs" or "devices." The Agency regularly uses the regulatory definition of "intended uses" to determine whether products should be classified as drugs or devices. *See, e.g., United States v. Articles of Drug*, 625 F.2d 665, 668 n.5 (5th Cir. 1980); *United States v. Undetermined Quantities of An Article or Drug Labeled as "Exachol,"* 716 F. Supp. 787, 791 (S.D.N.Y. 1989); *United States v. 22 . . . devices . . . "The Ster-o-lizer MD-200,"* 714 F. Supp. 1159, 1165 (D. Utah 1989); *United States v. Kasz Enterprises*, 855 F. Supp. 534, 539 (D.R.I. 1994), modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994); *United States v. Articles of Food and Drug Consisting of . . . Apricots*, 444 F. Supp. 266, 273 (E.D. Wis. 1977). Thus, the Agency relies on the test of objective intent in the regulation (including the foreseeability standard described above) to establish: (1) in the case of products already classified as drugs or devices, the intended uses that must appear on the product labeling; and (2) in the case of products not yet classified as drugs or devices, the intended uses that determine whether the product should be classified as a drug or device. The Agency's interpretation of its own regulation is reasonable and entitled to "controlling weight." *Thomas Jefferson Univ.* 114 S. Ct. 2381, 2386 (1994).

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further provides that “objective intent . . . may be shown by the circumstance that the article is, *with the knowledge of such persons* or their representatives, *offered and used for a purpose for which it is neither labeled nor advertised.*”²⁴ 21 CFR 201.128 (emphasis added).

The case law and administrative precedent interpreting the Act recognize that the foreseeable pharmacological effects and uses of a product are proper grounds for establishing intent. These precedents recognize that the Agency may consider evidence of the likely consumer use of a product in determining intended use. *See, e.g., Two Plastic Drums*, 761 F. Supp. at 72; *Kasz*, 855 F. Supp. at 539. They also recognize that a foreseeable drug effect is generally persuasive evidence that the product is intended to affect the structure and function of the body. For example, the court in *United States v. Undetermined Quantities . . . “Pets Smellfree”* found that the presence of chlortetracycline, a drug ingredient, at doses sufficient to reduce the level of bacteria in animal intestines was evidence that the product was intended to affect the structure and function of the body. 22 F.3d 235, 240 (10th Cir. 1994).²⁵ Indeed, the court found this evidence to be relevant even though the dose of chlortetracycline in the product was “subtherapeutic”—that is, the dose was sufficient to reduce bacteria levels, but not to cure

²⁴ The tobacco industry contends that the requirement that the product must be “offered” as well as used for an unlabeled or unadvertised use means that there must be a specific marketing representation promoting the use. The Agency does not so interpret the regulation. The ordinary definition of the word “offer” means simply “[t]o present for acceptance or rejection.” *American Heritage Dictionary of the English Language* (3d ed. 1992) at 1255. Moreover, the tobacco industry’s interpretation conflicts with the language in the regulation that provides that the use for which the product is offered is a use “for which it is neither labeled nor advertised.” Consistent with the language of the regulation, the Agency interprets the requirement that the product be “offered” to mean simply that the product be presented to the consumer for purchase.

²⁵ *See* section II.E., below, for an additional discussion of the relevant case law and administrative precedent.

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or treat a disease. *Id.* Administratively, the Agency has asserted jurisdiction over products such as khat, imitation cocaine, hormone-containing skin creams, and fluoride-containing toothpastes based primarily, if not exclusively, on evidence that these products have foreseeable drug effects and drug uses. *See* section II.E.1.e., below.

Cases interpreting other public health statutes establish a test for determining intended use that is the same as the one used by FDA and that permits reliance on foreseeable uses. In *N. Jonas & Co. v. EPA*, 666 F.2d 829 (3d Cir. 1981), for example, the court held that a product was “intended for use” as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) based on its foreseeable consumer use—even though the manufacturer did not promote the product as a pesticide (and even disclaimed use as a pesticide on the label). The court stated:

The Act [and] the regulations . . . focus inquiry on the intended use, implicit or expressed. *We take this to mean the use which a reasonable consumer would undertake In determining intent objectively, the inquiry cannot be restricted to a product's label and to the producer's representations. Industry claims and general public knowledge can make a product pesticidal notwithstanding the lack of express pesticidal claims by the producer itself.*

Id. at 833 (emphasis added).

Similarly, in *United States v. Focht*, 882 F.2d 55, 60 (3d Cir. 1989), the court held that under the Federal Hazardous Substances Act (FHSA), “[i]ntended use . . . , objectively defined, necessarily encompasses foreseeability.” In this case, the Consumer Product Safety Commission sought to take action against fireworks components that could be assembled to make banned fireworks. The court found that the testimony that 90% of consumers who order the components will use the components to make illegal fireworks “makes it foreseeable that the components in question will be used to build

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banned fireworks. Such knowledge must be attributed to [the defendants].” *Id.*; accord *United States v. Articles of Banned Hazardous Substances . . . Baby Rattles*, 614 F. Supp. 226 (E.D.N.Y. 1985).

The tobacco industry argues that the Agency may not rely on the interpretation of “intended use” in other statutes to interpret “intended use” under the Federal Food, Drug, and Cosmetic Act. The fact that FDA’s interpretation of “intended use” under the Federal Food, Drug, and Cosmetic Act parallels the interpretation under other public health statutes, however, strongly supports the reasonableness of the Agency’s analysis. Indeed, the court in *Jonas* relied in part on cases interpreting intended use under the Federal Food, Drug, and Cosmetic Act in holding that intended uses encompass readily foreseeable consumer uses, specifically citing *National Nutritional Foods Ass’n (NNFA) v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977), for the proposition that “FDA [is] not bound by manufacturer’s subjective claims of intent in assessing whether product is intended as a drug,” and *Bacto-Unidisk*, 394 U.S. 784 (1969), for the proposition that “the definition of drug [is] to be given liberal interpretation in light of remedial purpose of Federal Food, Drug and Cosmetic Act.” 666 F.2d at 833.²⁶

Moreover, contrary to the tobacco industry’s contention, the FHSA and FIFRA cannot be distinguished from the Federal Food, Drug, and Cosmetic Act on the ground that foreseeability principles are alien to the Federal Food, Drug, and Cosmetic Act. Several other provisions of the Act contemplate foreseeability principles. *See, e.g.*, 21

²⁶ Similarly, courts interpreting the Federal Food, Drug, and Cosmetic Act rely on interpretations of analogous consumer protection statutes. *See, e.g.*, “*Sudden Change*,” 409 F.2d 734, 741 n.8 (2d Cir. 1969) (citing a case interpreting the Federal Trade Commission Act because “the remedial purpose of the Federal Trade Commission Act is sufficiently analogous”).

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U.S.C. 321(n) (an article may be misbranded if its labeling and advertising fail to reveal “consequences which may result from . . . such conditions of use as are customary or usual”); 21 U.S.C. 360h (FDA authorized to recall devices that “present[] an unreasonable risk of substantial harm”).

Indeed, in *United States v. Park*, 421 U.S. 658 (1975), the Supreme Court concluded that the Federal Food, Drug, and Cosmetic Act imposes “requirements of foresight and vigilance” on manufacturers, stating:

the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of *foresight and vigilance* imposed on responsible corporate officials are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.

Id. at 672 (emphasis added).

Compelling policy reasons support the Agency’s interpretation that it may establish that a product is intended to affect the structure or function of the body when it is foreseeable that a product will produce significant pharmacological effects in consumers and be widely used by consumers for these effects. The manufacturers’ position is that they may ignore overwhelming scientific evidence that their product will have and be used for pharmacological effects so long as they avoid promoting their product for these pharmacological effects. Under this interpretation, however, the manufacturer of virtually any drug or device could avoid regulation under the Act—no matter how substantial and well-established the pharmacological effects and uses of the product—by simply avoiding making certain claims in the product’s labeling and advertising. For example, it is not

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difficult to imagine a manufacturer of a generic version of a drug like Prozac (fluoxetine hydrochloride), an antidepressant drug currently available only by prescription, seeking to avoid FDA regulation by advertising its product as intended solely for the “pleasure” of its consumers. *See* section II.F.1.e., below.

Accepting the manufacturers’ position would leave the public vulnerable to the unregulated distribution of products with known pharmacologically active ingredients. Moreover, it would reward manufacturers who deny the obvious pharmacological effects and uses of their products in their public statements, labeling, and advertising. Thus, the Agency concludes that the public health objectives of the Act require the Agency to regulate as “drugs” or “devices” products that can be foreseen to have widespread pharmacological effects and uses.

2. The Significant Pharmacological Effects and Uses of Cigarettes and Smokeless Tobacco Are Foreseeable

The evidence in the administrative record establishes that the pharmacological effects and uses of cigarettes and smokeless tobacco are so widespread and well-known that a reasonable manufacturer would foresee them. Since the Agency last considered the issue of whether cigarettes are drugs over 15 years ago, a scientific consensus has emerged that nicotine is addictive and has other significant pharmacological effects.

Nicotine—the essential ingredient in cigarettes and smokeless tobacco—is a pharmacological agent that substantially alters the structure and function of the brain and other systems of the body. After a single puff inhaled from a cigarette, nicotine enters the mouth, passes into the lungs, is absorbed from the lungs into the bloodstream, and diffuses

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from the blood into the brain. This process takes about 11 seconds.²⁷ When consumed in smokeless tobacco, nicotine is absorbed through the lining of the mouth into the bloodstream and flows to the brain.

Once inside the human brain, nicotine binds to unique receptors on the surfaces of brain cells. These nicotinic receptors normally interact with a natural chemical messenger called acetylcholine, but can also be stimulated by nicotine to alter mood, alertness, and cognition. Exposure to nicotine causes the number of nicotinic receptors on the surfaces of brain cells to increase²⁸ and significantly alters the brain's normal electrical and metabolic activity.²⁹ Nicotine's actions on the central nervous system produce both

²⁷ Department of Health and Human Services, Office on Smoking and Health, *The Health Consequences of Smoking: Nicotine Addiction, a Report of the Surgeon General* (Jul. 29, 1988), DHHS Publication No. (CDC) 88-8406 (Washington DC: GPO, 1988), at 13-14 (hereinafter cited as Surgeon General's Report, 1988). See AR (Vol. 129 Ref. 1592).

Benowitz NL, *Clinical Pharmacology of Inhaled Drugs of Abuse: Implications in Understanding Nicotine Dependence*, NIDA Research Monograph 99 (Rockville MD: National Institute on Drug Abuse, 1990), at 17. See AR (Vol. 3 Ref. 18).

²⁸ Benwell MEM, Balfour DJK, Anderson JM, Evidence that tobacco smoking increases the density of (-)-[³H]nicotine binding sites in human brain, *Journal of Neurochemistry* 1988;50:1243-1247. See AR (Vol. 136 Ref. 1570).

²⁹ Surgeon General's Report, 1988, at 79-123. See AR (Vol. 129 Ref. 1592).

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sedating and stimulating effects, depending on dose and circumstances.³⁰ Nicotine also plays a role in weight regulation.³¹

In addition to its sedating and stimulating effects, nicotine causes and sustains addiction. Nicotine directly affects an intrinsic brain system, known as the mesolimbic system, that signals pleasure and reward and modulates emotions. When stimulated by an addictive substance, the mesolimbic system responds by rewarding the repeated consumption of the substance.³² It is widely believed that amphetamine, cocaine, and nicotine all cause the compulsive drug-seeking behavior of drug addiction through the same mechanism: increasing the activity of the neurotransmitter dopamine within the mesolimbic system.³³

³⁰ Pritchard WS, Gilbert DG, Duke DW, Flexible effects of quantified cigarette-smoke delivery on EEG dimensional complexity, *Psychopharmacology* 1993;113:95-102. See AR (Vol. 3 Ref. 23-1).

Pritchard WS, Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490. See AR (Vol. 105 Ref. 965).

Norton R, Brown K, Howard R, Smoking, nicotine dose and the lateralisation of electrocortical activity, *Psychopharmacology* 1992;108:473-479. See AR (Vol. 3 Ref. 22).

Golding JF, Effects of cigarette smoking on resting EEG, visual evoked potentials and photic driving, *Pharmacology, Biochemistry and Behavior* 1988;29:23-32. See AR (Vol. 3 Ref. 23-3).

³¹ Surgeon General's Report, 1988, at 431-432. See AR (Vol. 129 Ref. 1592).

³² Pomerleau OF, Pomerleau CS, Neuroregulators and the reinforcement of smoking: towards a biobehavioral explanation, *Neuroscience and Biobehavioral Reviews* 1984;8:503-513. See AR (Vol. 3 Ref. 20-1).

Wise RA, Rompre PP, Brain dopamine and reward, *Annual Review of Psychology* 1989;40:191-225. See AR (Vol. 3 Ref. 19-1).

Clarke PBS, Mesolimbic dopamine activation—the key to nicotine reinforcement? *CIBA Foundation Symposium* 1990;152:153-168. See AR (Vol. 3 Ref. 19-2).

³³ *Id.*

Pontieri FE, Tanda G, Orzi F, *et al.*, Effects of nicotine on the nucleus accumbens and similarity to those of addictive drugs, *Nature* 1996;382:255-257. See AR (Vol. 711 Ref. 51).

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Extensive scientific evidence demonstrating the significant effects of nicotine in tobacco products on the structure and function of the body is discussed in detail in the remainder of this section. The magnitude and wide dissemination of the scientific evidence demonstrates that it is foreseeable to a reasonable person in the position of tobacco manufacturer that many consumers will use tobacco products for these pharmacological effects.

3. Nicotine Is Widely Recognized as Addictive, and It Is Foreseeable That Consumers Will Use Cigarettes and Smokeless Tobacco To Satisfy an Addiction

Nicotine's effects on the brain are the biological basis of nicotine addiction—an addiction that has been proven by a wealth of laboratory and epidemiological evidence and recognized by every major independent medical organization that has studied the question. Nicotine's widely recognized addictive properties make it foreseeable to any reasonable person that a substantial proportion of users of tobacco products will consume these products to satisfy their addiction.³⁴

a. Scientific Consensus

Overwhelming scientific evidence and broad recognition that nicotine is an

Di Chiara G, Imperato A, Drugs abused by humans preferentially increase synaptic dopamine concentrations in the mesolimbic system of freely moving rats, *Proceedings of the National Academy of Sciences of the United States of America* 1988;85:5274-5278. See AR (Vol. 66 Ref. 26).

Corrigall WA, Franklin KBJ, Coen KM, *et al.*, The mesolimbic dopaminergic system is implicated in the reinforcing effects of nicotine, *Psychopharmacology* 1992;107:285-289. See AR (Vol. 8 Ref. 93-4).

³⁴ FDA's conclusion that the pharmacological effects and uses of nicotine in cigarettes and smokeless tobacco are foreseeable rests on published literature, including widely disseminated government reports. FDA's conclusion that the tobacco industry knows that nicotine has substantial pharmacological effects and that consumers use tobacco for these effects, *see* section II.C., below, is based largely on internal company documents.

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addictive, dependence-producing substance emerged in the 1980's.³⁵ All leading expert and public health organizations in the United States and the international community with expertise in tobacco or drug addiction now recognize that nicotine is addictive. The first major organization to do so was the American Psychiatric Association in 1980, when its *Diagnostic and Statistical Manual of Mental Disorders, Third Edition* (DSM-III), defined the Tobacco Dependence Disorder and the Tobacco Withdrawal Syndrome.³⁶ Since 1980, nicotine in tobacco products has also been recognized as addictive by the U.S. Surgeon General (1986 and 1988)³⁷ American Psychological Association (1988),³⁸ the Royal Society of Canada (1989),³⁹ the World Health Organization (WHO) (1992),⁴⁰ the

³⁵ The terms "addictive" and "dependence-producing" are used interchangeably among experts and scientific organizations and generally refer to the persistent and repetitive intake of a psychoactive substance despite evidence of harm and a desire to quit. In this document, FDA also uses both terms interchangeably. The term "abuse liability" also refers to a substance's ability to produce dependence or addiction.

³⁶ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 3d ed. (Washington DC: American Psychiatric Association, 1987), at 159-160, 176-178. See AR (Vol. 535 Ref. 96, vol. III.A).

³⁷ Department of Health and Human Services, Office on Smoking and Health, *The Health Consequences of Using Smokeless Tobacco, A Report of the Advisory Committee to the Surgeon General* (Apr. 1986), NIH Publication No. 86-2874 (Bethesda, MD:1986). See AR (Vol. 128 Ref. 1591)

Surgeon General's Report, 1988. See AR (Vol. 129 Ref. 1592).

³⁸ *Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce*, U.S. House of Representatives, 100th Cong., 1st Sess. 1 (Jul. 29, 1988) (statement of the American Psychological Association). See AR (Vol. 5 Ref. 43-5).

³⁹ Royal Society of Canada, *Tobacco, Nicotine, and Addiction: A Committee Report*, prepared at the request of the Royal Society of Canada for the Health Protection Branch, Health and Welfare Canada (Aug. 31, 1989), at v-vi. See AR (Vol. 62 Ref. 814).

⁴⁰ WHO, *The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines* (Geneva: World Health Organization, 1992), at 76. See AR (Vol. 43 Ref. 175).

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American Medical Association (1993),⁴¹ and the Medical Research Council in the United Kingdom (1994).⁴² Every expert organization that has commented on whether nicotine is addictive has concluded that it is.

Recognition of nicotine addiction is now so universal that even the vast majority of scientists who have received funding from the tobacco industry believe that nicotine is addictive. In a survey of principal investigators of research projects funded by the tobacco industry in 1989, 83.3% agreed strongly and an additional 15.3% agreed somewhat that cigarette smoking is addictive.⁴³ Moreover, as demonstrated in section II.C., below, the tobacco industry itself, despite public pronouncements to the contrary, has long known nicotine to be addictive.

Salient findings that reflect nicotine's addictiveness include the following:

Epidemiological Evidence.

- Persons who have smoked at least one cigarette are about twice as likely to develop dependence as are persons who have ever tried cocaine or alcohol.⁴⁴

⁴¹ American Medical Association, Ethyl alcohol and nicotine as addictive drugs, in *1993 AMA Policy Compendium* (Chicago: AMA, 1993), at 35. See AR (Vol. 37 Ref. 2).

⁴² Medical Research Council, *The Basis of Drug Dependence*, MRC Field Review (London: Medical Research Council, 1994), at 11. See AR (Vol. 41 Ref. 105).

⁴³ Cummings KM, Sciandra R, Gingrass A, *et al.*, What scientists funded by the tobacco industry believe about the hazards of cigarette smoking, *American Journal of Public Health*, 1991;81(7):894-896. See AR (Vol. 5 Ref. 44).

⁴⁴ Anthony JC, Warner LA, Kessler RC, Comparative epidemiology of dependence on tobacco, alcohol, controlled substances and inhalants: basic findings from the National Comorbidity Survey, *Experimental and Clinical Psychopharmacology* 1994;2:244-268. See AR (Vol. 37 Ref. 4).

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- More than half of people presenting for treatment of alcohol or drug abuse who also smoke cigarettes report that quitting smoking would be harder than giving up their other drug of abuse.⁴⁵
- Despite the interest of 70% of smokers in quitting smoking, fewer than 3% succeed per year.⁴⁶
- About two of every five users of smokeless tobacco have attempted to quit and failed,⁴⁷ and 68% of smokeless tobacco users who have attempted to quit report an average of four such attempts.⁴⁸
- About 50% of smokers recovering from surgery for a smoking-related disease (e.g., lung cancer) and whose prognosis and symptoms would be improved by abstinence resume smoking.⁴⁹

Evidence from Animal and Human Laboratory Studies.

- Nicotine has been determined to have significant potential to produce addiction in humans on the basis of the same screening tests used to evaluate the addictive potential of any drug by the World Health Organization, the Drug Enforcement Administration,

⁴⁵ Kozlowski LT, Wilkinson A, Skinner W, *et al.*, Comparing tobacco cigarette dependence with other drug dependencies, *Journal of the American Medical Association* 1989;261(6):898-901. *See* AR (Vol. 41 Ref. 92).

⁴⁶ Centers for Disease Control and Prevention, Cigarette smoking among adults—United States, 1993, *Morbidity and Mortality Weekly Report* 1994 (Dec. 23);43:925-930. *See* AR (Vol. 36 Ref. 616-1).

⁴⁷ Novotny TE, Pierce JP, Fiore MC, *et al.*, Smokeless tobacco use in the United States: the adult use of tobacco surveys, *Monographs/National Cancer Institute* 1989;8:25-28. *See* AR (Vol. 41 Ref. 109).

⁴⁸ Severson HH, Enough snuff: ST cessation from the behavioral, clinical, and public health perspectives, in *Smokeless Tobacco or Health, An International Perspective*, Smoking and Tobacco Control Monograph 2, NIH Publication No. 93-3461 (Washington DC: DHHS, 1993), at 281-282. *See* AR (Vol. 18 Ref. 5-1).

⁴⁹ Surgeon General's Report, 1988, at 150. *See* AR (Vol. 129 Ref. 1592).

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the National Institute on Drug Abuse (NIDA), the College on Problems of Drug Dependence, pharmaceutical companies, and FDA's Drug Abuse Advisory Committee (the Committee).⁵⁰ See section II.A.3.c.i., below.

- Nicotine's effects in the brain have been shown to be critical in the self-administration of nicotine by both animals and humans.⁵¹ (The tendency of a substance to be self-administered demonstrates its ability to cause an animal or human to seek repeated doses of the substance.) This finding is a key element of addiction.
- The ability of nicotine to produce strong physiological and behavioral effects, including death at high doses, is no less than that of amphetamine or morphine.⁵²

Other Biological Evidence.

- Nicotine increases dopamine activity in the mesolimbic system of the brain. As with cocaine, amphetamine, and other drugs, this effect is believed to contribute to the compulsive drug-seeking behavior of addiction.⁵³
- Chronic nicotine exposure causes the number of nicotinic receptors on the surfaces of brain cells to increase. This phenomenon is associated with tolerance to the effects of nicotine and has been well documented in animals and people.⁵⁴

⁵⁰ *Id.* at 270.

⁵¹ *Id.* at 166, 173-175, 182-192.

Corrigall WA, Coen KM, Nicotine maintains robust self-administration in rats on a limited access schedule, *Psychopharmacology* 1989;99:473-478. See AR (Vol. 136 Ref. 1561).

⁵² Surgeon General's Report, 1988, at 272-274, 594. See AR (Vol. 129 Ref. 1592).

⁵³ Corrigall WA, Franklin KBJ, Coen KM, *et al.*, The mesolimbic dopaminergic system is implicated in the reinforcing effects of nicotine, *Psychopharmacology* 1992;107:285-289. See AR (Vol. 8 Ref. 93-4).

⁵⁴ Marks MJ, Burch JB, Collins AC, Effects of chronic nicotine infusion on tolerance development and nicotine receptors, *Journal of Pharmacology and Experimental Therapeutics* 1983;226:817-825. See AR (Vol. 41 Ref. 103).

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Commercial Evidence.

- Non-nicotine-containing tobacco products have never proved successful substitutes for tobacco despite the sophistication of some of them (e.g., Philip Morris' Next) in mimicking the non-nicotine-mediated effects of conventional cigarettes.

These data are just a few selections from the overwhelming evidence that has led the world's health authorities to classify nicotine as addictive. The following sections describe in detail the definition of addiction and how the widely known scientific evidence would lead any reasonable manufacturer to foresee that a significant proportion of tobacco consumers will become addicted to nicotine and will use tobacco products to satisfy their addiction.

b. Definition of Addiction

The tobacco industry is virtually alone in publicly contending that nicotine is not addictive. Its primary argument for rejecting the massive body of research and the expert opinion of every authoritative medical organization that has considered the issue is to claim that the entire scientific community is using the wrong definition of addiction.⁵⁵ According to the tobacco industry, the "traditional criteria" of addiction are "meaningful

Surgeon General's Report, 1988, at 53-54. See AR (Vol. 129 Ref. 1592).

Benwell MEM, Balfour DJK, Anderson JM, Evidence that tobacco smoking increases the density of (-)-[³H]nicotine binding sites in human brain, *Journal of Neurochemistry* 1988;50:1243-1247. See AR (Vol. 136 Ref. 1570).

⁵⁵ The tobacco industry cites the opinions of several physicians and scientists to support the contention that nicotine is not addictive. In most cases, as described below, the opinions have been taken out of context, and the cited individuals are on record as believing that nicotine is addictive. Those individuals who agree with the industry that nicotine is not addictive comprise a "handful of scientific supporters." Hwang SL, Ono Y, Tobacco dream team: experts who insist nicotine isn't addictive, *Wall Street Journal* (Mar. 23, 1995). See AR (Vol. 711 Ref. 29).

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intoxication, withdrawal, and tolerance.” Although withdrawal and tolerance are still considered criteria for addiction, “intoxication” has not been considered a necessary criterion for over thirty years. The industry cites no medical dictionary, expert panel, or scientific organization for this specific definition; the “criteria” are instead extracted from portions of a definition developed in the 1950’s and used by the editors of the 1964 Surgeon General’s Report on tobacco.⁵⁶ This definition was premised on the now-discarded, early twentieth-century conception of drug addiction as a personality disorder characterized by weakness of will, immaturity of character development, and immorality.⁵⁷

Within months of publication of the Surgeon General’s Report in 1964, its definition of addiction was cast aside by the scientific community. In a major report, the World Health Organization (WHO) recognized that intoxication was not a distinguishing characteristic of dependence for any drug under its purview.⁵⁸ Indeed, people dependent on stable daily doses of opiates may display no observable signs of intoxication.⁵⁹ Conversely, it is widely known that nonaddicting drugs such as antihistamines and atropine and scopolamine preparations can produce intoxication.⁶⁰ Moreover, under the

⁵⁶ Department of Health, Education, and Welfare, Public Health Service, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (Washington DC: GPO, 1964), at 349-352. See AR (Vol. 43 Ref. 156).

⁵⁷ Surgeon General’s Report, 1988, at 248. See AR (Vol. 129 Ref. 1592).

⁵⁸ WHO Expert Committee on Addiction-Producing Drugs, *WHO 1964*, World Health Organization Technical Report Series No. 273, Thirteenth Report (Geneva: World Health Organization, 1964), at 3-20. See AR (Vol. 43 Ref. 169).

⁵⁹ Surgeon General’s Report, 1988, at 251. See AR (Vol. 129 Ref. 1592).

⁶⁰ Garrison JC, Histamine, bradykinin, 5-hydroxytryptamine, and their antagonists, in *Goodman and Gilman’s The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 23, at 584, 586. See AR (Vol. 711 Ref. 14).

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old definition, cocaine and amphetamines would not clearly have been considered addictive because of lack of evidence at the time demonstrating physical dependence.⁶¹ The scientific community thus rejected the old definition of addiction because of new scientific insights about the nature of addiction, more than 15 years before finding nicotine to be addictive.

Today, drug addiction has been defined by scientific organizations from both laboratory and clinical perspectives. The laboratory perspective assesses experimentally whether a substance alters the central nervous system in a manner that can produce characteristic addictive behavior in humans.

While the laboratory perspective focuses on the chemical substance, the clinical perspective on drug addiction assesses whether an individual in society consumes the substance in a manner that demonstrates addiction. Consensus clinical criteria for diagnosing addiction have been developed by the American Psychiatric Association and were most recently published in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) in 1994:

Criteria for Substance Dependence

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

- (1) tolerance, as defined by either of the following:

Brown JH, Atropine, scopolamine, and related antimuscarinic drugs, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 8, at 157. See AR (Vol. 711 Ref. 14).

⁶¹ WHO Expert Committee on Addiction-Producing Drugs, *WHO 1964*, World Health Organization Technical Report Series No. 273, Thirteenth Report (Geneva: World Health Organization, 1964), at 3-20. See AR (Vol. 43 Ref. 169).

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- (a) a need for markedly increased amounts of the substance to achieve intoxication or desired effect
- (b) markedly diminished effect with continued use of the same amount of the substance
- (2) withdrawal, as manifested by either of the following
 - (a) the characteristic withdrawal syndrome for the substance . . .
 - (b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms
- (3) the substance is often taken in larger amounts or over a longer period than was intended
- (4) there is a persistent desire or unsuccessful efforts to cut down or control substance use
- (5) a great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain-smoking), or recover from its effects
- (6) important social, occupational, or recreational activities are given up or reduced because of substance use
- (7) the substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption)⁶²

Clinicians rely on these criteria to identify addictive behavior in patients.

In 1988, the U.S. Surgeon General used the most up-to-date laboratory tests and clinical criteria to develop the following consensus set of criteria for drug dependence:

Criteria for Drug Dependence.

Primary Criteria

- Highly controlled or compulsive use
- Psychoactive effects
- Drug-reinforced behavior

Additional Criteria

- Addictive behavior often involves:

⁶² American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 181. See AR (Vol. 37 Ref. 8).

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- stereotypic patterns of use
- use despite harmful effects
- relapse following abstinence
- recurrent drug cravings
- Dependence-producing drugs often produce:
 - tolerance
 - physical dependence
 - pleasant (euphoriant) effects⁶³

The laboratory and clinical perspectives on drug addiction embodied in the criteria of the U.S. Surgeon General and the American Psychiatric Association are entirely consistent. Moreover, the definitions of addiction used by all other world scientific authorities, such as WHO⁶⁴ and the Royal Society of Canada,⁶⁵ share the same principles, differing from each other only in wording and emphasis.

To assess whether nicotine is addictive and whether consumers are addicted to nicotine, FDA utilized these modern laboratory and clinical perspectives on addiction supported in principle by every relevant medical authority in the world.

The modern conception of addiction is not hazy. It does not—as the tobacco industry asserts in its comments—encompass food ingredients, activities, or daily rituals. The scientifically accepted method of identifying addictive drugs emphasizes the *pharmacological* basis of addiction, rather than the simple observation of compulsive-appearing behavior. Addictive drugs are now known to exert “psychoactive” or mood-

⁶³ Surgeon General's Report, 1988, at 7. See AR (Vol. 129 Ref. 1592).

⁶⁴ WHO, *The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines* (Geneva: World Health Organization, 1992), at 75-76. See AR (Vol. 43 Ref. 175).

⁶⁵ Royal Society of Canada, *Tobacco, Nicotine, and Addiction: A Committee Report*, prepared at the request of the Royal Society of Canada for the Health Protection Branch, Health and Welfare Canada (Aug. 31, 1989), at v. See AR (Vol. 62 Ref. 814).

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altering effects and to affect the structure and function of certain key portions of the brain that motivate repeated, compulsive use of the substance. By activating, inhibiting, or mimicking normal central nervous system processes, dependence-producing drugs exert control over the behavior of users. Consumers are strongly compelled to consume these substances for the pharmacological effect of satisfying addiction. Methods used to identify addictive drugs effectively exclude jogging, eating chocolate, playing computer games, or similar activities because these activities do not depend upon an exogenously administered drug.

Contrary to the suggestion of the tobacco industry, application of the criteria for identifying addictive drugs by the expert organizations responsible for this task⁶⁶ shows remarkable consistency across organizations and has resulted in the current identification of a very small number of truly dependence-producing drugs and drug types. These are cocaine, amphetamines, nicotine/tobacco, alcohol, hallucinogens, inhalants, cannabis, phencyclidine, opioids (including morphine and heroin), and the class of sedatives, hypnotics, and anxiolytics.⁶⁷ Application of the criteria has not led to the classification of

⁶⁶ These organizations include the World Health Organization's Expert Committee on Drug Dependence, the U.S. Drug Enforcement Administration, the National Institute on Drug Abuse, and the Food and Drug Administration.

⁶⁷ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 175-177. See AR (Vol. 37 Ref. 8).

WHO, *The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines* (Geneva: World Health Organization, 1992), at 75-76. See AR (Vol. 43 Ref. 175).

Since no two of these substances are chemically or biologically identical, no two addictions are exactly the same. The observation that dependence on nicotine can be distinguished in some respects from other addictions (as repeatedly asserted by tobacco industry comments) is thus irrelevant to whether nicotine should be classified as addictive.

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carrots or jogging or any of the other activities claimed by the tobacco industry in its comments as “addictive drugs.” A key reason for the reliability and validity of the modern definition of drug addiction is that scientific organizations rely upon the convergence of results from several different test procedures before determining that a substance is addictive. In assessing whether nicotine is addictive, FDA examined a wide range of such laboratory evidence, as well as epidemiological evidence of whether consumers are addicted to tobacco products.

c. Data Establish That Nicotine Is Addictive and That Consumers Use Cigarettes and Smokeless Tobacco To Satisfy an Addiction

Animal and human studies demonstrate that nicotine is a powerful psychoactive agent that can cause dependence by producing effects in the brain characteristic of other addictive substances. These findings have been widely published and presented and discussed at major international scientific and medical meetings since the 1980’s. Numerous laboratories throughout the world have replicated the core findings using a variety of techniques and have produced convergent results, demonstrating that the findings are reliable and valid. A wealth of epidemiological studies complements these laboratory data by showing that smokers and users of smokeless tobacco display clinical signs and symptoms of addiction. The evidence that has led to the nearly universal scientific conclusion that nicotine is addictive is discussed in the following sections.

i. Laboratory Studies Establish That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Substances. The tests used by the U.S. Surgeon General to develop its consensus definition of drug dependence are the following:

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- Animal and human “drug discrimination” tests, which assess a substance’s ability to produce psychoactive effects that can be distinguished from those of other psychoactive substances;
- Tests of human psychoactive or “subjective” effects, which assess a substance’s ability to produce changes in perception, mood, and behavior;
- Human and animal drug “self-administration” tests, which assess a substance’s ability to induce repeated, compulsive use by functioning as a “positive reinforcer”; and
- Tests for physiological dependence, which assess a substance’s ability to produce tolerance and a withdrawal syndrome.

These tests of an addictive drug are widely accepted for their validity.⁶⁸ They are the screening tests for addictiveness used most commonly by pharmaceutical manufacturers and regulatory agencies, as evidenced by their prominence in reports by WHO, reviews by the National Institute on Drug Abuse (NIDA) and the College on Problems of Drug Dependence, and deliberations by the Drug Abuse Advisory Committee, which primarily serves FDA.⁶⁹

Thus, these tests were not invented or selectively used to evaluate nicotine. Rather, they have been used to screen drugs of abuse for more than two decades before FDA’s current deliberations concerning nicotine. Upon review of the evidence in the

⁶⁸ Surgeon General’s Report, 1988, at 270-296. See AR (Vol. 129 Ref. 1592).

Balster RL, Drug abuse potential evaluation in animals, *British Journal of Addiction* 1991;86:1549-1558. See AR (Vol. 8 Ref. 89).

⁶⁹ Surgeon General’s Report, 1988, at 269-270. See AR (Vol. 129 Ref. 1592).

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administrative record, FDA concludes that nicotine tests positive in all relevant laboratory tests for addictive potential.

Testing for psychoactivity. Psychoactivity is a hallmark characteristic of all dependence-producing drugs. Psychoactive effects (sometimes also referred to as “subjective effects”) are changes in mood or feelings that result from the pharmacological effects of the substance on the central nervous system. Changes in mood or feelings that are not produced pharmacologically are not considered psychoactive effects. The psychoactivity of a drug is evaluated in “drug discrimination” studies and “subjective effects” studies.

Drug discrimination studies. Drug discrimination studies evaluate the psychoactivity of a drug by testing whether animal or human subjects can reliably differentiate the drug from placebo. A drug that can be so differentiated is considered a “discriminative stimulus.” The tests allow direct comparisons of a drug’s effects to known dependence-producing drugs.⁷⁰ The drug discrimination paradigm is routinely used in preclinical assessment of the abuse potential of a drug and is considered to be an animal model for human subjective reactions to drugs.⁷¹

Like other dependence-producing drugs, including cocaine, amphetamine, morphine, marijuana, and alcohol, nicotine tests positive in animal drug discrimination tests. FDA referred to numerous studies documenting this result in the Jurisdictional Analysis and its appendix.⁷² Using a variety of drug discrimination paradigms, researchers have shown that

⁷⁰ Balster RL, Drug abuse potential evaluation in animals, *British Journal of Addiction* 1991;86:1549-1558. See AR (Vol. 8 Ref. 89).

⁷¹ Surgeon General's Report, 1988, at 274-275. See AR (Vol. 129 Ref. 1592).

⁷² See appendix 1 to Jurisdictional Analysis at 23-25. See AR (Vol. 1 Appendix 1).

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nicotine can serve as a discriminative stimulus in rats⁷³ and squirrel monkeys.⁷⁴ Comparative studies have demonstrated that, although nicotine's stimulus effects are unique, they more closely resemble the stimulus effects elicited by amphetamine⁷⁵ than those of opioids, sedatives, or hallucinogens.⁷⁶

Nicotine's positive results in these drug discrimination tests are a consequence of its action in the central nervous system. Mecamylamine, a nicotine antagonist that acts in the brain, attenuates nicotine's ability to serve as a discriminative stimulus, whereas the peripheral antagonist hexamethonium—which does not enter the brain—does not affect nicotine

⁷³ Morrison CF, Stephenson JA, Nicotine injections as the conditioned stimulus in discrimination learning, *Psychopharmacologia* 1969;15:351-360. See AR (Vol. 41 Ref. 107).

Chance WT, Murfin D, Krynock GM, *et al.*, A description of the nicotine stimulus and tests of its generalization to amphetamine, *Psychopharmacology* 1977;55:19-26. See AR (Vol. 37 Ref. 22).

Stolerman IP, Discriminative stimulus effects of nicotine in rats trained under different schedules of reinforcement, *Psychopharmacology* 1989;97:131-138. See AR (Vol. 42 Ref. 152).

Craft RM, Howard JL, Cue properties of oral and transdermal nicotine in the rat, *Psychopharmacology* 1988;96:281-284. See AR (Vol. 74 Ref. 115).

Stolerman IP, Garcha HS, Pratt JA, *et al.*, Role of training dose in discrimination of nicotine and related compounds by rats, *Psychopharmacology* 1984;84:413-419. See AR (Vol. 8 Ref. 90-5).

Garcha HS, Goldberg SR, Reavill C, *et al.*, Behavioral effects of the optical isomers of nicotine and normicotine, and cotinine, in rats, *British Journal of Pharmacology* 1986;88:298. See AR (Vol. 38 Ref. 44).

⁷⁴ Takada K, Swedberg MDB, Goldberg SR, *et al.*, Discriminative stimulus effects of intravenous L-nicotine and nicotine analogs or metabolites in squirrel monkeys, *Psychopharmacology* 1989;99:208-212. See AR (Vol. 43 Ref. 153).

⁷⁵ Chance WT, Murfin D, Krynock GM, *et al.*, A description of the nicotine stimulus and tests of its generalization to amphetamine, *Psychopharmacology* 1977;55:19-26. See AR (Vol. 37 Ref. 22).

⁷⁶ Rosecrans JA, Meltzer LT, Central sites and mechanism of action of nicotine, *Neuroscience and Biobehavioral Reviews* 1981;5(4):497-501. See AR (Vol. 42 Ref. 127).

Pratt JA, Stolerman IP, Garcha HS, *et al.*, Discriminative stimulus properties of nicotine: further evidence for mediation at a cholinergic receptor, *Psychopharmacology* 1983;81:54-60. See AR (Vol. 8 Ref. 90-2).

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discrimination.⁷⁷ These studies demonstrate that nicotine's psychoactive effects are the direct results of its actions in the brain.

Human drug discrimination tests for nicotine are also positive. Using a drug discrimination procedure analogous to those employed with animals, Kallman and colleagues originally demonstrated that nicotine, as delivered by the inhalation of tobacco smoke, acts as a discriminative stimulus in humans.⁷⁸ Recently, Perkins *et al.* demonstrated that intranasally administered nicotine also functions as a discriminative stimulus in human volunteers. This result from a product that produces no sensory effects from smoke confirms that the pharmacological action of nicotine—rather than the taste or flavor of tobacco smoke—produces these hallmark psychoactive effects.⁷⁹

Psychoactive effects. Psychoactive or subjective effects produced by addictive drugs may range from very mild relaxation to intense intoxication or impaired cognitive abilities.⁸⁰ Assessment in humans of the subjective effects of addictive drugs involves giving either drug or placebo to volunteers and then asking them to report what they feel.

⁷⁷ Rosecrans JA, Chance WT, Cholinergic and non-cholinergic aspects of the discriminative stimulus properties of nicotine, in *Discriminative Stimulus Properties of Drugs*, ed. Lal H (New York: Plenum Press, 1977), at 155-185. See AR (Vol. 42 Ref. 126).

Rosecrans JA, Meltzer LT, Central sites and mechanism of action of nicotine, *Neuroscience and Biobehavioral Reviews* 1981;5(4):497-501. See AR (Vol. 42 Ref. 127).

Meltzer LT, Rosecrans JA, Aceto MD, *et al.*, Discriminative stimulus properties of the optical isomers of nicotine, *Psychopharmacology* 1980;68:283-286. See AR (Vol. 41 Ref. 106).

⁷⁸ Kallman WM, Kallman MJ, Harry GJ, *et al.*, Nicotine as a discriminative stimulus in human subjects, in *Drug Discrimination: Applications in CNS Pharmacology*, eds. Colpaert FC, Slangen JL (Amsterdam: Elsevier Biomedical Press, 1982), at 211-218. See AR (Vol. 41 Ref. 89).

⁷⁹ Perkins K, Grobe J, Scierka A, *et al.*, Discriminative stimulus effects of nicotine in smokers, in *International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II*, eds. Clarke PBS, Quik M, Thurau K, Adlkofer F (Basel: Birkhauser Verlag, 1994), at 111. See AR (Vol. 42 Ref. 111).

⁸⁰ Surgeon General's Report, 1988, at 270. See AR (Vol. 129 Ref. 1592).

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Individuals with histories of addictive drug use report what drug, if any, the test drug feels like. This testing helps determine whether the test drug produces any effects on mood and feeling that resemble those of previously studied drugs. Individuals with histories of using a variety of addictive drugs and who report “liking” the effects of several types of drugs help assess the addictiveness of the test drug. These individuals are asked to evaluate the ability to feel a drug effect, to rate how much they “like” the drug effect, and to attempt to identify the drug that was given from a list of widely used and abused drugs. Results that show consistent kinds of effects across drugs confirm that these drugs are appropriately categorized together as addicting drugs.⁸¹

Nicotine produces significant psychological sensations whether inhaled or injected. In one study, smokers with histories of abuse of other drugs identified intravenous or inhaled nicotine as being a euphoriant similar to cocaine or amphetamine.⁸² With a common measure of the subjective effects of addictive drugs (the Addiction Research Center Inventory), nicotine produced dose-related increases in the “euphoria” scale (also known as the Morphine-Benzedrine Group Scale or MBG) and the “liking” scale, showing that nicotine produces subjective effects similar to those of other addictive drugs. This study essentially extended the original finding of Johnston in 1942, who had argued from the premise that “smoking tobacco is essentially a means of administering nicotine, just as smoking opium is a means of administering morphine.”⁸³ In his study, Johnston administered intravenous injections

⁸¹ *Id.* at 271-272.

⁸² Henningfield JE, Miyasato K, Jasinski DR, Abuse liability and pharmacodynamic characteristics of intravenous and inhaled nicotine, *Journal of Pharmacology and Experimental Therapeutics* 1985;234:1-12. See AR (Vol. 39 Ref. 69).

⁸³ Johnston LM, Tobacco smoking and nicotine, *Lancet* 1942;2:742. See AR (Vol. 278 Ref. 3947).

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of nicotine, in doses comparable to those that people obtain from cigarettes or smokeless tobacco, to cigarette smokers to determine both nicotine's effects and its potential usefulness in helping people abstain from tobacco. He found that the nicotine injections produced "psychic" effects that "closely resembled" those of cigarette smoke inhalation, were pleasant for smokers, and left the smokers "disinclined to smoke." *See also* section II.C.6.b. (comment 1).

Similar findings were also obtained in a study by Jones *et al.*, who found that intravenous nicotine injections in doses comparable to those that people obtain from cigarettes or smokeless tobacco produced "a pleasurable stimulant-like sensation that many of them termed a 'rush.'" Half of the subjects tested requested substantially higher doses.⁸⁴ More recently, these early results have been confirmed by Pomerleau and Pomerleau, Perkins *et al.*, and Sutherland *et al.*, who have found that nicotine delivered from cigarettes, intravenous injection, and intranasal spray produces psychoactive and mood-altering effects consistent with those of other addictive drugs.⁸⁵

⁸⁴ Jones RT, Farrell TR III, Herning RI, Tobacco smoking and nicotine tolerance, in *Self-Administration of Abused Substances: Methods for Study*, ed. Krasnegro NA, NIDA Research Monograph 20 (Rockville MD: National Institute on Drug Abuse, 1978), at 202-208. *See* AR (Vol. 41 Ref. 88).

⁸⁵ Pomerleau CS, Pomerleau OF, Euphoriant effects of nicotine in smokers, *Psychopharmacology* 1992;108:460-465. *See* AR (Vol. 87 Ref. 426).

Perkins KA, Grobe JE, Epstein LH, *et al.*, Effects of nicotine on subjective arousal may be dependent on baseline subjective state, *Journal of Substance Abuse* 1992;4:131-141. *See* AR (Vol. 348 Ref. 5516).

Perkins KA, Grobe JE, Epstein LH, *et al.*, Chronic and acute tolerance to subjective effects of nicotine, *Pharmacology, Biochemistry and Behavior* 1993;45:375-381. *See* AR (Vol. 271 Ref. 3728).

Sutherland G, Stapleton JA, Russell MAH, *et al.*, Randomised controlled trial of nasal nicotine spray in smoking cessation, *Lancet* 1992;340:324-329. *See* AR (Vol. 91 Ref. 527).

Sutherland G, Russell MA, Stapleton J, *et al.*, Nasal nicotine spray: a rapid nicotine delivery system, *Psychopharmacology* 1992;108:512-518. *See* AR (Vol. 91 Ref. 526).

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The tobacco industry contends that tobacco is used for pleasure. So, too, is cocaine used for pleasure. These data establish, however, that receiving nicotine through a route that does not provide any sensory qualities of tobacco use (e.g., through the venous system) also is pleasurable. Thus, the pharmacological effects of nicotine administered through non-inhalation routes are able to produce the characteristic psychoactive effects of tobacco use.

Self-administration testing. In self-administration testing, human or animal subjects are given access to a drug and then evaluated for their tendency to seek repeated doses of the drug. The self-administration test determines the ability of a drug to sustain drug-seeking behavior—one of the key distinguishing features of drug dependence. The self-administration test is widely used to determine whether a drug can control behavior; a drug whose intake leads to more consumption is called a “positive reinforcer.” It is generally accepted in the scientific community that the ability of addictive drugs to serve as positive reinforcers is the core property that promotes the development and maintenance of addiction.⁸⁶

Self-administration procedures using primates and rats have been shown to be valid and reliable predictors of the potential for a compound to result in drug dependence. There is a strong correlation between the types of drugs that serve as reinforcers in animals and the drugs associated with addiction in humans.⁸⁷

Henningfield JE, Miyasato K, Jasinski DR, Abuse liability and pharmacodynamic characteristics of intravenous and inhaled nicotine, *Journal of Pharmacology and Experimental Therapeutics*, 1985;234(1):1-12. See AR (Vol. 39 Ref. 69).

⁸⁶ Balster RL, Drug abuse potential evaluation in animals, *British Journal of Addiction* 1991;86:1549-1558. See AR (Vol. 8 Ref. 89).

⁸⁷ Griffiths RR, Bigelow GE, Henningfield JE, Similarities in animal and human drug-taking behavior, *Advances in Substance Abuse* 1980;1:1-90. See AR (Vol. 8 Ref. 91-2).

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Animal self-administration studies, using a variety of administration schedules and controls, have shown that nicotine functions as a positive reinforcer across several species.⁸⁸ Nicotine is more avidly self-administered when available on an intermittent schedule than when freely available.⁸⁹ Since tobacco users self-administer intermittent doses of nicotine per cigarette or pinch of smokeless tobacco, the schedule of nicotine administration that is most reinforcing in animals corresponds to the pattern of actual tobacco consumption.

Consistent with animal self-administration studies, analogous studies with humans in the 1980's demonstrated that nicotine serves as a positive reinforcer under controlled laboratory conditions.⁹⁰ Subjects self-administered intravenous nicotine in a regular and

Woolverton WL, Nader MA, Experimental evaluation of the reinforcing effects of drugs, in *Modern Methods in Pharmacology*, eds. Adler MW, Cowen A (New York: Wiley-Liss, 1990), 6:165-192. See AR (Vol. 535 Ref. 96, vol. III.N).

⁸⁸ Goldberg SR, Spealman RD, Goldberg DM, Persistent behavior at high rates maintained by intravenous self-administration of nicotine, *Science* 1981;214:573-575. See AR (Vol. 5 Ref. 35-2).

Goldberg SR, Spealman RD, Maintenance and suppression of behavior by intravenous nicotine injections in squirrel monkeys, *Federation Proceedings* 1982;41(2):216-220. See AR (Vol. 39 Ref. 52).

Spealman RD, Goldberg SR, Maintenance of scheduled-controlled behavior by intravenous injections of nicotine in squirrel monkeys, *Journal of Pharmacology and Experimental Therapeutics* 1982;223(2):402-408. See AR (Vol. 42 Ref. 146).

Risner ME, Goldberg SR, A comparison of nicotine and cocaine self-administration in the dog: fixed-ratio and progressive-ratio schedules of intravenous drug infusion, *Journal of Pharmacology and Experimental Therapeutics* 1983;224(2):319-326. See AR (Vol. 42 Ref. 119).

Cox BM, Goldstein A, Nelson WT, Nicotine self-administration in rats, *British Journal of Pharmacology* 1984;83:49-55. See AR (Vol. 8 Ref. 93-1).

Slifer BL, Balster RL, Intravenous self-administration of nicotine: with and without schedule-induction, *Pharmacology, Biochemistry and Behavior* 1985;22:61-69. See AR (Vol. 8 Ref. 93-3).

Corrigall WA, Coen KM, Nicotine maintains robust self-administration in rats on a limited access schedule, *Psychopharmacology* 1989;99:473-478. See AR (Vol. 347 Ref. 5495).

⁸⁹ Surgeon General's Report, 1988, at 182-189. See AR (Vol. 129 Ref. 1592).

⁹⁰ Henningfield JE, Miyasoto K, Jasinski DR, Cigarette smokers self-administer intravenous nicotine, *Pharmacology, Biochemistry and Behavior* 1983;19:887-890. See AR (Vol. 8 Ref. 97).

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orderly pattern, giving themselves amounts of nicotine comparable to those they were accustomed to receiving from their cigarettes. These studies demonstrate that the pharmacological effects of nicotine can explain why people engage in compulsive consumption of tobacco.

At a molecular level, nicotine's reinforcing effects are widely believed to be a consequence of its actions on specific areas in the central nervous system. Within the scientific community, a consensus has emerged that nicotine, like other addictive drugs such as cocaine, amphetamine, and morphine, causes addiction by increasing the activity of the neurotransmitter dopamine within the mesolimbic system of the brain.⁹¹ A very recent study, which expands on and confirms earlier studies, has demonstrated that nicotine, at doses known to be self-administered, mimics the effects of cocaine, morphine, and amphetamines in the mesolimbic system, by selectively increasing dopamine transmission and energy metabolism in a specific region of the nucleus accumbens previously shown to be important in mediating the addictive effects of these drugs.⁹²

Surgeon General's Report, 1988, at 192. See AR (Vol. 129 Ref. 1592).

⁹¹ Clarke PBS, Mesolimbic dopamine activation—the key to nicotine reinforcement? *CIBA Foundation Symposium* 1990;152:153-168. See AR (Vol. 3 Ref. 19-2).

Corrigall WA, Coen KM, Selective dopamine antagonists reduce nicotine self-administration, *Psychopharmacology* 1991;104:171-176. See AR (Vol. 66 Ref. 30).

Corrigall WA, Franklin KBJ, Coen KM, *et al.*, The mesolimbic dopaminergic system is implicated in the reinforcing effects of nicotine, *Psychopharmacology* 1992;107:285-289. See AR (Vol. 8 Ref. 93-4).

Iverson LL, . . . harmful to the brain, *Nature* 1996;382:206-207. See AR (Vol. 711 Ref. 51).

⁹² Pontieri FE, Tanda G, Orzi F, *et al.*, Effects of nicotine on the nucleus accumbens and similarity to those of addictive drugs, *Nature* 1996;382:255-257. See AR (Vol. 711 Ref. 51).

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Observing that food, water, and salt also increase dopamine activity in the mesolimbic system, the tobacco industry comments that nicotine's action is not unique. FDA's finding, however, is not that nicotine's role in this system is unique, but that it is *significant*. Indeed, the tobacco industry's own observation on food, water, and salt reflects the significance of nicotine's action. As researchers have noted, the mesolimbic "reward" system of the brain naturally reinforces the intake of essential substances (such as food, water, and salt) because these substances are necessary for human existence. Without an intrinsic reward for eating and drinking, humans would perish. Researchers believe that addictive substances such as nicotine, amphetamine, cocaine, and morphine are so powerful precisely because they activate and even control this natural system of reward. Indeed, the same scientists quoted by the tobacco industry state that "nicotine could substitute for food or other reinforcers" in the mesolimbic system.⁹³ That nicotine can mimic life-sustaining substances and alter such a pivotal neurological system demonstrates its substantial effect on the structure and function of the human body.

Withdrawal and tolerance. Documentation of a drug withdrawal syndrome is the primary method of establishing that a substance causes physical dependence. According to the Surgeon General, "[m]easurement of drug withdrawal phenomena entails recording physiological, subjective, and behavioral responses that occur when drug administration is terminated."⁹⁴ Numerous studies document a characteristic withdrawal syndrome,

⁹³ Mifsud JC, Hernandez L, Hoebel BG, Nicotine infused into the nucleus accumbens increases synaptic dopamine as measured by in vivo microdialysis, *Brain Research* 1989;478(2):365-367, at 367. See AR (Vol. 535 Ref. 96, vol. IILJ).

⁹⁴ Surgeon General's Report, 1988, at 291. See AR (Vol. 129 Ref. 1592).

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including both physiological and psychological symptoms, associated with nicotine abstinence.⁹⁵ Widely used criteria for diagnosing withdrawal come from the American Psychiatric Association's DSM-IV, which defines Nicotine Withdrawal Syndrome as four (or more) of the following symptoms within 24 hours after cessation of use: dysphoric or depressed mood; insomnia; irritability, frustration, or anger; anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain.⁹⁶ Although nicotine withdrawal is not as life-threatening as withdrawal from alcohol or some barbiturates, it is comparable to or stronger than withdrawal from such other stimulants as cocaine and can be highly disruptive to personal life.⁹⁷ After several weeks of nicotine exposure, users who are deprived of nicotine for more than a few hours can develop withdrawal symptoms.⁹⁸ Withdrawal symptoms after quitting tobacco use can persist for months.⁹⁹

The tobacco industry contends that nicotine withdrawal is associated only with psychological changes; the evidence, however, demonstrates that tobacco abstinence also causes significant physiological effects on the body. These effects include decreased heart

⁹⁵ *Id.* at 197-207.

⁹⁶ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 244-245. See AR (Vol. 37 Ref. 8).

⁹⁷ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

⁹⁸ Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 548. See AR (Vol. 535 Ref. 96, vol. III.G).

⁹⁹ Ryan FJ, Cold turkey in Greenfield, Iowa: a follow-up study, in *Smoking Behavior: Motives and Incentives*, ed. Dunn WL (Washington DC: VH Winston & Sons, 1973), at 231-234. See AR (Vol. 8 Ref. 105).

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rate at rest and after standing, alteration of the electroencephalogram (EEG, a measure of brain electrical activity), skin temperature changes, and disruptions in sleep patterns.¹⁰⁰

Studies have also demonstrated that tobacco withdrawal can cause an increase in weight. This weight increase may be attributed to increased caloric intake, decreased metabolism, and decreased energy expenditure during nicotine withdrawal.¹⁰¹ The physiological signs of nicotine withdrawal are substantially reversed when nicotine is given in a form other than tobacco.¹⁰²

Significant behavioral and subjective symptoms common to nicotine withdrawal include depression, anger, irritability, anxiety, poor concentration, and restlessness.¹⁰³

¹⁰⁰ West RJ, Jarvis MJ, Russell MAH, *et al.*, Effect of nicotine replacement on the cigarette withdrawal syndrome, *British Journal of Addiction* 1984;79(2):215-219. See AR (Vol. 8 Ref. 102-1).

Hughes JR, Hatsukami D, Signs and symptoms of tobacco withdrawal, *Archives of General Psychiatry* 1986;43:289-294. See AR (Vol. 8 Ref. 102-2).

Hughes JR, Higgins ST, Hatsukami D, Effects of abstinence from tobacco: a critical review, *Research Advances in Alcohol and Drug Problems* 1990;10:317-398, at 382. See AR (Vol. 535 Ref. 96, vol. III.G).

¹⁰¹ Wack JT, Rodin J, Smoking and its effect on body weight and the systems of caloric regulations, *American Journal of Clinical Nutrition* 1982;35(2):366-380. See AR (Vol. 8 Ref. 103-1).

Glauser SC, Glauser EM, Reidenberg MM, *et al.*, Metabolic changes associated with the cessation of cigarette smoking, *Archives of Environmental Health* 1970;20:377-381. See AR (Vol. 8 Ref. 103-2).

¹⁰² Surgeon General's Report, 1988, at 208. See AR (Vol. 129 Ref. 1592).

¹⁰³ See, e.g., Hughes JR, Hatsukami D, Signs and symptoms of tobacco withdrawal, *Archives of General Psychiatry* 1986;43:289-294. See AR (Vol. 8 Ref. 102-2).

Centers for Disease Control and Prevention, Reasons for tobacco use and symptoms of nicotine withdrawal among adolescent and young adult tobacco users-United States, 1993, *Morbidity and Mortality Weekly Report* 1994;43(41):745-750. See AR (Vol. 7 Ref. 86).

Hughes JR, Nicotine withdrawal, dependence, and abuse, in *DSM-IV Sourcebook*, eds. Widiger T, Frances A, *et al.* (Washington DC: American Psychiatric Association, 1994), 1:109-116. See AR (Vol. 535 Ref. 96, vol. III.F).

West RJ, Jarvis MJ, Russell MAH, *et al.*, Effect of nicotine replacement on the cigarette withdrawal syndrome, *British Journal of Addiction* 1984;79(2):215-219. See AR (Vol. 8 Ref. 102-1).

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Dependent smokers also show substantial withdrawal symptoms within a day of nicotine abstinence.¹⁰⁴ These psychological symptoms are substantially reversible or preventable by providing nicotine in the form of conventional cigarettes or by providing equivalent or lower doses of nicotine in other forms (e.g., nicotine gum) including forms without the taste of nicotine (e.g., nicotine patches).¹⁰⁵

Withdrawal from smokeless tobacco also causes physiological changes attributable to nicotine abstinence. Hatsukami and colleagues showed the following changes in users deprived of chewing tobacco: (1) decreased heart rate at rest and after standing; (2) increased craving for tobacco; (3) increased confusion score on the Profile of Mood States (POMS) (this measures tension/anxiety, depression/dejection, confusion, anger/hostility, vigor, and fatigue); (4) increased eating; (5) increased number of sleep interruptions; and (6) increased total scores on a withdrawal symptom checklist for both self-rated and observer-rated measures.¹⁰⁶

¹⁰⁴ Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 548. See AR (Vol. 535 Ref. 96, vol. III.G).

¹⁰⁵ Surgeon General's Report, 1988, at 470-485. See AR (Vol. 129 Ref. 1592).

Robinson JH, Pritchard WS, Davis RA, Psychopharmacological effects of smoking a cigarette with typical "tar" and carbon monoxide yields but minimal nicotine, *Psychopharmacology* 1992;108:466-472. See AR (Vol. 59 Ref. 236).

Fagerstrom KO, Sawe U, Tonnesen P, Therapeutic use of nicotine patches: efficacy and safety, *Journal of Drug Development* 1993;5:191-205. See AR (Vol. 76 Ref. 156).

Fiore MC, Jorenby DE, Baker TB, *et al.*, Tobacco dependence and the nicotine patch, *Journal of the American Medical Association* 1992;268:2687-2694. See AR (Vol. 351 Ref. 5609).

¹⁰⁶ Hatsukami DK, Gust SW, Keenan RM, Physiologic and subjective changes from smokeless tobacco withdrawal, *Clinical Pharmacology and Therapeutics* 1987;41:103-107. See AR (Vol. 7 Ref. 73).

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A second key test of a substance's ability to produce physical dependence is whether it promotes tolerance.¹⁰⁷ Tolerance occurs when responses produced by an initial dose are diminished with repeated doses, so that increasing doses are necessary to reproduce the initial effects. Tolerance to some effects of a substance can be acute, occurring within hours to days, while tolerance to other effects develops chronically as a result of long-term substance exposure.

Tobacco users become tolerant to nicotine both acutely and chronically.¹⁰⁸ After a single night of abstinence, the nervous system¹⁰⁹ and the cardiovascular system¹¹⁰ are highly responsive to small doses of nicotine. But after the administration of the equivalent of a few cigarettes, the responsiveness of the human body to nicotine declines markedly. Thus, a cigarette smoked in the middle of the day may not elicit the same psychological or physiological response in a cigarette smoker as one smoked earlier in the morning. This severe degree of acute tolerance seems to greatly exceed that produced by cocaine and to be more comparable to that produced by morphine.¹¹¹

Tolerance to other effects of nicotine develops over weeks and months. For example, new smokers often experience nicotine-related effects such as dizziness, nausea, intoxication, vomiting, and headaches—symptoms that disappear eventually as the

¹⁰⁷ Surgeon General's Report, 1988, at 50-54. See AR (Vol. 129 Ref. 1592).

¹⁰⁸ Perkins KA, Grobe JE, Epstein LH, *et al.*, Chronic and acute tolerance to subjective effects of nicotine, *Pharmacology, Biochemistry and Behavior* 1993;45:375-381. See AR (Vol. 271 Ref. 3728).

¹⁰⁹ *Id.*

¹¹⁰ Surgeon General's Report, 1988, at 47-48. See AR (Vol. 129 Ref. 1592).

¹¹¹ Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 533, 543, 548. See AR (Vol. 535 Ref. 96, vol. III.G).

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smokers' bodies adapt to nicotine and tolerance to these effects develops.¹¹² These and other examples of chronic tolerance (such as faster nicotine metabolism among experienced smokers) are consistent with laboratory evidence of long-term structural changes in the brain and other parts of the body from nicotine use.¹¹³

There is also epidemiological evidence that the vast majority of smokers and smokeless tobacco users increase their consumption and usage of tobacco products over time. See section II.A.3.c.ii., below. This escalation of dose is an additional demonstration of the development of tolerance. Like users of other addictive drugs, tobacco users eventually reach a stable level of consumption.¹¹⁴

Laboratory studies on drug discrimination, psychoactive/subjective effects, self-administration, and withdrawal and tolerance thus demonstrate that nicotine has the properties of an addictive drug.

Nicotine compared to saccharin and caffeine. In its comments, the tobacco industry attempts to discount a multitude of laboratory studies of nicotine by selectively pointing to a single test used to screen for addictive substances and arguing that, in that test, nicotine's effect was similar to saccharin's. From this premise, the industry concludes that nicotine is no more addictive than saccharin. This argument misrepresents the published data on saccharin's and nicotine's properties and overlooks fundamental

¹¹² Department of Health and Human Services, Office on Smoking and Health, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (Washington DC: Government Printing Office, 1994), at 138. See AR (Vol. 133 Ref. 1596).

¹¹³ See section II.A.3.i. and ii., below, for a more detailed discussion.

¹¹⁴ Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-532). See AR (Vol. 535 Ref. 96, vol. III.G).

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differences between saccharin and nicotine. Contrary to the tobacco industry's argument, saccharin has not been shown to meet the most fundamental test of an addictive drug, namely, psychoactive effects in the brain that account for its appeal to humans and animals. Nicotine *has* been shown to have these effects.

In contrast to nicotine, which can be pleasurable even when injected intravenously, saccharin is liked primarily because of its taste. For example, rats can be trained to self-administer oral doses of saccharin in preference to water, demonstrating only that rats prefer the taste of saccharin to that of water. FDA is unaware of any studies, and the tobacco industry cites none, in which rats have self-administered saccharin intravenously. Such a study would be an essential step in proving that saccharin's appeal lies in its effects on the brain. Moreover, there is no evidence that saccharin produces any psychoactive effects. In contrast, nicotine, which produces no such pleasant taste, demonstrates all of the properties of an addictive drug, including self-administration and psychoactivity, through its actions on the central nervous system.

The tobacco industry also argues that nicotine is similar to caffeine in tests of addictive potential. FDA disagrees. In comparison to the more orderly pattern of self-administration observed with nicotine and stimulant drugs, the pattern of caffeine self-administration is generally weak and sporadic in animals.¹¹⁵ Hence, in comparison to known

¹¹⁵ Heishman SJ, Henningfield JE, Stimulus functions of caffeine in humans: relation to dependence potential, *Neuroscience and Biobehavioral Reviews* 1992;16:273-287. See AR (Vol. 79 Ref. 230).

Griffiths RR, Woodson PP, Reinforcing properties of caffeine: studies in humans and laboratory animals, *Pharmacology, Biochemistry and Behavior* 1988;29(2):419-427. See AR (Vol. 535 Ref. 96, vol. III.E).

Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 524. See AR (Vol. 535 Ref. 96, vol. III.G).

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drugs of dependence (e.g., cocaine, morphine, and nicotine), caffeine has a lower relative dependence potential as well as a low risk of adverse effects in amounts currently permitted in foods and beverages.¹¹⁶ Unlike nicotine, caffeine is not recognized as a dependence-producing substance by the American Psychiatric Association¹¹⁷ and the World Health Organization.¹¹⁸

The laboratory differences between nicotine and caffeine are reflected in the different patterns of substance consumption. Neal Benowitz, a prominent addiction researcher, noted that, “[i]n contrast to coffee drinkers, the vast majority of cigarette smokers exhibit addictive behavior.”¹¹⁹ The wide acceptance of decaffeinated beverages demonstrates a much more general ability to control intake and minimize undesirable effects of caffeine. Moreover, while nicotine/tobacco addiction is estimated to be one of the leading causes of premature death in the United States,¹²⁰ caffeine at customary doses poses few risks to the individual or to society.

¹¹⁶ Heishman SJ, Henningfield JE, Stimulus functions of caffeine in humans: relation to dependence potential, *Neuroscience and Biobehavioral Reviews* 1992;16:273-287. See AR (Vol. 79 Ref. 230).

Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

¹¹⁷ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 176. See AR (Vol. 37 Ref. 8).

¹¹⁸ WHO, *The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines* (Geneva: World Health Organization, 1992), at 75-76. See AR (Vol. 43 Ref. 175).

¹¹⁹ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437, at 430. See AR (Vol. 535 Ref. 96, vol. III.A).

¹²⁰ McGinnis JM, Foege WH, Actual causes of death in the United States, *Journal of the American Medical Association* 1993;270(18):2207-2212. See AR (Vol. 2 Ref. 15-1).

Hearing on Preventive Health: An Ounce of Prevention Saves a Pound of Cure, Before the Special Committee on Aging, U.S. Senate, 103d Cong., 1st Sess. 2 (May 6, 1993) (statement of Roger Herdman, Maria Hewitt, Mary Laschober, on smoking-related deaths and financial costs: Office of Technology Assessment estimates for 1990). See AR (Vol. 170 Ref. 2024).

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Thus, the average tobacco consumer—but not the average coffee drinker—uses tobacco despite severe health risks, a clinical sign of addiction.¹²¹

In summary, widely publicized laboratory studies show that tobacco use, like heroin and cocaine use, is a behavioral-pharmacological process in which the individual's continued consumption of tobacco is controlled by a psychoactive and reinforcing drug that exerts its control through the central nervous system. Thus, nicotine is similar to other addictive drugs in every relevant aspect. For this reason, every scientific authority that has reviewed the results of the laboratory evidence has concluded that nicotine is addictive.

ii. Epidemiological Data Establish That Many Tobacco Users Are Addicted.

Numerous well-publicized studies and health surveys have documented the characteristics of nicotine dependence among tobacco users. In the United States, clinical criteria to assess addiction come from the DSM-IV published by the American Psychiatric Association.

Several large studies have confirmed that most cigarette smokers qualify for a diagnosis of nicotine dependence. As described in depth in the appendix to the Jurisdictional Analysis, and discussed further in section II.B.2.a., below, as many as 92% of smokers are addicted to cigarettes.¹²² Smokers are more likely to become addicted than

¹²¹ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 181. See AR (Vol. 37 Ref. 8).

¹²² See appendix 1 to Jurisdictional Analysis, at 42-47. See AR (Vol. 1 Appendix 1).

In the Jurisdictional Analysis (60 FR 41576), FDA referred to rates of dependence among "frequent smokers" as being in the range of 75% to 90%. In this document, FDA does not use "frequent" but rather describes the definition of smokers used in each study. See section II.B.2., below.

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users of other dependence-producing drugs, including cocaine, alcohol, marijuana, inhalants, and heroin.¹²³ Consistent with the results from these large studies, which assessed the prevalence of nicotine dependence as defined by meeting three or more of the seven criteria for addiction, are the findings of other studies that assessed the proportion of tobacco users meeting individual criteria. Of the seven criteria listed in section II.A.3.b., above, DSM-IV observes that six are readily apparent among tobacco users: desire to quit or unsuccessful efforts to cut down, use continued despite medical problems, a great deal of time spent using, use of substance in larger amounts and longer than intended, withdrawal, and tolerance.¹²⁴ These results strongly support the conclusion that addiction to nicotine is widespread among smokers.

Although there have been no population-based studies using criteria from the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) to assess rates of addiction to smokeless tobacco, substantial evidence demonstrates that a high proportion of smokeless tobacco users meet individual DSM criteria for addiction. This evidence strongly supports the conclusion that a substantial proportion of such users are addicted. In 1992, the Inspector General of the Department of Health and Human Services estimated that approximately 75% of young regular users of smokeless tobacco are addicted.¹²⁵

¹²³ Anthony JC, Warner LA, Kessler RC, Comparative epidemiology of dependence on tobacco, alcohol, controlled substances and inhalants: basic findings from the National Comorbidity Survey, *Experimental and Clinical Psychopharmacology* 1994;2:244-268. See AR (Vol. 37 Ref. 4).

¹²⁴ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 243. See AR (Vol. 37 Ref. 8).

¹²⁵ Department of Health and Human Services, Office on Smoking and Health, *Spit Tobacco and Youth* (Washington DC: GPO, 1992), at 8. See AR (Vol. 7 Ref. 76).

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Data demonstrating that a high proportion of smokers and users of smokeless tobacco meet individual DSM criteria for addiction are now discussed.

Desire to quit or unsuccessful efforts to cut down. Each year, more than 15 million people in the United States—almost one-third of all daily smokers—try to quit smoking. Fewer than 3% of smokers achieve 1 year of abstinence.¹²⁶

Quitting smokeless tobacco is also difficult. In one study, only 2.3% of smokeless tobacco users at a cessation clinic were able to remain abstinent for 6 months; the study concluded that using smokeless tobacco may be more addicting than cigarette smoking.¹²⁷

The Centers for Disease Control and Prevention (CDC) found that the greater the level of use of the tobacco product, the more likely young people were to report that “it’s really hard to quit.” This increase in difficulty quitting as the amount of tobacco consumed increases demonstrates a dose-response relationship, one of the characteristic features of pharmacological effects. This dose-response relationship holds true for both cigarettes and smokeless tobacco used by 10- to 22-year-olds. For example, 74% of young people who used smokeless tobacco every day reported that it was very difficult to quit, compared to only 11% who used smokeless tobacco 1 to 14 days a month.¹²⁸

¹²⁶ Centers for Disease Control and Prevention, Smoking cessation during previous year among adults—United States, 1990 and 1991, *Morbidity and Mortality Weekly Report* 1993;42(26):504-507. See AR (Vol. 66 Ref. 2).

¹²⁷ Glover ED, Glover PN, Smokeless tobacco cessation and nicotine reduction therapy, in *Smokeless Tobacco or Health, an International Perspective*, Smoking and Tobacco Control, *NIDA Research Monograph* 2, NIH Publication No. 93-3461 (Rockville MD: Government Printing Office, 1993), at 291-295. See AR (Vol. 7 Ref. 79-1).

¹²⁸ Centers for Disease Control and Prevention, Reasons for tobacco use and symptoms of nicotine withdrawal among adolescents and young adult tobacco users—United States, 1993, *Morbidity and Mortality Weekly Report* 1994;43(41):745-750. See AR (Vol. 7 Ref. 86).

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Additional studies on the common desire to quit and the failure of the vast majority of attempts can be found in appendix 1 to Jurisdictional Analysis.¹²⁹

Use continued despite medical problems. As many as 90% of smokers know that tobacco products are harmful to their own health, 65% of current smokers believe that smoking “has already affected” their health, and 77% of smokers believe that they could “avoid or decrease serious health problems from smoking” if they quit.¹³⁰ Yet they keep smoking.

Consumers of smokeless tobacco also recognize the health risks of their tobacco use, but do not stop. In one study, 96% of young men who regularly used smokeless tobacco agreed that chewing tobacco and snuff can cause cancer.¹³¹ Another study of users age 17 and over revealed that 77.4% believe that smokeless tobacco is a health hazard.¹³²

People even continue tobacco use in the face of life-threatening, tobacco-related illnesses. For example, studies have shown that about half of smokers who have had

¹²⁹ See appendix 1 to Jurisdictional Analysis, at 52-55. See AR (Vol. 1 Appendix 1).

¹³⁰ Gallup GH, *Smoking Prevalence, Beliefs, and Activities by Gender and Other Demographic Indicators* (Princeton NJ: Gallup Organization, 1993). See AR (Vol. 38 Ref. 43a).

¹³¹ Department of Health and Human Services, Office on Smoking and Health, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (Washington DC: Government Printing Office, 1994), at 101. See AR (Vol. 133 Ref. 1596).

¹³² Novotny TE, Pierce JP, Fiore MC, *et al.*, Smokeless tobacco use in the United States: the adult use of tobacco surveys, *Monographs/National Cancer Institute* 1989;8:25-28. See AR (Vol. 41 Ref. 109).

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surgery for lung cancer resume smoking¹³³ and that almost 40% of smokers who have had their larynxes removed try smoking again.¹³⁴

Additional data on the use of tobacco products despite the health problems they have caused are presented in appendix 1 to the Jurisdictional Analysis.¹³⁵

Great deal of time spent using. Studies have demonstrated that tobacco users consume tobacco regularly and compulsively. For example, 90% of smokers consume five or more cigarettes every day.¹³⁶ Over two-thirds of smokers who consume five cigarettes a day smoke their first cigarette within the first half-hour after awakening;¹³⁷ according to many experts, this need is a key symptom indicating a very significant level of dependence.¹³⁸

Among users of chewing tobacco and moist snuff over 18, half use the products every day, and the proportion of daily users rises with age.¹³⁹ The Inspector General of

¹³³ Davison G, Duffy M, Smoking habits of long term survivors of surgery for lung cancer, *Thorax* 1982;37:331-333. See AR (Vol. 6 Ref. 58).

¹³⁴ West R, Himbury S, Smoking habits after laryngectomy, *British Medical Journal* 1985;291:514-515. See AR (Vol. 6 Ref. 59).

¹³⁵ See appendix 1 to Jurisdictional Analysis, at 56-58. See AR (Vol. 1 Appendix 1).

¹³⁶ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

Henningfield JE, Cohen C, Slade JD, Is nicotine more addictive than cocaine? *British Journal of Addiction* 1991;86:565-569. See AR (Vol. 277 Ref. 3904).

¹³⁷ Giovino GA, Zhu BP, Tomar S, et al., *Epidemiology of Tobacco Use and Symptoms of Nicotine Addiction in the United States: A Compilation of Data from Large National Surveys*, presentation of the Centers for Disease Control and Prevention to the FDA's Drug Abuse Advisory Committee (Aug. 2, 1994), slide 19 (from National Health Interview Survey 1987). See AR (Vol. 459 Ref. 7820).

¹³⁸ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), 245. See AR (Vol. 37 Ref. 8).

¹³⁹ Department of Health and Human Services, National Center for Health Statistics, *Vital and Health Statistics: Smoking and Other Tobacco Use: United States, 1987*, Series 10: Data from the National

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the U.S. Department of Health and Human Services reported that “our 1986 and 1992 users typically held their dip or chew 25 to 30 minutes, with most keeping it in over 30 minutes, and often up to one hour.”¹⁴⁰

Use of substance in larger amounts or longer than intended. Few beginning smokers plan to become daily smokers. Yet 90% of current smokers consume at least five cigarettes a day.¹⁴¹ Smokers also smoke for longer periods than they intend. Among high school seniors from the Monitoring the Future Project (1976–86), almost half of the daily smokers reported that they would either probably or definitely not be smoking 5 years after graduation.¹⁴² In a follow-up study conducted 5 to 6 years after graduation, more than two-thirds were smoking as frequently or more frequently than they had in high school (26% were smoking at the same level, and 40% were smoking more).¹⁴³

Other evidence that users of cigarettes and smokeless tobacco consume more than they intend comes from surveys demonstrating that many people try to quit but fail. For

Health Survey, No. 169, Sep. 1989, DHHS Publication No. (PHS) 89-1597 (Washington DC: Government Printing Office, 1989), at 24, 26. See AR (Vol. 711 Ref. 9).

¹⁴⁰ Department of Health and Human Services, Office on Smoking and Health, *Spit Tobacco and Youth* (Washington DC: Government Printing Office, 1992), at 7. See AR (Vol. 7 Ref. 76).

¹⁴¹ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

Henningfield JE, Cohen C, Slade JD, Is nicotine more addictive than cocaine? *British Journal of Addiction* 1991;86:565-569. See AR (Vol. 277 Ref. 3904).

¹⁴² Elders MJ, Perry CL, Eriksen MP, *et al.*, The report of the Surgeon General: preventing tobacco use among young people, *American Journal of Public Health* 1994;84(4):543-547, at 544. See AR (Vol. 38 Ref. 39).

¹⁴³ *Id.*

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example, two of every five adult users of smokeless tobacco have tried to quit.¹⁴⁴

Additional studies are discussed in detail in appendix 1 to the Jurisdictional Analysis.¹⁴⁵

Withdrawal. In addition to experimental evidence of withdrawal from nicotine described in section II.A.3.c.i., above, persuasive data from epidemiological studies also demonstrate that the vast majority of consumers who abstain from tobacco products experience withdrawal symptoms.¹⁴⁶

Studies show that the symptoms of irritability, nervousness, restlessness, and increased appetite each affect over half of abstinent smokers; indeed, about half of abstinent smokers qualify for a formal diagnosis of Nicotine Withdrawal Syndrome under the *Diagnostic and Statistical Manual of Mental Disorders*, 3d ed., revised (DSM-III-R).¹⁴⁷ Withdrawal symptoms show a dose-response relationship; heavier smokers are more likely than light smokers to experience the symptoms of difficulty concentrating, hunger, irritability, restlessness, and sadness when they try to quit.¹⁴⁸ A similar dose-response relationship between the likelihood of withdrawal symptoms and the level of

¹⁴⁴ Novotny TE, Pierce JP, Fiore MC, *et al.*, Smokeless tobacco use in the United States: the adult use of tobacco surveys, *Monographs/National Cancer Institute* 1989;8:25-28. See AR (Vol. 41 Ref. 109).

¹⁴⁵ See appendix 1 to Jurisdictional Analysis, at 48-55. See AR (Vol. 1 Appendix 1).

¹⁴⁶ See appendix 1 to Jurisdictional Analysis, at 58-61. See AR (Vol. 1 Appendix 1).

¹⁴⁷ Breslau N, Kilbey MM, Andreski MA, Nicotine withdrawal symptoms and psychiatric disorders: findings from an epidemiologic study of young adults, *American Journal of Psychiatry* 1992;149(4):464-469. See AR (Vol. 37 Ref. 18).

¹⁴⁸ Giovino GA, Zhu BP, Tomar S, *et al.*, *Epidemiology of Tobacco Use and Symptoms of Nicotine Addiction in the United States: A Compilation of Data from Large National Surveys*, presentation of the Centers for Disease Control and Prevention to the FDA's Drug Abuse Advisory Committee (Aug. 2, 1994), slides 27-32. See AR (Vol. 459 Ref. 7820).

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nicotine intake was found among British schoolgirls¹⁴⁹ and other populations studied.¹⁵⁰

Most people who quit smoking relapse within 1 week,¹⁵¹ when withdrawal symptoms are at or near their peak.¹⁵²

Smokeless tobacco users typically experience withdrawal symptoms similar to those reported by smokers. In a study of young smokeless tobacco users, over 90% of daily users reported at least one symptom of nicotine withdrawal when trying to discontinue use. Restlessness and irritability were reported by half of daily users during abstinence.¹⁵³

Tolerance. In addition to laboratory measures of tolerance to nicotine described in section II.A.3.c.i., above, epidemiological studies show that users of tobacco products require increasing amounts to maintain the same effects. The 1991 and 1992 National Household Survey on Drug Abuse found that 12% of smokers 25 years or older and 20% of smokers 12 to 24 years of age who smoke 16 to 25 cigarettes per day report feeling the need for an increased number of cigarettes over time to obtain the desired effects.¹⁵⁴

¹⁴⁹ McNeill AD, West RJ, Jarvis M, *et al.*, Cigarette withdrawal symptoms in adolescent smokers, *Psychopharmacology* 1986;90(4):533-536. See AR (Vol. 95 Ref. 683).

¹⁵⁰ Surgeon General's Report, 1988, at 206-207. See AR (Vol. 129 Ref. 1592).

¹⁵¹ Hughes JR, Gulliver SB, Fenwick JW, *et al.*, Smoking cessation among self-quitters, *Health Psychology* 1992;11:331-334. See AR (Vol. 348 Ref. 5512).

¹⁵² Hughes JR, Gust SW, Skoog K, *et al.*, Symptoms of tobacco withdrawal: a replication and extension, *Archives of General Psychiatry* 1991;48:52-59. See AR (Vol. 129 Ref. 1404).

¹⁵³ Centers for Disease Control and Prevention, Reasons for tobacco use and symptoms of nicotine withdrawal among adolescents and young adult tobacco users—United States, 1993, *Morbidity and Mortality Weekly Report* 1994;43(41):745-750. See AR (Vol. 7 Ref. 86).

¹⁵⁴ Giovino GA, Zhu BP, Tomar S, *et al.*, *Epidemiology of Tobacco Use and Symptoms of Nicotine Addiction in the United States: A Compilation of Data from Large National Surveys*, presentation of the Centers for Disease Control and Prevention to the FDA's Drug Abuse Advisory Committee (Aug. 2, 1994), slide 24. See AR (Vol. 459 Ref. 7820).

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Among those who have tried an addictive substance at least once, people who have tried cigarettes are more likely to report the need for larger doses to get the same effect than people who have tried cocaine, marijuana, and alcohol.¹⁵⁵

Most consumers of tobacco products escalate their doses over time. Whereas few cigarette smokers initially plan to be regular daily users, approximately 90% of them consume more than five cigarettes every day.¹⁵⁶

Smokeless tobacco users also increase their dose of nicotine. One study showed a positive relationship among the number of years of smokeless tobacco use, the number of minutes per day of reported use, and urinary nicotine and cotinine levels.¹⁵⁷ (Cotinine is a major metabolite of nicotine and an indicator of nicotine absorption.) Other studies on dose escalation of tobacco products can be found in appendix 1 to the Jurisdictional Analysis.¹⁵⁸

The epidemiological data demonstrate that a large proportion of tobacco users are dependent on nicotine and that overwhelming numbers of users show signs of addiction. These data complement laboratory evidence proving that nicotine is an addictive substance and have led to the nearly universal scientific recognition of nicotine as a drug whose

¹⁵⁵ Henningfield JE, Clayton R, Pollin W, Involvement of tobacco in alcoholism and illicit drug use, *British Journal of Addiction* 1990;85:279-292. See AR (Vol. 39 Ref. 66).

¹⁵⁶ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

Henningfield JE, Cohen C, Slade JD, Is nicotine more addictive than cocaine? *British Journal of Addiction* 1991;86:565-569. See AR (Vol. 277 Ref. 3904).

¹⁵⁷ World Health Organization, *Smokeless Tobacco Control: Report of a WHO Study Group*, WHO Technical Report Series No. 773 (Geneva: WHO, 1988), 36. See AR (Vol. 7 Ref. 83).

¹⁵⁸ See appendix 1 to Jurisdictional Analysis, at 48-51. See AR (Vol. 1 Appendix 1).

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pharmacological effects compel continued use. These widely disseminated public findings establish that a reasonable person in the position of a tobacco manufacturer would foresee that tobacco products would be consumed to satisfy an addiction to nicotine.¹⁵⁹

4. It Is Foreseeable That Consumers Will Use Cigarettes and Smokeless Tobacco for Other Pharmacological Purposes

In addition to its foreseeable addictive effects, nicotine produces a range of other well-known and foreseeable significant pharmacological effects of importance to tobacco users. Evidence demonstrating that consumers actually use tobacco products for these effects is discussed in section II.B.2., below.

Central Nervous System Effects: Sedation, Stimulation, Mood, and Cognition.

Nicotine significantly alters the structure and function of the brain. At the molecular level, nicotine acts by stimulating receptors on the surfaces of brain cells intended for natural neurotransmitters such as acetylcholine and by stimulating the release of other key substances such as dopamine.¹⁶⁰ Nicotine also changes the brain's molecular structure. Extensive animal research by both the tobacco industry and other researchers shows that nicotine exposure, ranging from a few days to a few weeks, within the range of doses equivalent to those received from smoking cigarettes, increases the number and changes the functional activity of nicotine receptors in the brain.¹⁶¹ In one study, doses of nicotine

¹⁵⁹ FDA notes that at least one major tobacco company appears to agree that information about the "addicting" properties of cigarettes is so widely disseminated that it must be considered foreseeable. In a lawsuit brought against RJR by a smoker, RJR argued that the "alleged habituating or 'addicting'" qualities of cigarette smoking are so well known that smokers must be held to have foreseen them. See section II.C.2.b.iv., below.

¹⁶⁰ See the discussion of dopamine in the mesolimbic system, section II.A.3.c.i., above.

¹⁶¹ Marks MJ, Burch JB, Collins AC, Effects of chronic nicotine infusion on tolerance development and nicotine receptors, *Journal of Pharmacology and Experimental Therapeutics* 1983;226:817-825. See AR (Vol. 41 Ref. 103).

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considered equivalent to those received by a fetus of a smoking mother increase the number of nicotine receptors in the brains of newborn rats.¹⁶² Consistent with animal data, cigarette smokers show clear evidence of increased numbers of cerebral nicotine receptors as a consequence of their smoking.¹⁶³

The result of these molecular actions is that nicotine clinically affects arousal, attention, mood, and, under certain conditions, cognition. Depending on the dose and the circumstances, nicotine delivered by cigarette smoking can have an arousal-increasing or arousal-reducing effect.¹⁶⁴ This is another respect in which nicotine is similar to such other addictive drugs as opiates, which can have both stimulating and sedating effects.

Nicotine's effects on mood and arousal have been confirmed using electroencephalographic (EEG) analysis, a measurement of electrical activity in the brain.¹⁶⁵ When smokers are placed in a stressful situation, smoking can have a depressant

Surgeon General's Report, 1988, at 53-54. See AR (Vol. 129 Ref. 1592).

Department of Health and Human Services, Office on Smoking and Health, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (Washington DC: GPO, 1994), at 32-33. See AR (Vol. 133 Ref. 1596).

¹⁶² Slotkin TA, Orband-Miller L, Queen KL, Development of (³H)nicotine binding sites in brain regions of rats exposed to nicotine prenatally via maternal injections or infusions, *Journal of Pharmacology and Experimental Therapeutics* 1987;242:232-237. See AR (Vol. 140 Ref. 1656).

¹⁶³ Benwell MEM, Balfour DJK, Anderson JM, Evidence that tobacco smoking increases the density of (-)-[³H]nicotine binding sites in human brain, *Journal of Neurochemistry* 1988;50:1243-1247. See AR (Vol. 136 Ref. 1570).

¹⁶⁴ Norton R, Brown K, Howard R, Smoking, nicotine dose and the lateralisation of electrocortical activity, *Psychopharmacology* 1992;108:473-479. See AR (Vol. 3 Ref. 22).

¹⁶⁵ Pritchard WS, Gilbert DG, Duke DW, Flexible effects of quantified cigarette-smoke delivery on EEG dimensional complexity, *Psychopharmacology* 1993;113:95-102. See AR (Vol. 3 Ref. 23-1).

Pritchard WS, Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490. See AR (Vol. 105 Ref. 965).

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effect on the EEG profile.¹⁶⁶ When smokers are placed in conditions of low arousal induced by mild sensory isolation, cigarette smoking can have a stimulant effect.¹⁶⁷ In other words, smoking can have a relaxing effect in stressful situations and a stimulating effect in otherwise nonstimulating circumstances.

The tobacco industry correctly observes that many substances affect the EEG. But what is significant is not *that* nicotine affects the EEG, but *how* nicotine does so. Nicotine's impact on the EEG: (1) is reproducible, (2) is clinically significant, (3) corresponds to other physiological and psychological changes of smoking, and (4) is similar to certain EEG changes associated with other addictive drugs such as benzodiazepines.¹⁶⁸ Altered electrical activity of the brain as demonstrated by EEG is convincing evidence of nicotine's significant pharmacological effects on the structure and function of the body.

Smokers perform better on some cognitive tests than do deprived smokers, but nicotine does not improve general learning or make smokers generally perform better than nonsmokers.¹⁶⁹ One leading researcher noted that, after a few hours of abstinence, "[P]eople are reporting they can't concentrate as well, they can't get the tasks done as

Golding JF, Effects of cigarette smoking on resting EEG, visual evoked potentials and photic driving, *Pharmacology, Biochemistry and Behavior* 1988;29:23-32. See AR (Vol. 3 Ref. 23-3).

¹⁶⁶ Pritchard WS, Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490. See AR (Vol. 105 Ref. 965).

¹⁶⁷ Golding J, Mangan GL, Arousing and de-arousing effects of cigarette smoking under conditions of stress and mild sensory isolation, *Psychophysiology* 1982;19(4):449-456. See AR (Vol. 48 Ref. 101).

¹⁶⁸ Pritchard WS, Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490, at 485, 488. See AR (Vol. 105 Ref. 965).

¹⁶⁹ Surgeon General's Report, 1988, at 441. See AR (Vol. 129 Ref. 1592).

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well, and our objective performance batteries confirm that. They're right . . . it's not just a psychological effect. They really aren't functioning as well."¹⁷⁰

Evidence on nicotine's effects on mood and cognition is strongly supported by the work of tobacco industry researchers, who concur that people use tobacco for the psychoactive effects of nicotine. These researchers contend that nicotine delivered by tobacco produces psychoactive effects comparable to the effects of prescription tranquilizers. For example, a researcher for the R.J. Reynolds Tobacco Company (RJR), W. S. Pritchard, reported that smoking cigarettes could produce "an EEG effect that in the benzodiazepine literature is associated with anxiety relief," leading him to conclude that "an important smoking motive for deep inhaling smokers might be anxiety reduction" and that his results were consistent with the theory that smoking provides beneficial psychological effects ("psychological tools" or "resources").¹⁷¹

In a significant extension of this work, Robinson *et al.* concluded that "the beneficial effects of smoking on cognitive performance are a function of nicotine absorbed from cigarette smoke upon inhalation."¹⁷² These RJR researchers performed their study because they thought that, although earlier work with various nicotine preparations was consistent with the hypothesis that people smoked for "psychopharmacological effects,"

¹⁷⁰ Henningfield J, Transcript to the FDA Drug Abuse Advisory Committee, Meeting 27, "Issues Concerning Nicotine-Containing Cigarettes and Other Tobacco Products" (Aug. 2, 1994), at 309. See AR (Vol. 255 Ref. 3445).

¹⁷¹ Pritchard WS, Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490, at 485, 488. See AR (Vol. 105 Ref. 965).

¹⁷² Robinson JH, Pritchard WS, Davis RA, Psychopharmacological effects of smoking a cigarette with typical "tar" and carbon monoxide yields but minimal nicotine, *Psychopharmacology* 1992;108:466-472. See AR (Vol. 59 Ref. 236).

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the role of nicotine in cigarettes was inconclusive. They therefore compared standard nicotine-delivering cigarettes to cigarettes that were similar in all other relevant characteristics (e.g., similar gases, tar, etc.) but that provided only “trace” or “minimal” levels of nicotine. The regular cigarettes provided psychopharmacological effects, while the minimal nicotine cigarettes did not.

One of the leading tobacco industry-funded proponents of the contention that nicotine is not addictive, D. M. Warburton, is also one of the leading proponents of the view that people smoke because of the pharmacological actions of nicotine in the brain, rather than in the mouth.¹⁷³ Warburton argues that nicotine is a “therapeutic agent” that is self-administered by smokers to “control their bodily state”¹⁷⁴ and that “the rapid absorption and rapid metabolism make this substance suitable for hour-by-hour self-medication because of the personal control [over dosage needs] that can be exercised. In this respect nicotine is superior to other compounds for medication.”¹⁷⁵ Thus, the conclusions of tobacco industry-funded researchers support FDA’s finding that a reasonable manufacturer would foresee that nicotine in tobacco products produces significant pharmacological effects important to users.

Other Effects: Weight Regulation. Nicotine also plays a role in weight regulation.

The 1988 Surgeon General’s Report summarized the available data:

In summary, there is substantial evidence of an inverse relationship between cigarette smoking and body weight. Of 71 studies reported since 1970, 62 (87%) collectively indicate that smokers

¹⁷³ Warburton DM, Nicotine: an addictive substance or a therapeutic agent, *Progress in Drug Research* 1989;33:9-41. See AR (Vol. 140 Ref. 1657).

¹⁷⁴ *Id.* at 11.

¹⁷⁵ *Id.* at 37.

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weigh less than nonsmokers and that people who quit smoking gain weight. . . .

Animal studies indicate that nicotine administration results in weight loss or decreased weight gains and that cessation of nicotine results in body weight gains greater than those of controls [animals that did not receive nicotine]. . . .

Recent research on nicotine polacrilex gum with humans corroborates the role of nicotine in body weight effects.¹⁷⁶

Numerous studies show that many tobacco consumers use tobacco to control their weight. For example, in two surveys, between one-third and one-half of young people reported that controlling weight was one of their reasons for smoking.¹⁷⁷

An extensive discussion of the physiological and central nervous system effects of nicotine is available in the 1988 Surgeon General's Report.¹⁷⁸

Thus, aside from addiction, there are other foreseeable pharmacological effects of nicotine use that are important to users; that these effects are actual reasons for consumption is discussed in section II.B.3., below.

5. Cigarettes and Smokeless Tobacco Deliver Pharmacologically Active Doses of Nicotine

Currently marketed cigarettes and smokeless tobacco deliver sufficient doses of nicotine to cause addiction and lead to other significant pharmacological effects that cause continued use of the products. This robust conclusion is supported by published research presented in section II.A., above, and thus is foreseeable to a reasonable tobacco manufacturer. For example, laboratory studies using commercial cigarettes demonstrate that the products contain pharmacologically active levels of nicotine; epidemiological data

¹⁷⁶ Surgeon General's Report, 1988, at 431-432. *See* AR (Vol. 129 Ref. 1592).

¹⁷⁷ *Id.* at 438-440.

¹⁷⁸ *Id.* at 381-458.

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show that actual tobacco consumers do become addicted. Four additional types of evidence conclusively demonstrate that tobacco products deliver sufficient doses of nicotine: (1) measurements of blood nicotine levels after consumption of tobacco products; (2) laboratory studies using doses of nicotine that are equivalent to those imparted by tobacco use; (3) studies demonstrating that nicotine levels control tobacco consumption behavior (known as “compensation”); and (4) studies of nicotine replacement therapy.

Measurement of Blood Nicotine Levels. Evidence demonstrates that tobacco users receive pharmacological doses of nicotine when they consume cigarettes and smokeless tobacco. A currently marketed cigarette typically delivers about 1 mg of nicotine to the bloodstream of a smoker,¹⁷⁹ with individual intake ranging from 0.3 to 3.2 mg of nicotine per cigarette.¹⁸⁰ Studies have also revealed that, with regular use throughout the day, the levels of nicotine in the blood of smokeless tobacco users are similar to those observed in cigarette smokers. Data demonstrating that these products deliver substantial, pharmacologically active doses of nicotine are summarized in the Jurisdictional Analysis. *See* 60 FR 41571–41575.

Laboratory Studies. Long before evidence emerged that nicotine is addictive, studies demonstrated that the quantitative and even qualitative nature of the effects of

¹⁷⁹ Benowitz NL, Henningfield JE, Establishing a nicotine threshold for addiction, *New England Journal of Medicine* 1994;331:123-125. *See* AR (Vol. 12 Ref. 130).

Gori GB, Lynch CJ, Analytical cigarette yields as predictors of smoke bioavailability, *Regulatory Toxicology and Pharmacology* 1985;5:314-326. *See* AR (Vol. 12 Ref. 142).

¹⁸⁰ Benowitz NL, Henningfield JE, Establishing a nicotine threshold for addiction, *New England Journal of Medicine* 1994;331:123-125. *See* AR (Vol. 12 Ref. 130).

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nicotine were dependent on the dose.¹⁸¹ In the 1980's, particularly important discoveries provided indisputable proof that the nicotine dose levels produced by cigarette smoking affect the structure and function of the body, and that many of these effects are similar to those of prototypic addictive drugs. For example, nicotine, administered in doses considered biologically equivalent to those from tobacco use, was found to affect the brain's use of energy (cerebral glucose utilization).¹⁸² Additionally, nicotine exposure at doses equivalent to those from tobacco use altered the brain so that excess nicotine receptors appeared on the surfaces of brain cells; this structural change was associated with altered responsiveness to nicotine.¹⁸³

In addition, nicotine administered to animals in doses and at intervals comparable to those humans obtain from smoking produces one of the hallmark effects of addictive drugs: brain-mediated reinforcement of self-administration behavior. In the early 1980's, Goldberg and colleagues at Harvard and the National Institute on Drug Abuse provided unequivocal evidence that nicotine in doses comparable to those obtained in humans could

¹⁸¹ See Surgeon General's Report, 1988, chaps. 2-6. See AR (Vol. 129 Ref. 1592).

¹⁸² *Id.* at 85-88.

¹⁸³ Marks MJ, Burch JB, Collins AC, Effects of chronic nicotine infusion on tolerance development and nicotine receptors, *Journal of Pharmacology and Experimental Therapeutics* 1983;226:817-825. See AR (Vol. 41 Ref. 103).

Surgeon General's Report, 1988, at 53-54. See AR (Vol. 129 Ref. 1592).

Id. at 32-33.

Benwell MEM, Balfour DJK, Anderson JM, Evidence that tobacco smoking increases the density of (-)-[³H]nicotine binding sites in human brain, *Journal of Neurochemistry* 1988;50:1243-1247. See AR (Vol. 136 Ref. 1570).

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function powerfully to engender repetitive drug-seeking behavior in monkeys.¹⁸⁴ In the late 1980's, Corrigall and Coen developed a rat model utilizing key dosing parameters of cigarette smoking and smokeless tobacco use. This model provided for the delivery of very rapid and small doses and led the animals to repeatedly administer nicotine to themselves.¹⁸⁵

Nicotine Control of Tobacco Use. Nicotine's key pharmacological role in actual tobacco products is also confirmed by evidence that tobacco users adjust their consumption based on the products' nicotine levels. Manipulation of nicotine levels in cigarettes while holding the tar content constant has shown that nicotine is responsible for the maintenance of cigarette smoking behavior. Cigarette smokers given cigarettes with a high nicotine content decrease the number of cigarettes smoked.¹⁸⁶ Modifying the amount of nicotine available by varying the length of cigarette smoked will influence the amount of the cigarette smoked¹⁸⁷ and the characteristics of smoking (e.g., number of puffs, puff duration, puff size, depth of inhalation, amount of tobacco smoked).¹⁸⁸ When cigarettes are shorter,

¹⁸⁴ Goldberg SR, Spealman RD, Goldberg DM, Persistent behavior at high rates maintained by intravenous self-administration of nicotine, *Science* 1981;214:573-575. See AR (Vol. 5 Ref. 35-2).

¹⁸⁵ Corrigall WA, Coen KM, Nicotine maintains robust self-administration in rats on a limited access schedule, *Psychopharmacology* 1989;99:473-478. See AR (Vol. 347 Ref. 5495).

¹⁸⁶ Goldfarb T, Gritz ER, Jarvik ME, *et al.*, Reactions to cigarettes as a function of nicotine and "tar," *Clinical Pharmacology and Therapeutics* 1976;19:767-772. See AR (Vol. 39 Ref. 53).

¹⁸⁷ Jarvik ME, Popek P, Schneider NG, *et al.*, Can cigarette size and nicotine content influence smoking and puffing rates? *Psychopharmacology* 1978;58:303-306. See AR (Vol. 41 Ref. 86).

¹⁸⁸ Surgeon General's Report, 1988, at 158-163. See AR (Vol. 129 Ref. 1592).

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people smoke more of them.¹⁸⁹ Nemeth-Coslett and Griffiths showed that puff duration and puff volume are inversely proportional to the length of the cigarette.¹⁹⁰

Studies conducted by Stolerman,¹⁹¹ Nemeth-Coslett *et al.*,¹⁹² and Pomerleau *et al.*¹⁹³ provide convincing evidence that tobacco products provide pharmacologically active doses of nicotine. Pretreatment of cigarette smokers with mecamylamine, an antagonist to nicotine that enters the brain, produced a dose-dependent increase in cigarette smoking (i.e., increases in puffs per cigarette, puff duration, and cigarettes per session and decreases in inter-cigarette interval and interpuff interval) that resembled what one would expect to see if the nicotine dose in the cigarette had been decreased. An increase in nicotine plasma levels also accompanied the increase in cigarette consumption. Pretreatment with another nicotine antagonist that did not enter the brain had no such effects. These studies clearly demonstrate that obtaining a pharmacologically active dose of nicotine in the brain motivates the amount of tobacco consumed on a daily basis.

Evidence from Nicotine Replacement Products. As described in the Jurisdictional Analysis, 60 FR 41565–41566, the ability of nicotine nasal spray to produce some of the classic characteristics of addiction to nicotine supports the position that tobacco users

¹⁸⁹ Jarvik ME, Popek P, Schneider NG, *et al.*, Can cigarette size and nicotine content influence smoking and puffing rates? *Psychopharmacology* 1978;58:303-306. See AR (Vol. 41 Ref. 86).

¹⁹⁰ Surgeon General's Report, 1988, at 161. See AR (Vol. 129 Ref. 1592).

¹⁹¹ Stolerman IP, Goldfarb T, Fink R, *et al.*, Influencing cigarette smoking with nicotine antagonists, *Psychopharmacologia* 1973;28:247-259. See AR (Vol. 42 Ref. 149).

¹⁹² Nemeth-Coslett R, Henningfield JE, O'Keffe MK, *et al.*, Effects of mecamylamine on human cigarette smoking and subjective ratings, *Psychopharmacology* 1986;88:420-425. See AR (Vol. 41 Ref. 108).

¹⁹³ Pomerleau CS, Pomerleau OF, Majchrzak MJ, Mecamylamine pretreatment increases subsequent nicotine self-administration as indicated by changes in plasma nicotine level, *Psychopharmacology* 1987;91:391-393. See AR (Vol. 42 Ref. 112).

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seek nicotine primarily for its systemic pharmacological effects and not for its acute sensory effects. In contrast to cigarette smoke, aqueous nicotine spray does not provide the user any pleasing sensory characteristics. In fact, the spray can be irritating and unpleasant to use, and excessive use can cause ulcerations of the nasal mucosa. Notwithstanding the unpleasantness of the nicotine delivery mechanism and the presence of painful ulcerations that were further aggravated by its continued use, the spray was used to maintain nicotine dependence for some participants in clinical trials submitted to FDA.¹⁹⁴

Studies of nicotine replacement therapies also demonstrate efficacy in maintaining abstinence from smoking.¹⁹⁵ The ability of nicotine to promote abstinence, even when delivered through the skin, without any taste or flavor, demonstrates its key role as a reinforcer of tobacco consumption. Based on these data, among others, organizations with expertise in pharmacology and addiction have determined that cigarettes and smokeless tobacco deliver pharmacologically active doses of nicotine. In the 1986 analysis of smokeless tobacco, the Surgeon General determined that smokeless tobacco use can be addictive.¹⁹⁶ In 1988, after an even more extensive consideration of the potential addictiveness of nicotine, the Surgeon General determined that: (1) “cigarettes and other forms of tobacco are addicting;” (2) “nicotine is the drug in tobacco that causes

¹⁹⁴ FDA Drug Abuse Advisory Committee Background Information (Aug. 1, 1994), Joint Abuse Liability Review of Nicotine Nasal Spray. See AR (Vol. 9 Ref. 117).

¹⁹⁵ See appendix 1 to Jurisdictional Analysis. See AR (Vol. 1 Appendix 1).

¹⁹⁶ Department of Health and Human Services, Public Health Service, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General, 1986*, NIH Publication No. 86-2874 (Bethesda MD: DHHS, PHS, 1986) (hereinafter cited as Surgeon General's Report, *Smokeless Tobacco*, 1986), at viii. See AR (Vol. 128 Ref. 1591).

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addiction;” and (3) “the pharmacological and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.”¹⁹⁷ On August 2, 1994, FDA’s Drug Abuse Advisory Committee, an independent group composed primarily of experts on addiction science, concluded that nicotine as delivered by commonly used tobacco products can produce strong physiological effects, including addiction.¹⁹⁸

6. Conclusion

Nicotine is addictive and produces foreseeable psychoactive and pharmacological effects in a substantial proportion of tobacco users. This conclusion is so robust—and the evidence for it is so voluminous—that every major public health organization and relevant scientific authority in the world is in agreement. It is FDA’s responsibility to base its regulatory actions on well-founded and accepted scientific facts. In this case, FDA believes that a very strong scientific basis exists on which to conclude that it is foreseeable that nicotine will produce pharmacological effects in a substantial number of tobacco consumers and that those consumers will use tobacco products to satisfy their addiction and to obtain the other pharmacological effects of nicotine. To conclude otherwise would not be credible.

¹⁹⁷ Surgeon General’s Report, 1988, at 13-17. *See* AR (Vol. 129 Ref. 1592).

¹⁹⁸ Transcript to the FDA Drug Abuse Advisory Committee, Meeting 27, “Issues Concerning Nicotine-Containing Cigarettes and Other Tobacco Products” (Aug. 2, 1994), at 336-342. *See* AR (Vol. 255 Ref. 3445).

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7. Response to Additional Comments**a. Comments on the Professional Consensus That Nicotine Is Addictive**

1. More than 150 professional health organizations or chapters, representing over 600,000 individuals and organizations, commented on whether nicotine is addictive.

Virtually all concluded that it is. These groups include the following:

- The American Cancer Society
- The American College of Physicians
- The American Heart Association
- The American Lung Association
- The American Medical Association
- The American Psychiatric Association
- The American Psychological Association
- The American Society of Addiction Medicine
- The College on Problems of Drug Dependence
- The Society of General Internal Medicine
- The Society for Head and Neck Surgeons
- The Society for Research on Nicotine and Tobacco
- The Virginia Society of Hospital Pharmacists

FDA also notes that, of the more than 1,100 physicians, pharmacists, and other health professionals who commented on whether nicotine is addictive, virtually all agreed that it is.

The Agency concurs with the unanimous conclusion of these organizations, most of which have expertise in this area. FDA notes that organizations with vast experience

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examining other addictive drugs reached the same conclusion as organizations with vast experience studying nicotine. The former organizations include the American Psychiatric Association, the American Society of Addiction Medicine, the National Institute on Drug Abuse, and the World Health Organization. The latter include the American College of Chest Physicians and the Surgeon General's expert committees on tobacco.

2. The tobacco industry disputes the process by which the American Psychiatric Association concluded that nicotine is addictive. The industry quotes several critical comments about the *Diagnostic and Statistical Manual* to suggest that the entire DSM structure of classifying all psychiatric diagnoses is flawed. This position, held by a small minority of psychiatrists, has been decisively rejected by the profession as a whole. The DSM-IV is now used throughout the world to classify psychiatric disorders, including drug dependence.

FDA notes that, aside from this argument against the American Psychiatric Association, the industry does not dispute the expertise or decision-making capabilities of any of the other medical authorities originally cited by FDA. These authorities—which unanimously have concluded that nicotine is addictive—include the U.S. Surgeon General, the World Health Organization, the American Medical Association, the American Psychological Association, the Royal Society of Canada, and the Medical Research Council of the United Kingdom.

b. Comments on the Definition of Addiction

1. Several tobacco industry comments argue that cigarettes and smokeless tobacco are not addictive under a now-discarded definition of addiction developed in the 1950's and used by the U.S. Surgeon General in 1964.

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FDA disagrees with these comments. First, the tobacco industry borrows only selectively from the 1950's definition of addiction, emphasizing only certain criteria from that definition. Second, while the scientific community has rejected this historical definition in part because it failed to clearly classify cocaine and amphetamines as addictive, *see* section II.A.3.b., above, subsequent evidence has shown that nicotine would now qualify as addictive *even by this outdated definition*. The criteria cited by the Surgeon General,¹⁹⁹ which were not met by nicotine on the basis of data available in the early 1960's, are all met on the basis of data available today. These include the following:

- Surgeon General's 1964 conclusion: No overpowering compulsion to use the drug.
Subsequent data: Ample documentation exists today that persons dependent upon cocaine, heroin, or alcohol find it as difficult to abstain from tobacco as from these other drugs and that persons who know that their lives are in imminent danger from smoking nevertheless continue to smoke.²⁰⁰
- Surgeon General's 1964 conclusion: No tendency to increase the dose.

¹⁹⁹ Department of Health, Education, and Welfare, Public Health Service, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (Washington DC: GPO, 1964), at 349-352. *See* AR (Vol. 43 Ref. 156).

²⁰⁰ Henningfield JE, Cohen C, Slade JD, Is nicotine more addictive than cocaine? *British Journal of Addiction* 1991;86:565-569. *See* AR (Vol. 277 Ref. 3904).

Kozlowski LT, Wilkinson DA, Skinner W, *et al.*, Comparing tobacco cigarette dependence with other drug dependencies, *Journal of the American Medical Association* 1989;261:898-901. *See* AR (Vol. 84 Ref. 350).

West R, Himbury S, Smoking habits after laryngectomy, *British Medical Journal* 1985;291:514-515. *See* AR (Vol. 6 Ref. 59).

Davison G, Duffy M, Smoking habits of long term survivors of surgery for lung cancer, *Thorax* 1982;37:331-333. *See* AR (Vol. 6 Ref. 58).

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Subsequent data: We now know that only about 10% of cigarette smokers are able to sustain a level of intake of five or fewer cigarettes per day. For example, one study found that 90% of people who smoke escalate to daily doses of five or more cigarettes.²⁰¹ Cigarettes are similar to morphine-like drugs in that, when either substance is readily available to the user, intake often escalates over a period of months or years and then stabilizes at a level that may vary little from day to day for many years.²⁰²

- Surgeon General's 1964 conclusion: No physical dependence on the effects of the drug.

Subsequent data: The documentation that nicotine produces physical dependence has now been provided by scores of clinical treatment studies and laboratory studies with humans and animals.²⁰³ There is a characteristic

²⁰¹ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

Henningfield JE, Cohen C, Slade JD, Is nicotine more addictive than cocaine? *British Journal of Addiction* 1991;86:565-569. See AR (Vol. 277 Ref. 3904).

²⁰² Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573). See AR (Vol. 535 Ref. 96, vol. III.G).

²⁰³ Henningfield JE, Cohen C, Slade JD, Is nicotine more addictive than cocaine? *British Journal of Addiction* 1991;86:565-569. See AR (Vol. 277 Ref. 3904).

Kozlowski LT, Wilkinson DA, Skinner W, *et al.*, Comparing tobacco cigarette dependence with other drug dependencies, *Journal of the American Medical Association* 1989;261:898-901. See AR (Vol. 84 Ref. 350).

Surgeon General's Report, 1988, at 145-240. See AR (Vol. 129 Ref. 1592).

Corrigall WA, Herling S, Coen KM, Evidence for a behavioral deficit during withdrawal from nicotine treatment, *Pharmacology Biochemistry and Behavior* 1989; 33:559-562. See AR (Vol. 139 Ref. 1626).

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tobacco withdrawal syndrome that has been recognized by leading medical organizations.²⁰⁴

- Surgeon General's 1964 conclusion: Detrimental effects on society are not well documented.

Subsequent data: The detrimental effects on smokers themselves were recognized in 1964; however, it was not until the 1980's that the direct adverse effects of smoking upon nonsmokers and the fetuses of pregnant smokers were unequivocally documented.²⁰⁵ Moreover, it is now recognized that nicotine has a severe adverse economic impact on many aspects of society.²⁰⁶

In addition to these four specific criteria, the Surgeon General in 1964 mentioned several other reasons for failing to categorize nicotine as addicting. These conclusions and the current data are as follows:

- Surgeon General's 1964 conclusion: Cigarette smokers did not become intoxicated.

Levin ED, Morgan MM, Galvez C, *et al.*, Chronic nicotine and withdrawal effects on body weight and food and water consumption in female rats, *Physiology and Behavior* 1987; 39:441-444. *See* AR (Vol. 278 Ref. 3932)

²⁰⁴ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 244-245. *See* AR (Vol. 37 Ref. 8).

²⁰⁵ Department of Health and Human Services, Office on Smoking and Health, *The Health Consequences of Involuntary Smoking: A Report of the Surgeon General* (Atlanta: DHHS, 1986) (hereinafter cited as Surgeon General's Report, *Involuntary Smoking*, 1986). *See* AR (Vol. 128 Ref. 1591).

²⁰⁶ McGinnis JM, Foege WH, Actual causes of death in the United States, *Journal of the American Medical Association* 1993;270(18):2207-2212. *See* AR (Vol. 2 Ref. 15-1).

Hearing on Preventive Health: An Ounce of Prevention Saves a Pound of Cure, Before the Special Committee on Aging, U.S. Senate, 103d Cong., 1st Sess. 2 (May 6, 1993) (statement of Roger Herdman, Maria Hewitt, Mary Laschober on smoking-related deaths and financial costs: Office of Technology Assessment Estimates for 1990). *See* AR (Vol. 170 Ref. 2024).

Hodgson TA, Cigarette smoking and lifetime medical expenditures, National Center for Health Statistics, *Milbank Quarterly* 1992;70(1):81-125. *See* AR (Vol. 19 Ref. 22).

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Subsequent data: It is now well understood that nicotine can intoxicate, intoxication is a sign of nicotine overdose, and first-time users often become intoxicated.²⁰⁷ The ability of nicotine to produce strong physiological and behavioral effects, including death at high doses, is no less than that of amphetamine or morphine.²⁰⁸ In practice, intoxication is rarely evident in regular users because they have developed an extremely high level of tolerance to this effect of nicotine.²⁰⁹

- Surgeon General's 1964 conclusion: Subjective effects of nicotine itself were not well documented. The 1942 study by Johnston showing that intravenous nicotine could mimic the effects of smoking²¹⁰ was apparently given little weight because the study did not have the appropriate control conditions to rule out bias.

Subsequent data: By the 1980's and 1990's, many properly controlled studies using nicotine delivered intravenously, intranasally, and by inhalation essentially confirmed Johnston's findings.²¹¹

²⁰⁷ Surgeon General's Report, 1988, at 593-594. See AR (Vol. 129 Ref. 1592).

²⁰⁸ *Id.* at 272-274, 594.

²⁰⁹ *Id.* at 593-595.

²¹⁰ Johnston LM, Tobacco smoking and nicotine, *Lancet* 1942;2:742. See AR (Vol. 278 Ref. 3947).

²¹¹ See, e.g., Jones RT, Farrell TR III, Herning RI, Tobacco smoking and nicotine tolerance, in *Self-Administration of Abused Substances: Methods for Study*, ed. Krasnegor NA, NIDA Research Monograph 20 (Rockville MD: National Institute on Drug Abuse, 1978), at 202-208. See AR (Vol. 41 Ref. 88).

Henningfield JE, Miyasato K, Jansinski DR, Abuse liability and pharmacodynamic characteristics of intravenous and inhaled nicotine, *Journal of Pharmacology and Experimental Therapeutics* 1985;234:1-12. See AR (Vol. 39 Ref. 69).

Pomerleau CS, Pomerleau OF, Euphoriant effect of nicotine in smokers, *Psychopharmacology* 1992;108:460-465. See AR (Vol. 87 Ref. 426).

Perkins KA, Grobe JE, Epstein LH, *et al.*, Chronic and acute tolerance to subjective effects of nicotine, *Pharmacology, Biochemistry and Behavior* 1993;45:375-381. See AR (Vol. 271 Ref. 3728).

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- Surgeon General's 1964 conclusion: No well-controlled demonstration that nicotine substitution could facilitate tobacco abstinence.

Subsequent data: The absence of a nicotine-delivering medication effective in helping people to achieve abstinence was also noted in the 1964 report. There is now powerful evidence that products devoid of any tobacco constituent except nicotine are effective aids to smoking cessation and to providing relief of withdrawal symptoms.²¹²

- Surgeon General's 1964 conclusion: Personality deficit criteria did not appear satisfied.

Subsequent data: It was noted that not categorizing tobacco use as an addiction avoided the inference that smokers would be considered to have "serious personality defects" under the definition of addiction then in place. We now understand that many people who develop addictions to cocaine, heroin, alcohol, or nicotine have no documented underlying personality disorder. Rather, the major cause of addiction is

Perkins KA, Grobe JE, Epstein LH, *et al.*, Effects of nicotine on subjective arousal may be dependent on baseline subjective state, *Journal of Substance Abuse* 1992;4:131-141. See AR (Vol. 348 Ref. 5516).

Sutherland G, Stapleton JA, Russell MAH, *et al.*, Randomised controlled trial of nasal nicotine spray in smoking cessation, *Lancet* 1992;340:324-329. See AR (Vol. 91 Ref. 527).

Sutherland G, Russell MA, Stapleton J, *et al.*, Nasal nicotine spray: a rapid nicotine delivery system, *Psychopharmacology* 1992;108:512-518. See AR (Vol. 91 Ref. 526).

²¹² Fagerstrom KO, Sawe U, Tonnesen P, Therapeutic use of nicotine patches: efficacy and safety, *Journal of Drug Development* 1993;5:191-205. See AR (Vol. 76 Ref. 156).

Fiore MC, Smith SS, Jorenby DE, *et al.*, The effectiveness of the nicotine patch for smoking cessation: a meta-analysis, *Journal of the American Medical Association* 1994;271:1940-1947. See AR (Vol. 6 Ref. 64-1).

Fiore MC, Jorenby DE, Baker TB, *et al.*, Tobacco dependence and the nicotine patch, *Journal of the American Medical Association* 1992;268:2687-2694. See AR (Vol. 351 Ref. 5609).

Surgeon General's Report, 1988, at 208. See AR (Vol. 129 Ref. 1592).

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the presence of a psychoactive, reinforcing drug and adequate access to the drug to enable the development and sustenance of addiction.

Thus, it is virtually certain that tobacco use would be considered an addiction under the definition used by the Surgeon General in 1964. Indeed, FDA notes that a study sponsored by the tobacco industry in 1963 concluded that tobacco was addictive under the same definition used by the Surgeon General in 1964.²¹³

2. The tobacco industry observes that definitions of addiction from several medical authorities are not identical, quotes several experts stating that whether tobacco is addictive depends on the definition of addiction, and presents excerpts from several scientific publications to suggest that no precise definition of addiction exists. The industry also argues that the use of the word “addiction” rather than “dependence” is political and claims that the modern definition of addiction is motivated by public health goals, morality, and lawsuits. The industry concludes that the modern definition of addiction is inappropriate for use in considering whether a product is a drug under the Act.

FDA disagrees. As discussed in section II.A.3.b., above, there is remarkable consensus among medical authorities around the world on the meaning of addiction. The subtle variations among written definitions reflect wording and emphasis, not significant differences in concepts; such variations are not surprising, given that medical organizations often write their own definitions of diseases and disease progression. International consistency on the meaning of addiction is demonstrated by the fact that all relevant

²¹³ Knapp PH, Bliss CM, Wells H, Addictive aspects in heavy cigarette smoking, *American Journal of Psychiatry* 1963;119:966. See AR (Vol. 528 Ref. 97, appendix 16).

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scientific bodies have concluded that nicotine is addictive. Indeed, the tobacco industry fails to suggest any reason to believe that the current international understanding of nicotine as addictive will change in the future.

The industry's quoting of addiction experts on the importance of defining addiction is not an argument against FDA's position. It is axiomatic that whether nicotine is addictive depends on the definition of addiction. The industry fails, however, to show that nicotine would not be considered addictive under any of the current definitions of addiction.

The industry's use of an article from the *Journal of the American Medical Association* to show that the definition of addiction is imprecise is equally unpersuasive.²¹⁴ The article describes how a national panel was appointed in 1983 to try to settle variations in definitions relating to substance abuse. The panel surveyed dozens of experts from major scientific organizations and produced a consensus definition of addiction: "A chronic disorder characterized by the compulsive use of a substance resulting in physical, psychological, or social harm to the user and continued use despite that harm."²¹⁵ This definition again is entirely consistent with the modern definition of addiction relied on by FDA, not the tobacco industry's preferred version from the 1950's.

The industry selectively quotes from several scientific publications that discuss subtle arguments over the precise definition of addiction. But these debates occur within a

²¹⁴ Rinaldi RC, Steindler EM, Wilford BB, *et al.*, Clarification and standardization of substance abuse terminology, *Journal of the American Medical Association* 1988;259(4):555-557. See AR (Vol. 535 Ref. 96 vol. III.L).

²¹⁵ *Id.*

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broad understanding of addiction that has garnered overwhelming consensus. This understanding universally considers nicotine to be addictive.

FDA, like many scientific and public health authorities, uses “addiction” and “dependence” interchangeably. Regardless of the terminology used, the concept that nicotine has substantial pharmacological effects on the brains of users that cause people to use tobacco compulsively is the same. Furthermore, any implication that the modern scientific understanding of addiction is motivated by public health goals, morals, or lawsuits is mistaken. As discussed in section II.A.3.b., above, the tobacco industry’s preferred definition was discarded on scientific grounds in 1964, 15 years before nicotine was first considered addictive.

Thus, there is no basis upon which to conclude that FDA’s finding that nicotine is addictive—a conclusion with nearly universal scientific backing—is not useful in determining whether nicotine is a “drug” under the Act. The fact that nicotine meets all currently accepted scientific definitions of a dependence-producing drug and that these definitions include as a criterion psychoactive effects on the brain is highly relevant to the Agency’s inquiry.

c. General Comments on Laboratory Evidence of Addictive Potential

1. Comments from numerous health professionals and scientists agree with FDA that laboratory data in animals and humans provide compelling evidence that nicotine in cigarettes and smokeless tobacco is a pharmacologically active agent that causes addiction. For example, the American Medical Association stated that it “concurs with the scientific rationale and legal basis for the FDA proposed action,” and that it “strongly supports the scientific basis regarding nicotine . . . and its essential role in maintaining demand for tobacco

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products.” Similarly, the Coalition on Smoking OR Health—an organization representing the American Heart Association, American Lung Association, and American Cancer Society—carefully reviewed the Jurisdictional Analysis “for accuracy, objectivity, and completeness” and concluded that “the FDA documents represent the most comprehensive, objective and scientifically accurate analysis of the impact of nicotine containing cigarettes and smokeless tobacco on the body ever conducted.”

2. The tobacco industry repeatedly comments that evidence from one laboratory test *by itself* is not enough to justify the conclusion that nicotine is addictive. For example, the industry argues that positive results in drug discrimination tests in animals are not sufficient to prove that nicotine is addictive, as some nonaddictive substances also test positive. The industry repeats this same argument for subjective effects testing and animal self-administration studies. On several occasions, the industry uses quotations from addiction experts to support these arguments.

FDA agrees that evidence from each test *alone* may not prove conclusively that nicotine is addictive. But addiction authorities around the world determine whether a substance is addicting by considering results from all of the tests *together*. Nicotine tests positive in animal and human drug discrimination tests, subjective effects tests, and animal and human self-administration tests. Considering such evidence, the scientific community has overwhelmingly concluded that nicotine is addictive.

The tobacco industry’s selective use of quotations from addiction experts illustrates the point. On several occasions, the industry tries to make it appear that the individuals quoted believe that addiction testing methods are not reliable or that nicotine is not addictive. In fact, these individuals are on record as reaching the opposite conclusions. For example, the

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tobacco industry selectively quotes from the work of Balster that “[t]he results of self-administration studies should not be used alone for evaluating abuse potential. A number of drugs which probably possess minimal or no abuse potential have been shown to function as reinforcers in preclinical drug self-administration studies.”²¹⁶ The industry also culls a quote from Woods that “[i]t should be clear that the proposition, viz., that the drugs that serve as reinforcers in animals are abused by humans, is greatly oversimplified.”²¹⁷ In both cases, however, the authors believe that demonstrating that a drug tests positive in both self-administration studies *and* drug discrimination studies is sufficient evidence of its abuse liability.²¹⁸ Nicotine has repeatedly proved positive in both tests.

d. Comments on Tests of Psychoactivity

1. The tobacco industry disputes FDA’s analysis of drug discrimination tests in animals. The industry argues that the purpose of drug discrimination studies is merely to demonstrate that the test subject “recognizes” or “identifies” a substance that has been administered. The industry further claims that laboratory animals have been able to

²¹⁶ Balster RL, Drug abuse potential evaluation in animals, *British Journal of Addiction* 1991;86:1549-1558, at 1555. See AR (Vol. 8 Ref. 89).

²¹⁷ Woods J, Some thoughts on the relations between animal and human drug-taking, *Progress in Neuropsychopharmacology and Biological Psychiatry* 1983;7:577-584, at 582. See AR (Vol. 535 Ref. 96, vol. III.N).

²¹⁸ Balster RL, Drug abuse potential evaluation in animals, *British Journal of Addiction* 1991;86:1549-1558, at 1555. See AR (Vol. 8 Ref. 89).

Woods J, Some thoughts on the relations between animal and human drug-taking, *Progress in Neuropsychopharmacology and Biological Psychiatry* 1983;7:577-584, at 582. See AR (Vol. 535 Ref. 96, vol. III.N).

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discriminate nicotine in the studies cited by FDA because researchers used amounts of nicotine that vastly exceed the nicotine yields in commercial cigarettes.

FDA disagrees. Drug discrimination studies are not just a measure of whether or not the subject can “recognize” or “identify” a substance; these studies assess the psychoactivity of a drug. Drugs that can be successfully discriminated from placebo are psychoactive.²¹⁹

FDA also disagrees that animals can discriminate nicotine’s stimulus properties only when receiving doses that vastly exceed those absorbed by human smokers. It is misleading to make a direct comparison between the training dose administered to animals and the nicotine yields of commercial cigarettes. Pharmacological effects elicited by a drug are the result of its plasma concentration and the amount of drug at the receptor site (i.e., site of action), not necessarily of how much drug is in the product or the amount of drug administered per kilogram of body weight. This distinction becomes critical when comparing animals with different abilities to metabolize drugs. The same amount of drug per kilogram administered to two species may lead to radically different plasma concentrations, for example, if one species breaks down and excretes the drug faster than the other.

A study by Pratt *et al.*²²⁰ cited by the comment actually demonstrates that doses of nicotine that can be discriminated by rats yield a plasma concentration of nicotine that is comparable to the plasma concentration of nicotine in human smokers. Accordingly, rats *can* learn to discriminate a dose of nicotine physiologically comparable to the dose received by

²¹⁹ Surgeon General's Report, 1988, at 170-171. See AR (Vol. 129 Ref. 1592).

²²⁰ Pratt JA, Stolerman IP, Garcha HS, *et al.*, Discriminative stimulus properties of nicotine: further evidence for mediation at a cholinergic receptor, *Psychopharmacology* 1983;81:54-60. See AR (Vol. 8 Ref. 90-2).

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cigarette smokers and smokeless tobacco users. Two studies by Stolerman *et al.*²²¹ also demonstrated that rats can discriminate from saline a dose of nicotine that is comparable to the dose delivered to human tobacco users.

2. The tobacco industry argues that nicotine's action as a discriminative stimulus is not exactly the same as that of cocaine and amphetamine.

It is well known that nicotine does not behave identically to cocaine and amphetamine in drug discrimination experiments. This difference does not mean that nicotine is not an addictive drug, however. Amphetamine, morphine, alcohol, and nicotine can all be differentiated from one another by animals and humans because of their unique effects. The fact that nicotine is not identical to cocaine is no more relevant than the fact that cocaine is not identical to morphine. What is critical is that all of these drugs are psychoactive because of their effects on the brain. The published data have shown that there are qualitative differences in these drugs' discriminative stimulus effects and that nicotine produces effects more amphetamine-like than morphine-like in animals and humans.²²² Thus, while nicotine's discriminative stimulus effects are unique, they resemble the effects of stimulants more closely than those of sedatives. These data confirm that nicotine produces critical discriminative and subjective effects shared by dependence-producing drugs.

²²¹ Stolerman IP, Garcha HS, Pratt JA, *et al.*, Role of training dose in discrimination of nicotine and related compounds by rats, *Psychopharmacology* 1984;84:413-419. See AR (Vol. 8 Ref. 90-5).

Stolerman IP, Discriminative stimulus effects of nicotine in rats trained under different schedules of reinforcement, *Psychopharmacology* 1989;97:131-138. See AR (Vol. 9 Ref. 90-6).

²²² Pratt JA, Stolerman IP, Garcha HS, *et al.*, Discriminative stimulus properties of nicotine: further evidence for mediation at a cholinergic receptor, *Psychopharmacology* 1983;81:54-60. See AR (Vol. 8 Ref. 90-2).

Stolerman IP, Garcha HS, Pratt JA, *et al.*, Role of training dose in discrimination of nicotine and related compounds by rats, *Psychopharmacology* 1984;84:413-419. See AR (Vol. 8 Ref. 90-5).

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3. The tobacco industry contests FDA's interpretation of three studies on drug discrimination in humans cited in the Jurisdictional Analysis. The industry concludes that there is no evidence to suggest that nicotine functions as a discriminative stimulus in humans.

Upon review of these studies and the administrative record, FDA concludes that there is convincing evidence that nicotine tests positive in human drug discrimination studies. The industry disputes the conclusion that a study by Kallman *et al.* proved that discrimination occurred in the central nervous system.²²³ FDA, however, never drew this conclusion. FDA cited this study to demonstrate that smokers can differentiate between high- and low-nicotine cigarettes, a finding conceded by the industry. Much other evidence in the administrative record, described in section II.A.3.c.i. of this document and in the 1988 Surgeon General's report,²²⁴ demonstrates that the discrimination occurs in the central nervous system.

The industry also claims that a study by Perkins *et al.* did not demonstrate discrimination.²²⁵ Noting that male subjects identified 2 ug/kg of nicotine (administered by nasal spray) versus placebo correctly 50% of the time, the industry claims that this is exactly the percentage that would do so by chance. The industry concludes that the drug discrimination demonstrated by this study was due purely to chance and was not due to any effects of nicotine in the brain.

²²³ Kallman WM, Kallman MJ, Harry GJ, *et al.*, Nicotine as a discriminative stimulus in human subjects, in *Drug Discrimination: Applications in CNS Pharmacology*, eds. Colpaert FC, Slangen JL (Amsterdam: Elsevier Biomedical Press, 1982), at 211-218. See AR (Vol. 41 Ref. 89).

²²⁴ Surgeon General's Report, 1988, at 176-178. See AR (Vol. 129 Ref. 1592).

²²⁵ Perkins K, Grobe J, Scierka A, *et al.*, Discriminative stimulus effects of nicotine in smokers, in *International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II*, eds. Clarke PBS, Quik M, Thurau K, *et al.* (Basel: Birkhauser Verlag, 1994), at 111. See AR (Vol. 42 Ref. 111).

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Upon review of the Perkins study, FDA notes that the industry has seriously misinterpreted its results. The study's objective was to determine whether subjects could differentiate the low dose of 12 ug/kg of nicotine versus placebo, and its finding was that 100% of all subjects correctly identified nicotine at this dose at least 80% of the time. The authors concluded, "These findings indicate that humans are able to discriminate among low doses of nicotine."²²⁶ (The dose of 12 ug/kg of nicotine is less than the typical dose of nicotine received from a cigarette.²²⁷) Having demonstrated this finding, the authors went on to test even smaller doses to determine the lowest dose of effective discrimination, that is, the dose at which subjects discriminated nicotine at least 50% of the time. That such a dose exists does not disprove nicotine's role as a discriminative stimulus, as implied by the tobacco industry; a minimal dose that cannot be differentiated from placebo exists for *all* psychoactive drugs.

Finally, the industry contends that a study by Goldfarb *et al.*²²⁸ is not a formal "discrimination" study. The Goldfarb study was cited not as a discrimination study but to demonstrate that humans can differentiate between cigarettes with different nicotine yields, a conclusion conceded by the industry.

4. The tobacco industry argues that studies of the "subjective effects" of nicotine have vague methods and use subjects who are not representative of all smokers. These

²²⁶ *Id.* at 111.

²²⁷ Perkins KA, Grobe JE, Epstein LH, *et al.*, Chronic and acute tolerance to subjective effects of nicotine, *Pharmacology, Biochemistry and Behavior* 1993;45:375-381. See AR (Vol. 271 Ref. 3728).

²²⁸ Goldfarb TL, Gritz ER, Jarvik ME, *et al.*, Reactions to cigarettes as a function of nicotine and "tar," *Clinical Pharmacology and Therapeutics* 1976;19:767-772. See AR (Vol. 39 Ref. 53).

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comments criticize a study by Henningfield *et al.*²²⁹ which was cited by the Agency. The industry further argues that the “subjective effects” of cigarettes could be secondary to tar and cites a study to suggest that nicotine-free cigarettes cause “liking.”²³⁰ The industry thus disputes FDA’s conclusion that nicotine produces subjective effects that are similar to those of other addictive drugs.

FDA disagrees. A wide range of evidence, discussed in section II.A.3.c.i., above, demonstrates that nicotine, whether administered alone or in a cigarette, behaves like other addictive drugs in “subjective effects” testing. Upon review of this evidence, FDA notes that the industry criticized only one of its cited studies.

FDA further concludes that the Henningfield study is accurate and consistent with the findings of other researchers. The study design used by Henningfield *et al.* is a standardized procedure for qualifying the abuse liability of drugs in humans; it is used nationally and internationally by addiction researchers.²³¹ The use of subjects with histories of drug abuse is also standard practice in such studies; indeed, as described in section II.A.3.c.i., above, these subjects are employed because they can use their history to distinguish the psychoactive effects of different drugs. Thus, for this type of abuse liability testing, it is critical that the population be composed of smokers with experience with other addictive drugs to enable them to compare the effects of nicotine to those of other drugs.

²²⁹ Henningfield JE, Miyasato K, Jasinski DR, Abuse liability and pharmacodynamic characteristics of intravenous and inhaled nicotine, *Journal of Pharmacology and Experimental Therapeutics* 1985;234:1-12. See AR (Vol. 39 Ref. 69).

²³⁰ See section II.A.3.c.i., above, for a description of the term “liking.”

²³¹ Jasinski DR, Henningfield JE, Human abuse liability assessment by measurement of subjective and physiological effects, in *Testing for Abuse Liability of Drugs in Humans*, eds. Fischman MW, Mello NK, NIDA Research Monograph 92 (Rockville MD: National Institute on Drug Abuse, 1989). See AR (Vol. 76 Ref. 172).

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The results from the study by Henningfield *et al.* demonstrate that nicotine, delivered by intravenous injection or by inhalation of tobacco smoke, produces similar subjective effects. These effects include dose-related elevation in the Morphine-Benzedrine Group Scale and the “liking” scale. There is no possibility that the subjects were responding to the “flavor” of nicotine or tar when they were able to discriminate nicotine injected intravenously. Nicotine produced results similar to those of other dependence-producing drugs (e.g., morphine, cocaine, and amphetamine) on the scales used in this study.

Furthermore, researchers who preceded and followed Henningfield obtained consistent findings. Researchers other than Henningfield *et al.*, using methods other than the MBG and the “liking” scale, also confirmed that nicotine produces positive subjective effects after intranasal and intravenous administration.²³² Subjects in these studies used the following adjectives to describe the positive subjective effects of nicotine: “head rush,” “feeling good,” or “high.” This evidence strongly demonstrates that nicotine—and not tar—is responsible for the “subjective effects” of cigarettes.

²³² Sutherland G, Stapleton JA, Russell MAH, *et al.*, Randomised controlled trial of nasal nicotine spray in smoking cessation, *Lancet* 1992;340:324-329. See AR (Vol. 91 Ref. 527).

Sutherland G, Russell MA, Stapleton J, *et al.*, Nasal nicotine spray: a rapid nicotine delivery system, *Psychopharmacology* 1992;108:512-518. See AR (Vol. 91 Ref. 526).

Perkins KA, Grobe JE, Epstein LH, *et al.*, Chronic and acute tolerance to subjective effects of nicotine, *Pharmacology, Biochemistry and Behavior* 1993;45:375-381. See AR (Vol. 271 Ref. 3728).

Perkins KA, Grobe JE, Epstein LH, *et al.*, Effects of nicotine on subjective arousal may be dependent on baseline subjective state, *Journal of Substance Abuse* 1992;4:131-141. See AR (Vol. 348 Ref. 5516).

Johnston LM, Tobacco smoking and nicotine, *Lancet* 1942;2:742. See AR (Vol. 278 Ref. 3947).

Jones RT, Farrell TR III, Herning RI, Tobacco smoking and nicotine tolerance, in *Self-Administration of Abused Substances: Methods for Study*, ed. Krasnegor NA, NIDA Research Monograph 20 (Rockville MD: National Institute on Drug Abuse, 1978), at 202-208. See AR (Vol. 41 Ref. 88).

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Finally, the industry cites a study by Butschky *et al.*²³³ to suggest that nicotine-free cigarettes cause “liking” too. What the industry does not mention is that the study was conducted in newly abstinent smokers and that these nicotine-free cigarettes were “liked” only when compared to lettuce cigarettes that the researchers acknowledged to be unpalatable. As described in section II.B.3., below, the repeated association of pharmacological effects and sensory effects over thousands of repetitions causes the sensory aspects of addictive behaviors (such as taste) to come to be associated with the pharmacological effect (such as “liking”) of addictive substances. Much as Pavlov’s dog salivated at the sound of the bell (a conditioned response), individuals addicted to drugs actually experience some of the effects of the psychoactive drug by conditioned cues associated with the act of self-administering the drug in the early stages of abstinence.²³⁴ This phenomenon has been described for many drugs, including heroin.²³⁵ Just as a heroin addict may experience a rush simply by injecting a saline solution, a cigarette smoker may experience pleasure when smoking a denicotinized cigarette. Thus, the finding that a denicotinized cigarette can trigger “liking” during withdrawal does not call into question the conclusion that nicotine has “subjective effects” in humans.

²³³ Butschky MF, Bailey D, Henningfield JE, *et al.*, Smoking without nicotine delivery decreases withdrawal in 12-hour abstinent smokers, *Pharmacology, Biochemistry and Behavior* 1995;50(1):91-96. See AR (Vol. 442 Ref. 7484).

²³⁴ O’Brien CP, Testa T, Ternes J, *et al.*, Conditioning effects of narcotics in humans, in *Behavioral Tolerance: Research and Treatment Implications*, NIDA Research Monograph 18 (Washington DC: Government Printing Office No. 017-024-00899-8, Jan. 1978), at 67-71. See AR (Vol. 535 Ref. 96, vol. III.L).

²³⁵ Surgeon General’s Report, 1988, at 308-311. See AR (Vol. 129 Ref. 1592).

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e. Comments on Self-Administration and Reinforcement

1. The tobacco industry argues that nicotine's reinforcing effects are different from those of heroin and cocaine, that animals need to be trained to self-administer nicotine, that the reinforcing efficacy of nicotine is more like that of caffeine, and that in one study cited by FDA a light stimulus associated with nicotine was required for self-administration. The industry concludes that animal self-administration studies do not support the finding that nicotine is addictive.

FDA disagrees. Upon review of the evidence in the administrative record, FDA notes that there are over ten studies demonstrating self-administration of nicotine by animals.²³⁶ Only one of these is specifically contested by the tobacco industry. Furthermore, none of the industry's arguments seriously call into question FDA's finding that animals self-administer nicotine in a manner consistent with other addictive substances.

It is true that the reinforcing effects of nicotine do differ from those of cocaine and heroin; all dependence-producing drugs are not alike. In fact, FDA noted that the range of environmental conditions under which nicotine functions as a positive reinforcer appears more limited than for cocaine.²³⁷ The limited conditions under which animals self-administer nicotine, however, closely correspond to the conditions of human tobacco use. That is, animals self-administer nicotine when it is given intermittently—in a fashion similar to nicotine delivery from cigarettes and smokeless tobacco.

²³⁶ See appendix 1 to Jurisdictional Analysis. See AR (Vol. 1 Appendix 1).

²³⁷ *Id.*

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FDA agrees that animals can be trained to self-administer nicotine. This method is widely accepted as standard practice in self-administration testing in animals. What is important is that, under these conditions, nicotine is self-administered significantly more than placebo and in a manner consistent with other addictive substances.

The tobacco industry cites a review chapter in a textbook on psychopharmacology to suggest that caffeine and nicotine self-administration are similar. The review article cited focuses on whether caffeine is a drug of abuse and, while casually noting similarities between some data on nicotine and caffeine, does not purport to analyze the studies on nicotine at all.²³⁸ Indeed, caffeine self-administration in animals is weak and sporadic.²³⁹ FDA further notes that the chapter on nicotine in this same textbook unequivocally concludes that nicotine is addictive.²⁴⁰

Finally, FDA agrees that the study by Goldberg *et al.*²⁴¹ showed that squirrel monkeys self-administer nicotine most actively when associated with a light stimulus. The tobacco

²³⁸ Griffiths RR, Mumford GK, Caffeine—A drug of abuse?, in *Psychopharmacology: The Fourth Generation of Progress*, eds. Bloom FE, Kupfer DJ (New York: Raven Press, 1995), at 1699-1713. See AR (Vol. 535 Ref. 96, vol. III.E).

²³⁹ Heishman SJ, Henningfield JE, Stimulus functions of caffeine in humans: relation to dependence potential, *Neuroscience and Biobehavioral Reviews* 1992;16:273-287. See AR (Vol. 79 Ref. 230).

Griffiths RR, Woodson PP, Reinforcing properties of caffeine: studies in humans and laboratory animals, *Pharmacology, Biochemistry and Behavior* 1988;29(2):419-427. See AR (Vol. 535 Ref. 96, vol. III.E).

Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 524. See AR (Vol. 535 Ref. 96, vol. III.G).

²⁴⁰ Henningfield JE, Schuh LM, Jarvik ME, Pathophysiology of tobacco dependence, in *Psychopharmacology: The Fourth Generation of Progress*, eds. Bloom FE, Kupfer DJ (New York: Raven Press, 1995), at 1715-1729. See AR (Vol. 39 Ref. 72).

²⁴¹ Goldberg SR, Speelman RD, Goldberg DM, Persistent behavior at high rates maintained by intravenous self-administration of nicotine, *Science* 1981;214:573-575. See AR (Vol. 5 Ref. 35-2).

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industry implies that this finding means that the light stimulus—not nicotine—was responsible for nicotine self-administration in this study. FDA disagrees. Rates of self-administration of nicotine with the light stimulus *were markedly higher than rates of self-administration of placebo* with the light stimulus. Indeed, the monkeys' self-administration of nicotine was so intense that it resembled cocaine use. Thus, the conclusion that nicotine was not self-administered is incorrect; the correct conclusion is that nicotine self-administration was most dramatic when associated with environmental cues that had been linked to nicotine injections.

2. The smokeless tobacco industry claims that its products provide a constant dose of nicotine, a regimen that animals did not self-administer. This claim is contrary to the evidence. As described in section II.D., below, moist snuff and chewing tobacco do not provide uniform release of nicotine from the products. In fact, each pinch of smokeless tobacco provides nicotine that is absorbed rapidly for the first 5 minutes; the rate of absorption then tapers off until the next pinch is consumed. This pattern of nicotine consumption is similar to the regimen that was self-administered by animals.

3. The tobacco industry criticizes the human self-administration study conducted by Henningfield *et al.*²⁴² on the grounds that the number of subjects used in the study was too small, that the study should have been conducted with subjects without a history of drug abuse, and that the subjects also self-administered saline.

FDA believes that the study's design was sound and that the results are reliable. The procedure utilized by these researchers is the standard procedure utilized by all investigators evaluating the abuse liability of a compound in humans. This well-

²⁴² Henningfield JE, Miyasoto K, Jasinski DR, Cigarette smokers self-administer intravenous nicotine, *Pharmacology, Biochemistry and Behavior* 1983;19:887-890. See AR (Vol. 39 Ref. 71).

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established procedure has been used to examine the abuse potential of a variety of compounds, such as alcohol, marijuana, heroin, and sedatives, in both inpatient and outpatient settings. In the evaluation of a new molecular entity (NME) that shows some structural and/or pharmacological similarities to known drugs of abuse, FDA requires that studies similar to this one be conducted in order to reach a regulatory decision on the abuse potential of the NME being considered for drug approval.²⁴³

In response to the concerns of the tobacco industry about the study methodology, the sample size of six is acceptable and the use of volunteers with histories of drug abuse is a valid method of conducting such research, according to the National Institute on Drug Abuse.²⁴⁴ Human studies evaluating the abuse potential of a compound in subjects without a history of drug abuse do not produce valid results. Such tests in non-drug abusers could lead to the conclusion that drugs, including heroin, have a low potential to produce dependence because first-time users may not find them pleasant.²⁴⁵

With respect to the self-administration of saline, the comment overlooks major distinctions between nicotine and saline: (1) "subjective effects" were not associated with the saline deliveries, thus saline was not psychoactive; (2) in comparison to the orderly pattern of self-administration observed with the nicotine injections, the pattern of saline deliveries was highly variable; (3) the number of self-administered saline injections

²⁴³ See Surgeon General's Report, 1988, at 270. See AR (Vol. 129 Ref. 1592).

²⁴⁴ Jasinski DR, Henningfield JE, Human abuse liability assessment by measurement of subjective and physiological effects, in *Testing for Abuse Liability of Drugs in Humans*, eds. Fischman MW, Mello NK, NIDA Research Monograph 92 (Rockville MD: National Institute on Drug Abuse, 1989). See AR (Vol. 76 Ref. 172).

²⁴⁵ Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 529. See AR (Vol. 535 Ref. 96, vol. III.G).

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decreased across sessions while nicotine injections were constant in those subjects who were tested repetitively with saline and nicotine; and (4) when saline and nicotine were simultaneously available in a follow-up study, the volunteers self-administered nicotine almost exclusively and not saline.²⁴⁶ Thus, saline was not psychoactive and did not function as a “positive reinforcer.”

4. The tobacco industry argues that caffeine, rapid eye movement (REM) sleep, magnetic fields, and stress increase dopamine levels in the brain. According to the industry, then, nicotine’s effect on dopamine activity is shared by several other compounds or experiences.

This argument is based on a mischaracterization of the relationship between addictive substances and dopamine activity. FDA found that nicotine and other addictive substances do more than increase dopamine levels in the brain; they increase dopamine activity in a specific system that signals reward and pleasure, thus leading to reinforcing behavior. Nicotine’s effect in this system is similar to that of other dependence-producing substances. These conclusions are based on reproducible studies and are widely accepted in the scientific community. Indeed, none of the industry’s cited studies casts any doubt on the profound effects of nicotine on this brain system.

One study, cited by the industry as proof of the effect of caffeine on dopamine levels, actually examined the effect of caffeine on aggressive behavior of rats. Dopamine levels were not even measured. The authors merely speculated at the end of the article

²⁴⁶ Surgeon General’s Report, 1988, at 192. See AR (Vol. 129 Ref. 1592).

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that caffeine may affect rat aggression via dopamine. Moreover, they did not extend their speculation to reward or reinforcement.²⁴⁷

Another study, cited by the industry as proof of the effect of REM sleep and magnetic fields on dopamine, actually described two patients treated with magnetic fields—without any control group. The authors merely speculated that REM sleep deprivation and magnetic fields may affect dopamine in the mesolimbic system. But without a control group, it is impossible to assess whether there was *any* true response to magnetic fields.²⁴⁸

The industry cites a third study to suggest that stress increases dopamine levels.²⁴⁹ This study delivered severe stimuli such as electric shocks to mice and studied dopamine responses. The authors concluded that a dopamine-based reward pathway exists and is altered under conditions of severe stress. This conclusion casts no doubt on the finding that nicotine also critically affects this pathway.

5. In a footnote, the tobacco industry argues that “it is not clear that nicotine’s effects on dopaminergic mechanisms play a significant role in smoking behavior.” This argument refers to a study by Corrigall and Coen.²⁵⁰

²⁴⁷ Petkov VV, Rousseva S, Effects of caffeine on aggressive behavior and avoidance learning of rats with isolation syndrome, *Methods and Findings in Experimental and Clinical Pharmacology* 1984;6(8):433-436. See AR (Vol. 535 Ref. 96, vol. III.L).

²⁴⁸ Sandyk R, Tsagas N, Anninos PA, *et al.*, Magnetic fields mimic the behavioral effects of REM sleep deprivation in humans, *International Journal of Neuroscience* 1992;65(1-4):61-68. See AR (Vol. 535 Ref. 96, vol. III.L).

²⁴⁹ Puglisi-Allegra S, Kempf E, Cabib S, Role of genotype in the adaptation of the brain dopamine system to stress, *Neuroscience and Biobehavioral Reviews* 1990;14(4):523-528. See AR (Vol. 535 Ref. 96, vol. III.L).

²⁵⁰ Corrigall W, Coen K, Dopamine mechanisms play at best a small role in the nicotine discriminative stimulus, *Pharmacology, Biochemistry and Behavior* 1994;48(3):817-820. See AR (Vol. 535 Ref. 96, vol. III.B).

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FDA has reviewed the study in question and concludes that the tobacco industry's conclusion seriously misrepresents the research. In this paper, the authors suggested that dopamine activity may not explain why smokers recognize low doses of nicotine in their brain, but the authors never doubted that dopamine activity is essential to the reward associated with smoking. The same article cited by the industry includes the statement that "the reinforcing effects of nicotine have a dopaminergic substrate, likely the ascending mesolimbic dopamine system"²⁵¹—exactly the finding of FDA. These researchers, misrepresented by the industry to suggest a small role for dopamine in smoking behavior, have demonstrated in their own laboratory that dopamine activity significantly affects nicotine consumption.²⁵²

f. Comments on Withdrawal, Tolerance, and Nicotine Replacement

1. The tobacco industry argues that the effects of withdrawal from nicotine are not substantial. This argument is based upon multiple overlapping and sometimes contradictory contentions: (1) nicotine withdrawal is not as severe as withdrawal from certain other drugs, and some people quit smoking easily; (2) physical and psychological symptoms experienced during nicotine withdrawal are not the same among all abstinent users; (3) withdrawal from nicotine produces psychological but not physical symptoms; (4) the psychological symptoms of abstinence may actually be a psychopathological condition previously suppressed by nicotine or may be frustration with losing a pleasurable activity; (5) what is thought to be nicotine withdrawal may actually be caffeine withdrawal

²⁵¹ *Id.* at 817.

²⁵² Corrigall WA, Franklin KBJ, Coen KM, *et al.*, The mesolimbic dopaminergic system is implicated in the reinforcing effects of nicotine, *Psychopharmacology* 1992;107:285-289. See AR (Vol. 8 Ref. 93-4).

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or caffeine toxicity; (6) the severity of withdrawal symptoms does not always correlate with relapse; and (7) epidemiological studies cited by FDA do not prove a substantial withdrawal syndrome.

Upon careful review of the industry's comments and the administrative record, FDA finds that nicotine clearly produces a withdrawal syndrome among abstinent tobacco users. This syndrome—which includes both psychological and physiological symptoms—is described in numerous scientific articles and reviews cited by FDA,²⁵³ only a few of which were criticized by the tobacco industry. Of the studies on withdrawal from smokeless tobacco cited by FDA, none is contested by the industry. The tobacco industry also accepts FDA's finding that tobacco withdrawal causes many significant autonomic changes, such as changes in heart rate. Several of the industry's arguments do not seriously contest the fact that nicotine has a substantial withdrawal syndrome. The remaining arguments contradict each other. The Agency's specific responses to the major industry contentions are as follows:

- Nicotine withdrawal is not as severe as withdrawal from certain other drugs, and some people quit smoking easily.

FDA agrees that withdrawal from nicotine is not as acutely life-threatening as withdrawal from certain addictive drugs such as alcohol or short-acting barbiturates. But the severity of nicotine withdrawal is comparable to that of other addictive drugs such as

²⁵³ See Jurisdictional Analysis, 60 FR 41560–41562

See also Surgeon General's Report, 1988, at 197-207. See AR (Vol. 129 Ref. 1592).

American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 244-245. See AR (Vol. 37 Ref. 8).

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cocaine.²⁵⁴ Medical authorities around the world have recognized the existence of a nicotine withdrawal syndrome that causes “clinically significant distress or impairment in social, occupational, or other areas of functioning.”²⁵⁵

FDA agrees that some people quit tobacco products easily. Similarly, some people quit cocaine and other addictive substances easily.²⁵⁶ However, for most addicted users of tobacco, quitting is very difficult. *See* section II.A.3.c.ii., above. The characteristic feature of an addictive substance is that it is difficult for most people to quit. Thus, the fact that some people can quit smoking easily is irrelevant to nicotine’s addictiveness and to the scientific consensus supporting a nicotine withdrawal syndrome. Moreover, it may actually be easier to quit other powerful substances than to quit nicotine. Smokers who consume about a pack or more of cigarettes per day are more than twice as likely to report withdrawal symptoms during abstinence as people who consume five or more drinks on five or more occasions in a month, people who repeatedly use cocaine, and people who repeatedly use marijuana.²⁵⁷

- Physical and psychological symptoms experienced during nicotine withdrawal are not the same among all abstinent users.

²⁵⁴ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437, at 429. *See* AR (Vol. 535 Ref. 96, vol. III.A).

²⁵⁵ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 245. *See* AR (Vol. 37 Ref. 8).

²⁵⁶ Kleber H, Don’t you believe that nicotine isn’t addictive, *New York Times*, Apr. 4, 1994. *See* AR (Vol. 196 Ref. 2497).

Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437, at 429. *See* AR (Vol. 535 Ref. 96, vol. III.A).

²⁵⁷ Henningfield JE, Clayton R, Pollin W, Involvement of tobacco in alcoholism and illicit drug use, *British Journal of Addiction* 1990;85:279-292, at 280-281. *See* AR (Vol. 39 Ref. 66).

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FDA agrees that there is variation among tobacco users' physical and psychological responses to abstinence. But, as described in section II.A.3.c.i., above, and in reviews cited by the Agency, several symptoms are so common as to be part of a defined syndrome.²⁵⁸ These symptoms include depressed mood, insomnia, irritability, anxiety, difficulty concentrating, restlessness, decreased heart rate, and increased appetite. Thousands of individuals around the world have reported these symptoms in studies of tobacco abstinence.

- Withdrawal from nicotine produces psychological but not physical symptoms.

The tobacco industry goes on to quote selectively from some researchers to suggest that nicotine withdrawal does not produce physical symptoms. This argument is at odds not only with the consensus understanding of nicotine withdrawal, but also with other quotations used by the tobacco industry in the same comment, which suggests that common withdrawal symptoms include, for example, "headache."²⁵⁹

Indeed, the very sources cited by the tobacco industry clearly agree with FDA's finding of a substantial tobacco withdrawal syndrome. For example, Balfour, who is quoted by the industry to suggest that withdrawal is mainly psychological, states that "many habitual smokers *experience significant and unpleasant withdrawal effects* when they first stop smoking which can be ameliorated by giving nicotine in another form."²⁶⁰

²⁵⁸ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 244-245. See AR (Vol. 37 Ref. 8).

²⁵⁹ Clark WG, Brater DC, Johnson AR, Drug abuse and dependence, in *Goth's Medical Pharmacology* (Baltimore: Mosby), 336-352, at 347. See AR (Vol. 535 Ref. 96, vol. III.B).

²⁶⁰ Balfour DJK, The neurochemical mechanisms underlying nicotine tolerance and dependence, in *The Biological Bases of Drug Tolerance and Dependence*, ed. Pratt JA (New York: Academic Press, 1991), 121-151, at 123 (citation omitted) (emphasis added). See AR (Vol. 535 Ref. 96, vol. III.A).

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Similarly, a quotation culled from a review by Hughes *et al.* is used to support the conclusion that the effects of nicotine withdrawal are not substantial. In fact, Hughes *et al.* attribute multiple physical and psychological symptoms to nicotine withdrawal and conclude that some symptoms can be so severe that they may “prevent smoking cessation.”²⁶¹

- The psychological symptoms of abstinence actually may be a psychopathological condition previously suppressed by nicotine or may be frustration with losing a pleasurable activity.

The tobacco industry cites the *Diagnostic and Statistical Manual of Mental Disorders* of the American Psychiatric Association for this assertion, but offers no evidence to suggest that any significant number of quitting smokers have psychiatric diagnoses or are just frustrated. Nor does the DSM. Its actual text merely alerts clinicians not to mistake symptoms of abstinence for psychopathology or frustration “in any given case.”²⁶²

- What is thought to be nicotine withdrawal may actually be caffeine withdrawal or caffeine toxicity.

FDA agrees that some symptoms are common to caffeine and nicotine withdrawal, and some are common to nicotine withdrawal and caffeine toxicity. Withdrawal from nicotine and cocaine also causes common symptoms of depressed mood, increased

²⁶¹ Hughes JR, Higgins ST, Hatsukami D, Effects of abstinence from tobacco: a critical review, *Research Advances in Alcohol and Drug Problems* 1990;10:317-398, at 381. See AR (Vol. 535 Ref. 96, vol. III.G).

²⁶² American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 3d ed., revised (Washington DC: American Psychiatric Association, 1987), at 150. See AR (Vol. 535 Ref. 96, vol. III.A).

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appetite, and insomnia.²⁶³ Such overlap has not led any credible scientific source to conclude that nicotine withdrawal has been confused with another drug's syndrome and therefore does not exist.

- The severity of withdrawal symptoms does not always correlate with relapse.

On several occasions in its comments, the tobacco industry claims that the severity of withdrawal does not directly predict relapse. Based on this observation, the industry concludes that the symptoms of withdrawal from tobacco are not significant and that physical dependence to nicotine is not real.

FDA disagrees. Severity of withdrawal does predict relapse; most people who quit smoking relapse within 1 week,²⁶⁴ when withdrawal symptoms are at or near their peak.²⁶⁵ Moreover, studies indicate that light smokers, who are less likely to suffer withdrawal symptoms, are more likely to succeed in quitting than are heavier smokers.²⁶⁶

The industry's argument is based on the mistaken assumption that, if withdrawal symptoms were significant, their presence would perfectly correlate with relapse. But, as described in depth in the 1988 Surgeon General's Report, multiple confounding factors are associated with relapse to use of *any* addictive substance, no matter how significant the withdrawal syndrome.²⁶⁷ These factors include psychiatric impairment, expectations,

²⁶³ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994). See AR (Vol. 535 Ref. 96, vol. III.B).

²⁶⁴ Hughes JR, Gulliver SB, Fenwick JW, *et al.*, Smoking cessation among self-quitters, *Health Psychology* 1992;11:331-334, at 333. See AR (Vol. 348 Ref. 5512).

²⁶⁵ Hughes JR, Gust SW, Skoog K, *et al.*, Symptoms of tobacco withdrawal: a replication and extension, *Archives of General Psychiatry* 1991;48:52-59, at 56. See AR (Vol. 129 Ref. 1404).

²⁶⁶ Surgeon General's Report, 1988, at 315-316. See AR (Vol. 129 Ref. 1592).

²⁶⁷ *Id.* at 315-324.

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demographics, enrollment in treatment programs, peer influence, and social support. Even life-threatening withdrawal symptoms associated with drugs such as alcohol do not necessarily lead to relapse. After a complete review of available evidence, the Surgeon General concluded that nicotine's pharmacological role in relapse is similar to the role of opioids and alcohol.²⁶⁸ Thus, the absence of a perfect correlation between withdrawal severity and the precise timing of a relapse does not compel the conclusion that withdrawal symptoms are insignificant or that physical dependence to nicotine is not real.

- Epidemiological studies cited by FDA do not prove a substantial withdrawal syndrome.

The tobacco industry criticizes several studies cited by FDA in support of a tobacco withdrawal syndrome. Upon review of these studies, FDA finds that the industry's comments take quotations out of context and make inappropriate inferences from researchers' findings. For example, the industry objects to a study by Hughes *et al.*²⁶⁹ on the grounds that the researchers tabulated withdrawal symptoms on only 105 of the 315 subjects. In fact, the analysis of withdrawal appropriately included *every subject* in the study who was abstinent from both tobacco and nicotine. The other 210 subjects received nicotine gum to reduce their withdrawal symptoms; these subjects were thus inappropriate for research on the severity of withdrawal.

Similarly, the industry claims to provide data to contradict FDA's citation of the 1991 and 1992 National Household Surveys. But FDA's data reported the prevalence of withdrawal symptoms for smokers who consume sixteen to twenty-five cigarettes per day.

²⁶⁸ *Id.* at 323.

²⁶⁹ Hughes JR, Gust SW, Skoog K, *et al.*, Symptoms of tobacco withdrawal: a replication and extension, *Archives of General Psychiatry* 1991;48:52-59. See AR (Vol. 129 Ref. 1404).

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The industry's data are based on a different set of smokers and, at any rate, are hardly different from FDA's.

Such arguments cannot seriously challenge the scientific consensus that led the American Psychiatric Association to define Tobacco Withdrawal Syndrome in 1980 and to ratify its decision again as recently as 1994 in DSM-IV.

2. The tobacco industry argues that nicotine does not induce pharmacological tolerance. This conclusion is based upon several arguments: (1) tolerance can be both pharmacological and nonpharmacological; (2) smokers and users of smokeless tobacco do not continue to increase their tobacco consumption over the course of their lives and thus do not escalate their dose; (3) FDA's studies on dose escalation are not persuasive; and (4) a study on low-nicotine snuff disproves tolerance.

FDA disagrees with the industry's analysis and conclusion. Much uncontested evidence in the administrative record demonstrates conclusively that nicotine causes tolerance in tobacco users. For example, the industry does not dispute evidence of diminished cardiovascular and nervous system responses to nicotine over the course of a day. Nor does the industry deny that many cigarette smokers escalate their doses of nicotine to daily use²⁷⁰ or that the age of young consumers of smokeless tobacco correlates with the amount of use.²⁷¹ Furthermore, the arguments that the industry does make are not persuasive, as discussed below.

²⁷⁰ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

Henningfield JE, Cohen C, Slade JD, Is nicotine more addictive than cocaine? *British Journal of Addiction* 1991;86:565-569. See AR (Vol. 277 Ref. 3904).

²⁷¹ World Health Organization, *Smokeless Tobacco Control: Report of a WHO Study Group*, WHO Technical Report Series No. 773 (Geneva: WHO, 1988), at 36. See AR (Vol. 7 Ref. 83).

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The industry's description of two kinds of tolerance is irrelevant. Sources in the administrative record cited by FDA refer exclusively to pharmacological tolerance. *See* sections II.A.3.c.i. and II.A.3.c.ii., above.

The tobacco industry makes the observation that smoking behavior reaches a plateau as the smoker grows older. Similarly, the smokeless tobacco industry points out that middle-aged users may consume less than young adults. But these observations do not disprove the existence of tolerance, which does not require forever-increasing consumption of a substance. Tolerance is a phenomenon that develops rapidly, leads the vast majority of beginning tobacco users to escalate their dose, and then can eventually result in a stable pattern of consumption. Some heroin addicts also eventually reach a level of consumption that may remain constant for years.²⁷²

The tobacco industry asserts that a study cited by FDA on the proportion of smokers who report needing more cigarettes to obtain desired effects does not support the idea of tolerance to nicotine and also does not prove that such tolerance is widespread or marked. FDA disagrees with these assertions. The industry cites no data or references to explain why the study does not demonstrate tolerance. In fact, the study's findings perfectly fit the tobacco industry's *own* definition of tolerance that "more drug is necessary to produce the desired effect." People who have tried cigarettes at least once are more likely to report the need for larger doses to get the same effect than people who have tried

²⁷² Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 531-532. *See* AR (Vol. 535 Ref. 96, vol. III.G).

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cocaine, marijuana, and alcohol at least once.²⁷³ Moreover, FDA notes that epidemiological data are just one demonstration of tolerance; most of the evidence on tolerance to nicotine presented by FDA is uncontested by the tobacco industry.

Finally, the smokeless tobacco industry cites a study that measures the response of oral tobacco users to a low-nicotine snuff. In the study, users increased their consumption of tobacco to compensate for its lower nicotine content. The industry's argument here confuses tolerance with compensation. FDA addresses the industry's comments on compensation in section II.A.7.i., above.

3. The tobacco industry cites research on nicotine replacement therapies to argue that nicotine is not a key reason for tobacco use. According to the industry, if nicotine were central to tobacco consumption, providing nicotine replacement should eliminate smoking behavior and all withdrawal symptoms. The industry contends that nicotine replacement trials cited by FDA do not demonstrate either efficacy of replacement therapy or elimination of withdrawal symptoms. The industry disputes FDA's summary of nicotine replacement trials and makes multiple objections to individual studies. The industry also contends that the study population is not generalizable to the entire smoking population.

Upon review of the industry's detailed comments and the data in the administrative record, FDA disagrees with the industry's position on nicotine replacement therapies. Scientific consensus supports the view that such therapies not only reduce withdrawal symptoms but increase abstinence. An extensive preapproval evaluation of such therapies

²⁷³ Henningfield JE, Clayton R, Pollin W, Involvement of tobacco in alcoholism and illicit drug use, *British Journal of Addiction* 1990;85:279-292. See AR (Vol. 39 Ref. 66).

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by FDA also concluded that they were safe and effective, and even sources cited by the tobacco industry agree. The efficacy of nicotine replacement therapies is strong proof of the central role of nicotine in tobacco consumption. The industry's position is based upon mistaken assumptions, misinterpretation of clinical trials, and misuse of FDA reviews.

According to the tobacco industry, replacing one form of an addictive substance with another form should completely eliminate the addict's desire to use the substance. If this assumption were correct, then no methadone user would ever relapse to heroin. In fact, providing oral methadone in substance abuse clinics helps only some opioid users to remain totally abstinent,²⁷⁴ and abstinence rates of former heroin users on methadone are similar to those of former smokers receiving nicotine replacement therapy.²⁷⁵ The industry's simplistic formulation ignores many factors, such as the importance of the route and speed of drug administration. Just as a heroin addict may want a "rush" from injection and reject the steady dose of oral methadone, a tobacco user may prefer the "rapid, peaking" dose of inhaled nicotine over the more steady dose from replacement therapy.²⁷⁶ Given the strength of addiction to tobacco products, it is noteworthy that there is a

²⁷⁴ Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 531-532. See AR (Vol. 535 Ref. 96, vol. III.G).

²⁷⁵ Henningfield JE, Griffiths RR, Jasinski DR, Cigarette smoking and opioid dependence: common factors, Presented at the meeting of the American Psychological Association (Sep. 2, 1980). See AR (Vol. 80 Ref. 254).

Surgeon General's Report, *Smokeless Tobacco*, 1986, at 155. See AR (Vol. 128 Ref. 1591).

Gorelick D, Transcript to the FDA Drug Abuse Advisory Committee, Meeting 27, "Issues Concerning Nicotine-Containing Cigarettes and Other Tobacco Products" (Aug. 2, 1994), 292. See AR (Vol. 255 Ref. 3445).

²⁷⁶ Research and Development/Quality, *Transdermal Nicotine*, at 3. See AR (Vol. 531 Ref. 124).

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significant increase in abstinence with replacement therapy, but it is not surprising that these products are not always effective.

The industry also argues that replacing an addictive substance with another form should eliminate all withdrawal symptoms. In fact, providing nicotine does dramatically reduce physiological withdrawal symptoms.²⁷⁷ Psychological withdrawal is reduced but not eliminated, primarily because users have associated tobacco consumption with certain stimuli, such as taste and ritual. Such “conditioned” cues become part of the tobacco consumption experience, and the denial of such cues can lead to behavioral symptoms. In this sense, nicotine is like other addictive drugs.²⁷⁸

The industry misinterprets data on the efficacy of nicotine replacement therapies. First, the industry argues that FDA’s data do not support the conclusion that the initial quit rate is “about 50%.” The actual studies cited 1-month quit rates of 35%, 61%, 50%, 50%, 26%, 57%, 47%, and 36%. The overall average for all studies was 49%.²⁷⁹

Second, the industry argues that some individual studies do not show a statistically significant increased quit rate with nicotine replacement therapy. The Jurisdictional Analysis, however, included a chart showing the overwhelming consistency among nineteen studies on nicotine replacement therapies in demonstrating efficacy.²⁸⁰

²⁷⁷ Surgeon General’s Report, 1988, at 208. See AR (Vol. 129 Ref. 1592).

²⁷⁸ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437, at 418. See AR (Vol. 535 Ref. 96, vol. III.A).

²⁷⁹ See appendix 1 to Jurisdictional Analysis. See AR (Vol. 1 Appendix 1).

²⁸⁰ *Id.*

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A definitive meta-analysis on the efficacy of the nicotine patch was cited by FDA, and its methods and results were not disputed by the tobacco industry. This study, published in the *Journal of the American Medical Association*, reviewed seventeen studies involving over 5,000 patients and concluded that “this meta-analysis provides *compelling evidence that the nicotine patch is a consistently effective aid to smoking cessation*. Individuals wearing the active nicotine patch were more than twice as likely to quit smoking as were individuals wearing a placebo patch.”²⁸¹

Third, the industry makes multiple objections to individual studies on nicotine replacement therapy. These objections dispute fine points of methodology and often cite FDA reviewers’ own criticisms of the studies. To the extent that the industry heavily relies on FDA’s critique of the studies, the industry should accept FDA’s conclusion that the studies demonstrate the efficacy of nicotine replacement therapy. Indeed, FDA has not only the statutory authority but also the expertise to determine whether a new drug therapy is efficacious. After extensive premarket review, FDA concluded that nicotine replacement therapies are efficacious. FDA’s conclusion is consistent with scientific consensus.

The tobacco industry also argues that the subjects in trials on nicotine replacement therapy are not representative of all smokers. But FDA’s reason for citing the research was to demonstrate that providing nicotine by another means enhances abstinence and reduces withdrawal where it has been studied. These results show the critical

²⁸¹ Fiore MC, Smith SS, Jorenby DE, *et al.*, The effectiveness of the nicotine patch for smoking cessation: a meta-analysis, *Journal of the American Medical Association* 1994;271:1940-1947, at 1945 (emphasis added). See AR (Vol. 6 Ref. 64-1).

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pharmacological role of nicotine in tobacco use. Indeed, if the tobacco industry were correct that nicotine's only important role in tobacco is for "flavor," then there should be absolutely no benefits in *any* study of transdermal nicotine replacement therapy. That nicotine replacement is effective is conclusive evidence of nicotine's role as a pharmacological reinforcer.

4. The tobacco industry argues that studies on nicotine replacement therapy cannot be relied upon to demonstrate that a high proportion of smokers are addicted.

FDA agrees with this comment. Other studies, cited in section II.B.2.a., below, however, do demonstrate that a high proportion of smokers are addicted.

g. Comments on Epidemiological Studies

1. The tobacco industry claims that studies of individual DSM criteria do not demonstrate that any group of smokers satisfied sufficient criteria to qualify for the diagnosis of addiction.

FDA cited these studies as support for the conclusion that a significant proportion of tobacco consumers are addicted to nicotine. This conclusion is primarily demonstrated by population-based studies, including the DSM-IV field trial, which show that the vast majority of smokers do meet sufficient DSM criteria to be considered nicotine dependent, discussed in more detail in section II.B., below. The field trial was a large, multicenter study conducted in 1991 and 1992 at five sites across the country (Burlington, VT; Philadelphia, PA; Denver, CO; St. Louis, MO; and San Diego, CA).²⁸² The population

²⁸² Woody GE, Cottler LB, Cacciola J, Severity of dependence: data from the DSM-IV field trials, *Addiction* 1993;88:1573-1579. See AR (Vol. 13 Ref. 150).

Cottler L, Comparing DSM-III-R and ICD-10 substance use disorders, *Addiction* 1993;88:689-696. See AR (Vol. 13 Ref. 149).

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studied represented a diverse sample and included African-Americans, women, others randomly selected from the general population, and still others with a range of diagnoses and substance use patterns. The field trial documents that 80% to 87% of smokers studied qualified for the diagnosis of nicotine dependence. In its comments, the American Psychiatric Association concurs with the Agency's findings: "DSM based studies also found that 80% to 90% of adult smokers are nicotine dependent."²⁸³

The tobacco industry's comments on population-based studies are addressed in section II.B.4.b., below. It is relevant to mention here that, if the industry's assertion that these population-based studies are not representative of all smokers is correct, then large surveys of whether all smokers meet individual DSM criteria would show inconsistent results. But this is not the case. Overwhelming evidence, cited in section II.A.3.c.ii., above, conclusively demonstrates that the vast majority of tobacco consumers meet individual criteria for addiction.

2. The tobacco industry disputes that use of tobacco products persists longer and in greater amounts than the user intends. According to the industry, studies cited by FDA demonstrate that, at most, 30% of people who have ever tried tobacco become "dependent" by FDA's definition. The industry also argues that the desire to quit is not evidence of intent to cut down.

FDA disagrees with the industry's position. It is widely accepted that users of tobacco products consume more than they originally intended.²⁸⁴ Longitudinal data, cited

²⁸³ American Psychiatric Association, Comment (Jan. 2, 1996), at 2. See AR (Vol. 700 Ref. 1020).

²⁸⁴ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 243. See AR (Vol. 37 Ref. 8).

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in section II.A.3.c.ii., above, demonstrate that smokers frequently underestimate how much they will be smoking in the future. As many as 90% of current users smoke more than five cigarettes a day,²⁸⁵ despite the evidence that nearly half of young consumers do not intend to become daily smokers.²⁸⁶ Although estimates vary from study to study, persons who have smoked at least one cigarette are about twice as likely to develop dependence as are persons who have ever tried cocaine or alcohol.²⁸⁷

If an individual wants to quit smoking but cannot, then the individual is smoking more than he or she intends. The overwhelming evidence presented in section II.A.3.c.ii., above, that many would-be quitters cannot attain abstinence supports the contention that consumers use cigarettes longer and in greater amounts than intended.

3. The tobacco industry disputes that tobacco use continues despite attempts to quit. The industry observes that 90% of cigarette smokers who quit succeed by themselves, and the smokeless tobacco industry suggests that 75% of successful quitters find it easy to quit. The tobacco industry also alleges that FDA mischaracterizes data on self-reports of dependence from the National Household Surveys and misrepresents

²⁸⁵ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

Henningfield JE, Cohen C, Slade JD, Is nicotine more addictive than cocaine? *British Journal of Addiction* 1991;86:565-569. See AR (Vol. 277 Ref. 3904).

²⁸⁶ Elders MJ, Perry CL, Eriksen MP, *et al.*, The report of the Surgeon General: preventing tobacco use among young people, *American Journal of Public Health* 1994;84(4):543-547, at 544. See AR (Vol. 38 Ref. 39).

²⁸⁷ Anthony JC, Warner LA, Kessler RC, Comparative epidemiology of dependence on tobacco, alcohol, controlled substances and inhalants: basic findings from the National Comorbidity Survey, *Experimental and Clinical Psychopharmacology* 1994;2:244-268. See AR (Vol. 37 Ref. 4).

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abstinence failure rates from a CDC study. The industry further argues that smokers may lie on surveys about their desire to quit.

After reviewing industry comments and the administrative record, FDA concludes that there is overwhelming evidence that tobacco use continues despite attempts to quit. Indeed, this fact is well known to the tobacco industry. For example, Brown & Williamson's data show that, while 32 million Americans attempted to quit each year from 1981 to 1983, fewer than a third were successful for 6 months. *See* Jurisdictional Analysis, 60 FR 41668. Philip Morris' data show similar success rates.²⁸⁸

The argument that most smokers and users of smokeless tobacco who quit do so without assistance relies on surveys of the small proportion of tobacco users who are able to quit each year. This population is not representative of the vast majority of current tobacco users, who have tremendous difficulty quitting. Furthermore, the fact that some smokers are able to quit without assistance does not reveal the difficulty experienced by these individuals or the extent to which they have previously relapsed. More than half of people presenting for treatment of alcohol or drug abuse who also smoke cigarettes report that quitting smoking would be harder than giving up their other drug of abuse.²⁸⁹ Two-thirds of smokers who try to quit on their own relapse within 2 days, and approximately

²⁸⁸ Ryan FJ (Philip Morris Inc.), Cold turkey in Greenfield, Iowa: a follow-up study, in *Smoking Behavior: Motives and Incentives*, ed. Dunn WL (Washington DC: VH Winston & Sons, 1973), at 231-234. *See* AR (Vol. 8 Ref. 105).

²⁸⁹ Kozlowski LT, Wilkinson A, Skinner W, *et al.*, Comparing tobacco cigarette dependence with other drug dependencies, *Journal of the American Medical Association* 1989;261:898-901. *See* AR (Vol. 41 Ref. 92).

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90% relapse within 3 months.²⁹⁰ Sixty-eight percent of smokeless tobacco users who have attempted to quit have tried to do so an average of four times.²⁹¹

The industry disputes FDA's analysis of 1991 and 1992 National Household Survey data, which reveal that 83% to 87% of moderate to heavy smokers feel addicted. The industry first argues that the question to smokers has no validity; FDA disagrees and notes that the industry cited the same survey result from the 1985 survey at another point in its comments. The industry then suggests that FDA's analysis of the 1991 and 1992 data is inconsistent with published reports. This is not true. The Substance Abuse and Mental Health Services Administration (SAMHSA) conducted two National Household Surveys, one in 1991 and another in 1992. The data referred to in the Proposed Rule were a calculation by the Centers for Disease Control and Prevention (CDC) of raw data obtained in the 1991 and 1992 surveys and presented at FDA's Drug Abuse Advisory Committee meeting in August 1994.²⁹² The CDC pooled the raw data from both surveys, weighted them accordingly, and then evaluated the data using parameters different from those outlined in the main findings of each survey. The CDC used the data to look at different age groups of users and different numbers of cigarettes smoked per day than did SAMHSA. Even if the calculations performed by SAMHSA had been used, the data

²⁹⁰ Hughes JR, Gulliver SB, Fenwick JW, *et al.*, Smoking cessation among self-quitters, *Health Psychology* 1992;11:331-334. See AR (Vol. 348 Ref. 5512).

²⁹¹ Severson HH, Enough snuff: ST cessation from the behavioral, clinical, and public health perspectives, in *Smokeless Tobacco or Health, an International Perspective*, Smoking and Tobacco Control Monograph 2, NIH Publication No. 93-3461 (Washington DC: GPO, 1993), at 281-282. See AR (Vol. 18 Ref. 5-1).

²⁹² Giovino GA, Zhu BP, Tomar S, *et al.*, *Epidemiology of Tobacco Use and Symptoms of Nicotine Addiction in the United States: A Compilation of Data from Large National Surveys*, presentation of the Centers for Disease Control and Prevention to the FDA's Drug Abuse Advisory Committee (Aug. 2, 1994). See AR (Vol. 459 Ref. 7820).

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would still show that, among those who smoke about a pack or more of cigarettes per day, 81% report feeling dependent.²⁹³

The tobacco industry also argues that FDA mischaracterized a 1993 report from the CDC that FDA cited in the Jurisdictional Analysis for the statement that more than 15 million Americans “tried to quit” each year and about 3% ultimately succeeded.²⁹⁴ The industry contends that the survey did not ask specifically whether smokers had tried to quit, but whether smokers did not smoke at least 1 day during the preceding year. The industry concludes that this report is not relevant to whether smokers try to quit.

FDA disagrees. For daily smokers, the CDC counted one day of abstinence only if the smokers stated “they *quit* for at least 1 day.”²⁹⁵ The CDC logically interpreted these results as showing that 17 million daily smokers who reported not smoking for at least 1 day made an attempt to quit. According to the report, “the findings from this survey indicate that, in 1990 and 1991, approximately 42% of daily smokers abstained from smoking cigarettes for at least 1 day but that approximately 86% of these persons subsequently resumed smoking. The high rate of relapse is likely because of the addictive nature of nicotine.”²⁹⁶ FDA accepts CDC’s interpretation of its survey.

²⁹³ Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Office of Applied Studies, *National Household Survey on Drug Abuse: Main Findings, 1991*, DHHS Publication Number (SMA)93-1980 (Rockville MD: DHHS, Public Health Service, 1993), at 127. See AR (Vol. 535 Ref. 96, vol. III.M).

²⁹⁴ Centers for Disease Control and Prevention, Smoking cessation during previous year among adults—United States, 1990 and 1991, *Morbidity and Mortality Weekly Report* 1993;42(26):504-507. See AR (Vol. 66 Ref. 2).

²⁹⁵ *Id.* at 504.

²⁹⁶ *Id.* at 504-507.

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FDA also notes that CDC's estimate is consistent with other published estimates²⁹⁷ and the tobacco industry's own tabulations of long-term quit rates. For example, a tobacco company has estimated that fewer than 4% of smokers who attempt to quit are able to quit permanently. *See* Jurisdictional Analysis, 60 FR 41668–41669.

FDA disagrees that survey results significantly distort the numbers of smokers who want to and have tried to quit. This method of data collection is a scientifically recognized and accepted mode of inquiry for prevalence studies, which is relied upon to determine the population prevalence of other disorders, including alcohol dependence, cocaine dependence, and depression.²⁹⁸ Some of these are disorders for which, compared to tobacco use, interview methods would be less likely to reveal accurate results because of the criminal consequences associated with illicit drug use. Moreover, the authors of a study on this subject cited by the tobacco industry merely speculate that *some* smokers who say they want to quit *may* be dissembling, primarily on the basis of evidence that some smokers who claim to have quit smoking have been shown to be still smoking. At no time do these authors suggest that most smokers do not want to quit.²⁹⁹

4. The tobacco industry disputes that tobacco consumers continue to use despite knowledge of physical problems attributable to tobacco. The industry notes that, in one survey, a majority of smokers rated their overall health as good or excellent and

²⁹⁷ See, e.g., Hughes JR, Gulliver SB, Fenwick JW, *et al.*, Smoking cessation among self-quitters, *Health Psychology* 1992;11:331-334. *See* AR (Vol. 348 Ref. 5512).

²⁹⁸ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 175-272. *See* AR (Vol. 535 Ref. 96, vol. III.B).

²⁹⁹ Kozlowski LT, Herman CP, Frecker RC, What researchers make of what cigarette smokers say: filtering smokers' hot air, *Lancet* 1980;1(8170):699-700. *See* AR (Vol. 535 Ref. 96, vol. III.I).

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concludes from this that the smokers were not suffering ill health from tobacco use. The industry also criticizes studies cited by FDA that document high rates of smoking after catastrophic illness on the basis that (1) the sample sizes were small; and (2) some fraction of the subjects in the studies were able to quit.

After reviewing the evidence in the administrative record, FDA disagrees with the industry's position. To argue that a majority of smokers generally believe themselves in "good" or "excellent" health, the industry cites a Gallup poll originally cited by FDA.³⁰⁰ In fact, contrary to the industry's argument, this Gallup poll demonstrates that smokers continue to use tobacco despite health problems. Sixty-five percent of smokers in the survey admitted that "smoking has already affected their health." Moreover, the data reveal that: (1) *significantly fewer* smokers than nonsmokers rated their health as "excellent"; and (2) smokers rated their overall condition as *significantly less healthy* than nonsmokers did. Thus, this survey supports FDA's contention that smokers persist in using tobacco despite knowledge that their health has been harmed by smoking.

The industry's criticism of data cited by FDA on smokers continuing to use tobacco after myocardial infarction, lung cancer, and laryngeal cancer is not persuasive. The industry offers no contradicting evidence, nor does it suggest any reason why the studies cited by FDA might not be generalizable to the larger population. In the absence of such reasons, FDA believes that the sample sizes were adequate to permit such generalization.

³⁰⁰ Gallup GH, *Smoking Prevalence, Beliefs, and Activities by Gender and Other Demographic Indicators* (Princeton NJ: Gallup Organization, 1993), at 20, 37. See AR (Vol. 86 Ref. 1165).

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The industry finally makes the argument that some people with devastating disease from tobacco are able to quit smoking. This contention misses the point. Even in the most drastic of circumstances, when patients have lost part of their body to cancer from smoking or had part of their heart muscle die from smoking, many still cannot stop. That any significant number of people return to smoking after such devastating tobacco-related disease is a powerful illustration of the addictiveness of nicotine.

h. Comments on Nicotine's Other Significant Pharmacological Effects

1. The tobacco industry argues that many substances and activities tangentially affect the brain, but that a reliable criterion for a "substantial" pharmacological effect is intoxication. According to the comment, nicotine does not produce intoxication, and therefore its pharmacological effects are not substantial.

FDA disagrees. FDA has presented dozens of scientific studies and reviews to show that nicotine has numerous substantial pharmacological effects on the human body. The most significant of these is addiction, discussed at length in section II.A.3., above. Other examples of substantial effects include significant molecular changes in the brain, effects on weight regulation, and substantial alterations of mood, alertness, and cognition, none of which the industry contests. The vast majority of drugs that FDA already regulates, whose pharmacological effects are indisputable, do not produce intoxication. FDA notes that nicotine can cause intoxication. Indeed, first-time users often become intoxicated.³⁰¹ Regular users do so rarely because they have developed an extremely high level of tolerance to this effect of nicotine.³⁰²

³⁰¹ Surgeon General's Report, 1988, at 594. See AR (Vol. 129 Ref. 1592).

³⁰² *Id.* at 593-596.

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i. Comments on Whether Cigarettes and Smokeless Tobacco Deliver Pharmacologically Active Doses of Nicotine

1. Several professional organizations with expertise in pharmacology and addiction comment on the ability of cigarettes and smokeless tobacco to provide addictive doses of nicotine. These comments uniformly agree with the conclusion that cigarettes and smokeless tobacco do provide pharmacologically active doses of nicotine capable of producing addiction. These organizations include the College on Problems of Drug Dependence, which states:

Nicotine is appropriately categorized as an addictive drug. Data from both animals and humans indicate that nicotine produces tolerance, physical dependence, reinforcing psychoactive effects and it thus has the potential for becoming an abused substance. Regular cigarette smokers and habitual smokeless tobacco users obtain sufficient quantities of nicotine to produce these effects *Cigarettes and smokeless tobacco serve as highly effective and efficient drug delivery devices. They provide nicotine in quantities and patterns that enable users readily to develop and sustain dependence.*³⁰³

The American Society of Addiction Medicine concludes that *“nicotine in cigarettes and in smokeless tobacco is a pharmacologically active agent that causes addiction in a high proportion of users.”*³⁰⁴

Similar conclusions were reached by the American Psychological Association, which observes that *“[c]igarettes and smokeless tobacco serve as highly effective and*

³⁰³ College on Problems of Drug Dependence, Comment (Nov. 6, 1995), at 1 (emphasis added). See AR (Vol. 700 Ref. 1021).

³⁰⁴ American Society of Addiction Medicine, Comment (Dec. 29, 1995), at 1 (emphasis added). See AR (Vol. 528 Ref. 97).

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efficient drug delivery systems, which by their very design enable people to readily develop and sustain nicotine addiction."³⁰⁵

FDA agrees with these independent scientific bodies.

2. The tobacco industry takes issue with FDA's citations of studies to show that certain levels of nicotine cause pharmacological effects.

The tobacco industry argues that three studies cited by FDA to estimate the minimum pharmacological dose of nicotine do not show that tobacco products cause significant pharmacological effects. The industry also contends that two studies cited by FDA to show that smokers can control their nicotine intake do not reflect common tobacco consumption behavior.

The industry mischaracterizes FDA's reasons for citing the studies. FDA did not cite animal research and a study on the nicotine nasal spray to prove that cigarettes cause pharmacological effects in humans. Rather, the studies were cited to demonstrate that a very low blood level of nicotine that is easily attainable with cigarettes produces pharmacological effects across species. This observation complements overwhelming evidence from clinical, epidemiological, and laboratory studies showing that cigarettes and smokeless tobacco cause significant pharmacological effects in humans.

Similarly, FDA did not cite studies on the extremes of nicotine intake to demonstrate exactly how much nicotine every smoker obtains. Rather, the studies were cited to demonstrate that nicotine intake from cigarettes has the potential to vary widely across a range of levels that produce significant pharmacological effects in humans.

³⁰⁵ American Psychological Association, Comment (Dec. 28, 1995), at 2 (emphasis added). See AR (Vol. 531 Ref. 123).

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FDA also notes that the industry offers no data contradicting FDA's studies. The industry also fails to contest other sources cited by FDA—including some from the tobacco industry—that clearly support the conclusion that nicotine levels in commercial tobacco products produce significant pharmacological effects in consumers. *See* Jurisdictional Analysis, 60 FR 41571–41572, 41632–41640.

Finally, FDA notes that the industry misinterprets a study by Perkins *et al.*³⁰⁶ on nicotine nasal spray. *See* section II.A.7.d., above.

3. The industry contends that nicotine doses provided by cigarettes produce only a “minimal response in laboratory animals and a small number of human subjects” and that, therefore, FDA has not established that nicotine doses delivered by cigarettes produce substantial pharmacological effects.

FDA disagrees. Many studies demonstrate such significant effects as systemic cardiovascular reactions in nontolerant humans and animals,³⁰⁷ sickness produced by a single tobacco exposure in nontolerant individuals,³⁰⁸ and changes in brain electrical activity comparable to those produced by other addictive drugs.³⁰⁹ As described in sections II.A.4., above, and II.B.2., below, use of tobacco also produces significant effects on attention, mood, cognition, and weight regulation. These are not minimal effects.

³⁰⁶ Perkins K, Grobe J, Scierka A, *et al.*, Discriminative stimulus effects of nicotine in smokers, in *International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II*, eds. Clarke PBS, Quik M, Thurau K, Adlkofer F (Basel: Birkhauser Verlag, 1994), at 111. *See* AR (Vol. 42 Ref. 111).

³⁰⁷ Surgeon General's Report, 1988, at 47. *See* AR (Vol. 129 Ref. 1592).

³⁰⁸ *Id.* at 594.

³⁰⁹ Pritchard WS, Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485–490, at 485, 488. *See* AR (Vol. 105 Ref. 965).

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Nicotine's capacity to produce and sustain addiction, as described in section II.A.2., above, is another example of a significant pharmacological effect.

Because the vast majority of chronic smokers are highly tolerant to nicotine, not all of the pharmacological effects of nicotine are evident with every cigarette and pinch of smokeless tobacco. As described in section II.A.3.c.i., above, the severe degree of tolerance produced by nicotine seems to greatly exceed that produced by cocaine and to be more comparable to that produced by morphine in the reduction of responsiveness to acute doses after a period of repeated exposure.

4. The tobacco industry argues that there is no "addictive level" of nicotine. This contention is partly based on the claim that nicotine intake is not well correlated with quitting success. The industry also argues that FDA's Drug Abuse Advisory Committee did not identify a threshold addictive dose of nicotine. Without such an "addictive level," the industry concludes, the nicotine in tobacco products cannot have a substantial pharmacological effect.

FDA disagrees. The tobacco industry misinterprets the scientific literature on cessation studies, the actual conclusion reached by the Committee, and the concept of "addictive level."

A large body of literature has shown that nicotine dependence level is among the strongest general predictors of withdrawal severity and duration of abstinence. *See* section II.A.7.f., above.³¹⁰ These data support the conclusion that the relationship between level of drug intake and dependence level is similar to that observed with other

³¹⁰ Surgeon General's Report, 1988, at 315-321, 522-523. *See* AR (Vol. 129 Ref. 1592).

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forms of drug addiction, namely that level of drug intake is generally but not precisely correlated positively with dependence level and that there is wide individual variability.³¹¹ It is because drug intake alone is not a perfect measure of dependence that diagnostic instruments such as the DSM are necessary for clinical practice.

The industry also misrepresents the findings of the FDA Committee, which concluded that all currently marketed cigarettes contain an addictive dose of nicotine, but that the data were not sufficient to determine a threshold dose below which the product would *not* pose a risk of addiction.³¹² The main concern of the Committee was that, in attempting to set a lower limit, any error on the high side would permit the industry to market products that would be addictive to some persons. The Committee was particularly concerned that persons who have not developed tolerance to nicotine, such as children, might find even the doses posed by Benowitz and Henningfield (approximately one-tenth of the delivery of a typical cigarette) to be addictive.³¹³

FDA concurs with the Committee that all currently marketed cigarettes contain addictive levels of nicotine.

5. The tobacco industry argues that any compensation occurring in response to cigarettes with lower yields of tar and nicotine is limited and of short duration. Thus, according to the industry, smokers of low-yield cigarettes do not obtain pharmacologically active doses of nicotine. The industry contends that this proposition is supported by an

³¹¹ *Id.* at 315-321.

³¹² Transcript to the FDA Drug Abuse Advisory Committee, Meeting 27, "Issues Concerning Nicotine-Containing Cigarettes and Other Tobacco Products" (Aug. 2, 1994), at 346-353. *See* AR (Vol. 255 Ref. 3445).

³¹³ *Id.* at 346-353.

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article by Benowitz and Henningfield.³¹⁴ The industry also argues that smokers actually compensate for changes in tar delivery rather than nicotine delivery. Furthermore, it denies that cigarette vent-hole blocking is a significant means of compensation. The industry thus argues that compensation for nicotine does not occur.

FDA disagrees. Tobacco industry research demonstrates that smokers significantly compensate for nicotine. For example, research presented at a tobacco industry conference in 1974 demonstrated that, “whatever the characteristics of cigarettes as determined by smoking machines, the smoker adjusts his pattern to deliver his own nicotine requirements.” *See* Jurisdictional Analysis, 60 FR 41663. Other examples of the tobacco industry’s understanding of compensation are documented in the Jurisdictional Analysis. *See* 60 FR 41572–41575.

Furthermore, FDA cited research in the Jurisdictional Analysis demonstrating that the actual amount of nicotine delivered to the smoker does not correlate with the machine-measured yield of the cigarette and that smokers who smoke “low-yield” cigarettes have been shown to obtain substantially more nicotine than the advertised yield. *See* 60 FR 41659-41665. In one study, for example, the advertised yield of tested cigarettes ranged from 0.1 to 1.6 mg of nicotine, but the actual nicotine intake by the smokers asked to smoke these cigarettes ranged from 0.75 to 1.25 mg.³¹⁵ Other studies have also found that the nicotine levels measured in smokers’ blood bear either no relationship or a minimal

³¹⁴ Benowitz NL, Henningfield JE, Establishing a nicotine threshold for addiction, *New England Journal of Medicine* 1994;331:123-125. *See* AR (Vol. 28 Ref. 218).

³¹⁵ Gori GB, Lynch CJ, Analytical cigarette yields as predictors of smoke bioavailability, *Regulatory Toxicology and Pharmacology* 1985;5:314-326. *See* AR (Vol. 12 Ref. 142).

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relationship to the nicotine yield of the cigarettes being smoked and that machine-measured yields of low-tar/low-nicotine cigarettes significantly underestimate true rates of nicotine absorption. In most of these studies, the subjects were people who were smoking their usual brand of cigarettes and showed levels of nicotine not related to Federal Trade Commission (FTC) yields, thus refuting the suggestion that compensation is short-lived.³¹⁶

The tobacco industry misrepresents the position of Benowitz and Henningfield on compensation. These authors have repeatedly published research demonstrating that smokers compensate with current cigarettes by smoking harder or by blocking the vent holes.³¹⁷

In the Benowitz and Henningfield paper cited by the tobacco industry, the authors were discussing cigarettes—not currently on the market—with so little available nicotine that it would be impossible to compensate for reduced nicotine except by smoking an impractical number of cigarettes. The total nicotine content of these cigarettes would have been only about 5% of the content of currently marketed cigarettes and would have permitted a maximum delivery of only about 10% that of current cigarettes. The authors predicted that few smokers would permanently smoke the 200 or more cigarettes needed to obtain the nicotine intake typically delivered by 20 conventional cigarettes. Thus, Benowitz and Henningfield believed that, if denied access to regular nicotine cigarettes, smokers would either quit or adjust over time to substantially reduced nicotine intake.

³¹⁶ Surgeon General's Report, 1988, at 158-159. See AR (Vol. 129 Ref. 1592).

³¹⁷ *Id.* at 158-163.

Henningfield JE, Kozlowski LT, Benowitz NL, A proposal to develop meaningful labeling for cigarettes, *Journal of the American Medical Association* 1994;272:312-314. See AR (Vol. 313 Ref. 4846).

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This prediction is entirely inapplicable to currently marketed “low-yield” cigarettes delivering 0.1 mg of nicotine as measured by the smoking machine; a smoker need smoke only about 30 of these to obtain the amount of nicotine obtained with 20 “full flavor” cigarettes.³¹⁸

The tobacco industry’s denial that vent blocking occurs misses important points of FDA’s position on this issue. FDA has simply posed vent blocking as the most likely explanation for the well-documented fact that there is almost no difference in the nicotine levels observed in the bodies of smokers who smoke brands with widely varying FTC yields. Smoking more cigarettes is only one means by which smokers compensate. Vent blocking is another means at the smoker’s disposal to compensate. Indeed, the studies relied on by the tobacco industry suggest that the frequency of vent blocking is inversely proportional to the yield of the cigarette. In other words, the lower the tar and nicotine yield of the cigarette, the more the smoker blocks the vent holes. These data support the position that vent blocking plays an important role in compensation. There are, in addition, other compensation mechanisms, such as smoking more of the cigarette than is smoked in testing machines, smoking more aggressively, and taking deeper inhalations.³¹⁹

The tobacco industry contends that smokers may compensate for tar rather than for nicotine. This contention is contradicted by a very extensive body of literature, documented in detail in the 1988 Surgeon General’s Report,³²⁰ showing that, when the

³¹⁸ Transcript to the FDA Drug Abuse Advisory Committee, Meeting 27, “Issues Concerning Nicotine-Containing Cigarettes and Other Tobacco Products” (Aug. 2, 1994), at 106. See AR (Vol. 255 Ref. 3445).

³¹⁹ Surgeon General’s Report, 1988, at 153-158. See AR (Vol. 129 Ref. 1592).

³²⁰ *Id.* at 153-169, 282-283.

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level of nicotine in cigarettes is manipulated, smokers alter their smoke intake. Although the relationship is not perfect, it is similar to that which has been observed with other addictive drugs in numerous animal studies and some human studies. That is, when the dose of the drug in the cigarette is increased, the number of unit doses that are self-administered decreases generally, although not proportionally. This results in the frequent observation of increased overall drug intake.³²¹

Conversely, when the dose is decreased, the number of unit doses that are self-administered generally increases, although usually not proportionally. The relationship has been demonstrated with respect to cigarette smoking by: (1) administering nicotine to smokers via other routes, which results in decreased smoking; and (2) administering the nicotine blocker mecamylamine to smokers (which reduces the effects of nicotine on receptors in the brain), resulting in increased smoking.³²² A study on compensation for smokeless tobacco cited by the smokeless tobacco industry showed that users increased their consumption when switched to a low-nicotine product.³²³

³²¹ *Id.* at 282-283.

³²² *Id.* at 165-169.

³²³ Andersson G, Axell T, Curvall M, Reduction in nicotine intake and oral mucosal changes among users of Swedish oral moist snuff after switching to a low-nicotine product, *Journal of Oral Pathology & Medicine* 1995;24:244-250. See AR (Vol. 526 Ref. 95, vol. VII).

The low-nicotine product had a lower pH than the higher-nicotine product. Because lower pH reduces absorption see section II.D., below, measurements of nicotine intake cited by the industry do not accurately reflect compensation in this study.

II.B.**B. CONSUMERS USE CIGARETTES AND SMOKELESS TOBACCO TO OBTAIN THE PHARMACOLOGICAL EFFECTS OF NICOTINE AND TO SATISFY THEIR ADDICTION**

In section II.A., above, the Agency concludes that the foreseeable pharmacological uses of cigarettes and smokeless tobacco establish that tobacco manufacturers intend their products to affect the structure and function of the body. The Agency may find additional evidence of such intent through evidence that consumers commonly use tobacco products for pharmacological effects. Where consumers use a product predominantly or nearly exclusively to obtain any of the effects on the structure or function of the body produced by a substance, such evidence would alone be sufficient to establish manufacturer intent. *See ASH v. Harris*, 655 F.2d 239-240.

The Agency made extensive findings regarding consumer use of tobacco products in the Jurisdictional Analysis. *See* 60 FR 41576-41581. FDA received comments from the tobacco industry, public health and medical organizations and practitioners, and other members of the public. Upon review of the evidence in the administrative record and careful analysis of the comments on the Jurisdictional Analysis, the Agency concludes that the evidence demonstrates that consumer use of cigarettes and smokeless tobacco for the pharmacological effects of nicotine is predominant, in fact nearly exclusive. Moreover, the Agency finds that other factors associated with tobacco use—including taste and habit—are significant to almost all consumers only by their association with nicotine's pharmacological effects on the brain. Thus, FDA finds that actual consumer use of cigarettes and smokeless tobacco for the pharmacological effects of nicotine provides an

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independent basis for the conclusion that these products are intended to affect the structure and function of the human body.³²⁴

In section II.B.1., below, FDA discusses its authority to consider evidence of consumer use in establishing intended use. FDA presents its major findings and responds to significant comments in sections II.B.2. and 3., below. In section II.B.4., below, FDA responds to all other substantive comments.

1. “Intended Use” May Be Established on the Basis of Actual Consumer Use

The legislative history of the Act clearly states that consumer use can be probative of a product’s intended use. For example, the House Report on the Medical Device Amendments of 1976 states that “[t]he Secretary may consider . . . use of a product in determining whether or not it is a device.” H.R. Rep. 853, 94th Cong., 2d Sess. 14 (1976) (emphasis added), *reprinted in* An Analytical Legislative History of the Medical Device Amendments of 1976, Appendix III (Daniel F. O’Keefe, Jr. & Robert A. Spiegel, eds. 1976). Similarly, the legislative history of the 1938 Act states expressly that “the use to which the product is to be put *will determine the category into which it will fall.*” S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935) (emphasis added), *reprinted in* 3 Legislative History 660, 663.

³²⁴ In this case, there is evidence not only of actual consumer use, but other evidence of manufacturer intent, including: (1) evidence that nicotine’s addictive properties and other pharmacological effects are foreseeable to a reasonable tobacco manufacturer; and (2) evidence from the statements, research, and actions of manufacturers establishing that they intend their products to affect the structure or function of the bodies of tobacco users. See sections II.A., C., and D. Thus, although the evidence establishes that consumers use cigarettes and smokeless tobacco predominantly or nearly exclusively for the pharmacological effects of nicotine, this finding is not necessary to permit reliance on the evidence of actual consumer use. Relied on in conjunction with the other evidence of manufacturer intent, evidence of actual consumer use provides substantial additional support for the Agency’s conclusion.

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Like the legislative history, FDA's regulations on adequate directions for the use of drugs and devices also demonstrate that actual consumer use can be a basis for establishing a product's intended use. 21 CFR 201.5 (drugs); 21 CFR 801.5 (devices). Section 201.5, which specifies the "adequate directions" that must be provided on drug labeling, provides examples of the "intended uses" of a drug that must be included in any adequate labeling. These intended uses include both: (1) "uses for which it is prescribed, recommended, or suggested in its oral, written, print, or graphic advertising;" and (2) "*uses for which the drug is commonly used.*" 21 CFR 201.5 (emphasis added). Section 801.5 contains parallel provisions for devices. Because adequate directions for use are required only for the intended uses of a product, these regulations make the "common use" of a product a basis for determining "intended use."

Courts have also recognized that actual consumer use can be a persuasive basis for determining intent—even in the absence of other evidence that the manufacturer intends to affect the structure or function of the body. In *ASH*, the court explicitly recognized that actual "consumer intent" by itself could be a basis for imputing intent to the manufacturer:

Clearly, it is well established "that the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source." *Whether evidence of consumer intent is a "relevant source" for these purposes depends upon whether such evidence is strong enough to justify an inference as to the vendors' intent.* This requires a substantial showing. . . . In cases such as the one at hand, consumers must use the product predominantly—and in fact nearly exclusively—with the appropriate intent before the requisite statutory intent can be inferred.

655 F.2d at 239-240 (emphasis added). Similarly, in *NNFA v. Weinberger*, the court held that evidence before the Commissioner that vitamins "were used almost exclusively for

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therapeutic purposes” could be a proper basis to determine that the manufacturer intended a pharmacological use. 512 F.2d at 703.

When a finding of an intent to affect the structure and function of the body is based exclusively on evidence of actual consumer use, the evidence must meet a high threshold. As quoted above, the courts in *ASH* and *NNFA* have indicated that the evidence should show that the actual consumer use for drug purposes is “predominant” or “nearly exclusive.” FDA’s regulations contemplate that the use be shown to be at least “common.” 21 CFR 201.5.

There is no requirement, however, that a product be used nearly exclusively as a drug before FDA may regulate it as a drug. To the contrary, a product that has both pharmacological uses and nonpharmacological uses can be regulated as a drug. *See United States v. Guardian Chemical Corp.*, 410 F.2d 157, 162-163 (2d Cir. 1969)(a solvent used both to dissolve kidney stones (a drug use) and to clean instruments (a nondrug use) was properly regulated as a drug). Consistent with this principle, the courts recognize that where, as here, there is other evidence of manufacturer intent, consumer use for drug purposes may be relevant evidence of intended use even if that use is not predominant or nearly exclusive. *See, e.g., United States v. An Article of Device . . . Toftness Radiation Detector*, 731 F.2d 1253, 1257 (7th Cir. 1984); *United States v. 789 Cases . . . Latex Surgeons’ Gloves*, 799 F. Supp. 1275, 1285, 1294-95 (D.P.R. 1992); *United States v. 22 . . . devices . . . “The Ster-o-lizer MD-200,”* 714 F. Supp. at 1165; *United States v. An Article of Device . . . “Cameron Spitler Amblo-Syntonizer,”* 261 F. Supp. 243, 245 (D. Neb. 1966).

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Consistent with these authorities, the Agency finds that actual consumer use can be a basis for establishing the manufacturer's intended use for the product. Where the only evidence of intended use is the actual consumer use of the product, the Agency may need to show that the use of the product for pharmacological purposes is "predominant" or "nearly exclusive" before establishing that a product is intended to affect the structure or any function of the body. At a minimum, as set forth in FDA's regulations, the Agency should show that the use is "common" before relying exclusively on evidence of consumer use to establish intended use. Where, however, actual consumer use is only one of several types of evidence relied upon by the Agency, more limited evidence of consumer use can be used to support a finding that a product is "intended to affect the structure or any function of the body."

In the case of cigarettes and smokeless tobacco, as discussed below, the evidence establishes that the standard of "predominant" or "nearly exclusive" consumer use is met even though other types of evidence exist. Thus, the evidence of actual consumer use of cigarettes and smokeless tobacco provides an independent basis for establishing these products' intended pharmacological uses.

2. Consumers Use Cigarettes and Smokeless Tobacco for the Pharmacological Effects of Nicotine

The evidence on consumer use of cigarettes and smokeless tobacco convincingly demonstrates the intended use of such products for pharmacological purposes. In the following sections, FDA explains this conclusion and the epidemiological and experimental data that confirm that consumers *do* use cigarettes and smokeless tobacco predominantly for one or more of the pharmacological effects of nicotine.

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a. Epidemiological Evidence Shows That Consumers Use Cigarettes and Smokeless Tobacco for Pharmacological Effects

Epidemiological studies establish that the vast majority of consumers use tobacco for at least one of three pharmacological purposes: to satisfy a nicotine addiction; to receive the accompanying psychoactive effects, such as relaxation and stimulation; or to control weight.

To satisfy nicotine addiction. If a tobacco consumer is addicted to nicotine, then the key reason for use of the tobacco product is a pharmacological effect: the satisfaction of the addiction.

Based upon internationally accepted definitions of addiction from the American Psychiatric Association and the World Health Organization (WHO), major recent studies show that 77% to 92% of smokers are addicted to cigarettes. In various studies, smokers who met the criteria for addiction included those identified by self-report (90% addicted),³²⁵ those who used tobacco six or more times (87% addicted),³²⁶ those who were daily users for at least one month (77% to 92% addicted),³²⁷ and those who reported any current use of cigarettes (80% addicted).³²⁸ Studies show a *higher* percentage of

³²⁵ Hughes JR, Gust SW, Pechacek TF, Prevalence of tobacco dependence and withdrawal, *American Journal of Psychiatry* 1987;144(2):205-208. See AR (Vol. 81 Ref. 292).

³²⁶ Woody GE, Cottler LB, Cacciola J, Severity of dependence: data from the DSM-IV field trials, *Addiction* 1993;88:1573-1579. See AR (Vol. 13 Ref. 150).

³²⁷ Cottler L, Comparing DSM-III-R and ICD-10 substance use disorders, *Addiction* 1993;88:689-696. See AR (Vol. 13 Ref. 149).

³²⁸ Hale KL, Hughes JR, Oliveto AH, Helzar JE, Higgins ST, Bickel WK, Cottler LB, Nicotine dependence in a population-based sample, in *Problems of Drug Dependence, 1992*, NIDA Research Monograph 132 (Washington DC: Government Printing Office, 1993). See AR (Vol. 39 Ref. 60).

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addiction among tobacco users than among users of other addictive drugs, including cocaine and heroin.³²⁹

Although there have been no population-based studies using DSM or WHO criteria to assess rates of addiction to smokeless tobacco, substantial evidence demonstrates that a high proportion of smokeless tobacco users meet individual criteria for addiction. *See* section II.A.3.c.ii., above. This evidence strongly supports the conclusion that a substantial proportion of such users are addicted.³³⁰ In 1992, the Inspector General of the U.S. Department of Health and Human Services estimated that approximately 75% of young regular users of smokeless tobacco are addicted.³³¹

Evidence also demonstrates that many tobacco users continue to consume tobacco for an additional pharmacological reason related to addiction: to avoid withdrawal symptoms.³³² As addiction specialist Jerome Jaffe has noted, “[w]ithdrawal from nicotine . . . regularly motivates continued smoking.”³³³

³²⁹ Anthony JC, Warner LA, Kessler RC, Comparative epidemiology of dependence on tobacco, alcohol, controlled substances and inhalants: basic findings from the National Comorbidity Survey, *Experimental and Clinical Psychopharmacology* 1994;2:244-268. *See* AR (Vol. 37 Ref. 4).

³³⁰ Benowitz NL, Pharmacology of smokeless tobacco use: nicotine addiction and nicotine-related health consequence, in *Smokeless Tobacco or Health*, Smoking and Tobacco Control Monograph 2 (Washington DC: Government Printing Office, 1993), at 224. *See* AR (Vol. 93 Ref. 606).

³³¹ Department of Health and Human Services, Office on Smoking and Health, *Spit Tobacco and Youth* (Washington DC: Government Printing Office, 1992), at 8. *See* AR (Vol. 7 Ref. 76).

³³² Hughes JR, Higgins ST, Hatsukami D, Effects of abstinence from tobacco: a critical review, *Research Advances in Alcohol and Drug Problems* 1990;10:3170398, at 381. *See* AR (Vol. 535 Ref. 96, vol. III.G).

³³³ Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 529. *See* AR (Vol. 535 Ref. 96, vol. III.G).

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For stimulation, sedation, mood alteration, and cognition. Studies also reveal that a large proportion of consumers use tobacco for other psychoactive effects. For example, a recent survey of young people 10 to 22 years old found that 72.8% of daily smokers and 53.8% of daily consumers of smokeless tobacco said they used tobacco for relaxation.³³⁴ The 1988 Surgeon General's Report reviewed the epidemiological literature on the effects of smoking on mood: "The conclusion from this literature is that in the general population, persons perceive that smoking has functions that are relevant for mood regulation. Persons report that they smoke more in situations involving negative mood, and they perceive that smoking helps them to feel better in such situations."³³⁵ The Surgeon General's Report also noted that "some cigarette smokers believe that smoking helps them to think and concentrate."³³⁶ This is the belief of several prominent tobacco industry researchers.³³⁷ Data demonstrating significant consumer use for the pharmacologically mediated effects of nicotine on mood and arousal are summarized in the Jurisdictional Analysis. See 60 FR 41579-41580.

To control weight. Numerous studies show that tobacco use by many people is at least partially motivated by their belief that tobacco will help them control their weight.

³³⁴ Centers for Disease Control and Prevention, Reasons for tobacco use and symptoms of nicotine withdrawal among adolescents and young adult tobacco users—United States, 1993, *Morbidity and Mortality Weekly Report* 1994;43(41):745-750. See AR (Vol. 43 Ref. 162).

³³⁵ Surgeon General's Report, 1988, at 399. See AR (Vol. 129 Ref. 1592).

³³⁶ *Id.* at 382.

³³⁷ Robinson J, Transcript to the FDA Drug Abuse Advisory Committee, Meeting 27, "Issues Concerning Nicotine-Containing Cigarettes and Other Tobacco Products" (Aug. 2, 1994), at 227. See AR (Vol. 255 Ref. 3445).

Warburton DM, Nicotine: an addictive substance or a therapeutic agent, *Progress in Drug Research* 1989;33:9-41, at 25. See AR (Vol. 140 Ref. 1657).

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For example, in two surveys of young people, between one-third and one-half of smokers said that weight control was a reason for their smoking.³³⁸ Additional data on the use of tobacco products for weight control are summarized in the Jurisdictional Analysis. *See* 60 FR 41580–41581.

b. Experimental Evidence Shows That Consumers Use Cigarettes and Smokeless Tobacco Products for Pharmacological Effects

As described in section II.A.3.c.i., above, overwhelming laboratory data demonstrate that nicotine's pharmacological effects are central to tobacco use. Three findings from experimental studies particularly show that consumers smoke cigarettes and consume smokeless tobacco for the pharmacological effects of nicotine.

Nicotine reinforces tobacco consumption. Like other addictive substances such as amphetamine, morphine, and cocaine, nicotine acts on a key “reward” pathway in the brain—known as the mesolimbic system—to reinforce its own consumption.³³⁹ As even the tobacco industry has noted, the “reward” generated by this pathway may explain why people eat food, drink water, and consume salt. The ability of nicotine to generate a similar “reward” for tobacco consumption reflects its pharmacological power and represents a clear reason why consumers use tobacco products. The data supporting nicotine's role in the “reward” system are discussed in section II.A.3.c.i., above.

Nicotine controls smoking behavior. It has been convincingly demonstrated that smokers adapt their cigarette consumption to maintain the pharmacological effect of nicotine in

³³⁸ Surgeon General's Report, 1988, at 438–441. *See* AR (Vol. 129 Ref. 1592).

³³⁹ *See, e.g.,* Corrigan WA, Franklin KBJ, Coen KM, *et al.*, The mesolimbic dopaminergic system is implicated in the reinforcing effects of nicotine, *Psychopharmacology* 1992;107:285–289. *See* AR (Vol. 8 Ref. 93–4).

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the brain. Thus, smokers given cigarettes lower in nicotine change their smoking behavior to obtain more nicotine, and those given cigarettes higher in nicotine than their usual brand modify their behavior to obtain less. When given a drug to reduce the effect of nicotine in the brain, smokers will consume more of the same cigarettes, even though nothing else has changed. This is compelling evidence that nicotine plays a pivotal role in why consumers use tobacco products. These data are discussed in detail in section II.A.5., above.

Nicotine in other forms affects tobacco consumers. The ability of nicotine nasal spray to produce some of the classic characteristics of addiction to nicotine supports the position that tobacco users seek tobacco primarily for the systemic pharmacological effects of nicotine. In contrast to cigarette smoke, aqueous nicotine spray does not provide any pleasing sensory characteristics. In fact, the spray can be irritating and unpleasant to use, and excessive use can cause nasal ulcerations. Notwithstanding the unpleasantness of the nicotine delivery mechanism and the presence of painful ulcerations that were further aggravated by continued use of the spray, some participants in clinical trials submitted to FDA used the spray to maintain nicotine dependence.³⁴⁰

Studies on nicotine replacement therapies also demonstrate efficacy in maintaining abstinence from smoking.³⁴¹ The ability of nicotine to promote abstinence, even when delivered through the skin, without any taste or flavor, demonstrates its key role in maintaining tobacco consumption.

³⁴⁰ FDA Drug Abuse Advisory Committee background information (Aug. 1, 1994), Joint Abuse Liability Review of Nicotine Nasal Spray. *See* AR (Vol. 9 Ref. 117).

³⁴¹ *See* appendix 1 to Jurisdictional Analysis at 62-82. *See* AR (Vol. 1 Appendix 1).

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c. The Data Do Not Support the Industry's Claim That Consumers Seek Nicotine for Its Sensory Effects Rather than Its Pharmacological Effects

The tobacco industry responds to the overwhelming evidence that nicotine's pharmacological actions are central reasons for tobacco consumption by arguing instead that nicotine's key role in tobacco products is for flavor. According to the industry, the nonpharmacological actions of nicotine such as "flavor" are so essential to consumers that the nicotine level in each cigarette and unit of smokeless tobacco must be carefully controlled.

This argument in no way contradicts any of the experimental and epidemiological evidence showing that consumers use tobacco products for the pharmacological effects of nicotine. These studies prove nicotine's central pharmacological importance by demonstrating, for example, that: (1) nicotine causes psychoactive effects characteristic of addiction even when delivered by nonoral routes, where there is no "flavor" at all; and (2) the vast majority of smokers are addicted to tobacco products.

Moreover, the industry's position that nicotine's primary role is to provide flavor is inconsistent with the evidence. First, the industry's position is flatly contradicted by numerous statements of its own scientists and executives. Several industry documents dismiss the role of nicotine in flavor. For example, in 1974, an American Tobacco Company manager concluded that Pall Mall and Lucky Strike cigarettes tasted virtually the same even after the addition of extraneous nicotine (referred to as "Compound W"); according to the manager, "increasing the level of nicotine in the smoke by the addition of

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Compound W has *little, if any*, effect on taste.”³⁴² A Philip Morris presentation that discusses the importance of flavor in ultra-low cigarettes states flatly that “nicotine is an inexpensive, *tasteless* constituent.”³⁴³ Philip Morris’ comments similarly contradict the industry’s position that nicotine has a significant role in the flavor of cigarettes. These comments state that Philip Morris conducted extensive investigations into the flavors in cigarette smoke using an “olfactometer,” yet Philip Morris claims that “[n]one of that olfactometer work involved nicotine at all,” an unlikely omission if nicotine is an important flavor component.³⁴⁴

Tobacco industry documents also reveal that the industry draws a consistent distinction between nicotine’s role in tobacco use and the role of flavor. A Brown & Williamson study emphasized the importance of nicotine delivery over all other product features and specifically distinguished the effects of nicotine from the taste and flavor characteristics of tobacco:

In considering which product features are important in terms of consumer acceptance, the nicotine delivery is one of the more obvious candidates. *Others include the taste and flavour characteristics* of the smoke, physical features such as draw resistance and rate of burn, and the general uniformity of the product, to name but a few. The importance of nicotine hardly needs to be stressed, as it is so widely recognised.³⁴⁵

³⁴² Memorandum from Irby RM (manager, new products division) to McCarthy JB (executive vice president, research and development), *Nicotine Content of Reconstituted Tobacco* (Jun. 5, 1974), at 3-4 (emphasis added). See AR (Vol. 26 Ref. 357-3)

³⁴³ Philip Morris Inc., First Speaker, Merit Team Remarks (Jan. 14, 1976), at 3 (emphasis added). See AR (Vol. 640 Ref. 2).

³⁴⁴ Philip Morris Inc., Comment (Apr. 19, 1996), at 47. See AR (Vol. 700 Ref. 226).

³⁴⁵ BATCO, *Project Wheat-Part 1: Cluster profiles of U.K. male smokers and their general smoking habits*, Southampton, England (Jul. 10, 1975), at 3-4 (emphasis added). See AR (Vol. 20 Ref. 204-1).

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An internal RJR document shows that the industry views nicotine's role as pharmacological and distinct from the smoke components that provide flavor:

If nicotine is the sine qua non of tobacco products, and tobacco products are recognized as being attractive dosage forms of nicotine, then it is logical to design our product - and where possible our advertising - *around nicotine delivery rather than tar delivery or flavor.*³⁴⁶

Other industry documents further demonstrate that the industry understands that nicotine's role is primarily pharmacological and that any sensory role is secondary. A variety of industry documents shows that industry knows that "satisfaction" comes from inhalation of nicotine into the lungs and absorption into the bloodstream. *See* Jurisdictional Analysis, 60 FR 41773-41774. Inhalation is necessary only to provide systemic pharmacological effects; it would be unnecessary if nicotine's role were to provide sensory effects. The statements of tobacco industry scientists confirm that nicotine's pharmacological effects are the primary reason for tobacco use. A leading tobacco research director noted as early as 1972 that "[t]he primary incentive to cigarette smoking is the immediate salutary effect of inhaled smoke upon body function *the physiological effect serves as the primary incentive; all other incentives are secondary.*"³⁴⁷ As recently as 1992, RJR researchers recognized that "smokers use cigarettes primarily as a 'tool' or 'resource' that provides them with needed psychological benefits (increased mental alertness; anxiety reduction, coping with stress)."³⁴⁸

³⁴⁶ Teague CE, *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Feb. 2, 1973), at 3 (emphasis added). *See* AR (Vol. 531 Ref. 125).

³⁴⁷ Dunn WL, Philip Morris Research Center, *Motives and Incentives in Cigarette Smoking* (1972), at 3-4 (emphasis added). *See* AR (Vol. 34 Ref. 582).

³⁴⁸ Robinson JH, Pritchard WS, The role of nicotine in tobacco use, *Psychopharmacology* 1992; 108: 397-407 (emphasis added). *See* AR (Vol. 104 Ref. 945).

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Literally dozens of such statements—made over decades by tobacco researchers and executives from virtually every major company—expose the industry’s knowledge that consumers use tobacco products primarily for pharmacological effects. These statements are analyzed in depth in section II.C.2., below. By contrast, over this long period, there are virtually no tobacco company studies supporting the importance of the purported “sensory effects” of nicotine.

Second, the industry offers no persuasive data that nicotine contributes significantly to desirable flavor. FDA has reviewed all seven studies cited by the tobacco industry to demonstrate a significant “sensory” role for nicotine and finds them unpersuasive.

The industry cites a single abstract, based on research partially funded by RJR, to justify the claim that nicotine provides “trigeminal (‘throat grab’) stimulation that is enjoyed by smokers.” The abstract describes a single study of trigeminal nerve manipulation in rats.³⁴⁹ It is impossible to conclude from this study that nicotine stimulates the human trigeminal nerve in any manner significant to smokers.³⁵⁰

The industry cites a single paper to show that nicotine provides aroma “that is enjoyed by smokers.” This research is based on recordings of the olfactory nerve in frogs.

³⁴⁹ Silver WL, Walker DB, *Nasal trigeminal chemoreception: response to nicotine*, presented at the Ninth Annual Meeting of the Association for Chemoreceptor Sciences, Sarasota FL (1987). See AR (Vol. 535 Ref. 96, vol. III.M).

³⁵⁰ The industry’s “trigeminal nerve” theory seems to be based in part on an anatomic misunderstanding. The industry proposes that the sensation of “throat grab” is caused by nicotine stimulation “in the back of the throat (where trigeminal nerve endings are located).” In fact, sensation to the back of the throat (pharynx) in humans is provided by the glossopharyngeal nerve, not by the trigeminal nerve. See Williams PL, Warwick R, eds., *Gray’s Anatomy*, 37th ed. (Philadelphia: WB Saunders, 1989), at 1112. See AR (Vol. 711 Ref. 8).

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It is impossible to conclude from this study that nicotine creates an aroma of any significance to smokers.³⁵¹ Indeed, another study also cited by the industry concluded that reducing the olfactory stimulus of cigarettes had a minor effect on smoking behavior.³⁵²

RJR cites one article from 1952 and three recent studies to support the contention that the sensory aspects of nicotine consumption are more important to users than its pharmacological effects.

In a 1952 article cited by RJR for the proposition that nicotine plays an important role in the taste and flavor of cigarette smoke, there are no data on this subject.³⁵³ The relevant statements are merely the authors' speculations. In fact, the authors speculated about the flavors of various types of tobacco leaves, not about the specific flavor of nicotine. Nor did the authors distinguish between flavor and pharmacological effects of nicotine; to the contrary, a portion of the article omitted by the comment states that "the smoker's desires are not satiated by" a low-nicotine leaf. This observation is consistent with the conclusion that consumers value nicotine for its pharmacological effects.

A more recent study cited by RJR attempted to quantify the sensory responses to cigarettes containing varying levels of nicotine.³⁵⁴ This study did not even consider

³⁵¹ Thurauf N, Renner B, Kobal G, Responses recorded from the frog olfactory epithelium after stimulation with r(+) - and S(-) - nicotine, *Chemical Senses* 1995;20(3):337-344, at 342. See AR (Vol. 535 Ref. 96, vol. III.M).

³⁵² Baldinger B, Hasenfratz M, Battig K, Switching to ultralow nicotine cigarettes: effects of different tar yields and blocking of olfactory cues, *Pharmacology, Biochemistry and Behavior* 1995;50(2):233-239, at 238. See AR (Vol. 535 Ref. 96, vol. III.A).

³⁵³ Darkis FR, Baisden LA, Gross PM, Wolf FA, Flue-cured tobacco: chemical composition of rib and blade tissue, *Industrial and Engineering Chemistry* 1952;44(2):297-301, at 300-301. See AR (Vol. 519 Ref. 103, vol. II).

³⁵⁴ Gordin HH, Perfetti TA, Mangan PP, A quantification of sensory responses related to dynamic cigarette performance variables, *Tobacco Science* 1987;31:23-27. See AR (Vol. 519 Ref. 103, vol. II).

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whether any sensory responses to nicotine are important to smokers. The authors did not mention the number of subjects in the study. Nor did they account for the fact that cigarettes with varying nicotine levels also were different in many other ways; for example, they had different tip drafts, tipping porosities, plug wraps, and air dilution. Much of the data were not published with the study. FDA notes that this study—despite serious flaws—still found that tobacco taste was *not* associated with nicotine content.

A second recent study cited by RJR attempted to determine the smallest amount of nicotine change detectable to the user.³⁵⁵ It did not address whether any nicotine change produces any important sensory effects. The authors concluded only that there is a detectable “perceptual response” to nicotine, which could be described as either throat harshness or “strength.” The study did not distinguish between sensory and central pharmacological effects of nicotine.

The third recent study is an RJR presentation at a conference held in 1994, after FDA’s investigation into nicotine was under way.³⁵⁶ The presentation purported to show that nicotine’s sensory effects are important in a consumer’s acceptance of tobacco products, but the study failed to support this claim. Indeed, a principal author of the study conceded to FDA in 1994 that “we were not able to separate out the importance of the

³⁵⁵ Gordin HH, Perfetti TA, Hawley RW, Nicotine just noticeable difference study of full flavor low “tar” and ultra low “tar” non-menthol 85mm products, *Tobacco Science* 1988;32:62-65. See AR (Vol. 519 Ref. 103, vol. II).

³⁵⁶ Pritchard WS, Robinson JH, *The Sensory Role of Nicotine in Cigarette “Taste,” Smoking Satisfaction and Desire to Smoke*, presented at the International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II, Montreal (Jul. 21-24, 1994). See AR (Vol. 519 Ref. 103, vol. II).

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sensory aspects versus the pharmacological.”³⁵⁷ FDA notes that this study, despite serious flaws, still found that nicotine levels had *no* effect on smooth taste, harsh taste, or aftertaste of cigarettes.

Thus, the industry has presented no data that show that nicotine’s flavor or sensory effects are important to consumer acceptance. Even if the industry had produced evidence to support its position, however, nicotine’s pharmacological effects would still explain virtually all consumer use. As described in section II.B.3., below, the sensory aspects of tobacco consumption are important to consumers only in how they are linked to the pharmacological effects of nicotine.

Compared with the hundreds of studies conducted around the world demonstrating the pharmacological significance of nicotine to tobacco consumers—a conclusion that reflects universal scientific agreement—the evidence to support the assertion that nicotine’s sensory role is important to consumers is unconvincing. Thus, the industry has provided no basis to conclude that nicotine’s role in tobacco use is to provide taste, flavor, or any other nonpharmacological sensation.

3. Other Factors Associated with Tobacco Use Are Secondary to Pharmacological Effects

FDA has established above that consumers use tobacco products for the pharmacological effects of nicotine. The tobacco industry argues that consumers use tobacco for a variety of nonpharmacological purposes, including for taste, out of habit and ritual, and for social reasons. The Agency recognizes that there are many effects of

³⁵⁷ Robinson J, Transcript to the FDA Drug Abuse Advisory Committee, Meeting 27, “Issues Concerning Nicotine-Containing Cigarettes and Other Tobacco Products” (Aug. 2, 1994), at 228. See AR (Vol. 255 Ref. 3445).

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tobacco use perceived by some consumers as nonpharmacological in nature. In surveys, for example, some tobacco users say they like the taste of the product; others report enjoying the ritual involved in its consumption. The evidence before the Agency demonstrates, however, that the nonpharmacological factors associated with tobacco consumption are secondary to the pharmacological reasons for consumer use of tobacco. Indeed, FDA concludes that consumers use tobacco products “nearly exclusively” for the pharmacological effects of nicotine.

This conclusion is supported by comments from the Coalition on Smoking OR Health, representing the American Heart Association, American Lung Association, and American Cancer Society. The Coalition explains:

The physicians and health professionals who comprise our organizations provide the health care for virtually all tobacco users in the United States. Based upon our long term experience as well as our review of the scientific literature, it is our conclusion that the *vast majority of people who use nicotine containing cigarettes and smokeless tobacco products do so to satisfy their craving for the pharmacological effects of nicotine*; that is, to satisfy their drug dependence or addiction. While the published scientific literature on the point is conclusive in our scientific opinion, there may be no better evidence of the reason people use these products than the accumulative, daily experience of the health care professionals who are our members.³⁵⁸

One basis for FDA’s finding of nearly exclusive tobacco use for nicotine’s pharmacological effects is that tobacco products do not exist commercially without nicotine. If taste, for example, were an independent reason for use of tobacco products—as claimed by the industry—one would expect to find that very-low-nicotine products that

³⁵⁸ Coalition on Smoking or Health, Comment (Jan. 2, 1996), at 6 (emphasis added). See AR (Vol. 533 Ref. 102).

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preserve tobacco taste would be popular on the market. But there are no such products. The tobacco industry itself knows that a tobacco product without nicotine is not acceptable to consumers. For example, an attorney representing RJR stated that the company would never eliminate nicotine from its cigarette alternative, because “without nicotine, you don’t have a cigarette.”³⁵⁹ A former Philip Morris researcher similarly stated that it was well-known within Philip Morris that nicotine delivery was more important than flavor in consumer acceptance of cigarettes. According to this researcher, it was believed within the company that while consumers might accept a cigarette that had adequate nicotine but marginal flavor, they were unlikely to accept a cigarette with relatively good flavor but “not enough” nicotine.³⁶⁰

A second basis for FDA’s finding is that the details of tobacco use can be distinguished from the basic motivation for tobacco use. For example, researchers have demonstrated that consumers will pick a favorite cigarette brand among several that deliver adequate nicotine.³⁶¹ Habits may also explain specific patterns of cigarette consumption. For example, a smoker may enjoy smoking during his afternoon work break; another may like to smoke in the company of a particular friend. These factors commonly determine the details of use of many addictive substances, including opioids

³⁵⁹ Memorandum of meeting between Hutt PB, representing RJR Nabisco Inc., and FDA representatives (Oct. 23, 1987). *See* AR (Vol. 34 Ref. 558).

³⁶⁰ Declaration of Uydess IL (Feb. 29, 1996), at 11-14. Comments concerning this declaration are addressed in section II.C.6., below. *See* AR (Vol. 638 Ref. 1).

³⁶¹ Boren JJ, Stitzer ML, Henningfield JE, Preference among research cigarettes with varying nicotine yields, *Pharmacology, Biochemistry and Behavior* 1990;36(1):191-193. *See* AR (Vol. 535 Ref. 96, vol. III.A).

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and alcohol.³⁶² But they are separate from the underlying reason for such use, the pharmacological effects of the drugs.

Third, FDA agrees with experts in the field of addiction medicine that nonpharmacological factors associated with tobacco use are important to consumers only because they have become inextricably linked to nicotine's pharmacological effects. Extensive research in the field of behavioral psychology has demonstrated how animals and people come to associate environmental stimuli (taste, rituals, etc.) with the pharmacological effects of addictive drugs. In the extreme form, providing the stimulus alone leads to the user experiencing the pharmacological effect of the drug. This is called a "conditioned response." Thus, a heroin user who says he likes the feel of the needle in his arm has linked the sensation with the pharmacological "high" that inevitably follows. This heroin addict may even report a "high" after the injection of saline.³⁶³ But he or she still injects "nearly exclusively" for the pharmacological effects of heroin.

Similarly, evidence in animals and humans demonstrates that nonpharmacological factors such as taste and habit are important to tobacco consumers only because they have become inextricably linked to the effects of the addictive drug. As one prominent addiction specialist noted, "Animal experiments support the view that the sensory and

³⁶² Surgeon General's Report, 1988, at 15. See AR (Vol. 129 Ref. 1592).

³⁶³ O'Brien CP, Testa T, Ternes J, Greenstein R, Conditioning Effects of Narcotics in Humans, in *Behavioral Tolerance: Research and Treatment Implications*, NIDA Research Monograph 18 (Washington DC: Government Printing Office No. 017-024-00899-8, Jan. 1978), at 67-71. See AR (Vol. 535 Ref. 96, vol. ILL).

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olfactory stimuli associated with tobacco-using behavior function as conditioned stimuli due to their previous association with nicotine.”³⁶⁴

Clinicians who treat patients dependent upon tobacco products have reached the same conclusion.³⁶⁵ For example, some smokers identify the sensation of “tracheal scratch” associated with inhalation as pleasurable. But, as the American Society of Addiction Medicine (ASAM) comments:

The tracheal ‘scratch’ which arises from the inhalation of cigarette smoke is a sensation which has become paired with the absorption of nicotine into the bloodstream and the consequent effects of nicotine on the brain. *People do not smoke for the ‘scratch’; they smoke for the nicotine.* The “scratch” tells the smoker that nicotine is on its way to the brain and provides some indication of the relative dose which will shortly be coming.³⁶⁶

Other evidence of “conditioned responses” comes from studies of the early stages of tobacco withdrawal, when providing the environmental stimuli of smoking without nicotine (i.e., very-low-nicotine cigarettes) alleviates some of the abstinent smokers’ discomfort.³⁶⁷ This is analogous to heroin users feeling a psychological benefit from injecting saline when heroin is not available.³⁶⁸ In both cases, the benefits of the

³⁶⁴ Jaffe JH, Tobacco smoking and nicotine dependence, in *Nicotine Psychopharmacology* (Oxford: Oxford University Press, 1990), 1-29, at 14. See AR (Vol. 535 Ref. 96, vol. III.G).

³⁶⁵ Benowitz NL, Cigarette smoking and nicotine addiction, *Medical Clinics of North America* 1992;76(2):415-437. See AR (Vol. 535 Ref. 96, vol. III.A).

³⁶⁶ American Society of Addiction Medicine, Comment (Dec. 29, 1995), at 5 (emphasis added). See AR (Vol. 528 Ref. 97).

³⁶⁷ Butschky MF, Bailey D, Henningfield JE, Pickworth WB, Smoking without nicotine delivery decreases withdrawal in 12-hour abstinent smokers, *Pharmacology, Biochemistry and Behavior* 1995;50(1):91-96. See AR (Vol. 442 Ref. 7484).

³⁶⁸ O’Brien CP, Testa T, Ternes J, Greenstein R, Conditioning Effects of Narcotics in Humans, in *Behavioral Tolerance: Research and Treatment Implications*, NIDA Research Monograph 18 (Washington DC: Government Printing Office No. 017-024-00899-8, Jan. 1978), at 67-71. See AR (Vol. 535 Ref. 96, vol. III.L).

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nonpharmacological stimuli rapidly decrease as the stimuli are no longer associated with the drug's effects.³⁶⁹

ASAM concluded: "People who use tobacco products build up rituals around nicotine ingestion and experience sensations in the process of using tobacco that become valuable to them. However, *these rituals would not exist, and the sensations would be of no value, but for the associated delivery of nicotine to the brain.*"³⁷⁰ Thus, when someone says he or she smokes for the "taste" or "feel" or "ritual" of cigarette consumption, these "reasons for use" are inextricably tied to the pharmacological effects of nicotine.³⁷¹

Accordingly, FDA concludes that consumers use tobacco products "predominantly" and "nearly exclusively" for one or more of the pharmacological effects of nicotine.

4. Responses to Additional Comments

a. General Comments on Consumer Use

1. The American Society of Addiction Medicine (ASAM) argues that the common practice of inhaling cigarette smoke demonstrates that consumers use cigarettes for the pharmacological effects of nicotine. According to ASAM, because of the relatively

³⁶⁹ *Id.*

Butschky MF, Bailey D, Henningfield JE, Pickworth WB, Smoking without nicotine delivery decreases withdrawal in 12-hour abstinent smokers, *Pharmacology, Biochemistry and Behavior* 1995;50(1):91-96. See AR (Vol. 442 Ref. 7484).

³⁷⁰ American Society of Addiction Medicine, Comment (Dec. 29, 1995), at 14 (emphasis added). See AR (Vol. 528 Ref. 97).

³⁷¹ Surgeon General's Report, 1988, at 58-59. See AR (Vol. 129 Ref. 1592).

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low pH of cigarette smoke, nicotine absorption occurs to a significant extent only in the lungs. Conversely, ASAM notes that no important sensory effects are known to result from cigarette smoke in the lungs. Thus, ASAM concludes that “inhalation is the key to nicotine absorption from cigarettes, and there is no reason other than nicotine absorption for the consumer to inhale the smoke.”³⁷²

ASAM further notes that tobacco advertisements historically encouraged consumers to inhale cigarette smoke; according to ASAM, such evidence demonstrates industry intent to ensure adequate nicotine delivery to smokers and thereby achieve substantial pharmacological effects.

FDA agrees that inhalation demonstrates that consumers use cigarettes for substantial pharmacological effects. According to *Gray's Anatomy*, there are no taste or smell receptors below the level of the larynx.³⁷³ No evidence suggests that smokers enjoy any physical sensations associated with smoke in their lungs other than by association with the pharmacological effects of nicotine. Yet smokers learn to inhale—despite such unpleasant reactions as coughing—when the only reason to do so is nicotine absorption.

Indeed, the industry itself has recognized that nicotine absorption is the reason people inhale smoke. In 1982, a leading industry researcher wrote that “[i]t is well known that nicotine can be removed from smoke by the lung and transmitted to the brain within seconds of smoke inhalation. Since it is the major or sole pharmacologically active agent

³⁷² American Society of Addiction Medicine, Comment (Dec. 29, 1995), at 5. See AR (Vol. 528 Ref. 97).

³⁷³ Williams PL, Warwick R, eds., *Gray's Anatomy*, 37th ed. (Philadelphia: WB Saunders, 1989), at 1169-1180. See AR (Vol. 711 Ref. 8).

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in smoke, it must be presumed that this is its preferred method of absorption and *thus why people inhale smoke.*"³⁷⁴

2. The smokeless tobacco industry argues that FDA fails to distinguish among different smokeless tobacco products. The comment contends that FDA has based its conclusions entirely on evidence about moist snuff and that this evidence is inapplicable to chewing tobacco.

FDA disagrees that it has ignored the distinction between moist snuff and chewing tobacco or that its evidence applies only to moist snuff. As described in the Jurisdictional Analysis, Benowitz and colleagues found that the rate and amount of nicotine absorption was similar for oral snuff and chewing tobacco in ten healthy volunteers.³⁷⁵ See Jurisdictional Analysis, 60 FR 41572. The total amount of nicotine absorbed from snuff and chewing tobacco was estimated to be 3.6 mg and 4.5 mg, respectively.³⁷⁶ This study confirms that as much or more nicotine is absorbed from each of these products as from cigarettes.

Additionally, in a study submitted by the industry, Walsh and colleagues reported on the use of smokeless tobacco in 1,300 U.S. college athletes.³⁷⁷ Of those surveyed who

³⁷⁴ Letter from Ayres CI (BATCO) to Kohnhorst EE (Brown & Williamson), transmitting partial summary of issues presented at Montebello Research Conference in 1982, at BW-W2-03949 (emphasis added). See AR (Vol. 34 Ref. 584-1).

³⁷⁵ Benowitz NL, Porchet H, Sheiner L, *et al.*, Nicotine absorption and cardiovascular effects with smokeless tobacco use: comparison with cigarettes and nicotine gum, *Clinical Pharmacology and Therapeutics* 1988;44:23-28. See AR (Vol. 12 Ref. 134-1).

³⁷⁶ *Id.*

³⁷⁷ Walsh MM, Hilton JF, Ernster VL, Masouredis CM, Grady DG, Prevalence, patterns, and correlates of spit tobacco use in a college athlete population, *Addictive Behavior* 1994;19:411-427. See AR (Vol. 526 Ref. 95, appendix VIII).

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used smokeless tobacco, 39% reported using snuff only, 41% reported using both snuff and chewing tobacco, and 16% reported using chewing tobacco only. (Four percent failed to indicate the type of smokeless tobacco used.) Athletes who used both snuff and chewing tobacco generally reported patterns of use that were similar to those of athletes who used snuff only. This study supports similar patterns of use in both snuff and chewing tobacco users and demonstrates use of either moist snuff or chewing tobacco for similar pharmacological effects, such as relieving stress, satisfying strong cravings, and relieving the discomfort of withdrawal.

Thus the use, effects, and nicotine absorption from chewing tobacco compare with moist snuff and cigarettes. *See also* section II.D., below.

b. Comments on Tobacco Use To Satisfy Addiction

1. The tobacco industry argues that FDA's claim in the Jurisdictional Analysis that 75% to 90% of smokers consume cigarettes to satisfy addiction is factually unsupported. The industry contends that FDA selectively extracted pieces of data from various studies to support this rate of nicotine dependence and that the studies FDA relied upon were conducted in sample populations of patients of substance abuse clinics who would have higher "scales of dependence" than the general population.

FDA disagrees. The Agency did not selectively choose studies or selectively extract data from the studies on which it relied to support the reported rates of nicotine dependence. Rather, FDA chose from the published literature those studies that met the following criteria: the study used a definition of addiction established internationally by major public health organizations, the study was capable of estimating the prevalence of nicotine addiction in a well-defined population, and the study used appropriate research

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methods, such as random sampling of a well-defined population, to estimate the prevalence of nicotine addiction. No study relied on surveying smokers at tobacco cessation clinics.

The four studies identified by FDA as satisfying the stated selection criteria for determining the population prevalence of nicotine addiction utilize two data sets and smoking populations. These sample populations represent a generalizable spectrum of smokers.

One of these populations (utilized in a study by Hughes *et al.*)³⁷⁸ included otherwise healthy, non-drug-abusing patients representative of a well-defined population. This was not a selectively extracted population, nor did it have an elevated prevalence of nicotine addiction, as argued by the tobacco industry. It consisted of over 1,000 middle-aged smokers randomly sampled from a well-defined population of male heads of households, who were otherwise representative of men of that age. The men entered the study by identifying themselves as smokers. These men, on average about 51.1 years of age, were estimated to have a lifetime prevalence of nicotine addiction of 90%. The authors report that smoking habits of the men in this study were similar to those reported in previous studies of middle-aged men.

The tobacco industry contests these data on the grounds that: (1) the subjects are representative of the heaviest 22% of U.S. smokers; and (2) the authors at the time argued that the DSM criteria for nicotine addiction were too expansive. The industry's first point is based on a statistical misinterpretation. The industry argues that since the average

³⁷⁸ Hughes JR, Gust SW, Pechacek TF, Prevalence of tobacco dependence and withdrawal, *American Journal of Psychiatry* 1987;144(2):205-208. See AR (Vol. 81 Ref. 292).

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cigarette consumption in the study was 28 cigarettes per day, and because 22% of smokers in 1991 consumed over 25 cigarettes per day, then the study applies to “at most, 22 percent of smokers.” But this reasoning confuses average and median consumption. The heaviest 22% of smokers, on average, consume far more than 25 or 28 cigarettes per day. For example, in 1985, almost half of the smokers in the group who smoked more than 21 cigarettes per day reported smoking 40 or more cigarettes a day.³⁷⁹ Thus, the average number of cigarettes smoked by heavy smokers is well above 28 per day. Accordingly, the smokers represented in the Hughes study smoke less, on average, than “the heaviest” smokers identified by the comment.

The industry’s second argument concerning the authors’ view of the DSM criteria is irrelevant. Although the researchers were initially surprised at the high rates of dependence revealed in this study, the DSM criteria have retained credibility and are widely accepted by clinicians for diagnosing substance dependence.

The second sample of data (utilized in studies by Woody *et al.*, Cottler, and Hale *et al.*)³⁸⁰ is derived from a population studied during the Substance Abuse Disorders Field Trials for DSM-IV. This sample population came from five sites around the United States

³⁷⁹ Department of Health and Human Services, Public Health Service, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, *Reducing the Health Consequences of Smoking—25 Years of Progress, a Report of the Surgeon General* (Atlanta: 1989), at 295. See AR (Vol. 130 Ref. 1593).

³⁸⁰ Woody GE, Cottler LB, Cacciola J, Severity of dependence: data from the DSM-IV field trials, *Addiction* 1993;88:1573-1579. See AR (Vol. 13 Ref. 150).

Cottler L, Comparing DSM-III-R and ICD-10 substance use disorders, *Addiction* 1993;88:689-696. See AR (Vol. 13 Ref. 149).

Hale KL, Hughes JR, Oliveto AH, Helzar JE, Higgins ST, Bickel WK, Cottler LB, Nicotine dependence in a population-based sample, in *Problems of Drug Dependence, 1992*, NIDA Research Monograph 132, (Washington DC: Government Printing Office, 1993). See AR (Vol. 39 Ref. 60).

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and ranged in age from 18 to 44 years. Some of the subjects were from the general population, and others were selected, by a random digit dialing method, from subjects treated for substance abuse. Three separate analyses, using different assumptions and methods, were performed on these data, and the estimates of nicotine dependence reported in three published articles ranged from 77% to 92%. There is no evidence that these rates of nicotine dependence in these sample populations are greater than those for a nonpredisposed population that smoked for the same period. Indeed, the population of non-drug-abusing middle-aged men studied by Hughes *et al.* had a rate of nicotine dependence that was consistent with, and even higher than, the rates found in the Woody *et al.*, Cottler, and Hale *et al.* studies.

One study of nicotine addiction rates cannot be used to establish the prevalence of nicotine addiction because the population examined was not representative of the spectrum of smokers. The sample population in this study by Breslau *et al.* consisted of 394 smokers 21 to 30 years of age who were randomly selected from a well-defined population in a health maintenance organization (HMO).³⁸¹ The median age was 26 years, and 51% of the smokers were addicted to nicotine. These studies reflect that rates of dependence on nicotine increase substantially with duration of exposure and with the smoker's age: Although 51% of these young smokers were dependent on nicotine, fully 90% of the middle-aged smokers in the study by Hughes *et al.* were dependent on nicotine. Moreover, Breslau *et al.* acknowledge that the rate of dependence found in this sample of young smokers may not be representative of the rate among all smokers.

³⁸¹ Breslau N, Kilbey MM, Andreski MA, Nicotine dependence, major depression, and anxiety in young adults, *Archives of General Psychiatry* 1991;48:1069-1074. See AR (Vol. 37 Ref. 17).

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In conclusion, the studies relied on by FDA were not chosen in a preferentially selected manner, but on the basis of study design and methodological considerations. The data sets reflect populations that can be considered representative of cross sections of the U.S. smoking population. There is no evidence to suggest that these studies are not generalizable to the population of smokers. FDA believes that these studies support the claim that 75% to 90% of smokers consume cigarettes to satisfy nicotine addiction. Comments of the American Psychiatric Association agree with this assessment, stating that "DSM based studies . . . found that 80%-90% of adult smokers are nicotine dependent."³⁸²

2. The tobacco industry argues that dependence can never be measured in a large population. This contention is disproved by the successful population-based studies just described. The industry's comments were premised on selective quotations from researchers, none of whom were actually agreeing with the assertion that all such studies are impossible or invalid.

3. The tobacco industry criticizes the data collection methods in the population studies FDA relied upon to support tobacco dependence rates. The industry argues that self-reporting results in inaccurate conclusions and cites an article by Kozlowski *et al.* to support this contention.³⁸³

FDA disagrees. This method of data collection is a scientifically recognized and accepted mode of inquiry for prevalence studies and is relied upon to determine the

³⁸² American Psychiatric Association, Comment (Jan. 2, 1996), at 2. See AR (Vol. 700 Ref. 1020).

³⁸³ Kozlowski LT, Herman CP, Frecker RC, What researchers make of what cigarette smokers say: filtering smokers' hot air, *Lancet* 1980;1(8170):699-700. See AR (Vol. 535 Ref. 96, vol. III.I).

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population prevalence of other disorders, including alcohol dependence, cocaine dependence, and depression.³⁸⁴ Some of these are disorders for which, compared to tobacco use, interview methods would be less likely to reveal accurate results because of the criminal consequences associated with illicit drug use. Moreover, agencies that have expertise in tracking the prevalence of disease in this country, such as the Centers for Disease Control and Prevention, rely on such studies.³⁸⁵ The tobacco industry itself cites multiple surveys based on self-reporting in its comments.

The industry also mischaracterizes the article by Kozlowski *et al.* The article does not support the industry's argument that all self-reported data in population studies are inaccurate. In the article, the authors suggest that self-reports of abstinence among people quitting smoking may be inflated. The authors do not suggest that any other information obtained by self-reporting is unreliable, nor do they give any reason to extrapolate their observations to reporting of other information about smoking behavior. Finally, despite their belief that some smokers may exaggerate the number and success of their attempts at abstinence, the authors never doubt that a large proportion of smokers try to quit.

Accordingly, FDA concludes that the methods used in the population prevalence studies are accepted and reliable.

³⁸⁴ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 175-272. See AR (Vol. 535 Ref. 96, vol. III.B).

³⁸⁵ See, e.g., Centers for Disease Control and Prevention, Reasons for tobacco use and symptoms of nicotine withdrawal among adolescents and young adult tobacco users—United States, 1993, *Morbidity and Mortality Weekly Report* 1994;43(41):745-750. See AR (Vol. 43 Ref. 162).

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c. Comments on Tobacco Use for Effects on Mood and Weight

1. The tobacco industry contends that FDA has not established that consumers use cigarettes or smokeless tobacco nearly exclusively either to affect mood or to control weight. According to the comment, the studies cited by FDA do not show that a high percentage of consumers use tobacco to affect mood or control weight and that there are an insufficient number of such studies upon which to base a conclusion.

This comment misinterprets the standard for establishing that a product is “intended to affect the structure or any function of the body” through consumer use. As noted in section II.B.1., above, some courts have suggested that where the Agency relies solely on consumer use to establish intended use, consumers must use the product predominantly or nearly exclusively for pharmacological purposes. These cases contain no requirement, however, that consumers use the product in question nearly exclusively for *each* individual pharmacological effect the product produces. Thus, there is no requirement that consumers use nicotine nearly exclusively for each of its pharmacological effects. It is sufficient to establish that consumers as a group use tobacco to obtain any of the several effects on structure or function sought by consumers (for example, to satisfy addiction, for other psychoactive effects, and to control weight). *See ASH v. Harris*, 655 F.2d at 240; *NNFA v. Mathews*, 557 F.2d at 334-336.

FDA also disagrees that there are insufficient studies to support the conclusion that consumers use tobacco to affect mood and control weight. The many studies cited by FDA conclusively show that the majority of tobacco consumers rely on tobacco products to achieve a relaxing or calming effect. *See Jurisdictional Analysis*, 60 FR 41579-41580.

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For example, one survey found that over 60% of smokers aged 16 to 44 believe that smoking reduces nervous irritation.³⁸⁶

The use of cigarettes for weight control is similarly established in numerous studies. These studies show that smokers believe that smoking keeps weight down and that weight control is a significant motivation to continue smoking. The Surgeon General's 1988 Report on Nicotine Addiction reviewed a large number of studies demonstrating that weight control is a powerful motivator for initiation and maintenance of smoking in as many as one-third to one-half of young smokers.³⁸⁷

d. Comments on Nonpharmacological Factors Associated with Tobacco Use

1. The tobacco industry quotes several addiction experts stating that there are social, emotional, and behavioral variables that explain patterns of tobacco use. The industry concludes that consumers do not use tobacco products "nearly exclusively" for the pharmacological effects of nicotine.

FDA disagrees. The industry confuses the details of tobacco use with the reason for use. While multiple factors may explain why a particular person decides to smoke a particular cigarette at a particular moment, data support only one reason why the vast majority of consumers use tobacco products day after day, year after year: to obtain the drug effects of nicotine.

³⁸⁶ McKennell AC, Smoking motivation factors, *British Journal of Social and Clinical Psychology* 1970;49(1):8-22. See AR (Vol. 13 Ref. 152-1).

³⁸⁷ Surgeon General's Report, 1988, at 438-439. See AR (Vol. 129 Ref. 1592).

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Indeed, the scientific consensus holds that nonpharmacological factors are important to consumers only because they are linked to the pharmacological effects of nicotine. Thus, Jed Rose, one of the key researchers cited by the industry to support the contention that consumers use tobacco for nonpharmacological reasons, refers to nonpharmacological factors as “sensory cues” that are used to meter nicotine intake.³⁸⁸

As described in section II.B.3., above, such cues become “conditioned” as they are associated with the pharmacological effects of nicotine on the brain. These environmental factors are certainly important to tobacco consumers, as they are to users of other addictive drugs,³⁸⁹ but they are not the primary reasons for use. As a tobacco industry executive in a speech to the company’s board of directors said:

[T]he psychosocial motive is not enough to explain continued smoking. Some other motive force takes over to make smoking rewarding in its own right. Long after adolescent preoccupation with self-image has subsided, the cigarette will even preempt food in times of scarcity on the smoker’s priority list . . . We are of the conviction . . . that the ultimate explanation for the perpetuated cigarette habit resides in the pharmacological effect of smoke upon the body of the smoker, the effect being most rewarding to the individual under stress.³⁹⁰

2. The cigarette manufacturers cite research suggesting that nicotine-free cigarettes have flavor³⁹¹ and may help smokers to quit.³⁹² They draw particular attention

³⁸⁸ Rose JE, Behm FM, Levin ED, Role of nicotine dose and sensory cues in the regulation of smoke intake, *Pharmacology, Biochemistry and Behavior* 1993;44:891-900. See AR (Vol. 8 Ref. 100).

³⁸⁹ Surgeon General’s Report, 1988, at 59. See AR (Vol. 129 Ref. 1592).

³⁹⁰ Wakeham H (Philip Morris, Inc.), *Smoker Psychology Research*, presented to Philip Morris board of directors (Nov. 26, 1969), at 237, 240. See AR (Vol. 11 Ref. 142).

³⁹¹ Levin ED, Behm FM, Rose JE, The use of flavor in cigarette substitutes, *Drug and Alcohol Dependence* 1990;26:155-160, at 159. See AR (Vol. 535 Ref. 96, III.J).

³⁹² Butschky MF, Bailey D, Henningfield JE, Pickworth WB, Smoking without nicotine delivery decreases withdrawal in 12-hour abstinent smokers, *Pharmacology, Biochemistry and Behavior* 1995;50(1):91-96. See AR (Vol. 442 Ref. 7484).

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to a recent presentation by Rose *et al.*, in which smokers given a denicotinized cigarette reported the same or slightly less relief of craving than smokers given intravenous nicotine, and less relief than smokers given their usual brand of cigarettes.³⁹³ They also reported more immediate satisfaction from the denicotinized cigarette than from intravenous nicotine, although less than from their usual brand. The denicotinized cigarette provided less psychological reward than did intravenous nicotine. The smokeless tobacco manufacturers also suggest that no-nicotine substitutes for smokeless tobacco may have helped some users remain abstinent. According to the industry, this research demonstrates that consumers use tobacco products for reasons other than nicotine.

FDA disagrees. The cited studies do suggest that low- or no-nicotine products can be used in research and in a small proportion of former users of tobacco products. Yet the products have been uniformly rejected by *tobacco consumers*, who do not view them as acceptable substitutes for cigarettes. When given a choice, tobacco users will not abandon nicotine for flavor, demonstrating the real reason they smoke. For example, Next, a denicotinized cigarette that was briefly marketed by Philip Morris, was removed from the market because, according to the company, it was not accepted by consumers.

The cited studies replicate many others that show that the most consistent and strongest effects are produced by nicotine-delivering cigarettes. It is not surprising that nicotine injections, which, according to the studies produced significant pain and burning at the site of injection, do not produce all the satisfaction of smoking nor duplicate the

³⁹³ Rose JE, Westman EC, Behm FM, Comparative effects of intravenous nicotine and de-nicotinized cigarette smoke, poster presented at the annual meeting of the Society for Research on Nicotine and Tobacco (Mar. 15-17, 1996), Washington, D.C. See AR (Vol. 711 Ref. 21).

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taste and throat sensations of smoking. As described in section II.B.3., above, the efficacy of nicotine-free cigarettes in alleviating some of the symptoms of withdrawal is consistent with the conclusion that social and environmental factors become associated with obtaining the pharmacological effects of nicotine, and thus are perceived as pleasurable as a “conditioned response,” but in and of themselves are not the reason people smoke. Low- or no-nicotine cigarettes may temporarily provide some relief to consumers as a result of the conditioned response to the sensorimotor aspects of smoking, but this response is subject to “rapid extinction” when nicotine is withheld.³⁹⁴ This phenomenon is similar to the temporary finding that heroin addicts feel pleasure from injecting themselves with saline.³⁹⁵

The study by Rose is entirely consistent with these findings. The study evaluated only the immediate effects of a denicotinized cigarette on craving reduction, satisfaction, and psychological reward. It did not attempt to evaluate any effects of denicotinized cigarettes on sustained satisfaction or relief of withdrawal symptoms. Rose himself has stated that smokers seek the sensory cues of smoking because “the repetition of the smoking act thousands of times per year by a moderately heavy smoker leads to a strong conditioned association between the sensory aspects of smoking . . . and the pharmacological effects of nicotine.”³⁹⁶ Therefore, according to Rose, “effective

³⁹⁴ *Id.*

³⁹⁵ O'Brien CP, Testa T, Ternes J, Greenstein R, Conditioning effects of narcotics in humans, in *Behavioral Tolerance: Research and Treatment Implications*, NIDA Research Monograph 18 (Washington DC: Government Printing Office No. 017-024-00899-8, Jan. 1978), at 67-71. See AR (Vol. 535 Ref. 96, vol. III.L).

³⁹⁶ Rose JE, Levin ED, Inter-relationships between conditioned and primary reinforcement in the maintenance of cigarette smoking, *British Journal of Addiction* 1991;86:605-609, at 605. See AR (Vol. 67 Ref. 58).

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treatment of tobacco abuse needs to take into account the influence of these sensory cues,”³⁹⁷ by, for example, providing the smoker with de-nicotinized cigarettes, in addition to strategies to eliminate nicotine dependency.³⁹⁸ He is explicit, however, that nicotine is the primary reinforcer of smoking behavior, and that desire for the sensory aspects of tobacco use is the result of conditioned reinforcement maintained by nicotine’s primary reinforcement.³⁹⁹

3. To support the argument that consumers use tobacco products for flavor, the tobacco industry cites research in which smokers’ satisfaction with smoking decreased when their upper airways were anesthetized.

Upon review of this research, FDA finds that the studies do not support the contention that consumers smoke cigarettes primarily for flavor. As described above, the researcher who led the study, Rose, believes that nonpharmacological factors associated with tobacco consumption are “cues” important to smokers only by association with nicotine’s pharmacological impact.

Moreover, the research cited does not establish that the reason for the drop in smoking satisfaction upon airway anesthetization was the blockade of sensory input from smoke. These decreases in satisfaction might have been due simply to the unpleasant sensation of upper airway anesthetization, not to any blockade of sensory input from smoke. In this study, satisfaction with “sham smoke” also dropped with anesthesia. Sham smoke was so diluted as to provide few pharmacological or sensory effects. Thus,

³⁹⁷ *Id.*

³⁹⁸ *Id.* at 607.

³⁹⁹ *Id.* at 605-606.

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providing anesthesia decreased the satisfaction of consuming real cigarette smoke *and placebo smoke*.⁴⁰⁰

The study does, however, provide data addressing the importance of the pharmacological aspects of smoking. Thirty minutes after smoking, the subjects who had received smoke delivering nicotine—*regardless of whether their throats had been anesthetized*—felt similarly satisfied. And their satisfaction was greater than that of those who had received “sham smoke.” Thus, the study indicated that nicotine produces smoking satisfaction *even in the absence of mouth and throat sensation*.

4. The tobacco industry cites three studies to support the argument that consumers use tobacco products out of “habit and ritual.”

Upon review of these studies, FDA concludes that they provide no evidence that “habit and ritual” are the primary motivation for use of tobacco products. As described at length above, “habit and ritual” are important to consumers of all addictive drugs, but only through their linkage to the pharmacological effects of the drug.

First, the industry cites a study in which some smokers did not consider the first cigarette of the day their favorite.⁴⁰¹ The observation relates to a detail of smoking rather than to underlying motivation; as described in section II.B.3., above, there are many reasons why an individual may desire a particular cigarette at a particular time. This is not evidence that “habit or ritual” is the driving biological force for maintenance of tobacco use.

⁴⁰⁰ Rose JE, Tashkin DP, Ertle A, Zinser MC, Lafer R, Sensory blockade of smoking satisfaction, *Pharmacology, Biochemistry and Behavior* 1985;23:289-293, at 290 (emphasis added). See AR (Vol. 42 Ref. 124).

⁴⁰¹ Jarvik M, Killen JD, Varady A, Fortmann SP, The favorite cigarette of the day, *Journal of Behavioral Medicine* 1993;16:413-422. See AR (Vol. 535 Ref. 96, III.A).

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The industry then quotes the speculative conclusion of a study without any description of the research. In fact, the study's main finding was that the smell of cigarettes was *not* important for smoking behavior.⁴⁰²

The industry cites another conclusion of a study without any description of the research.⁴⁰³ One of the study's major findings was that enforced abstinence (smokers were not allowed to smoke for an afternoon) had different effects on subsequent smoking behavior than natural abstinence (smokers did not smoke while asleep at night). Basic biological imperatives undoubtedly affect the details of smoking behavior but certainly cannot explain the reason for tobacco use.

5. The tobacco industry argues that the "social aspects" of smoking explain consumer use of tobacco. No studies are cited to support this conclusion. As the Surgeon General's Report noted in 1988, social factors influence initiation and patterns of use of many addictive drugs;⁴⁰⁴ the primary reason for the drug's use, however, is pharmacological. In this respect, nicotine is similar to heroin.⁴⁰⁵

6. The smokeless tobacco industry argues that the evidence cited by FDA in support of its conclusion that consumers use tobacco products nearly exclusively for pharmacological effects has little to do with smokeless tobacco. Five studies were

⁴⁰² Baldinger B, Hasenfratz M, Battig K, Switching to ultralow nicotine cigarettes: effects of different tar yields and blocking of olfactory cues, *Pharmacology, Biochemistry and Behavior* 1995;50(2):233-239, at 238. See AR (Vol. 535 Ref. 96, vol. III.A).

⁴⁰³ Jacober A, Hasenfratz M, Battig K, Cigarette smoking: habit of nicotine maintenance? *Human Psychopharmacology* 1994;9:117-123, at 117. See AR (Vol. 535 Ref. 96, vol. III.G).

⁴⁰⁴ Surgeon General's Report, 1988, at 15. See AR (Vol. 129 Ref. 1592).

⁴⁰⁵ Jaffe JH, Drug addiction and drug abuse, in *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 8th ed. (New York: Pergamon Press, 1990), chap. 22 (522-573), at 529. See AR (Vol. 535 Ref. 96, vol. III.G).

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submitted with the comment that are claimed to demonstrate that smokeless tobacco consumers use those products because they “enjoy the taste” or simply “like it,” not for any “pharmacological effects.”⁴⁰⁶

FDA disagrees with the industry’s interpretation of these studies. As discussed in section II.B.3., above, when people use drugs with powerful pharmacological effects such as nicotine they commonly associate many environmental stimuli with the pleasurable experience of consuming the substance. Thus, a survey result that consumers “enjoy the taste” indicates only that a significant portion of consumers have linked the sensory cues to the pharmacological effects of nicotine.

None of the five studies cited by the industry noted whether users who did not give pharmacological reasons for using smokeless tobacco had ever tried to quit. Thus, many of these users may not have been aware of their pharmacological addiction. As an expert quoted by the Inspector General of the Department of Health and Human Services

⁴⁰⁶ Walsh MM, Hilton JF, Ernster VL, Masouredis CM, Grady DG, Prevalence, patterns, and correlates of spit tobacco use in a college athlete population, *Addictive Behavior* 1994;19:411-427. See AR (Vol. 526 Ref. 95, vol. VIII).

Lopez LC, Smokeless tobacco consumption by Mexican-American university students, *Psychology Reports* 1994;75:279-284. See AR (Vol. 526 Ref. 95, vol. VIII).

Glover ED, Laflin M, Flannery D, Albritton DL, Smokeless tobacco use among American college students, *Journal of American College Health* 1989;38:81-84. See AR (Vol. 526 Ref. 95, vol. VII).

Wisniewski JF, Bartolucci AA, Comparative patterns of smokeless tobacco usage among major league baseball personnel, *Journal of Oral Pathology and Medicine* 1989;18:322. See AR (Vol. 526 Ref. 95, vol. VIII).

Connolly GN, Orleans GT, Kogan M, Use of smokeless tobacco in major-league baseball, *New England Journal of Medicine* 1988;318(19):1281-1285. See AR (Vol. 526 Ref. 95, vol. VII).

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explained, "Many haven't tried to quit. But when we tell them the health consequences, and then they try to quit, they can't."⁴⁰⁷

In studies cited by the industry, some users of smokeless tobacco stated that they "enjoy the taste," but a significant percentage of these users also reported that they use smokeless tobacco for psychological reasons. For example, in one study, a majority of 195 users of snuff and chewing tobacco reported using tobacco for one or more pharmacological effects, including relieving stress, relief of "strong cravings," and relieving the discomfort of withdrawal.⁴⁰⁸ These statements support the conclusion that the majority of people who use smokeless tobacco do so for the well-established pharmacological effects of nicotine: stimulation, sedation, and addiction. These studies thus constitute additional evidence that smokeless tobacco is primarily used by consumers to obtain the pharmacological effects of nicotine.

⁴⁰⁷ Department of Health and Human Services, Office on Smoking and Health, *Spit Tobacco and Youth* (Washington DC: Government Printing Office, 1992), at 8. See AR (Vol. 7 Ref. 76).

⁴⁰⁸ Walsh MM, Hilton JF, Ernster VL, Masouredis CM, Grady DG, Prevalence, patterns, and correlates of spit tobacco use in a college athlete population, *Addictive Behavior* 1994;19:411-427. See AR (Vol. 526 Ref. 95, vol. VIII).

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C. THE STATEMENTS, RESEARCH, AND ACTIONS OF THE CIGARETTE MANUFACTURERS SHOW THAT THE MANUFACTURERS INTEND THEIR PRODUCTS TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY

In sections II.A. and II.B., above, the Agency has concluded that cigarettes and smokeless tobacco are intended to affect the structure and function of the body on the basis of the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco and the widespread actual use of cigarettes and smokeless tobacco by consumers for pharmacological purposes. In this section, the Agency considers another category of persuasive evidence of intended use: the statements, research, and actions of the cigarette manufacturers themselves. In section II.D., below, the Agency considers the statements, research, and actions of the smokeless tobacco manufacturers.

The administrative record includes extensive evidence of the cigarette manufacturers' statements, research, and manufacturing practices. Much of this evidence has only recently become available as a result of the Agency's investigation, congressional hearings, and other investigations and sources. This evidence is part of the relevant objective evidence that the Agency may consider in determining the manufacturer's "intended uses" of a product.

In the Jurisdictional Analysis, the Agency made extensive findings based on the evidence then available regarding the statements, research, and actions of the cigarette manufacturers. FDA received comments on these findings from the individual tobacco companies and tobacco industry trade associations, as well as from public health organizations and other interested groups and members of the public. After careful consideration of the evidence in the record and the public comments, the Agency finds that

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the evidence described in this section provides a third independent basis for concluding that cigarettes are in fact intended to affect the structure and function of the bodies of smokers.

In section II.C.1., FDA discusses its legal authority to consider evidence of the manufacturers' statements, research, and actions in establishing intended use. This discussion shows that an intent to affect the structure or function of the body can be established by evidence showing that (1) the manufacturer "has in mind" that the product will be used by consumers for pharmacological purposes, or (2) the manufacturer has "designed" the product to provide pharmacological effects. The Agency's role in making these determinations is that of a fact finder. It weighs the statements, research, and actions of the manufacturer to determine the particular uses the manufacturer has in mind or designs its product to provide.

The Agency's fact-finding task has been made more difficult by the manufacturers' general refusal to cooperate with the Agency's investigation. Although some manufacturers did permit FDA investigators to visit their manufacturing plants in the spring of 1994, the manufacturers have failed to provide FDA with information and documents requested by FDA in July 1994 regarding nicotine in cigarettes.⁴⁰⁹ In particular, the manufacturers have failed to comply with FDA's request for company documents regarding the pharmacological effects of nicotine and the role of nicotine in cigarette design and manufacturing. The limited number of company documents provided

⁴⁰⁹ See, e.g., Letter from Chesemore RG (FDA) to Bible GC (Philip Morris Inc.) (Jul. 11, 1994). See AR (Vol. 54 Ref. 617). Similar letters were sent to other cigarette and smokeless tobacco manufacturers.

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by the manufacturers with their comments sheds little light on the role of nicotine in cigarettes and does not significantly change the evidence in the record.

The Agency's discussion of the evidence of the manufacturers' statements, research, and actions is divided into several parts. In section II.C.2., the Agency discusses the statements and research of each of the major cigarette companies and the Council for Tobacco Research, a trade association to which they belong. This evidence shows that the manufacturers have known for decades that nicotine has the characteristics of addictive drugs and causes other significant pharmacological effects and that consumers use cigarettes primarily to obtain the pharmacological effects of nicotine, including satisfaction of their addiction. This evidence also shows that in internal discussions, senior researchers for the cigarette manufacturers refer to cigarettes as drug delivery systems, calling them a "dispenser for a dose unit of nicotine,"⁴¹⁰ a vehicle for delivery of nicotine,⁴¹¹ and other similar terms. This evidence is sufficient by itself to establish that cigarettes are intended to affect the structure and function of the body, because it shows that the manufacturers "have in mind" that their products will be used specifically for pharmacological purposes.

In sections II.C.3. and II.C.4., the Agency discusses the second basis for determining the manufacturers' intent through their statements, research, and actions—namely, the evidence that manufacturers have "designed" cigarettes to provide pharmacologically active doses of nicotine to consumers. In section II.C.3., the Agency discusses the product research and development activities of the manufacturers. This

⁴¹⁰ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5. See AR (Vol. 12 Ref. 133).

⁴¹¹ Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1. See AR (Vol. 531 Ref. 125).

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evidence shows that the manufacturers have conducted extensive product research and development to establish the dose of nicotine necessary to produce pharmacological effects and to optimize the delivery of nicotine to consumers.

In section II.C.4., the Agency discusses the evidence that the manufacturers do in fact manipulate and control nicotine deliveries in their commercial cigarettes. This evidence supports a finding that the manufacturers manipulate and control the delivery of nicotine in commercial cigarettes to provide a pharmacologically active dose of nicotine to consumers. Taken together, the evidence in sections II.C.3. and II.C.4. establishes yet another basis for finding that cigarettes are intended to affect the structure and function of the body.

In section II.C.5., the Agency concludes that, when considered cumulatively, the evidence from the statements, research, and actions of the manufacturers is internally consistent and mutually corroborating, further supporting the finding that the effects of cigarettes on the structure and function of the body are “intended” by the manufacturers. Finally, in section II.C.6., the Agency responds to substantive comments concerning the evidence of the manufacturers’ statements, research, and actions that are not addressed in sections II.C.2. to II.C.5.⁴¹²

⁴¹² The discussion of the statements, research, and actions of the manufacturers in this section cites hundreds of documents. It is the totality of the evidence from these documents that the Agency relies upon. No single document cited by the Agency is essential to the Agency’s conclusion in section II.C. that the manufacturers intend their products to affect the structure and function of the body. In particular, although considerable evidence of the statements, research, and actions of the manufacturers was submitted to the Agency after the publication of the Jurisdictional Analysis on August 11, 1995, none of this evidence is essential to the Agency’s finding of intended use in section II.C. The new evidence is summarized below because it provides persuasive corroboration that the cigarette manufacturers do intend to affect the structure and function of the body. However, the Agency would reach the same conclusions regarding the intent of the manufacturers even without this additional evidence. In addition, none of the documents in the Agency’s docket of confidential documents is essential to the Agency’s determination. See AR (Vol. 505-518).

II.C.1.

1. “Intended Use” May Be Established on the Basis of the Statements, Actions, and Research of the Manufacturers

Reliance on the statements, research, and actions of manufacturers to establish intended use is consistent with the plain language of the statute. The statute provides that products “intended” to affect the structure or any function of the body are drugs or devices. Sections 201(g)(1)(C) and 201(h)(3). According to a canon of statutory construction, words used by Congress, unless otherwise defined, will be interpreted as taking their ordinary meaning. *See, e.g., Smith v. United States*, 508 U.S. 223, 228 (1993); *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 860 (1984). In this case, the ordinary meaning of “intend” includes “to have in mind” and “to design” for a particular use. These plain meanings allow the Agency to consider the manufacturer’s statements, research, and actions in determining intended use.

The *American Heritage Dictionary*, for instance, defines “intend” as: “1. To have in mind; plan. 2.a. To design for a specific purpose. b. To have in mind for a particular use. . . .”⁴¹³ Consistent with this meaning, the Agency interprets “intended” uses to include those specific uses that are “in the mind” of the manufacturer or for which the manufacturer “designs” the product. The plain meaning of the statute thus permits the Agency to inquire into the statements, research, and actions of the manufacturer. What the manufacturer says in internal documents, the kind of research the manufacturer conducts, and the actions of the manufacturer in producing its product can all be evidence

⁴¹³ *The American Heritage Dictionary of the English Language*, 2d ed. (Boston: Houghton Mifflin Co., 1991), 668. *See* AR (Vol. 526 Ref. 95, vol. V). Other dictionary definitions are similar. *See, e.g., Webster’s New World Dictionary of American English*, 3d college ed. (New York: Simon & Schuster, Inc., 1988), 702 (“intend 1. *to have in mind as a purpose*; plan 2. *to mean (something) to be or be used (for); design. . . .*”) (emphasis added).

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of the particular uses the manufacturer has in mind or for which the manufacturer has designed the product.

FDA's regulations on the meaning of "intended uses" are consistent with the statutory language and explicitly contemplate that FDA may examine the knowledge, actions, and expressions of manufacturers and other vendors. 21 CFR 201.128 and 801.4. These regulations state that intended uses are to be established on the basis of "objective intent." FDA's "objective intent" standard means that the Agency may consider objective evidence to determine a manufacturer's intent, notwithstanding the manufacturer's assertions that pharmacological effects and uses are not intended. As the courts have recognized, "FDA is not bound by the manufacturer's subjective claims of intent but *can find actual therapeutic intent on the basis of objective evidence.*" *NNFA v. Mathews*, 557 F.2d at 334 (emphasis added); *accord United States v. Storage Spaces Designated Nos. "8" and "49,"* 777 F.2d 1363, 1366 n. 5 (9th Cir. 1985) ("self-serving labels cannot be used to mask true intent"), *cert. denied*, 479 U.S. 1086 (1987).

The regulations recognize that as a fact finder, FDA may consider a broad range of evidence of intended use, including evidence of the statements, research, and actions of the manufacturer. For example, the regulations state that "the objective intent is determined by such persons' *expressions . . . or oral or written statements.*" 21 CFR 201.128 (emphasis added). These "expressions" and "oral or written statements" can include relevant and probative intracompany memoranda or research.

Indeed, the regulations provide express authority for FDA to consider evidence of the manufacturer's actual intent. The regulations state that "objective intent . . . may be shown by the circumstances that the article is, *with the knowledge of [the manufacturer],*

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offered and used for a purpose for which it is neither labeled nor advertised.” *Id.* (emphasis added). The regulations also direct FDA to consider circumstances in which the manufacturer “*knows, or has knowledge of facts* that would give him notice” that a product is to be used for purposes other than those expressly promoted by the manufacturer. *Id.* (emphasis added). Proving whether a manufacturer “knows” or has “knowledge of facts that would give him notice” of pharmacological uses of a product can include an inquiry into the actual understanding of the manufacturer, including consideration of the statements, research, and actions that may be probative of the manufacturer’s actual knowledge.

Moreover, the regulations provide that objective intent may be shown by the “*circumstances surrounding the distribution of the article.*” *Id.* (emphasis added). This broad phrase allows the fact finder to infer the intended uses of a product based on, among other factors, the conduct of the manufacturer that occurs prior to distribution. For example, evidence that shows how distributed tobacco products are designed and formulated is reasonably considered a “circumstance surrounding distribution of the article.”

Courts have also recognized that the Agency may consider “objective evidence” to determine a manufacturer’s intent. *See NNFA v. Mathews*, 557 F.2d at 334; *United States v. Storage Spaces*, 777 F.2d at 1366; *Latex Surgeons’ Gloves*, 799 F. Supp. at 1295 (circumstances surrounding manufacture and distribution of product demonstrated intended use despite manufacturer’s claim to FDA that product was not a device); *Hanson*, 417 F. Supp. at 35 (statements by plaintiff distributors and importers that drug was needed by patients to treat cancer is relevant to intended use).

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The Agency's role in determining intended use on the basis of the statements, research, and actions of the manufacturer is that of a fact finder. The Agency's responsibility is to reach the best factual judgments it can from the record of the statements, research, and actions before it, including evidence submitted during the comment period.

2. The Cigarette Manufacturers Understand That Nicotine Has Addictive and Other Pharmacological Effects and That Smokers Use Cigarettes To Obtain These Effects

As discussed below, the evidence in the record shows that the cigarette manufacturers have extensive knowledge of effects of nicotine on smokers. The manufacturers know that nicotine has the characteristics of other addictive drugs; that it provides other significant pharmacological effects; and that it is the primary reason that smokers use cigarettes. This evidence establishes that when the manufacturers offer cigarettes to the public, they "have in mind" that their cigarettes will be used by smokers to obtain the pharmacological effects of nicotine. This evidence is thus sufficient by itself to establish that the manufacturers intend the pharmacological uses of their products.

a. The Statements and Research of Philip Morris

The administrative record includes over three decades of internal statements and research on nicotine by Philip Morris, the nation's largest cigarette manufacturer. These documents indicate that senior researchers and officials at Philip Morris have long viewed nicotine as a "powerful pharmacological agent"⁴¹⁴ and "the primary reason"⁴¹⁵ people

⁴¹⁴ Charles JL (Philip Morris Inc.), *Nicotine Receptor Program-University of Rochester* (Mar. 18, 1980), in 141 Cong. Rec. H7680 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁴¹⁵ Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table*, at 1. See AR (Vol. 531 Ref. 122).

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smoke. This knowledge shows that Philip Morris understands that its product will affect the structure and function of the body and will be used by consumers for these drug effects.

i. The Views of Senior Researchers and Officials. Philip Morris officials recognized the importance of the pharmacological effects of nicotine in cigarettes as early as 1961. That year, Helmut Wakeham, a senior Philip Morris research scientist, informed the company's research and development committee that "nicotine is believed essential to cigarette acceptability."⁴¹⁶ Wakeham also explained the pharmacological effects of nicotine, stating that "low nicotine doses stimulate, but high doses depress functions" and that nicotine contributes to the "pleasurable reactions or tranquillity" produced by smoking.⁴¹⁷

By 1969, the views of the Philip Morris scientists on the pharmacological effects of cigarettes were communicated to the Philip Morris board of directors. During that year, Wakeham, who was then vice president for research and development, briefed the Philip Morris board of directors on why people smoke. He expressed his department's "conviction" that "the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker." He further stated that smokers' craving for cigarettes is so strong that "the cigaret will even preempt food in times of scarcity":

Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 6. See AR (Vol. 638 Ref. 2).

⁴¹⁶ Wakeham H (Philip Morris Inc.), *Tobacco and Health—R&D Approach* (Nov. 15, 1961), at 43. See AR (Vol. 125 Ref. 1314).

⁴¹⁷ *Id.* at 40.

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[T]he psychosocial motive is not enough to explain continued smoking. Some other motive force takes over to make smoking rewarding in its own right. Long after adolescent preoccupation with self-image has subsided, the cigaret will even preempt food in times of scarcity on the smoker's priority list. . . . The question is "Why?"

. . . . We are of the conviction, . . . that the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker, the effect being most rewarding to the individual under stress.⁴¹⁸

Wakeham's views on the central importance of the "pharmacological effect" of nicotine were shared by other senior researchers and officials at Philip Morris, as the following examples demonstrate:

- In 1972, Philip Morris scientist William Dunn characterized cigarettes as a nicotine delivery system in the following language:

Think of the cigarette pack as a storage container for a day's supply of nicotine. . . .

Think of the cigarette as a dispenser for a dose unit of nicotine. . . .

Think of a puff of smoke as the vehicle of nicotine

*Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.*⁴¹⁹

- In 1974, Philip Morris' director of research, Thomas Osdone, who subsequently became vice president for science and technology, approved and sent to Wakeham and other senior Philip Morris officials a report that analogized smoking to drug use. The report's "working hypothesis" is that "[d]ose-control continues even after the puff of smoke is drawn into the mouth." The report postulates that the consumer regulates

⁴¹⁸ Wakeham H (Philip Morris Inc.), *Smoker Psychology Research*, presented to Philip Morris board of directors (Nov. 26, 1969), at 237, 240. See AR (Vol. 11 Ref. 142).

⁴¹⁹ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5-6 (emphasis added). See AR (Vol. 12 Ref. 133).

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smoke intake “to achieve his habitual quota of the pharmacological action,” and notes that if smokers deprived of cigarettes display an increase in aggression, it may be explained as “the emergence of reactions . . . not unlike those to be observed upon withdrawal from any of a number of habituating pharmacological agents.”⁴²⁰

- In 1976, Philip Morris researcher A. Udow wrote a memorandum on “Why People Start To Smoke.” The memorandum observes that once people start to smoke, one of the reasons they will continue to smoke is that cigarettes serve as “*a narcotic, tranquilizer, or sedative.*”⁴²¹
- In 1978, the authors of Philip Morris’ 5-year plan for research and development stated that “*nicotine may be the physiologically active component of smoke having the greatest consequence to the consumer.*”⁴²²
- In 1980, Philip Morris researcher Jim Charles, who subsequently became vice president for research and development, wrote the then vice president for research and development, Robert Seligman, that:

Nicotine is a powerful pharmacological agent with multiple sites of action and may be the most important component of cigarette smoke. Nicotine and an understanding of its properties are important to the continued well being of our cigarette business since this alkaloid has been cited often as “the reason for smoking.” . . . Nicotine is known to have effects on the central and

⁴²⁰ Philip Morris Research Center, *Behavioral Research Annual Report, Part II* (Nov. 1, 1974) (approved by Osdene TS), in 141 Cong. Rec. H7658, H7660 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁴²¹ Udow A (Philip Morris Inc.), *Why People Start to Smoke* (Jun. 2, 1976), in 141 Cong. Rec. H7664 (daily ed. Jul. 25, 1995) (emphasis added). See AR (Vol. 14 Ref. 175a).

⁴²² Philip Morris Inc., *Research and Development Five-Year Plan, 1979-1983* (Sep. 1978), in 141 Cong. Rec. H7668 (daily ed. Jul. 25, 1995) (emphasis added). See AR (Vol. 14 Ref. 175a).

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peripheral nervous system as well as influencing memory, learning, pain perception, response to stress and level of arousal.⁴²³

A statement that the Agency received from a former Philip Morris research director, William Farone, expresses similar views. Farone was the director of applied research at Philip Morris from 1976-1984, during which period he supervised five divisions and 150 employees. According to Farone's statement:

It is well recognized within the cigarette industry that *there is one principal reason why people smoke—to experience the effects of nicotine*, a known pharmacologically active constituent in tobacco. . . .

. . . .
*The strongly held conviction of most industry scientists and product developers was that nicotine was the primary reason why people smoked.*⁴²⁴

The administrative record contains many additional statements by Philip Morris researchers and officials acknowledging the significant pharmacological effects of nicotine and their importance to the smoker. *See, e.g.*, 60 FR 41584–41603, 41621–41667. Collectively, these statements show that Philip Morris' senior scientists and officials have known for decades that cigarettes function as a drug delivery system, providing the pharmacological effects of nicotine to consumers who smoke cigarettes for the primary purpose of obtaining these effects.

ii. Research into Nicotine Pharmacology. The foregoing views of Philip Morris' top research scientists and officials were based on extensive in-house research on

⁴²³ Charles JL (Philip Morris Inc.), *Nicotine Receptor Program—University of Rochester* (Mar. 18, 1980), in 141 Cong. Rec. H7680 (daily ed. Jul. 25, 1995) (emphasis added). *See* AR (Vol. 14 Ref. 175a).

⁴²⁴ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 1,6 (emphasis added). *See* AR (Vol. 638 Ref. 2).

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nicotine pharmacology. The studies conducted by Philip Morris ranged from traditional pharmacology involving animal experiments to EEG experiments.

Philip Morris conducted a large number of studies. In 1979 alone at least 16 different studies on nicotine pharmacology were conducted by three different research groups within Philip Morris' Behavioral Research Laboratory.⁴²⁵ The Animal Behavior Group conducted six experiments on the drug effects of nicotine in rats. The Neuropsychology Laboratory conducted five experiments to determine the pharmacological effects of nicotine on the human brain, including experiments on "[t]he Effects of Cigarette Smoking on the Electroencephalogram" and "[L]ong-Term Smoke Deprivation and the Electrical Activity of the Brain."⁴²⁶ The Smoking Behavior Group conducted studies on the behavioral consequences of smoking, including studies to determine the consequences of smoking low-nicotine cigarettes.

Beginning before 1980 and continuing until 1984, Philip Morris conducted research in search of a "nicotine analogue." This research demonstrates Philip Morris' knowledge that nicotine has the hallmark properties of a drug of abuse and shows the company's intention to preserve these properties in new products. As described by former Philip Morris scientist Victor DeNoble, the purpose of the research was "to come up with a molecule that would *mimic nicotine's effect in the brain*, and would not affect the peripheral nervous system and therefore not have cardiovascular liability."⁴²⁷ Thus, while

⁴²⁵ Dunn WL (Philip Morris Inc.), *Plans and Objectives—1979* (Dec. 6, 1978), in 141 Cong. Rec. H7668-7670 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁴²⁶ *Id.* at H7669-7670.

⁴²⁷ *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 33 (Apr. 28, 1994) (testimony of Victor DeNoble) (emphasis added). See AR (Vol. 708 Ref. 2).

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the company attempted to eliminate an adverse effect of nicotine, it deliberately sought to retain nicotine's effects on the brain.

To conduct this work, Philip Morris scientists had to identify and compare the pharmacological and behavioral effects of nicotine on the brain. The pharmacological and behavioral profiles of the nicotine analogues synthesized by Philip Morris chemists were then compared to those of nicotine.⁴²⁸ Since the primary goal of the nicotine analogue program was to develop a nicotine analogue that would retain the physiological and behavioral effects of nicotine on the brain, especially its reinforcing properties, the newly synthesized nicotine analogues were screened in animal behavioral tests designed to assess their reinforcing properties. (A substance has reinforcing properties if it is able to induce repeated, compulsive use. *See* section II.A.3.c.i., above.) The tests used were "exactly the same tests" that the National Institute on Drug Abuse (NIDA) uses "to determine if a drug has an abuse potential."⁴²⁹

One of the principal NIDA tests used by Philip Morris was a series of "self-administration" experiments with rats. These studies determine addiction potential by assessing whether rats will press a lever to give themselves repeated injections of the test substance. There is a strong correlation between substances that are found to be self-

⁴²⁸ *Id.* at 5.

See also Declaration of Victor DeNoble of Feb. 2, 1995, at 2-9. *See* AR (Vol. 31 Ref. 524-5).

⁴²⁹ *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 17 (Apr. 28, 1994) (testimony of Victor DeNoble). *See* AR (Vol. 708 Ref. 2).

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administered in rats and substances that are addictive in humans.⁴³⁰ Philip Morris found that rats would self-administer nicotine.⁴³¹ According to the director of NIDA, “[t]hese findings from the DeNoble study indicate that nicotine has reinforcing properties, *one of the hallmark characteristics of an addictive drug*.”⁴³² The Philip Morris researchers also found that rats would develop a tolerance to nicotine, another characteristic of an addictive drug.⁴³³

The senior management and top officials of Philip Morris “continually reviewed . . . and approved” this research.⁴³⁴ In fact, in November 1983, the president of Philip Morris, Shep Pollack, visited the laboratory conducting the self-administration experiments and watched rats inject themselves with nicotine. Pollack was informed by the Philip Morris researcher in charge of the study, Victor DeNoble, that Philip Morris’ self-administration studies followed “the exact procedure that NIDA would use to demonstrate abuse liability,” and that the studies demonstrated that nicotine is “a reinforcing agent.”⁴³⁵ DeNoble further informed Pollack that although a finding of self-

⁴³⁰ Gardner EL, Brain reward mechanism, in *Substance Abuse, A Comprehensive Textbook*, 2d ed., eds. Lowinson JH, Ruiz P, Millman RB, *et al.* (Baltimore: Williams and Wilkins 1992), at 70. See AR (Vol. 8 Ref. 88).

See also section II.A.3.c.i.

⁴³¹ *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 5 (Apr. 28, 1994) (testimony of Victor DeNoble). See AR (Vol. 708 Ref. 2).

⁴³² *Id.* at 20 (letter from Leshner AI (NIDA) to Waxman HA (Apr. 13, 1994) (emphasis added)).

⁴³³ *Id.* at 5 (testimony of Victor DeNoble). The Philip Morris researchers did not, however, find evidence of nicotine withdrawal.

⁴³⁴ *Id.* at 5-6.

⁴³⁵ *Id.* at 54.

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administration does not by itself prove that nicotine is addictive, it “predicts abuse liability.”⁴³⁶ Despite several attempts, DeNoble and his colleague Paul Mele were not allowed to publish the results of their self-administration studies or present their results at a meeting sponsored by the American Psychological Association.⁴³⁷

These studies were conducted for their potential commercial applicability. The memorandum describing the “plans and objectives” for the Behavioral Research Laboratory in 1979 states expressly that “the rationale for the program rests on the premise that such knowledge will strengthen Philip Morris R&D capability in developing new and improved smoking products.”⁴³⁸

Some of Philip Morris’ research attempted to assess the pharmacological effects of nicotine on youths. One study on the hyperkinetic child as prospective smoker observed that “amphetamines, which are strong stimulants, have the anomalous effect of quieting these children down”; the Philip Morris researchers initiated a study to determine “whether such children may not eventually become cigarette smokers in their teenage years as they discover *the advantage of self-stimulation via nicotine*.”⁴³⁹ This study was apparently

⁴³⁶ *Id.*

⁴³⁷ *Id.* at 51-52, 57-94.

⁴³⁸ Dunn WL, *Plans and Objectives—1979* (Dec. 6, 1978), in 141 Cong. Rec. H7669. See AR (Vol. 14 Ref. 175a).

⁴³⁹ Ryan FJ (Philip Morris Inc.), Relationship between smoking and personality, in *Smoker Psychology/May 1-31, 1974* (Jun. 10, 1974), in 141 Cong. Rec. H7651 (daily ed. Jul. 25, 1995) (emphasis added). See AR (Vol. 14 Ref. 175a).

For a further description of Philip Morris’ research into hyperkinetic children, see the following documents reprinted in 141 Cong. Rec. H7651-7657 (daily ed. Jul. 25, 1995):

Ryan FJ (Philip Morris Inc.), Relationship between smoking and personality, in *Smoker Psychology/May 1-31, 1974* (Jun. 10, 1974). See AR (Vol. 14 Ref. 175a).

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never completed because “[o]bstacles presented by school systems and physicians . . . have made it very difficult for us to conduct studies using school and medical records of minors.”⁴⁴⁰ Another study initiated by Philip Morris involved administering “painful” electric shocks to college students to determine the anxiety-reducing effects of cigarettes.⁴⁴¹ Although preliminary findings supported the hypothesis that students with a high anxiety factor on personality tests would puff more frequently,⁴⁴² the study apparently had to be discontinued because “fear of shock is scaring away some of our more valuable

Ryan FJ (Philip Morris Inc.), Hyperkinesis as a precursor of smoking, in *Smoker Psychology/Feb. 1-28, 1975* (Mar. 10, 1975). See AR (Vol. 14 Ref. 175a).

Philip Morris Research Center, *Behavioral Research Annual Report* (Jul. 18, 1975) (approved by Dunn WL). See AR (Vol. 14 Ref. 175a).

Ryan FJ (Philip Morris Inc.), Hyperactivity, in *Smoker Psychology/Apr. 1-30, 1977* (May 13, 1977). See AR (Vol. 14 Ref. 175a).

Ryan FJ (Philip Morris Inc.), Hyperkinetic children, in *Smoker Psychology/Feb. 1-28, 1978* (Mar. 10, 1978). See AR (Vol. 14 Ref. 175a).

⁴⁴⁰ Ryan FJ (Philip Morris Inc.), Hyperkinetic children, in *Smoker Psychology/Feb. 1-28, 1978* (Mar. 10, 1978), in 141 Cong. Rec. H7657 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁴⁴¹ Ryan FJ (Philip Morris Inc.), *Proposed Research Project: Smoking and Anxiety* (Dec. 23, 1969), in 141 Cong. Rec. H7648 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

For a further description of Philip Morris’ research involving the administration of electric shocks, see the following documents printed in 141 Cong. Rec. H7648-7649 (daily ed. Jul. 25, 1995):

Ryan FJ (Philip Morris Inc.), Shock I, II, III, and IV, in *Consumer Psychology* (Sep. 16 - Oct. 15, 1971). See AR (Vol. 14 Ref. 175a).

Ryan FJ (Philip Morris Inc.), Shock V, in *Consumer Psychology* (Jan. 15 - Feb. 15, 1972). See AR (Vol. 14 Ref. 175a).

Dunn WL (Philip Morris Inc.), *Quarterly Report-Projects 1600 and 2302* (Oct. 5, 1972). See AR (Vol. 14 Ref. 175a).

⁴⁴² Ryan FJ (Philip Morris Inc.), Shock I, II, III, and IV, in *Consumer Psychology Monthly Report* (Sep. 16 - Oct. 15, 1971), in 141 Cong. Rec. H7648-7649 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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subjects.”⁴⁴³ In another study, Philip Morris proposed injecting nicotine into human subjects in order “to yield a broader picture of the role of the spike, the level, and the reinforcement characteristics of the substance.”⁴⁴⁴

In congressional testimony, the former Philip Morris president, William Campbell, testified that to the extent that Philip Morris controls nicotine levels in cigarettes through blending, this is done “for taste.”⁴⁴⁵ Philip Morris’s research program does not support this statement, however. The internal research documents in the administrative record show that Philip Morris exhaustively investigated the pharmacological properties of nicotine—not its gustatory properties. The intensive focus on nicotine pharmacology reflected in the documents indicates that Philip Morris regarded nicotine’s contribution to cigarettes as pharmacological, not taste-related. Moreover, in its comments Philip Morris did not provide evidence of internal Philip Morris research into the taste characteristics of nicotine.

⁴⁴³ Eichorn PA, Dunn WL (Philip Morris Inc.), *Quarterly Reports—Projects 1600 and 2302* (Oct. 5, 1972), in 141 Cong. Rec. H7649 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁴⁴⁴ Dunn WL (Philip Morris Inc.), *Plans and Objectives—1981* (Nov. 26, 1980), in 141 Cong. Rec. H7682 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

For a further description of Philip Morris’ proposed research involving nicotine injections, see:

Dunn WL (Philip Morris Inc.), *Behavioral Research Accomplishments, 1977* (Dec. 19, 1977), in 141 Cong. Rec. H7666 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

Dunn WL (Philip Morris Inc.), *Plans and Objectives—1979* (Dec. 6, 1978), in 141 Cong. Rec. H7669 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁴⁴⁵ *Regulation of Tobacco Products (Part 1): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 764 (Apr. 14, 1994) (testimony of William Campbell). See AR (Vol. 707 Ref. 1).

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Further examples of Philip Morris' research on nicotine pharmacology are presented in the Jurisdictional Analysis. *See* 60 FR 41590–41591, 41595–41599. Taken together, these studies show that Philip Morris conducted an extensive, sustained, and sophisticated investigation into the pharmacological effects of nicotine that gave the company knowledge that nicotine has significant pharmacological effects on smokers, including reinforcing effects. The research was conducted because of its commercial significance to Philip Morris; used techniques that are employed by government agencies to identify the “abuse potential” of drugs; and found that nicotine has hallmark characteristics of an addictive drug, including reinforcing effects and the development of tolerance.

iii. Project Table. Philip Morris' recognition of the important pharmacological role of nicotine in cigarettes has been consistent for over three decades. New evidence received by the Agency during the comment period, for instance, indicates that officials inside Philip Morris continued to recognize the importance of nicotine's pharmacological effects and uses in the 1990's.

A draft Philip Morris report on “Project Table,” a proposal to develop “a nicotine delivery device” that relies on “heating rather than burning the tobacco” to “produce[] a cleaner, safer smoking experience,” written around 1992, acknowledges that although “[d]ifferent people smoke for different reasons. . . . *the primary reason is to deliver nicotine into their bodies.*”⁴⁴⁶ The report describes nicotine in cigarettes in explicit drug-like terms:

⁴⁴⁶ Philip Morris, Inc., Draft Report Regarding a Proposal for a “Safer” Cigarette, Code-named *Table*, at 1,5 (emphasis added). *See* AR (Vol. 531 Ref. 122).

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Nicotine . . . is a physiologically active, nitrogen containing substance. *Similar organic chemicals include . . . quinine, cocaine, atropine and morphine.* While each of these substances can be used to affect human physiology, nicotine has a particularly broad range of influence.⁴⁴⁷

Project Table provides a detailed description of the pharmacological action of nicotine on the brain:

During the smoking act, nicotine is inhaled into the lungs in smoke, enters the bloodstream and travels to the brain in about eight to ten seconds. The nicotine alters the state of the smoker by becoming a neurotransmitter and a stimulant. *Nicotine mimics the body's most important neurotransmitter, acetylcholine (ACH), which controls heart rate and message sending within the brain. The nicotine is used to change physiological states leading to enhanced mental performance and relaxation.* A little nicotine seems to stimulate, while a lot sedates a person.⁴⁴⁸

The report also expressly places cigarettes and smokeless tobacco products in the same category of “nicotine delivery devices” that includes nicotine patches and inhalers, stating that “nicotine delivery devices range from snuff, chewing tobacco, cigars, pipes and conventional cigarettes to unique smoking articles, chewing gum, patches, aerosol sprays and inhalers.”⁴⁴⁹ The report thus indicates that the views of Philip Morris on the role of nicotine in cigarettes have been remarkably consistent. Twenty years after senior Philip Morris scientist William Dunn called cigarettes “a dispenser for a dose unit of nicotine,”⁴⁵⁰ Philip Morris officials continue to regard nicotine as a drug and cigarettes as a “nicotine delivery device.” The evidence of Philip Morris’ statements and research on

⁴⁴⁷ *Id.* at 1 (emphasis added).

⁴⁴⁸ *Id.* (emphasis added).

⁴⁴⁹ *Id.* at 2.

⁴⁵⁰ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5. See AR (Vol. 12 Ref. 133).

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nicotine pharmacology persuasively documents that its cigarettes are intended to affect the structure or function of the body.

b. The Statements and Research of R. J. Reynolds

R.J. Reynolds Tobacco Company (RJR) is the nation's second largest cigarette manufacturer. The information in the administrative record shows that researchers and senior officials at RJR hold views on the pharmacological effects and uses of nicotine in cigarettes that are similar to those of the researchers and senior officials at Philip Morris.

i. The Teague Memoranda. During the comment period, FDA received two documents written by Claude Teague in 1972 and 1973, when he was the assistant director of research at RJR. Teague was subsequently promoted to director of corporate research in 1978.⁴⁵¹ These internal memoranda show that RJR scientists regarded nicotine as a "potent" and "habit-forming" drug; considered cigarettes to be "a vehicle for delivery of nicotine"; and conceived of the tobacco industry itself as "a specialized, highly ritualized and stylized segment of the pharmaceutical industry."

Teague's 1972 memorandum, entitled "Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein," makes four significant points. First, the memorandum describes nicotine as a powerful and habituating drug. According to the memorandum, nicotine is "a potent drug with a variety of physiological effects."⁴⁵² It is also "*known to be a habit-forming alkaloid.*"⁴⁵³ Nicotine's specific effects on the body are described as follows:

⁴⁵¹ *American Men and Women of Science, 1995-1996*, 19th ed. (New Providence: R.R. Bowker, 1995), 7:62. See AR (Vol. 711 Ref. 13).

⁴⁵² Teague CE, (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1. See AR (Vol. 531 Ref. 125).

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The habituated user of tobacco products is said to derive “satisfaction” from nicotine. Although much studied, the physiological actions of nicotine are still poorly understood and appear to be many and varied. For example, . . . *at different dose levels, nicotine appears to act as a stimulant, depressant, tranquilizer, psychic energizer, appetite reducer, anti-fatigue agent, or energizer*, to name but a few of the varied and often contradictory effects attributed to it.”⁴⁵⁴

Second, the memorandum acknowledges that nicotine is the “primary” reason for smoking. According to the memorandum:

*[T]he confirmed user of tobacco products is primarily seeking the physiological “satisfaction” derived from nicotine—and perhaps other active compounds. His choice of product and pattern of usage are primarily determined by his individual nicotine dosage requirements. . . .*⁴⁵⁵

Third, the Teague memorandum describes cigarettes as drug delivery systems.

According to the memorandum, “*a tobacco product is, in essence, a vehicle for delivery of nicotine*, designed to deliver the nicotine in a generally acceptable and attractive form.”⁴⁵⁶ The memorandum further states:

If what we have said about the habituated smoker is true, then products designed for him should emphasize nicotine, nicotine delivery efficiency, nicotine satisfaction, and the like. *What we should really make and sell would be the proper dosage form of nicotine with as many other built-in attractions and gratifications as possible—that is, an efficient nicotine delivery system with satisfactory flavor, mildness, convenience, cost, etc. . . . Would it not be better, in the long run, to identify in our minds and in the minds of our customers what we are really selling, i.e., nicotine satisfaction?*⁴⁵⁷

⁴⁵³ *Id.* (emphasis added).

⁴⁵⁴ *Id.* at 1-2 (emphasis added).

⁴⁵⁵ *Id.* at 1 (emphasis added).

⁴⁵⁶ *Id.*

⁴⁵⁷ *Id.* at 5 (emphasis added).

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Indeed, the memorandum describes the tobacco industry itself as a “segment of the pharmaceutical industry”:⁴⁵⁸

*In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. . . . Our Industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine, and our Company’s position in our Industry is determined by our ability to produce dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our competitors.*⁴⁵⁹

Finally, the memorandum recommends improvements in the delivery of nicotine to consumers. In the short term, the memorandum recommends reducing tar levels while maintaining nicotine levels in cigarettes:

*Our critics have lumped “tar” and nicotine together in their allegations about health hazards. . . . An accompanying Research Planning Memorandum suggests an approach to reducing the amount of “tar” in cigarette smoke per unit of nicotine. That is probably the most realistic approach in today’s market for conventional cigarette products.*⁴⁶⁰

In the long term, the memorandum recommends a “more futuristic approach”:⁴⁶¹

If our business is fundamentally that of supplying nicotine in useful dosage form, why is it really necessary that allegedly harmful “tar” accompany that nicotine? There should be some simpler, “cleaner”, more efficient and direct way to provide the desired nicotine dosage than the present system involving combustion of tobacco or even chewing of tobacco. . . . It should be possible to obtain pure nicotine by synthesis or from high-nicotine tobacco. It should then be possible, using modifications of techniques developed by the pharmaceutical and other

⁴⁵⁸ *Id.* at 2.

⁴⁵⁹ *Id.* (emphasis added).

⁴⁶⁰ *Id.* at 6 (emphasis added).

⁴⁶¹ *Id.*

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*industries, to deliver that nicotine to the user in efficient, effective, attractive dosage form, accompanied by no "tar", gas phase, or other allegedly harmful substances. The dosage form could incorporate various flavorants, enhancers, and like desirable additives, and would be designed to deliver the minimum effective amount of nicotine at the desired release-rate to supply the "satisfaction" desired by the user. Such a product would maximize the benefits derived from nicotine, minimize allegedly undesirable over-dosage side effects from nicotine, and eliminate exposure to other materials alleged to be harmful to the user.*⁴⁶²

Evidence in the record indicates that RJR acted on both of these recommendations. See sections II.C.2.b.iii. and II.C.3.b., below.

Claude Teague's 1973 memorandum, entitled "Some Thoughts about New Brands of Cigarettes for the Youth Market," recommends that RJR develop "new brands tailored to the youth market."⁴⁶³ According to the memorandum, one of the design features that should be tailored to the youth market is nicotine delivery. The memorandum reaffirms that the "nicotine effects" and the other physical effects of smoking are "highly desirable to the confirmed smoker."⁴⁶⁴ For the "pre-smoker" or "learner," however, the memorandum states that the physical effects of smoking, including the effects of nicotine, are "largely unknown, unneeded, or actually quite unpleasant or awkward."⁴⁶⁵ Consequently, the memorandum recommends that "the effort here should be to affect a compromise to minimize the undesirable effects while retaining these which later become

⁴⁶² *Id.* at 7 (emphasis added).

⁴⁶³ Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on Some Thoughts about New Brands of Cigarettes for the Youth Market* (Feb. 2, 1973), at 1. See AR (Vol. 531 Ref. 125).

⁴⁶⁴ *Id.* at 4.

⁴⁶⁵ *Id.* at 2, 4.

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desirable.”⁴⁶⁶ With respect to nicotine, the memorandum recommends that “nicotine should be delivered at about 1.0-1.3 mg/cigarette, the minimum for confirmed smokers. The rate of absorption of nicotine should be kept low by holding pH down, probably below 6.”⁴⁶⁷

Teague’s analysis shows that, as at Philip Morris, scientists at RJR have long understood that nicotine has significant pharmacological effects on the body and is the “primary” reason people smoke. His analysis further shows that, like Philip Morris scientists, RJR scientists also expressly conceived of cigarettes as a drug delivery system.

ii. Other Statements and Research of RJR Scientists and Officials. The views in the Teague memoranda about the “crucial role” of the pharmacological effects of nicotine continued to be expressed within RJR in later years. In approximately 1977, for instance, RJR researchers told the RJR marketing department that “[w]ithout any question, the desire to smoke is based on the effect of nicotine on the body”;⁴⁶⁸ that “a confirmed smoker attempts to get a certain desired level of nicotine”;⁴⁶⁹ and that “[t]he nicotine in the blood acts upon the central nervous system and produces in the average smoker a sensation one could describe as either stimulating or relaxing.”⁴⁷⁰ According to the RJR researchers, while nicotine has a role in “mouth taste” and “mouth satisfaction,”

⁴⁶⁶ *Id.* at 4.

⁴⁶⁷ *Id.*

⁴⁶⁸ Senkus M (R. J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 4 (emphasis added). See AR (Vol. 700 Ref. 593).

⁴⁶⁹ *Id.* at 5 (emphasis added).

⁴⁷⁰ *Id.* at 3.

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that is not nicotine's primary role; rather, "the ultimate satisfaction comes from the nicotine which is extracted . . . *in the lungs*."⁴⁷¹

In the late 1980's and early 1990's, moreover, RJR researchers conducted a series of experiments on how nicotine affects the brain. The published reports from these experiments revealed that 20 years after the Teague memoranda, RJR researchers continued to believe that: (1) nicotine has pharmacological effects on the brain; and (2) smokers smoke cigarettes primarily to obtain these pharmacological effects.

In a 1989 report entitled "Effects of Smoking/Nicotine on Anxiety, Heart Rate, and Lateralization of EEG During a Stressful Movie," RJR used an EEG to test its hypothesis that "nicotine and smoking help smokers to relax and cope with stress and negative affect" through "activation-reducing effects on the EEG."⁴⁷² The experiment's results supported RJR's hypothesis, indicating that nicotine produced the expected "anxiolytic" or anxiety-reducing effects in the brain:

The present results support the view that the electrocortical effects of smoking are a function of environmental stress level, cigarette nicotine delivery, and cortical site. *They are also consistent with previous evidence that nicotine reduces anxiety and with our hypothesis that nicotine's anxiolytic properties are mediated by the right hemisphere.* Normal/high-nicotine delivery cigarettes, relative to low-nicotine control cigarettes, produced cortical activation (decreased alpha power) in both hemispheres during the no-stress control condition . . . but produced the opposite effect, decreased activation (increased alpha power), at the right parietal site during the three stressful movie scenes.⁴⁷³

⁴⁷¹ *Id.* at 7-9 (emphasis added).

⁴⁷² Gilbert DG, Robinson JH, Chamberlin CL (R.J. Reynolds Tobacco Co.), *et al.*, Effects of smoking/nicotine on anxiety, heart rate, and lateralization of EEG during a stressful movie, *Psychophysiology* 1989;26(3):311-319, at 311. See AR (Vol. 14 Ref. 174-2).

⁴⁷³ *Id.* at 316 (citation omitted) (emphasis added).

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The 1989 study used the EEG to measure smokers' brain waves while they watched a film containing graphic images of industrial accidents. In a 1991 study entitled "Electroencephalographic Effects of Cigarette Smoking," RJR researchers measured the effects of smoking on brain waves under "levels of mental workload representative of those encountered in day-to-day living."⁴⁷⁴ They found that the pharmacological effects of smoking are affected by how deeply the smoker inhaled. According to the report:

In light inhaling smokers, . . . smoking was found to attenuate EEG activity in the delta, theta, and alpha frequency bands In deep inhaling smokers, smoking produced a symmetrical central midline increase in beta2 magnitude, *an EEG effect that . . . is associated with anxiety relief.*⁴⁷⁵

These results led the RJR researchers to propose that light inhalers and deep inhalers smoke to obtain different pharmacological effects from nicotine and that the effects produced in deep-inhalers were comparable to the effects of benzodiazepines, a class of addictive drugs used for anxiety relief. According to the report:

The results of the present investigation indicate that *light inhaling . . . smokers may smoke primarily for purposes of mental activation and performance enhancement.* This does not appear to be the case for deeper inhaling . . . smokers. . . . An extensive literature suggests that increased beta2 activity may reflect the anxiolytic properties of the benzodiazepines independently of sedative effects. *Thus, an important smoking motive for deep inhaling smokers might be anxiety reduction.*⁴⁷⁶

A year later, the RJR researchers reported the results of a study designed to isolate the precise effects of nicotine on the brain. In this study, some smokers were given

⁴⁷⁴ Pritchard WS (R.J. Reynolds Tobacco Co.), *Electroencephalographic effects of cigarette smoking, Psychopharmacology* 1991;104:485-490, at 486. See AR (Vol. 3 Ref. 23-2).

⁴⁷⁵ *Id.* at 485 (emphasis added).

⁴⁷⁶ *Id.* at 488 (citations omitted) (emphasis added).

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regular “light” cigarettes to smoke while others were given experimental cigarettes with virtually no nicotine. The results from the EEG showed that the regular “light” cigarette produced “a significant increase in beta2 magnitude,” an effect associated with anxiety relief, and “a significant decrease in delta magnitude,” an effect associated with improved mental alertness.⁴⁷⁷ According to the researchers, “*this indicates that the beneficial effects of smoking on cognitive performance . . . are a function of nicotine absorbed from cigarette smoke upon inhalation.*”⁴⁷⁸

In another report written in 1992, the RJR researchers addressed the question “why do people smoke?” The researchers reject the claim that people smoke to satisfy an addiction, but they do not reject the claim that people smoke to obtain other pharmacological effects from nicotine. To the contrary, as Claude Teague did 20 years earlier, they assert that the reason people smoke is precisely to obtain these pharmacological effects:

We believe that a more reasonable hypothesis concerning why people smoke . . . is that *smokers use cigarettes primarily as a ‘tool’ or ‘resource’ that provides them with needed psychological benefits (increased mental alertness, anxiety reduction, coping with stress).*⁴⁷⁹

In its comments, RJR asserts that nicotine is important in cigarettes because “nicotine plays an important role in the taste and flavor of cigarette smoke.”⁴⁸⁰ The

⁴⁷⁷ Robinson JH, Pritchard WS, Davis RA (R.J. Reynolds Tobacco Co.), Psychopharmacological effects of smoking a cigarette with typical “tar” and carbon monoxide yields but minimal nicotine, *Psychopharmacology* 1992;108:466-472, at 469. See AR (Vol. 11 Ref. 129-3).

⁴⁷⁸ *Id.* at 471 (emphasis added).

⁴⁷⁹ Robinson J, Pritchard W (R.J. Reynolds Tobacco Co.), The role of nicotine in tobacco use, *Psychopharmacology* 1992;108:397-407, at 398 (emphasis added). See AR (Vol. 34 Ref. 589).

⁴⁸⁰ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 50. See AR (Vol. 519 Ref. 103).

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history of RJR's research does not support the company's public position, however. If nicotine were important because of its role in taste, FDA would expect to find that RJR's research would focus on nicotine's impact on taste. The administrative record, however, contains virtually no RJR research demonstrating or investigating nicotine's influence on taste.⁴⁸¹ In contrast, RJR has extensively investigated the pharmacological impacts of nicotine. In total, the administrative record before FDA contains more than 20 studies published or funded by RJR on the effects of nicotine on the body.⁴⁸² The actual number

⁴⁸¹ There is little scientific support for the proposition that nicotine has an important role in cigarette taste. The four studies cited by RJR are all discussed in section II.B.2.c, above. Only one of the studies relied upon by RJR was actually conducted by RJR. This limited investigation by RJR into nicotine's role in taste was presented *after FDA's investigation had commenced*. Pritchard, WS, Robinson, JH, *The Sensory Role of Nicotine in Cigarette "Taste," Smoking Satisfaction and Desire to Smoke*, presented at the International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II (Montreal: Jul. 21-24, 1994). See AR (Vol. 519 Ref. 103, vol. II). As discussed in section II.B.2.c, above, RJR researchers conceded that the study was unable to distinguish the importance of any sensory aspects of nicotine from its pharmacological effects.

⁴⁸² Bjerkce RJ, Langone JJ, Anti-idiotypic antibody probes of neuronal nicotinic receptors, *Biochem Biophys Res Commun* 1989;162(3):1085-1092. See AR (Vol. 46 Ref. 53).

Brazell MP, Mitchell SN, Gray JA, Effect of acute administration of nicotine on in vivo release of noradrenaline in the hippocampus of freely moving rats: a dose-response and antagonist study, *Neuropharmacology* 1991;30(8):823-833. See AR (Vol. 46 Ref. 58).

Byrd GD, Chang KM, Greene JM, *et al.*, Evidence for urinary excretion of glucuronide conjugates of nicotine, cotinine, and trans-3'-hydroxycotinine in smokers, *Drug Metab Dispos Biol Fate Chem* 1992;20(2):192-197. See AR (Vol. 120 Ref. 1131).

Caldwell WS, Green JM, Byrd GD, *et al.*, Characterization of the glucuronide conjugate of cotinine: a previously unidentified major metabolite of nicotine in smokers' urine, *Chem Res Toxicol* 1992;5(2):280-285. See AR (Vol. 46 Ref. 62).

Caldwell WS, Greene JM, Dobson GP, *et al.*, Intragastric nitrosation of nicotine is not a significant contributor to nitrosamine exposure, *Ann NY Acad Sci* 1993;686:213-227. See AR (Vol. 128 Ref. 1388).

Collins AC, Bhat RV, Pauly JR, *et al.*, Modulation of nicotine receptors by chronic exposure to nicotinic agonists and antagonists, in *The Biology of Nicotine Dependence*, eds. Bock G, Marsh J (CIBA Foundation Symposium 152, 1990), at 68-82. See AR (Vol. 47 Ref. 71).

deBethizy JD, Borgerding MF, Doolittle DJ, Chemical and biological studies of a cigarette that heats rather than burns tobacco, *J Clin Pharmacol* 1990;30(8):755-763. See AR (Vol. 47 Ref. 78).

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deBethizy JD, Robinson JH, Davis RA, *et al.*, Absorption of nicotine from a cigarette that does not burn tobacco, *Pharmacology* 1988;37(5):328-332. *See* AR (Vol. 47 Ref. 79).

Gilbert DG, Robinson JH, Chamberlin CL, *et al.*, Effects of smoking/nicotine on anxiety, heart rate, and lateralization of EEG during a stressful movie, *Psychophysiology* 1989;26(3):311-319. *See* AR (Vol. 14 Ref. 174-2).

Hammond DK, Bjerkce R.J, Langone JJ, *et al.*, Metabolism of nicotine by rat liver cytochromes P-450, Assessment utilizing monoclonal antibodies to nicotine and cotinine, *Drug Metab Dispos Biol Fate Chem* 1991;19(4):804-808. *See* AR (Vol. 48 Ref. 110).

Kyerematen GA, Morgan ML, Chattopadhyay B, *et al.*, Disposition of nicotine and eight metabolites in smokers and nonsmokers, *Clin Pharmacol Ther* 1990;48(6):641-651. *See* AR (Vol. 49 Ref. 146).

Kyerematen GA, Taylor LH, deBethizy JD, *et al.*, Pharmacokinetics of nicotine and 12 metabolites in the rat, Application of a new radiometric high performance liquid chromatography assay, *Drug Metab Dispos Biol Fate Chem* 1988;16(1):125-129. *See* AR (Vol. 49 Ref. 145).

Lippiello PM, Femandes KG, The binding of L-[3H]nicotine to a single class of high affinity sites in rat brain membranes, *Mol Pharmacol* 1986;29(5):448-454. *See* AR (Vol. 55 Ref. 165).

Lippiello PM, Mencherif M, Prince RJ, The role of desensitization in CNS nicotinic receptor function, in *International Symposium on Nicotine: The Effects of Nicotine on Biological Systems* 1994, S11. *See* AR (Vol. 55 Ref. 166).

Lippiello PM, Sears SB, Femandes KG, Kinetics and mechanism of L-[3H]nicotine binding to putative high affinity receptor sites in rat brain, *Mol Pharmacol* 1987;31(4):392-400. *See* AR (Vol. 55 Ref. 162).

Marks MJ, Grady SR, Collins AC, Downregulation of nicotinic receptor function after chronic nicotine infusion, *J Pharmacol Exp Ther* 1993;266(3):1268-1276. *See* AR (Vol. 55 Ref. 176).

Mitchell SN, Brazell MP, Joseph MH, *et al.*, Regionally specific effects of acute and chronic nicotine on rates of catecholamine and 5-hydroxytryptamine synthesis in rat brain, *Eur J Pharmacol* 1989;167(3):311-322. *See* AR (Vol. 57 Ref. 200).

Mitchell SN, Brazell MP, Schugens MM, *et al.*, Nicotine-induced catecholamine synthesis after lesions to the dorsal or ventral noradrenergic bundle, *European Journal of Pharmacology* 1990;179(3):383-391. *See* AR (Vol. 57 Ref. 197).

Pritchard WS, Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490. *See* AR (Vol. 3 Ref. 23-2).

Pritchard WS, Gilbert DG, Duke DW, Flexible effects of quantified cigarette smoke delivery on EEG dimensional complexity, *Psychopharmacology* 1993;113:95-102. *See* AR (Vol. 3 Ref. 23-1).

Pritchard WS, Robinson JH, Guy TD, Enhancement of continuous performance task reaction time by smoking in non-deprived smokers, *Psychopharmacology* 1992;108:437-442. *See* AR (Vol. 67 Ref. 72).

Robinson JH, Pritchard WS, Davis RA, Psychopharmacological effects of smoking a cigarette with typical "tar" and carbon monoxide yields but minimal nicotine, *Psychopharmacology* 1992;108:466-472. *See* AR (Vol. 59 Ref. 236).

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of RJR studies may be much higher. According to an RJR spokesperson, “[w]e’ve not only done research on the pharmacological effects of nicotine but we’ve published it in at least 250 peer-reviewed journals and symposia.”⁴⁸³

RJR’s sustained and sophisticated research into nicotine pharmacology demonstrates that RJR knows that (1) its product will affect consumers in a drug-like manner and (2) consumers will use its product to obtain these drug effects.

iii. RJR’s Alternative Tobacco Products. Further evidence of RJR’s understanding of the central role of nicotine in smoking is provided by RJR’s development of alternative tobacco products that are designed to deliver nicotine, but not other constituents of cigarette smoke, to the consumer.

RJR’s efforts to develop alternative nicotine delivery systems began more than 20 years ago. As noted above, Claude Teague recommended in 1972 that RJR develop “some simpler, ‘cleaner’, more efficient and direct way to *provide the desired nicotine dosage* than the present system involving combustion of tobacco.”⁴⁸⁴ In recent years, RJR has developed at least two alternative tobacco products.

Smith KM, Mitchell SN, Joseph MH, Effects of chronic and subchronic nicotine on tyrosine hydroxylase activity in noradrenergic and dopaminergic neurones in the rat brain, *J Neurochem* 1991;57(5):1750-1756. See AR (Vol. 60 Ref. 266).

Wonnacott S, Drasdo AL, Presynaptic actions of nicotine in the CNS, in *Effects of Nicotine on Biological Systems*, eds. Adlkofer F, Thureau K (1991), at 295-305. See AR (Vol. 62 Ref. 302).

⁴⁸³ Collins G, Legal attack on tobacco intensifies, *New York Times*, Jun. 9, 1995. See AR (Vol. 21 Ref. 240a).

⁴⁸⁴ Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 7 (emphasis added). See AR (Vol. 531 Ref. 125).

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First, in the late 1980's, RJR developed and briefly marketed Premier, a product that worked by heating nicotine and glycerol-coated aluminum beads contained in an aluminum cylinder rather than by burning tobacco. Premier resembled a conventional cigarette in appearance only. Inside, it contained a carbon tip, which served as the heat source for the aluminum cylinder.⁴⁸⁵ RJR documents show that RJR was acutely interested in Premier's ability to deliver nicotine to the smoker's blood and brain. For instance, RJR conducted extensive plasma studies to show that smokers using Premier would achieve approximately the same level of nicotine in their blood as smokers using conventional cigarettes.⁴⁸⁶ Other smoke components, however, were reduced by about 90%.⁴⁸⁷ Premier functioned like the alternative nicotine delivery system recommended by Teague. Indeed, RJR used Teague's terminology to market Premier, advertising the product as a "cleaner" cigarette.⁴⁸⁸

More recently, RJR has begun test-marketing a low-smoke product called Eclipse.⁴⁸⁹ Like Premier, Eclipse relies on a carbon tip as a heat source. The tip heats a

⁴⁸⁵ *Chemical and Biological Studies on New Cigarette Prototypes that Heat Instead of Burn Tobacco* (Winston-Salem NC: R.J. Reynolds Tobacco Co., 1988), at 1-10. See AR (Vol. 107 Ref. 980).

⁴⁸⁶ *Id.* at vii, 457-458, 479-483, 490-492.

deBethizy JD, Borgerding MF, Doolittle DJ, *et al.* (R.J. Reynolds), *Chemical and Biological Studies of a Cigarette that Heats Rather than Burns Tobacco*, *J. Clin. Pharmacol.*, 1990;30:755-763. See AR (Vol. 47 Ref. 78).

⁴⁸⁷ *Id.* at 757.

⁴⁸⁸ Pollay RW, Carter-Whitney D, *More Chronological Notes on the Promotion of Cigarettes* (History of Advertising Archives, Aug. 1990), at 29. See AR (Vol. 215 Ref. 2891).

⁴⁸⁹ Cabell B, Smokeless cigarette makers hope to Eclipse market, *Live Report* (Jun. 3, 1996). See AR (Vol. 711 Ref. 11).

Jones C, Reynolds not blowing smoke when it comes to keeping a lid on Eclipse, *The Richmond Times Dispatch* (Jun. 10, 1996). See AR (Vol. 711 Ref. 12).

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glycerin supply in the cigarette rod, which vaporizes and extracts nicotine, but is intended to produce very little of the normal constituents of tar, as it passes through the rod to the smoker's mouth. The final Eclipse smoke vapor is 85% water, glycerol, and nicotine (versus 25% in standard cigarette smoke) and only 15% tar (versus 75% in standard smoke).⁴⁹⁰ Thus, Eclipse is intended to deliver nicotine at levels similar to conventional ultra-low-tar cigarettes, but much lower levels of tar.⁴⁹¹

In its comments, RJR asserts that "Premier was a cigarette" because it provided the smoker with "smoking taste and pleasure."⁴⁹² Likewise, RJR asserts that "Eclipse is a cigarette."⁴⁹³ But the major similarity in the vapor from Premier and Eclipse and the smoke from a conventional cigarette is the nicotine delivery. The implication of RJR's work on Premier and Eclipse is that nicotine delivery is the defining characteristic of a cigarette. As RJR informed FDA officials during the launch of Premier, "without nicotine, you don't have a cigarette."⁴⁹⁴ Premier and Eclipse are thus evidence that conventional cigarettes are, in effect, simply nicotine delivery systems.

iv. RJR's Legal Briefs. Before the Agency, RJR argues that nicotine is not addictive and that the Agency should not believe the widespread "allegations" to the

⁴⁹⁰ Hiltz P, Little smoke, but still lots of nicotine, *New York Times*, Nov. 27, 1994. See AR (Vol. 34 Ref. 568).

⁴⁹¹ Feder BJ, Ready to test new cigarette, maker fears tough rules, *New York Times*, Apr. 8, 1996. See AR (Vol. 700 Ref. 225).

⁴⁹² R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 34-35 (emphasis added). See AR (Vol. 519 Ref. 103).

⁴⁹³ R.J. Reynolds Tobacco Co., Comment (Apr. 19, 1996). See AR (Vol. 700 Ref. 225).

⁴⁹⁴ Department of Health and Human Services, Memorandum of meeting, *RJR's "Smokeless" Cigarette* (Oct. 23, 1987), at 3. See AR (Vol. 34 Ref. 558-2).

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contrary. However, RJR has taken exactly the opposite position in court cases. There RJR argues that the risk of becoming addicted to cigarettes is so foreseeable to consumers that consumers must be held to have assumed the risk. For instance, in one case RJR argued that consumers should not be allowed to sue cigarette manufacturers on the grounds that they become addicted, because they should have foreseen this risk:

There can be no serious suggestion that ordinary consumers do not expect to find nicotine in cigarettes, or that ordinary consumers have not long been well aware that it may be very difficult to stop smoking. *The common knowledge of the alleged habituating or "addicting" properties of cigarettes has resulted in almost casual references to these properties in decisions from around the country throughout this century.*⁴⁹⁵

RJR asserts that this statement does not acknowledge addiction because RJR is merely stating that "allegations" concerning the addictive properties of cigarettes are well known. However, RJR's position in the litigation and its position before the Agency are in fundamental conflict. RJR cannot consistently deny its awareness of nicotine's addictive properties while at the same time claiming that its consumers should be deemed to have an awareness of these properties. RJR's recognition of "the common knowledge of the alleged habituating or 'addicting' properties of cigarettes" is thus further evidence of RJR's awareness of the addictive and other pharmacological effects of cigarettes.

In sum, the internal RJR memoranda in the administrative record, RJR's published research into nicotine pharmacology, RJR's development of alternative tobacco products that function as nicotine delivery devices, and even RJR's litigation briefs all point to the

⁴⁹⁵ Appellees brief in reply to appellants' opposition to petition for transfer, *Rogers v. R.J. Reynolds et al.* (Sup. Ct. Ind.) (No. 49A02-8904 CV 164) (1990), at 7-8 (citation omitted) (emphasis added). See AR (Vol. 21 Ref. 229).

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conclusion that RJR knows that its cigarettes will have pharmacological effects, that consumers will purchase its products to obtain these effects, and that, in essence, its cigarettes function as nicotine delivery devices. This is persuasive evidence that RJR intends its product to affect the structure and function of the body.

c. The Statements and Research of Brown & Williamson

The administrative record includes a large array of documents from the Brown & Williamson Tobacco Corporation, the third largest cigarette manufacturer in the United States, and its corporate parent, BAT Industries PLC, formerly British-American Tobacco Company (BATCO). These documents show that Brown & Williamson and BATCO have conducted extensive research on nicotine's pharmacological effects and that for over 30 years senior researchers and officials at Brown & Williamson and BATCO have considered nicotine to be "addictive;"⁴⁹⁶ "an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses"⁴⁹⁷ and the reason "why people inhale smoke."⁴⁹⁸

The documents from Brown & Williamson and BATCO in the administrative record include many unpublished reports from company research, internal memoranda, and reports from conferences of company scientists. These documents are summarized in the following chronology, which illustrates that the companies have long regarded

⁴⁹⁶ See, e.g., Yeaman A (Brown & Williamson), *Implications of Battelle Hippo I and II and the Griffith Filter* (Jul. 17, 1963), at 4. See AR (Vol. 21 Ref. 221).

⁴⁹⁷ BATCO Group R&D, *Method for Nicotine and Cotinine in Blood and Urine* (May 21, 1980), at 2. See AR (Vol. 23 Ref. 300-1).

⁴⁹⁸ Greig CC (BATCO), *Short Lived Species in Smoke* (Jan. 26, 1984), attached to letter from Ayres CI (BATCO) to Kohnhorst EE (Brown & Williamson) (Feb. 9, 1984), at 10. See AR (Vol. 34 Ref. 584).

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themselves as “in a nicotine rather than a tobacco industry.”⁴⁹⁹ Although the statements of company scientists and officials seem to become somewhat more guarded with time, the documents show a consistent recognition of nicotine’s pharmacological effects and uses, including its role in causing and sustaining addiction.

i. Statements and Research in the 1960’s. In the 1960’s, senior officials at BATCO and Brown & Williamson and their senior researchers candidly discussed nicotine’s “addictive” and “drug” effects in internal meetings. In a 1962 conference of BATCO researchers, for instance, Charles Ellis, the science advisor to the BATCO board, acknowledged that “*smoking is a habit of addiction.*”⁵⁰⁰ He described the role of nicotine in cigarettes as follows:

*It is my conviction that nicotine is a very remarkable beneficent drug that both helps the body to resist external stress and also can as a result show a pronounced tranquillising effect. . . . Nicotine is not only a very fine drug, but the techniques of administration by smoking has [sic] considerable psychological advantages and a built-in control against excessive absorption. It is almost impossible to take an overdose of nicotine in the way it is only too easy to do with sleeping pills.*⁵⁰¹

Charles Ellis recommended that BATCO conduct research “to investigate whether cigarette smoke produces effects on the central nervous system characteristic of tranquilising or stimulating drugs and, if so, to see if such activity is due solely to nicotine.”⁵⁰² The Battelle Memorial Institute in Geneva, Switzerland, conducted this

⁴⁹⁹ Johnson RR (BATCO), *Comments on Nicotine* (Jun. 30, 1963), at 10-11. See AR (Vol. 21 Ref. 242).

⁵⁰⁰ Ellis C (BATCO), *The smoking and health problem*, in *Smoking and Health—Policy on Research*, Research Conference, Southampton, England (1962), at 4 (emphasis added). See AR (Vol. 21 Ref. 220).

⁵⁰¹ *Id.* at 15-16 (emphasis added).

⁵⁰² *Id.* at 16.

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research for BATCO, producing a series of reports in 1963 called “HIPPO I,” “HIPPO II,” “The Fate of Nicotine in the Body,” and “A Tentative Hypothesis on Nicotine Addiction.”

These reports substantiated and explained nicotine’s drug-like and addictive effects. “HIPPO II,” for instance, suggested that “*the key to the explanation of both phenomena of tolerance and of addiction*” to nicotine could be found through “[a] quantitative investigation of the relations with time of nicotine—and of some possible brain mediators—on adreno-corticotrophic activity.”⁵⁰³ The report further stated that “the so-called ‘beneficial effects’ of nicotine are of two kinds: 1. Enhancing effect on the pituitary-adrenal response to stress; 2. Regulation of body weight.”⁵⁰⁴

Similarly, “The Fate of Nicotine in the Body” found that nicotine “*appears to be intimately connected with the phenomena of tobacco habituation (tolerance) and/or addiction.*”⁵⁰⁵ It also reported “[t]here is increasing evidence that *nicotine is the key factor in controlling, through the central nervous system, a number of beneficial effects of tobacco smoke*, including its action in the presence of stress situations.”⁵⁰⁶

“A Tentative Hypothesis on Nicotine Addiction” stated that “the hypothalamo-pituitary stimulation of nicotine is *the beneficial mechanism which makes people smoke*,

⁵⁰³ Haselbach C, Libert O, *Final Report on Project HIPPO II* (Mar. 1963), at 4 (emphasis added). See AR (Vol. 64 Ref. 321).

⁵⁰⁴ *Id.* at 2.

⁵⁰⁵ Geissbuhler H, Haselbach C, *The Fate of Nicotine in the Body* (May 1963), at 1 (emphasis added). See AR (Vol. 21 Ref. 243).

⁵⁰⁶ *Id.* at 1 (emphasis added).

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in other words, nicotine helps people to cope with stress.”⁵⁰⁷ The report then suggested that nicotine addiction could be explained as follows:

If nicotine intake, however, is prohibited to chronic smokers, the corticotropin-releasing ability of the hypothalamus is greatly reduced, so that these individuals are left with an unbalanced endocrine system. *A body left in this unbalanced status craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine.*⁵⁰⁸

The Battelle reports were distributed to the top officials at Brown & Williamson and other tobacco companies. Charles Ellis sent copies of the Battelle reports to the president of Brown & Williamson, William S. Cutchins. Brown & Williamson in turn sent the Project Hippo reports to RJR.⁵⁰⁹

In July 1963, Brown & Williamson’s general counsel, Addison Yeaman, wrote an internal memorandum entitled “Implications of Battelle Hippo I and II and the Griffith Filter.” He stated that “*nicotine is addictive*” and that “[w]e are, then, in the business of selling nicotine, an addictive drug . . .”⁵¹⁰

⁵⁰⁷ Haselbach C, Libert O, *A Tentative Hypothesis on Nicotine Addiction* (May 30, 1963), at 1 (emphasis added). See AR (Vol. 20 Ref. 197).

⁵⁰⁸ *Id.* at 2 (emphasis added).

⁵⁰⁹ Note to Cutchins WS (Brown & Williamson) (Jun. 19, 1963). See AR (Vol. 14, Ref. 165-4).

Letter from Ellis C (BATCO) to Yeaman AY (Brown & Williamson) (Jun. 28, 1963). See AR (Vol. 14 Ref. 165-2).

Letter from Yeaman AY (Brown & Williamson) to Jacob EJ (R.J. Reynolds Co.) (Aug. 5, 1963). See AR (Vol. 14 Ref. 165-3).

⁵¹⁰ Yeaman AY (Brown & Williamson), *Implications of Battelle Hippo I and II and the Griffith Filter* (Jul. 17, 1963), at 4 (emphasis added). See AR (Vol. 21 Ref. 221).

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These views were frequently reiterated. In June of 1967, Charles Ellis stated, “*we are in a nicotine rather than a tobacco industry.*”⁵¹¹ Several months later, at an October 1967 meeting, BATCO researchers agreed that “[*s*]moking is an addictive habit attributable to nicotine.”⁵¹²

In 1968, Sidney J. Green, who was a member of BATCO’s board as well as the company’s director of research, acknowledged that one “recognisable type” of smoking behavior is “addictive” smoking. He added, “it seems a good assumption that *nicotine plays a predominant role for many smokers. . . . [A] good part of the tobacco industry is concerned with the administration of nicotine to consumers.*”⁵¹³

Similarly, at another BATCO research conference in 1968, the researchers agreed that nicotine has “*pre-eminent importance*” and that “the pharmacology of nicotine should continue to be kept under review.”⁵¹⁴

A year later, at a 1969 meeting of BATCO researchers, BATCO scientist D. J.

Wood stated:

The presence of nicotine is the reason why the tobacco plant was singled out from all other plants for consumption in this rather unusual way.

Nicotine has well documented pharmacological action. It is claimed to have a dual effect, acting both as a stimulant and a tranquilliser. It is believed to be responsible for the “satisfaction”

⁵¹¹ Johnson RR (BATCO), *Comments on Nicotine* (Jun. 30, 1963), at 10 (emphasis added). See AR (Vol. 21 Ref. 242).

⁵¹² Minutes of BATCO Group R&D Conference at Montreal, Canada (Oct. 24, 1967), at 2 (emphasis added). See AR (Vol. 21 Ref. 206-4). FDA notes that the version of this document made public by Congress contains a handwritten edit changing “an addictive habit” to “a habit.”

⁵¹³ Green SJ (BATCO), *BAT Group Research* (Sep. 4, 1968), at 1-2 (emphasis added). See AR (Vol. 15 Ref. 192).

⁵¹⁴ Minutes of BATCO Research Conference at Hilton Head, SC (Sep. 24-30, 1968), at 3 (emphasis added). See AR (Vol. 31 Ref. 525-1).

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*of smoking, using this term in the physiological rather than the psychological sense.*⁵¹⁵

And at another 1969 conference of BATCO scientists, the following conclusion was reached: “[t]he Conference agreed that all the evidence continues to demonstrate the importance of nicotine to the smoker. . . .”⁵¹⁶

Numerous other similar statements were made by Brown & Williamson and BATCO researchers and officials in the 1960’s. They are described in the Jurisdictional Analysis. See 60 FR 41584–41586. Collectively, these statements show that even as early as the 1960’s, Brown & Williamson and BATCO officials knew the addictive and other pharmacological effects of nicotine, knew that consumers smoked cigarettes for these effects, and viewed themselves as in the drug delivery business.

ii. Statements and Research in the 1970’s and 1980’s. Throughout the 1970’s and 1980’s, Brown & Williamson and BATCO officials continued to emphasize the importance of nicotine in cigarettes. At a 1970 conference of BATCO researchers, for instance, the researchers postulated that “[n]icotine is important, and there is probably a minimum level necessary for consumer acceptance in any given market.”⁵¹⁷

In 1972, S.J. Green, the BATCO board member and research director, stated that “[t]he tobacco smoking habit is reinforced or dependent upon the psycho-

⁵¹⁵ Wood DJ (BATCO), *Aspects of the R&DE Function*, Notes for a talk given by Wood DJ at Chelwood, Sep. 1969 (Jul. 20, 1970), at 7 (emphasis added). See AR (Vol. 22 Ref. 287).

⁵¹⁶ Minutes of BATCO Research Conference at Kronberg (Jun. 2-6, 1969), at 7 (emphasis added). See AR (Vol. 14 Ref. 172-4).

⁵¹⁷ Summary and conclusions of BAT Group Research Conference at St. Adele, Quebec (Nov. 9-13, 1970), at 1 (emphasis added). See AR (Vol. 23 Ref. 294).

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*pharmacological effects mainly of nicotine.*⁵¹⁸ Similarly, a 1972 BATCO research report observed:

It has been suggested that a considerable proportion of smokers depend on the pharmacological action of nicotine for their motivation to continue smoking.

*If this view is correct, the present scale of the tobacco industry is largely dependent on the intensity and nature of the pharmacological action of nicotine.*⁵¹⁹

These statements demonstrate an awareness that nicotine has “reinforcing” effects, one of the hallmarks of an addictive substance, and that the tobacco industry is built upon these effects.

At a 1974 BATCO conference, company scientists reported that BATCO research had found that consumers appear to smoke to fulfill their “nicotine requirements,” stating that “the Kippa study suggests that whatever the characteristics of cigarettes as determined by smoking machines, *the smoker adjusts his pattern to deliver his own nicotine requirements (about 0.8 mg per cigarette).*”⁵²⁰

At a 1976 BATCO conference on smoking behavior, the researchers again stated that nicotine has reinforcing effects on smokers, observing that nicotine is “*known to be pharmacologically active in the brain*” and is “*considered to be the reinforcing factor in the smoking habit for at least 80% of smokers.*”⁵²¹

⁵¹⁸ Green SJ (BATCO), *The Association of Smoking and Disease* (Jul. 26, 1972), at 1 (emphasis added). See AR (Vol. 15 Ref. 193).

⁵¹⁹ Kilburn KD, Underwood JG (BATCO), *Preparation and Properties of Nicotine Analogues* (Nov. 9, 1972), at 2 (citations omitted) (emphasis added). See AR (Vol. 31 Ref. 524-1).

⁵²⁰ Notes on BATCO Group R&D Conference at Duck Key, FL (Jan. 12-18, 1974), at 2 (emphasis added). See AR (Vol. 25 Ref. 327).

⁵²¹ Minutes of BATCO Group R&D Conference on Smoking Behaviour at Southampton, England (Oct. 11-12, 1976), at BW-W2-02145, BW-W2-02152–BW-W2-02153 (emphasis added). See AR (Vol. 14 Ref. 180).

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At a 1977 conference, nicotine was once more the “focal point.” A Brown & Williamson summary of the conference stated that “[i]n many cases, psychological and physiological changes observed in subjects . . . were shown to be due to nicotine” and “[m]ost researchers conclude that *the nicotine effect is biphasic and dosage dependent; small doses stimulate and large doses depress.*”⁵²²

A year later, BATCO board member and chief researcher S.J. Green explicitly acknowledged that nicotine is addictive. Specifically, he wrote “[t]he strong addiction to cigarette[s] removes freedom of choice from many individuals.”⁵²³

A 1980 BATCO research report stated that “[n]icotine is an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses in vivo.”⁵²⁴

A 1981 report on the pharmacology of nicotine by the Tobacco Advisory Council, which represents U.K. tobacco manufacturers including BATCO, stated that “*nicotine is regarded as the most pharmacologically-active compound in tobacco smoke*” and concluded that “[i]n a nutshell, our approach has been to regard nicotine as a ‘drug.’”⁵²⁵

⁵²² Trip report of BATCO International Smoking Behavior Conference at Chelwood Vachery, England (Jan. 6, 1978), at 1-2 (emphasis added). See AR (Vol. 178 Ref. 2075).

⁵²³ Notes of Green SJ (1978) (emphasis added). See AR (Vol. 528 Ref. 97, appendix 18).

⁵²⁴ BATCO Group R&D, *Method for Nicotine and Cotinine in Blood and Urine* (May 21, 1980), at 2 (emphasis added). See AR (Vol. 23, Ref. 300-1).

⁵²⁵ Cohen AJ, Roe FJC (Tobacco Advisory Council), *Monograph on the Pharmacology and Toxicology of Nicotine* (1981), at 1, 17 (emphasis added). See AR (Vol. 14 Ref 184).

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In 1982, a market research report for Imperial Tobacco Ltd., BATCO's Canadian subsidiary, referred to attitudes of adolescents "[o]nce addiction does take place," and states that "addicted they do indeed become."⁵²⁶ The report goes on:

Recidivism has several causes . . . [including] the belief that after a few weeks off cigarettes, one could begin again to smoke 'just a few.' . . . This 'just a few' business is actually *a surrender to addiction* while trying to . . . *pretend to oneself and to others that addiction is no longer present, which is nonsense.*⁵²⁷

At a 1983 BATCO research conference, the minutes of the proceedings state that "[t]he basic assumption is that nicotine . . . is almost certainly the key smoke component for satisfaction . . ."⁵²⁸

In a 1984 letter, C. I. Ayres of BATCO wrote to E. E. Kohnhorst, the executive vice president and chief operating officer of Brown & Williamson, enclosing a report stating that nicotine is "why people inhale smoke":

*It is well known that nicotine can be removed from smoke by the lung and transmitted to the brain within seconds of smoke inhalation. Since it is the major or sole pharmacologically active agent in smoke, it must be presumed that this is its preferred method of absorption and thus why people inhale smoke.*⁵²⁹

In 1984, BATCO also held two research conferences at which nicotine was extensively discussed. At the first conference, BATCO researchers held sessions on

⁵²⁶ Kwechansky Marketing Research (report prepared for Imperial Tobacco Ltd.), *Project Plus/Minus* (May 7, 1982), at i, 26 (emphasis added). See AR (Vol. 108 Ref. 1571).

⁵²⁷ *Id.* at 36-37 (emphasis added).

⁵²⁸ Minutes of BATCO Research Conference at Rio de Janeiro (Aug. 22-26, 1983), at 10 (emphasis added). See AR (Vol. 179 Ref. 2087).

⁵²⁹ Greig CC, *Short Lived Species in Smoke* (Jan. 26, 1984), attached to letter from Ayres CI (BATCO) to Kohnhorst EE (Brown & Williamson) (Feb. 9, 1984), at 10 (emphasis added). See AR (Vol. 34 Ref. 584).

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“Nicotine Dose Requirement-Background,” “Nicotine Dose Estimation,” “Effects of Nicotine—Interaction with the Brain (Pharmacology),” and “Product Modification for Maximal Nicotine Effects.”⁵³⁰ The researchers reported that “[i]ntuitively it is felt that ‘satisfaction’ must be related to nicotine. Many people believe it [is] a ‘whole body response’ and involves the action of nicotine in the brain.”⁵³¹ They also acknowledged “the central role of nicotine in the smoking process and our business generally.”⁵³²

At the second conference, BATCO researchers reported that “in its simplest sense puffing behaviour is the means of providing nicotine dose in a metered fashion.”⁵³³

According to one BATCO researcher speaking at the conference:

Smoking is . . . a personal tool used by the smoker to refine his behaviour and reactions to the world at large.

It is apparent that *nicotine largely underpins these contributions through its role as a generator of central physiological arousal effects* which express themselves as changes in human performance and psychological well-being.”⁵³⁴

Other similar statements are summarized in the Jurisdictional Analysis. See 60 FR 41584-41666. Like the statements quoted above, they show that scientists at Brown &

⁵³⁰ Ayres CI (BATCO), Notes from the GR&DC [Group Research and Development Centre] Nicotine Conference at Southampton, England (Jul. 9-12, 1984) (slide), at BW-W2-02639. See AR (Vol. 14 Ref. 172).

⁵³¹ Minutes of BATCO Nicotine Conference at Southampton, England (Jun. 6-8, 1984), at BW-W2-01977 (emphasis added). See AR (Vol. 22 Ref. 287-6).

⁵³² Ayres CI (BATCO), Notes from the GR&DC [Group Research and Development Centre] Nicotine Conference at Southampton, England (Jul. 9-12, 1984), at 62 (emphasis added). See AR (Vol. 14 Ref. 172-1).

⁵³³ Proceedings of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session I (Jul. 9-12, 1984) (slide), at BW-W2-03242 (emphasis added). See AR (Vol. 21 Ref. 238).

⁵³⁴ Ferris RP, *The role of smoking behaviour in product development: some observations on the psychological aspects of smoking behaviour*, in Proceedings of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III (Jul. 9-12, 1984), at 79 (emphasis added). See AR (Vol. 192 Ref. 2172).

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Williamson and BATCO devoted extensive attention to understanding the pharmacological effects and uses of nicotine, consistently regarded nicotine as being the primary reason consumers smoked, and viewed cigarettes as nicotine delivery devices.

iii. Statements and Research in the 1990's. New documents received by FDA during the public comment period demonstrate that researchers and officials of Brown & Williamson and BATCO continue to hold similar views about nicotine in cigarettes in the 1990's. The new documents are a series of memoranda relating to the potential purchase in 1992 by BATCO of a manufacturer of nicotine patches, Stowic Resources Ltd.⁵³⁵

Brown & Williamson's research department evaluated the potential purchase in a memorandum entitled "Transdermal Nicotine Patches." Brown & Williamson researchers observed that "[t]here is currently a void in the market for a product that provides tobacco satisfaction in a form that is acceptable and available to many segments of the market" and recommended that "[w]e should be looking for opportunities to fill the void."⁵³⁶

However, Brown & Williamson researchers expressed doubts that a nicotine patch could provide consumers with the same pharmacological effects obtained by smoking:

The pattern of the blood nicotine concentrations attained by smoking vs the patch, however, are different. *With smoking, blood nicotine absorption is very rapid.* Blood nicotine concentrations go through a series of peaks and troughs with successive cigarette smoking throughout the day. . . . With the patch, nicotine absorption is relatively slow and continuous and peak blood levels are not as high as with cigarette smoking. *A major advantage of cigarette smoking over the nicotine patch system is the ability for*

⁵³⁵ Salter R, *Transdermal Nicotine* (Apr. 3, 1992); Research and Development, *Response to BAT Industries Note on Transdermal Nicotine* (28.02.92) (Mar. 27, 1992); Kausch, Research and Development/Quality, *Transdermal Nicotine*; Research and Development/Quality, *Transdermal Nicotine Patches*; McGraw M (Brown & Williamson), *Nicotine Delivery Systems* (Apr. 24, 1992). See AR (Vol. 531 Ref. 124).

⁵³⁶ *Transdermal Nicotine Patches*, at 3. See AR (Vol. 531 Ref. 124).

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*the smoker to have very flexible control over titrating his desired dose of nicotine.*⁵³⁷

Similar views were expressed by other BAT Industries subsidiaries. BAT Industries' German subsidiary, for instance, stated that “[t]he rapid, peaking intake of nicotine which the smoker clearly wants cannot be achieved with nicotine application via . . . plaster.”⁵³⁸

The German subsidiary further acknowledged that nicotine can produce dependency and addiction. According to the German report, which was distributed by BAT Industries to the then president of Brown & Williamson, R. J. Pritchard, “[t]he disadvantage of rapid nicotine intake similar to that achieved with a cigarette is seen in the danger of people possibly becoming dependent on it.”⁵³⁹ The German subsidiary observed that even with nicotine gum there is a “danger of addiction,” stating that “the smoker can organize intake to suit himself” and achieve “[a]ctive control over intake and the condition it produces.”⁵⁴⁰

Brown & Williamson's legal department argued against the purchase of Stowic on legal grounds, warning that it would suggest that Brown & Williamson is in “the nicotine delivery business” and cause Brown & Williamson to “run a serious risk of facing FDA jurisdiction.” The lawyers also argued that the purchase of Stowic would have “disastrous” implications for product liability litigation because “[t]he marketing of any

⁵³⁷ *Id.* at 2 (emphasis added).

⁵³⁸ Research and Development/Quality, *Re: Transdermal Nicotine*, at 3 (emphasis added). See AR (Vol. 531 Ref. 124).

⁵³⁹ *Id.* at 3 (emphasis added).

⁵⁴⁰ *Id.* at 2.

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nicotine delivery system undercuts our position on addiction.”⁵⁴¹ Ultimately, BAT Industries rejected the purchase of Stowic.

iv. The Wigand Deposition. A comment from public health organizations has also urged FDA to consider a 1995 deposition of Jeffrey S. Wigand, the vice president of research and development at Brown & Williamson from 1989 to 1993. According to Wigand’s deposition, which was submitted to the Agency with the comment, and which has been widely publicized in the media, a number of officers of Brown & Williamson, including Thomas Sandefur, the company president and chief executive officer, made “numerous statements . . . that *we’re in the nicotine delivery business.*”⁵⁴² Wigand also testified in the deposition that Sandefur “frequently” stated the opinion and belief that nicotine is “*addictive*”;⁵⁴³ that Brown & Williamson manipulates nicotine levels in tobacco, using various techniques including blending of tobacco leaves and adding ammonia compounds to change the pH of smoke;⁵⁴⁴ that BATCO scientists had done studies to identify “the boundaries of nicotine pharmacology,” and that BATCO showed that nicotine below “0.4 milligrams does not sustain satisfaction.”⁵⁴⁵

⁵⁴¹ McGraw M (Brown & Williamson), *Nicotine Delivery Systems* (Apr. 24, 1992), at 1-2 (emphasis added). See AR (Vol. 531 Ref. 124).

⁵⁴² Deposition transcript of Wigand JS (Nov. 29, 1995), at 12 (emphasis added). See AR (Vol. 700 Ref. 224, exhibit 2).

⁵⁴³ *Id.* at 12-13.

⁵⁴⁴ *Id.* at 27-29.

⁵⁴⁵ *Id.* at 27, 33.

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Wigand's assertions in the deposition have been disputed by Brown & Williamson, which contends that they are untrue.⁵⁴⁶ His statements, however, are consistent with and corroborated by the views expressed by Brown & Williamson and BAT Industries officials since the 1960's. Although the Agency finds Wigand's testimony to be additional relevant evidence of the manufacturers' intent to affect the structure and function of the body, his testimony is not essential to any of the Agency's determinations.

Cumulatively, the three decades of documents from Brown & Williamson, BATCO, and BAT Industries demonstrate that these companies have long understood that nicotine is addictive and has other significant pharmacological effects; that consumers smoke cigarettes to obtain the drug effects of nicotine; and that cigarettes are a drug delivery system, functioning as "the means of providing nicotine in a metered fashion."⁵⁴⁷

d. The Statements and Research of Other Cigarette Manufacturers

The administrative record establishes that the other major cigarette companies, the American Tobacco Company, the Lorillard Tobacco Company, and the Liggett Group Inc., funded research studies similar to the research conducted by Philip Morris, RJR, and Brown & Williamson, and as a result of the research have acquired a detailed knowledge of the pharmacological effects of nicotine on the brain.

For instance, American Tobacco which merged with Brown & Williamson in 1995, funded extensive research on nicotine pharmacology. From 1940 through 1970, American

⁵⁴⁶ See, e.g., Freedman AM, Cigarette defector says CEO lied to Congress about view of nicotine, *Wall Street Journal*, Jan. 26, 1996. See AR (Vol. 639 Ref. 2).

⁵⁴⁷ Proceedings of BATCO Group R&D Smoking Behaviour Marketing Conference, Session I (Jul. 9-12, 1984) (slide), at BW-W2-03242. See AR (Vol. 24 Ref. 316).

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Tobacco funded 111 studies on the biological effects of cigarettes.⁵⁴⁸ According to a staff report of the House Subcommittee on Health and the Environment, ninety-three of these studies (over 80%) related to the effects of nicotine on the body.⁵⁴⁹ In one 1945 study funded by the company, entitled "The Role of Nicotine in the Cigarette Habit," smokers were given cigarettes with extremely low levels of nicotine. The study found that half of the subjects "definitely missed the nicotine."⁵⁵⁰

The activities of the Council for Tobacco Research (CTR), an industry trade association that conducts research on behalf of the major tobacco producers in the United States,⁵⁵¹ are further evidence of the extent of the industry's knowledge of the pharmacological effects of nicotine on the human brain. On behalf of the tobacco industry, CTR has funded numerous studies on the pharmacology of nicotine. The goal of these studies was to learn why nicotine makes people want to smoke:

Most of the pharmacological studies currently being supported by The Council are concerned with the effects of nicotine and/or smoking on the central nervous system (the brain) with *the object of learning more about why people like, want or need to smoke.*⁵⁵²

⁵⁴⁸ Staff Report, *Evidence of Nicotine Manipulation by the American Tobacco Company*, and exhibits, prepared by the Majority Staff Subcommittee on Health and the Environment (Dec. 20, 1994), at 3. See AR (Vol. 292 Ref. 4064-4066).

⁵⁴⁹ *Id.*

⁵⁵⁰ Finnegan JK, Larson PS, Haag HB (American Tobacco Co.), *The role of nicotine in the cigarette habit*, in *Biologic Research on Tobacco* (American Tobacco Company: 1962), at 65-66 (originally published in *Science* 1945;102). See AR (Vol. 14 Ref. 178-1).

⁵⁵¹ All the major cigarette manufacturers have participated in CTR. The current members include Philip Morris, R.J. Reynolds, Brown & Williamson, and Lorillard Tobacco Co. Although the Liggett Group is not currently a member of CTR, it has been so in the past. See Letter from Yeaman to Ahrensfield *et al.* of Dec. 6, 1977. See AR (Vol. 478 Ref. 8069).

⁵⁵² Council for Tobacco Research, *Report of the Scientific Director, 1969-1970*, at 13 (emphasis added). See AR (Vol. 16 Ref. 195-4).

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The body of CTR research on nicotine pharmacology is extensive. For example:

- Thirty-nine CTR studies identify the sites and mechanisms of nicotine receptors in the brain;⁵⁵³

⁵⁵³ These CTR documents, along with the other CTR documents cited in this section, can be found in the administrative record, Volumes 45-64 of Docket 95N0253J:

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⁵⁵⁴ Andersson K, Fuxe K, Agnati LF, *et al.*, Effects of acute central and peripheral administration of nicotine on ascending dopamine pathways in the male rat brain. Evidence for nicotine induced increases of dopamine turnover in various telencephalic dopamine nerve terminal systems, *Med Biol* 1981;59(3):170-176.

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II.C.2.

- Nine CTR studies show that nicotine induces both arousal and calming effects;⁵⁵⁶

Fuxe K, Andersson K, Eneroth P, *et al.*, Neuroendocrine actions of nicotine and of exposure to cigarette smoke: medical implications, *Psychoneuroendocrinology* 1989;14(1-2):19-41.

Fuxe K, Andersson K, Eneroth P, *et al.*, Neurochemical mechanisms underlying the neuroendocrine actions of nicotine: focus on the plasticity of central cholinergic nicotinic receptors, *Prog Brain Res* 1989;79: 197-207.

Fuxe K, Andersson K, Eneroth P, *et al.*, Effects of Nicotine and exposure to cigarette smoke on discrete dopamine and noradrenaline nerve terminal systems of the telencephalon and diencephalon of the rat: Relationship to reward mechanisms and neuroendocrine functions and distribution of nicotinic binding sites in brain, in *Tobacco Smoking and Nicotine: A Neurobiological Approach*, eds. Martin WR, Van Loo G, Iwamoto ET, Davis L, 1987:225-262.

Marty MA, Erwin VG, Cornell K, *et al.*, Effects of nicotine on beta-endorphin, alpha MSH, and ACTH secretion by isolated perfused mouse brains and pituitary glands, in vitro, *Pharmacol Biochem Behav* 1985;22(2):317-325.

Rubin RP, Warner W, Nicotine-induced stimulation of steroidogenesis in adrenocortical cells of the cat. *Br J Pharmacol* 1975;53(3):357-362.

Siegel RA, Andersson K, Fuxe K, *et al.*, Rapid and discrete changes in hypothalamic catecholamine nerve terminal systems induced by audiogenic stress, and their modulation by nicotine-relationship to neuroendocrine function, *Eur J Pharmacol* 1983 ;91:49-56.

Westfall TC, Brasted M, Effect of 4,4'-biphenylenebis-((2-oxoethylene)-bis-(2,2- diethoxyethyl)) dimethylammonium dibromide (DMAE) on accumulation and nicotine-induced release of norepinephrine in the heart, *J Pharmacol Exp Ther* 1973;184:198-204.

Westfall TC, Brasted M, Specificity of blockade of the nicotine-induced release of 3H-norepinephrine from adrenergic neurons of the guinea-pig heart by various pharmacological agents, *J Pharmacol Exp Ther* 1974; 189(3):659-664.

⁵⁵⁶ Domino EF, Electroencephalographic and behavioral arousal effects of small doses of nicotine: a neuropsychopharmacological study. The effects of nicotine and smoking on the central nervous system, *Ann N Y Acad Sci* 1967;142:216-244.

Heimstra NW, Fallesen JJ, Kinsley SA, *et al.*, The effects of deprivation of cigarette smoking on psychomotor performance, *Ergonomics* 1980;23(11):1047-1055.

Marks MJ, Burch JB, Collins AC, Genetics of nicotine response in four inbred strains of mice, *J Pharmacol Exp Ther* 1983 ;226(1):291-302.

Nelsen JM, Goldstein L, Improvement of performance on an attention task with chronic nicotine treatment in rats, *Psychopharmacologia* 1972;26(4):347-360.

Pradhan SN, Effects of nicotine on several schedules of behavior in rats, *Arch Int Pharmacodyn Ther* 1970; 183(1):127-138.

Schaeppi U, Nicotine treatment of selected areas of the cat brain: effects upon EEG and autonomic system, *Int J Neuropharmacol* 1968;7(3):207-220.

II.C.2.

- Nine CTR studies use an EEG to examine the effects of nicotine on brain waves;⁵⁵⁷
- Nine CTR studies investigate the physiological effects of nicotine on the brain and their time course;⁵⁵⁸

Stadnicki SW, Schaeppi UH, Nicotinic changes in EEG and behavior after intravenous infusion in awake unrestrained cats, *Arch Int Pharmacodyn Ther* 1972;197(1):72-85.

Stadnicki SW, Schaeppi U, Nicotine infusion into the fourth ventricle of unrestrained cats: changes in EEG and behavior, *Arch Int Pharmacodyn Ther* 1970; 183(2):277-288.

Yamamoto KI, Domino EF, Nicotine-induced EEG and behavioral arousal. *Int J Neuropharmacol* 1965;4(6):359-373.

⁵⁵⁷ Domino EF, Electroencephalographic and behavioral arousal effects of small doses of nicotine: a neuropsychopharmacological study. The effects of nicotine and smoking on the central nervous system, *Ann N Y Acad Sci* 1967;142:216-244.

Erwin VG, Cornell K, Towell JF, Nicotine alters catecholamines and electrocortical activity in perfused mouse brain, *Pharmacol Biochem Behav* 1986;24(1):99-105.

Kawamura H Somino EF, Differential actions of m and n cholinergic agonists on the brainstem activating system, *Int J Neuropharmacol* 1969;8(2):105-115.

Marty MA, Erwin VG, Cornell K, *et al.*, Effects of nicotine on beta-endorphin, alpha MSH, and ACTH secretion by isolated perfused mouse brains and pituitary glands, in vitro, *Pharmacol Biochem Behav* 1985;22(2):3 17-325.

Nelsen JM, Pelley K, Goldstein L, Chronic nicotine treatment in rats 2. Electroencephalographic amplitude and variability changes occurring within and between structures, *Res Commun Chem Pathol Pharmacol* 1973;5(3):694-704.

Schaeppi U, Nicotine treatment of selected areas of the cat brain: effects upon EEG and autonomic system, *Int J Neuropharmacol* 1968;7(3):207-220.

Stadnicki SW, Schaeppi UH, Nicotinic changes in EEG and behavior after intravenous infusion in awake unrestrained cats, *Arch Int Pharmacodyn Ther* 1972;197(1):72-85.

Stadnicki SW, Schaeppi U, Nicotine infusion into the fourth ventricle of unrestrained cats: changes in EEG and behavior, *Arch Int Pharmacodyn Ther* 1970;183(2):277-288.

Yamamoto KI, Domino EF, Nicotine-induced EEG and behavioral arousal, *Int J Neuropharmacol* 1965;4(6):359-373.

⁵⁵⁸ Aboud LG, Grassi S, Noggle HD, Comparison of the binding of optically pure (-)- and (+)-[3H] nicotine to rat brain membranes, *Neurochem Res* 1985;10(2):259-267.

Andersson K, Fuxe K, Eneroth P, *et al.*, Effects of withdrawal from chronic exposure to cigarette smoke on hypothalamic and preoptic catecholamine, nerve terminal systems and on the secretion of pituitary hormones in the male, *Naunyn Schmiedeberg Arch Pharmacol* 1989;339(4):387-396.

II.C.2.

- Six CTR studies characterize the effect of nicotine on behavioral performance and cognitive function;⁵⁵⁹
- Six CTR studies research the general pharmacokinetics of nicotine;⁵⁶⁰

Andersson K, Fuxe K, Eneroth P, *et al.*, Effects of acute intermittent exposure to cigarette smoke on catecholamine levels and turnover in various types of hypothalamic DA and NA nerve terminal systems as well as on the secretion of adenohipophyseal hormones and corticosterone, *Acta Physiol Scand* 1985;124(2):277-285.

Bhagat B, Influence of chronic administration of nicotine on the turnover and metabolism of noradrenaline in the rat brain, *Psychopharmacologia* 1970;18(4):325-332.

Fuxe K, Andersson K, Harfstrand A, *et al.*, Increases in dopamine utilization in certain limbic dopamine terminal populations after a short period of intermittent exposure of male rats to cigarette smoke, *J Neural Transm* 1986;67(1-2):15-29.

Fuxe K, Andersson K, Eneroth P, *et al.*, Effects of Nicotine and exposure to cigarette smoke on discrete dopamine and noradrenaline nerve terminal systems of the telencephalon and diencephalon of the rat: Relationship to reward mechanisms and neuroendocrine functions and distribution of nicotinic binding sites in brain, in *Tobacco Smoking and Nicotine: A Neurobiological Approach*, eds. Martin WR, Van Loo GR, Iwamoto ET, *et al.*, 1987:225-262.

Tung CS, Ugedo L, Grenhoff J, *et al.*, Peripheral induction burst firing in locus coeruleus neurons by nicotine mediated via excitatory amino acids, *Synapse* 1989;4(4):313-318.

Wong LA, Gallagher JP, Pharmacology of nicotinic receptor-mediated inhibition in rat dorsolateral septal neurones, *J Physiol (Lond)* 1991;436:325-346.

Yamamoto KI, Domino EF, Nicotine-induced EEG and behavioral arousal, *Int J Neuropharmacol* 1965;4(6):359-373.

⁵⁵⁹ Bhagat B, Wheeler N, Effect of nicotine on the swimming endurance of rats, *Neuropharmacology* 1973;12(12):1161-1165.

Heimstra NW, Fallesen JJ, Kinsley SA, *et al.*, The effects of deprivation of cigarette smoking on psychomotor performance, *Ergonomics* 1980;23(11):1047-1055.

Marks MJ, Burch JB, Collins AC, Genetics of nicotine response in four inbred strains of mice, *J Pharmacol Exp Ther* 1983 ;226(1):291-302.

Nelsen JM, Pelley K, Goldstein L, Chronic nicotine treatment in rats 2. Electroencephalographic amplitude and variability changes occurring within and between structures, *Res Commun Chem Pathol Pharmacol* 1973;5(3):694-704.

Nelsen JM, Pelley K, Goldstein L, Protection by nicotine from behavioral disruption caused by reticular formation stimulation in the rat, *Pharmacol Biochem Behav* 1975;3(5):749-754.

Nelsen JM, Goldstein L, Improvement of performance on an attention task with chronic nicotine treatment in rats, *Psychopharmacologia* 1972;26(4):347-360.

II.C.2.

- Five CTR studies describe the development of sophisticated techniques for determining the presence of nicotine in body fluids;⁵⁶¹
- Four CTR studies evaluate plasma profiles of nicotine;⁵⁶²

⁵⁶⁰ Becker RF, King JE, Studies on nicotine absorption during pregnancy. II. The effects of acute heavy doses on mother and neonates, *Am J Obstet Gynecol* 1966;95(4):515-522.

Haines CF Jr, Mahajan DK, Miljkovic D, *et al.*, Radioimmunoassay of plasma nicotine in habituated and naive smokers, *Clin Pharmacol Ther* 1974;16(6):1083-1089.

Hibberd AR, Gorrod JW, Enzymology of the metabolic pathway from nicotine to cotinine, *in vitro*, *Eur J Drug Metab Pharmacokinet* 1983;8:151-162.

Kershbaum A, Bellet S, Cigarette, cigar, and pipe smoking. Some differences in biochemical effects, *Geriatrics* 1968;23(3):126-134.

Monji N, Castro A, Plasma nicotine pharmacokinetics in dogs after intravenous administration: determination by radioimmunoassay, *Res Commun Chem Pathol Pharmacol* 1979;23(2):267-277.

Rama Sastry BV, Chance MB, Singh G, *et al.*, Distribution and retention of nicotine and its major metabolite cotinine in the rat as a function of time, in *International Symposium on Nicotine*, eds. Clarke PBS, Quik M, Thureau K, *et al.*, 1994:125.

⁵⁶¹ Castro A, Monji N, Nicotine enzyme immunoassay, *Res Commun Chem Pathol Pharmacol* 1986; 51(3):393-404.

Castro A, Malkus H, Radioimmunoassays of drugs of abuse in humans: a review, *Res Commun Chem Pathol Pharmacol* 1977;16(2):291-309.

Haines CF Jr, Mahajan DK, Miljkovic D, *et al.*, Radioimmunoassay of plasma nicotine in habituated and naive smokers, *Clin Pharmacol Ther* 1974;16(6):1083-1089.

McNiven NL, Raisinghani KH, Patashnik S, *et al.*, Determination of nicotine in smokers' urine by gas chromatography, *Nature* 1965;208:788-789.

Monji N, Castro A, Plasma nicotine pharmacokinetics in dogs after intravenous administration: determination by radioimmunoassay, *Res Commun Chem Pathol Pharmacol* 1979;23(2):267-277.

⁵⁶² Castro A, Monji N, Nicotine enzyme immunoassay, *Res Commun Chem Pathol Pharmacol* 1986; 51(3):393-404.

Haines CF Jr, Mahajan DK, Miljkovic D, *et al.*, Radioimmunoassay of plasma nicotine in habituated and naive smokers, *Clin Pharmacol Ther* 1974;16(6):1083-1089.

Monji N, Castro A, Plasma nicotine pharmacokinetics in dogs after intravenous administration: determination by radioimmunoassay, *Res Commun Chem Pathol Pharmacol* 1979;23(2):267-277.

Rama Sastry BV, Chance MB, Singh G, *et al.*, Distribution and retention of nicotine and its major metabolite cotinine in the rat as a function of time, in *International Symposium on Nicotine*, eds. Clarke PBS, Quik M, Thureau K, *et al.*, 1994:125.

II.C.2.

- Four CTR studies research the factors affecting the onset and duration of nicotine's effects on the body;⁵⁶³
- Three CTR studies investigate the metabolic fate of nicotine;⁵⁶⁴
- Two CTR studies specifically investigate the enzymatic systems involved in nicotine metabolism;⁵⁶⁵
- Two CTR studies show that smokers metabolize nicotine faster than nonsmokers;⁵⁶⁶
- Two CTR studies examine the factors affecting the absorption of nicotine into the bloodstream;⁵⁶⁷

⁵⁶³ Domino EF, Electroencephalographic and behavioral arousal effects of small doses of nicotine: A neuropsychopharmacological study. The effects of nicotine and smoking on the central nervous system, *Ann N Y Acad Sci* 1967;142:216-244.

Hoff EC, Hockman CH, Neurophysiological aspects of the action of nicotine. The effects of nicotine and smoking on the central nervous system, *Ann N Y Acad Sci* 1967;142:121-125.

Lapin EP, Maker HS, Sershen H, *et al.*, Dopamine-like action of nicotine: lack of tolerance and reverse tolerance, *Brain Res* 1987;407(2):351-363.

Stitzer M, Morrison J, Domino EF, Effects of nicotine on fixed-interval behavior and their modification by cholinergic antagonists, *J Pharmacol Exp Ther* 1970;171(2):166-177.

⁵⁶⁴ Aboud LG, Grassi S, Junig J, *et al.*, Specific binding and metabolism of (-)- and (+)-[3H] nicotine in isolated rat hepatocytes and hepatocyte membranes, *Arch Int Pharmacodyn Ther* 1985;273(1):62-73.

Hibberd AR, Gomod JW, Nicotine delta 1 '(5)' iminium ion: a reactive intermediate in nicotine metabolism, *Adv Exp Med Biol* 1981:1121-1131.

Vincek WC, Martin BR, Aceto MD, *et al.*, Synthesis of 4,4-ditritio-(+)-nicotine: comparative binding and distribution studies with natural enantiomer, *J Pharm Sci* 1981;70(11):1292-1293.

⁵⁶⁵ Hibberd AR, Gorrod JW, Enzymology of the metabolic pathway from nicotine to cotinine, in vitro, *Eur J Drug Metab Pharmacokinet* 1983;8:151-162.

Wilson KL Jr, Chang, RS, Bowman ER, *et al.*, Nicotine-like actions of cis-metanicotine and trans-metanicotine, *J Pharmacol Exp Ther* 1976;196(3):685-696.

⁵⁶⁶ Hatchell PC, Collins AC, The influence of genotype and sex on behavioral sensitivity to nicotine in mice, *Psychopharmacology (Berl)* 1980;71(1):45-49.

Jusko WJ, Role of tobacco smoking in pharmacokinetics, *J Pharmacokinet Biopharm* 1978;6(1):7-39.

II.C.2.

- Two CTR studies examine the distribution of nicotine to the brain;⁵⁶⁸
- Two CTR studies research the relationship of nicotine's physiological effects on the body to nicotine blood levels;⁵⁶⁹ and
- One CTR study shows that there may be gender differences in the metabolism of nicotine.⁵⁷⁰

The results of the CTR-funded research show that nicotine has significant pharmacological effects on the body. In fact, numerous CTR studies demonstrate that nicotine produces pharmacological effects similar to those of other addictive substances. For example:

- Thirteen CTR studies demonstrate that nicotine, like other addictive drugs, acts on dopaminergic receptors in the brain to release dopamine, a chemical in the brain's reward system that reinforces the intake of certain substances;⁵⁷¹

⁵⁶⁷ Haines CF Jr, Mahajan DK, Miljkovic D, *et al.*, Radioimmunoassay of plasma nicotine in habituated and naive smokers, *Clin Pharmacol Ther* 1974;16(6):1083-1089.

Kershbaum A, Bellet S, Cigarette, cigar, and pipe smoking. Some differences in biochemical effects, *Geriatrics* 1968;23(3):126-134.

⁵⁶⁸ Hatchell PC, Collins AC, The influence of genotype and sex on behavioral sensitivity to nicotine in mice, *Psychopharmacology (Berl)* 1980;71(1):45-49.

Vincek WC, Martin BR, Aceto MD, *et al.*, Synthesis of 4,4-ditritio-(+)-nicotine: comparative binding and distribution studies with natural enantiomer, *J Pharm Sci* 1981;70(11):1292-1293.

⁵⁶⁹ Hatchell PC, Collins AC, The influence of genotype and sex on behavioral sensitivity to nicotine in mice, *Psychopharmacology (Berl)* 1980;71(1):45-49.

Westfall TC, Anderson GP, Influence of nicotine on catecholamine metabolism in the rat, *Arch Int Pharmacodyn Ther* 1967;169(2):421-428.

⁵⁷⁰ Jusko WJ, Role of tobacco smoking in pharmacokinetics, *J Pharmacokinet Biopharm* 1978;6(1):7-39.

⁵⁷¹ Abood LG, Lu X, Banerjee S, Receptor binding characteristics of a 3H-labeled azetidine analogue of nicotine, *Biochem Pharmacol* 1987;36(14):2337-2341.

II.C.2.

- Twelve CTR studies demonstrate that tolerance to nicotine occurs;⁵⁷²

Andersson K, Fuxe K, Eneroth P, *et al.*, Mecamylamine induced blockade of nicotine induced inhibition of gonadotrophin and TSH secretion and of nicotine induced increases of catecholamine turnover in the rat hypothalamus, *Acta Physiol Scand Suppl* 1980;479:27-29.

Andersson K, Fuxe K, Eneroth P, *et al.*, Effects of acute intermittent exposure to cigarette smoke on catecholamine levels and turnover in various types of hypothalamic DA and NA nerve terminal systems as well as on the secretion of adenohipophyseal hormones and corticosterone, *Acta Physiol Scand* 1985;124(2):277-285.

Andersson K, Fuxe K, Eneroth P, *et al.*, Involvement of cholinergic nicotine-like receptors as modulators of amine turnover in various types of hypothalamic dopamine and noradrenaline nerve terminal systems and of prolactin, LH, FSH and TSH secretion in the castrated male rat, *Acta Physiol Scand* 1982;116(1):41-50.

Andersson K, Fuxe K, Eneroth P, *et al.*, Interactions of nicotine and pentobarbitone in the regulation of telencephalic and hypothalamic catecholamine levels and turnover and of adenohipophyseal hormone secretion in the normal male rat, *Naunyn Schmiedebergs Arch Pharmacol* 1982;321(4):287-292.

Andersson K, Fuxe K, Eneroth P, *et al.*, Effects of acute central and peripheral administration of nicotine on hypothalamic catecholamine nerve terminal systems and on the secretion of adenohipophyseal hormones in the male rat, *Med Biol* 1982;60(2):98-111.

Erwin VG, Cornell K, Towell JF, Nicotine alters catecholamines and electrocortical activity in perfused mouse brain, *Pharmacol Biochem Behav* 1986;24(1):99-105.

Fuxe K, Andersson K, Harfstrand A, *et al.*, Increases in dopamine utilization in certain limbic dopamine terminal populations after a short period of intermittent exposure of male rats to cigarette smoke, *J Neural Transm* 1986;67(1-2):15-29.

Grenhoff J, Svensson TH, Selective stimulation of limbic dopamine activity by nicotine, *Acta Physiol Scand* 1988;133(4):595-596.

Harsing LG, Sershen H, Vizi SE, *et al.*, N-type calcium channels are involved in the dopamine releasing effect of nicotine, *Neurochem Res* 1992;17(7):729-734.

Lapin EP, Maker HS, Sershen H, *et al.*, Action of nicotine on accumbens dopamine and attenuation with repeated administration, *Eur J Pharmacol* 1989;160(1):53-59.

Lapin EP, Maker HS, Sershen H, *et al.*, Dopamine-like action of nicotine: lack of tolerance and reverse tolerance, *Brain Res* 1987;407(2):351-363.

Westfall TC, Effect of nicotine and other drugs on the release of 3H-norepinephrine and 3H-dopamine from rat brain slices, *Neuropharmacology* 1974;13(8):693-700.

⁵⁷² Aboud LG, Lowy K, Booth H, Acute and chronic effects of nicotine in rats and evidence for a non-cholinergic site of action, *NIDA Res Monogr* 1979:136-149.

Aboud LG, Grassi S, Costanzo M, *et al.*, Behavioral and biochemical studies in rats after chronic exposure to nicotine, *NIDA Res Monogr* 1984;54:348-355.

II.C.2.

- Three CTR studies research the neurochemical mechanisms of nicotine withdrawal;⁵⁷³

Andersson K, Fuxe K, Eneroth P, *et al.*, Effects of withdrawal from chronic exposure to cigarette smoke on hypothalamic and preoptic catecholamine, nerve terminal systems . and on the secretion of pituitary hormones in the male, *Naunyn Schmiedebergs Arch Pharmacol* 1989;339(4):387-396.

Cronan T, Conrad J, Bryson R, Effects of chronically administered nicotine and saline on motor activity in rats, *Pharmacol Biochem Behav* 1985;22(5):897-899.

Domino EF, Lutz MP, Tolerance to the effects of daily nicotine on rat bar pressing behavior for water reinforcement, *Pharmacol Biochem Behav* 1973; 1(4):445-448.

Fuxe K, Andersson K, Eneroth P, *et al.*, Effects of Nicotine and exposure to cigarette smoke on discrete dopamine and noradrenaline nerve terminal systems of the telencephalon and diencephalon of the rat: Relationship to reward mechanisms and neuroendocrine functions and distribution of nicotinic binding sites in brain, in *Tobacco Smoking and Nicotine: A Neurobiological Approach*, eds. Martin WR, Van Loo GR, Iwamoto ET, *et al.*, 1987;225-262.

Lapin EP, Maker HS, Sershen H, *et al.*, Dopamine-like action of nicotine: lack of tolerance and reverse tolerance, *Brain Res* 1987;407(2):351-363.

Nelsen JM, Goldstein L, Improvement of performance on an attention task with chronic nicotine treatment in rats, *Psychopharmacologia* 1972;26(4):347-360.

Rosecrans JA, Noncholinergic mechanisms involved in the behavioral and stimulus effects of nicotine, and relationships to the process of nicotine dependence, in *Tobacco Smoking and Nicotine: A Neurobiological Approach*, eds. Martin WR, Van Loo GR, Iwamoto ET, *et al.*, 1987:125-139.

Stitzer M, Morrison J, Domino EF, Effects of nicotine on fixed-interval behavior and their modification by cholinergic antagonists, *J Pharmacol Exp Ther* 1970;171(2):166-177.

Wenzel DG, Azmeh N, Clark II, Studies on the acute and chronic depressor actions of nicotine in the rat, *Arch Int Pharmacodyn Ther* 1971;193(1):23-36.

Westfall TC, Brase DA, Studies on the mechanism of tolerance to nicotine-induced elevations of urinary catecholamines, *Biochem Pharmacol* 1971;20(7):1627-1635.

⁵⁷³ Andersson K, Effects of withdrawal from chronic exposure to cigarette smoke on hypothalamic and preoptic catecholamine nerve terminal systems and the secretion of pituitary hormones in the male, *Naunyn Schmiedebergs Arch Pharmacol* 1989;339(4):387-396.

Fuxe K, Effects of Nicotine and exposure to cigarette smoke on discrete dopamine and noradrenaline nerve terminal systems of the telencephalon and diencephalon of the rat: relationship to reward mechanisms and neuroendocrine functions and distribution of nicotinic binding sites in brain, in *Tobacco Smoking and Nicotine: A Neurobiological Approach*, eds. Martin WR, Van Loo GR, Iwamoto ET, *et al.*, 1987:225-262.

Rosecrans JA, Noncholinergic mechanisms involved in the behavioral and stimulus effects of nicotine, and relationships to the process of nicotine dependence, in *Tobacco Smoking and Nicotine: A Neurobiological Approach*, eds. Martin WR, Van Loo GR, Iwamoto ET, *et al.*, 1987:125-139.

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- Two CTR studies investigate the effects of nicotine withdrawal on performance,⁵⁷⁴
- Two CTR studies show that nicotine is psychoactive and produces clearly discriminable stimulus effects,⁵⁷⁵ and
- Two CTR studies show that nicotine can enhance the rewarding effects of electrical brain stimulation.⁵⁷⁶

Indeed, seven CTR studies state expressly that nicotine is an addictive or dependence-producing drug.⁵⁷⁷ For instance, one CTR-funded study stated that “*smoking*

⁵⁷⁴ Heimstra NW, Fallesen JJ, Kinsley SA, *et al.*, The effects of deprivation of cigarette smoking on psychomotor performance, *Ergonomics* 1980;23(11):1047-1055.

Heimstra NW, Bancroft NR, DeKock AR, Effects of smoking upon sustained performance in a simulated driving task, in the effects of nicotine and smoking on the central nervous system, *Ann NY Acad Sci* 1967;142:295-307.

⁵⁷⁵ Chance WT, Kallman MD, Rosecrans JA, *et al.*, A comparison of nicotine and structurally related compounds as discriminative stimuli, *Br J Pharmacol* 1978;63(4):609-616.

Rosecrans JA, Nicotine as a discriminative stimulus: a neurobehavioral approach to studying central cholinergic mechanisms, *J Subst Abuse* 1989;1(3):287-300.

⁵⁷⁶ Olds ME, Domino EF, Comparison of muscarinic and nicotinic cholinergic agonists on self-stimulation behavior, *J Pharmacol Exp Ther* 1969;166(2):189-204.

Pradhan SN, Bowling C, Effects of nicotine on self-stimulation in rats, *J Pharmacol Exp Ther* 1971;176(1):229-243.

Deneau GA, Inoki R, Nicotine self-administration in monkeys, in The effects of nicotine and smoking on the central nervous system, *Ann NY Acad Sci* 1967;142:277-279.

Other research jointly funded by the tobacco industry examines nicotine's ability to serve as a positive reinforcer in self-administration studies involving monkeys. See 60 FR 41642.

⁵⁷⁷ Bosse R, Gamery AJ, Glynn RJ, Age and addiction to smoking, *Addict Behav* 1980;5(4):341-351.

Martin WR, Van Loo GR, Iwamoto ET, *et al.*, *Tobacco Smoking and Nicotine: A Neurobiological Approach* (New York: Plenum Press, 1987).

Rosecrans JA, Noncholinergic mechanisms involved in the behavioral and stimulus effects of nicotine, and relationships to the process of nicotine dependence, in *Tobacco Smoking and Nicotine: A Neurobiological Approach*, eds. Martin WR, Van Loo GR, Iwamoto ET, *et al.*, 1987:125-139.

Rosecrans JA, Nicotine as a discriminative stimulus: a neurobehavioral approach to studying central cholinergic mechanisms, *J Subst Abuse* 1989;1(3):287-300.

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*is a form of dependence no less binding than that of other addictive drugs.”*⁵⁷⁸ Similarly, another CTR-funded study observed that “*compelling evidence now exists that regular smoking is a form of drug addiction to nicotine.*”⁵⁷⁹

The Agency received no comments disputing FDA’s characterization in the Jurisdictional Analysis of any of these CTR-funded studies. Thus, these uncontested studies demonstrate that the entire cigarette industry had detailed knowledge of the pharmacological effects of nicotine on the brain, including knowledge of research funded by the industry that found nicotine to be an addictive drug.

Collectively, these CTR studies and the studies conducted by individual cigarette manufacturers show that the cigarette manufacturers have acted like traditional pharmaceutical companies. Before marketing a prescription drug, a pharmaceutical company studies the pharmacokinetics of the drug (how it is absorbed into the body, metabolized, and excreted), the pharmacodynamics of the drug (what specific effects the drug has on the body’s chemistry and metabolism as it makes its way through the body), and the clinical effects of the drug (whether the drug is effective in producing the desired

Svensson TH, Grenhoff J, Engberg G, Effect of nicotine on dynamic function of brain catecholamine neurons, in *The Biology of Nicotine Dependence*, eds. Bock G, Marsh J, *CIBA Foundation Symposium* 1990;152:169-180.

Tung CS, Ugedo L, Grenhoff J, *et al.*, Peripheral induction burst firing in locus coeruleus neurons by nicotine mediated via excitatory amino acids, *Synapse* 1989;4(4):313-318.

Williams JS, Crumpacker DW, Krier MJ, Stability of a factor-analytic description of smoking behavior, *Drug Alcohol Depend* 1980;5(6):467-478.

⁵⁷⁸ Bosse R Gamery AJ, Glynn RJ, Age and addiction to smoking, *Addict Behav* 1980;5(4):341-351 (emphasis added).

⁵⁷⁹ Svensson TH, Grenhoff J, Engberg G, Effect of nicotine on dynamic function of brain catecholamine neurons, in *The Biology of Nicotine Dependence*, eds. Bock G, Marsh J, *CIBA Foundation Symposium* 1990;152:169-180 (emphasis added).

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therapeutic or physiological effects). The cigarette manufacturers have conducted or funded the same studies for nicotine. As a result, the cigarette manufacturers' understanding of the pharmacological effects and uses of nicotine are closely analogous to—if not more extensive and sophisticated than—the understanding any pharmaceutical company has of traditional drug products.

e. Three Decades of Statements and Research by Cigarette Manufacturers Are Sufficient to Establish Intent

As discussed in section II.C.1., above, the statements and research of a manufacturer are relevant evidence of the uses of a product that are “intended” by the manufacturer. This evidence shows that when the manufacturers offer cigarettes for sale, they “have in mind” that their products will be purchased for specific pharmacological uses by consumers. Hence, the evidence is sufficient to establish that the effects of cigarettes on the structure and function of the body are “intended” by the manufacturers.

The cigarette manufacturers assert, however, that the statements and research relied upon by the Agency are not reliable evidence of the cigarette manufacturers' intent in this case. Among other things, they argue that the three decades of tobacco company statements and research on the addictive and other pharmacological effects of nicotine contained in the administrative record are irrelevant to the intended use of cigarettes and smokeless tobacco because the statements were made and the research was conducted over a period of many years and are not contemporaneous with the sale of currently marketed products.⁵⁸⁰

⁵⁸⁰ Other arguments of the manufacturers concerning the evidence that may be used to establish intended use are addressed in section II.E., below.

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FDA disagrees. The extensiveness of the statements and research of the cigarette manufacturers in the administrative record, most of which have only recently become available, reflects a remarkably consistent pattern of the industry's views, repeated frequently over time. These documents and statements establish the knowledge and belief of tobacco company officials that cigarettes have, and are predominantly used by consumers for, pharmacological effects. The fact that these statements span three decades simply demonstrates that the companies' knowledge and beliefs about the pharmacological effects and uses of cigarettes are both long-standing and consistent. As described in section II.A.5., above, commercial cigarettes marketed today contain a level of nicotine that is sufficient to produce addiction and other pharmacological effects. Thus, statements made 30 years ago about the pharmacological effects of nicotine in cigarettes are equally relevant to the cigarettes being marketed today. Moreover, as discussed above, many of the statements and research relied upon by FDA are of recent origin.

Tobacco industry comments also argue that statements of individuals employed, or formerly employed, by the manufacturers are not relevant to establishing the intent of any manufacturer because they are not formal statements of company policy. According to one manufacturer's comments, the only statements that are evidence of the manufacturer's "institutional intent" are those that have been adopted by the manufacturer "after whatever formalities required by the decision-making procedures of the institution have been followed."⁵⁸¹

⁵⁸¹ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 24. See AR (Vol. 519 Ref. 103).

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FDA disagrees that the statements of tobacco industry employees are not evidence of the intended use of the product. FDA is relying on the statements as evidence that the tobacco companies know that nicotine in tobacco has pharmacological effects and that consumers use tobacco to obtain those effects. Many of the statements come from executives at the companies. As one court observed, in a case relied upon by a tobacco company comment:

When a major company executive speaks, "everybody listens" in the corporate hierarchy, and when an executive's comments prove to be disadvantageous to a company's subsequent litigation posture, it cannot compartmentalize this executive as if he had nothing more to do with company policy than the janitor or watchman.

Ezold v. Wolf, 983 F.2d 509, 546 (3d Cir. 1992) (internal citation omitted).

Moreover, many of the statements relied upon by FDA come from individuals whose function within the company was to research and understand the motives for smoking and who regularly communicated those views to company management. A corporation ordinarily relies on its research department to answer scientific questions, such as the pharmacologic effects of its product on users and the purposes for which consumers use the product. The statements quoted by FDA show a highly consistent pattern of views within and among the research departments of the cigarette companies, demonstrating that the statements are not the idiosyncratic opinions of a few individuals within one company, but widely shared views.

Indeed, the record shows that the cigarette manufacturers did in fact rely upon and regularly consult with their research scientists. In the case of Philip Morris, for instance, the CEO of Philip Morris, the president of Philip Morris USA, and vice presidents and directors from functions such as marketing met on a monthly basis with senior officials and

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scientists from the company's research and development department to discuss Philip Morris' basic and applied research and other topics.⁵⁸² These regular meetings, the occurrence of which Philip Morris does not dispute, show that the knowledge and views of the Philip Morris scientists were regularly sought by and communicated to the officers at the head of the company.

For these reasons, the statements and research of the cigarette manufacturers are sufficient evidence to establish that the manufacturers intend to affect the structure and function of the body. As FDA's regulations recognize, "objective intent" can be established by evidence that "a manufacturer knows, or has knowledge of, facts that would give him notice," that a product will be used for pharmacological purposes.

21 CFR 201.128, 801.4.⁵⁸³

3. The Cigarette Manufacturers Have Conducted Extensive Product Research and Development To Optimize the Delivery of Nicotine

The tobacco industry documents in the administrative record show not only that the cigarette manufacturers "have in mind" that cigarettes will be used for specific pharmacological purposes, but also that they have "designed" cigarettes to ensure that smokers receive a pharmacologically active dose of nicotine. The evidence in the record contains two categories of evidence of the manufacturers' design: (1) the evidence of the

⁵⁸² Declaration of Uydess IL (Feb. 29, 1996), at 22-23. *See* AR (Vol. 638 Ref. 1).

⁵⁸³ The Freedom of Information Act (FOIA) and Title VII cases cited by the comments do not purport to set forth a standard for assessing objective intent under public health statutes like the Federal Food, Drug, and Cosmetic Act, and the two statutes serve different purposes than the Act. They are, therefore, not controlling here. The FDA regulation cited by the comments is similarly inapplicable to the question of what evidence is relevant to establishing intended use. FDA is not contending that the statements of a single tobacco company employee can bind the company in such a way that the totality of the remaining evidence of intent can be overridden. Here, however, there is a consistent pattern of internal statements that, taken as a whole, are highly relevant to intent.

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manufacturers' extensive product research and development to identify the doses of nicotine needed to produce pharmacological effects and to optimize the delivery of nicotine to smokers, which is discussed below; and (2) the evidence of the manufacturers' control and manipulation of nicotine in marketed cigarettes, which is discussed in section II.C.4., below.

The product research and development efforts described in the administrative record indicate that for three decades the cigarette manufacturers have strived to develop ways to maintain pharmacologically active doses of nicotine despite consumer demands for "healthier," lower-yield products. A primary focus of the cigarette manufacturers' efforts has been to deliver sufficient nicotine to provide the desired pharmacological effects of nicotine while at the same responding to consumer health concerns by reducing tar deliveries. Industry documents disclose research to determine the dose of nicotine that must be delivered to ensure "pharmacological satisfaction,"⁵⁸⁴ as well as estimates by company scientists of the range of acceptable nicotine doses to produce pharmacological effects. These documents show that the manufacturers are aware that consumers will not accept cigarettes that do not deliver a pharmacologically active dose of nicotine.

The manufacturers' product research and development efforts have involved a wide variety of approaches to ensure delivery of an adequate dose of nicotine, including changes in tobacco blends; chemical manipulation to liberate "free" nicotine; filter and ventilation designs that selectively remove more tar than nicotine; the development of high-technology nicotine delivery devices that provide smokers nicotine but virtually no

⁵⁸⁴ BATCO Group R&D Research Programme, 1984: Proposed revisions for 1985-87, Research Conference, Southampton, England (Sep. 1984), at 2. See AR (Vol. 26 Ref. 369-1).

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tar; genetic engineering of tobacco plants to enhance nicotine content; the search for nicotine “analogues” that retain nicotine’s reinforcing abilities; and research into compounds that act synergistically to strengthen nicotine’s pharmacological effects. As discussed in section II.C.4., below, many (but not all) of these methods are used in cigarettes currently marketed to the public.⁵⁸⁵

a. Philip Morris’ Product Research and Development Efforts

Evidence on the research and development efforts of Philip Morris demonstrates that the company believes that cigarettes must deliver sufficient nicotine to produce pharmacological effects in smokers and that the company conducted extensive research to optimize nicotine delivery from its cigarettes.

In a 1972 document, Philip Morris senior scientist William Dunn discussed the basis for the company’s concerns about lowering nicotine levels below a certain minimum. Dunn related consumers’ lack of interest in cigarettes providing less than 1 mg of nicotine to the fact that 1 mg of nicotine “readily” produces the desired “physiological response”:

Despite many low nicotine brand entries into the marketplace, none of them have captured a substantial segment of the market. In fact, critics of the industry would do well to reflect upon the indifference of the consumer to the industry’s efforts to sell low-delivery brands. 94% of the cigarettes sold in the U.S. deliver more than 1 mg of nicotine. 98.5% deliver more than 0.9 mg.⁵⁸⁶ *The physiological response to nicotine can readily be elicited by cigarettes delivering in the range of 1 mg of nicotine.*⁵⁸⁷

⁵⁸⁵ The evidence discussed in section II.C.3. is also relevant to, and provides further support for, the Agency’s finding that the cigarette manufacturers “have in mind” that their products will be used for pharmacological purposes.

⁵⁸⁶ Dunn WL, *Motives and Incentives in Cigarette Smoking* (1972) (summary of CTR-sponsored conference in St. Martin), at 4. See AR (Vol. 12 Ref. 133).

⁵⁸⁷ *Id.* (emphasis added).

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A 1978 Philip Morris document shows a similar focus on identifying the minimum amount of nicotine necessary to produce pharmacological effects, referred to as the threshold level of nicotine in the body that satisfies consumers' "nicotine need."⁵⁸⁸ The document discussed plans to study cigarettes in which the tar level was kept constant, but the nicotine level was varied. The purpose of the study was to determine how smokers react to levels of nicotine so close to the minimum that "the total nicotine in the [smoker's] system remains at or near the nicotine need threshold."⁵⁸⁹

This focus on producing cigarettes that provide pharmacologically active doses of nicotine is a prominent feature of Philip Morris' development of low-tar cigarettes. William Farone, the former director of applied research at Philip Morris, described the goals of Philip Morris' product research and development efforts in a statement submitted to the Agency. According to Farone, "*a key objective of the cigarette industry over the last 20-30 years*" was decreasing tar while maintaining the delivery of nicotine, and that tobacco company researchers therefore considered it a "top priority" to "[m]inimiz[e] the exposure to the potential negative health effects of the undesirable chemical components in tar *while maintaining an acceptable and pharmacologically active nicotine level.*"⁵⁹⁰

This involved extensive product research and development. Farone stated:

Extensive, in some instances ground breaking, research by the tobacco industry was necessary to construct a cigarette that ensured an adequate delivery of nicotine as the cigarette market evolved from the traditional full flavored, unfiltered product of the

⁵⁸⁸ Dunn WL, *Plans and Objectives—1979* (Dec. 6, 1978), in 141 Cong. Rec. H7670 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁵⁸⁹ *Id.*

⁵⁹⁰ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 4 (emphasis added). See AR (Vol. 638 Ref. 2).

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1950's to the filtered, low tar cigarette demanded by many smokers for the last 30-40 years. *The objective of industry scientists and product developers, simply stated, was to provide the consumer with the same pharmacological satisfaction derived from nicotine in the natural blends and flavor of the full strength cigarettes of the 1950's as the marketplace shifted to the naturally less flavorful and satisfying low tar and nicotine cigarette demanded by the more health conscious consumer.*⁵⁹¹

The declaration of Ian Uydess, an associate senior scientist at Philip Morris from 1977 to 1989, confirms the company's extensive interest in nicotine delivery. According to Uydess, "*Philip Morris wanted to know everything there was to know about nicotine.*"⁵⁹² Sophisticated equipment, such as liquid and gas chromatographs, mass spectrometers, infra-red spectrometers, and nuclear magnetic resonance instruments, was acquired by Philip Morris to research questions such as:

(1) How nicotine levels varied in the tobacco plant with regard to cultivar, stalk position, seasonal variations and 'ripeness,' (2) What happened to nicotine after 'curing' and during processing, (3) What chemical 'forms' was it in, and (4) How much of it wound up in the smoke when burned under different conditions (such as . . . in the presence . . . of varying amounts of other tobacco constituents, etc.).⁵⁹³

The evidence in the administrative record shows that to achieve the goal of maintaining an acceptable and pharmacologically active nicotine level, Philip Morris developed ways to manipulate the ratio of nicotine to tar delivered by the cigarette. This

⁵⁹¹ *Id.* at 7 (emphasis added). These statements and those by another former Philip Morris employee discussed below corroborate the other evidence before the Agency indicating that the tobacco industry conducted extensive research on nicotine levels.

⁵⁹² Declaration of Uydess IL (Feb. 29, 1996), at 14 (emphasis added). See AR (Vol. 638 Ref. 1).

⁵⁹³ *Id.* at 14.

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research was conducted in the 1970's and had as its goal "to determine what combinations of tar and nicotine make for optimal acceptability in a low delivery cigarette."⁵⁹⁴

The nicotine/tar ratio in cigarettes compares the amount of nicotine delivered by a cigarette with the amount of tar delivered by the cigarette. In public statements, officials of the tobacco industry have maintained that, as tar levels have been reduced through techniques such as filtration and ventilation, nicotine levels have been automatically reduced by a corresponding amount. For instance, one industry executive testified before Congress in 1994, "[w]e do not set levels of nicotine for particular brands of cigarettes. Nicotine follows the tar levels. . . . The correlation . . . is essentially perfect correlation between tar and nicotine and shows that there is no manipulation of nicotine."⁵⁹⁵ Thus, according to the cigarette manufacturers, a proportional reduction of tar and nicotine demonstrates that the industry has not manipulated nicotine deliveries.

The goal of Philip Morris' research, however, was to determine whether cigarette acceptability could be improved by changing this "essentially perfect correlation" between tar and nicotine, i.e., by allowing tar to fall but maintaining a *disproportionately* high level

⁵⁹⁴ Dunn WL, *et al.* (Philip Morris Inc.), *Plans for 1972* (Sep. 8, 1971), in 141 Cong. Rec. H8128 (daily ed. Aug. 1, 1995). See AR (Vol. 711 Ref. 6).

There is evidence that Philip Morris' product research and development on maintaining adequate nicotine deliveries may have begun before the 1970's. A comment submitted to the Agency the handwritten notes of a Philip Morris research executive, Ronald A. Tamol. According to 1965 note from Tamol, an objective of his research at that time was to "*determine minimum nicotine. . . to keep normal smoker 'hooked.'*" Tamol RA (Philip Morris), Handwritten Notes (Feb. 1, 1965) (emphasis added). See AR (Vol. 700 Ref. 593). The Agency is not relying on these notes, however, because it has not independently authenticated the notes.

⁵⁹⁵ *Regulation of Tobacco Products (Part 1): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 143, 378 (Mar. 25, 1994) (statement of Alexander Spears). See AR (Vol. 707 Ref. 1).

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of nicotine. To this end, Philip Morris researchers in 1970 began to alter cigarette designs to study:

*the effect of systematic variation of the nicotine/tar ratios upon smoking rate and acceptability measures. Using the Marlboro as a base cigarette, we will reduce the tar delivery incrementally by filtration and increase the nicotine delivery incrementally by adding a nicotine salt. All cigarettes will be smoked for several days by each of a panel of 150 selected volunteers.*⁵⁹⁶

The search for the optimal nicotine/tar ratio was a significant research priority at Philip Morris. In 1973, a 5-year research and development plan stated: "This program comprises a number of studies expected to provide insight leading to new cigaret designs. These include *studies of optimum nicotine/tar ratios, [and] nicotine/menthol relationships.*"⁵⁹⁷

That same year, the director of research at Philip Morris, Thomas Osdene, distributed a five-year plan stating that "R&D management will concentrate a large part of the resources at its disposal" on two "major long-range" programs, one of which was directed at achieving:

*a dramatic reduction in cigaret tar level while maintaining the subjective responses equal to our present major brands The task requires . . . discovering which constituents contribute positively to the smoker's response . . . and . . . developing means of increasing the relative concentration of desirable constituents.*⁵⁹⁸

⁵⁹⁶ Eichorn PA, Dunn WL (Philip Morris Inc.), *Quarterly Report of Projects 1600 and 2302* (Dec. 31, 1970), in 141 Cong. Rec. H8127-8128 (daily ed. Aug. 1, 1995) (emphasis added). See AR (Vol. 711 Ref. 6).

⁵⁹⁷ Philip Morris USA, *Research and Development Five Year Plan, 1974-1978* (May 1973), in 141 Cong. Rec. H8130-8131 (daily ed. Aug. 1, 1995) (emphasis added). See AR (Vol. 711 Ref. 6).

⁵⁹⁸ Osdene TS (Philip Morris Inc.), *Five-Year Plan* (Oct. 29, 1973) attaching Dunn WL, Lowitz DA, Will F, *R&D Strategy Outline*, in 141 Cong. Rec. H8131-8132 (daily ed. Aug. 1, 1995) (emphasis added). See AR (Vol. 711 Ref. 6).

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According to the Philip Morris researchers, the natural nicotine/tar ratio in tobacco is about 0.07.⁵⁹⁹ By 1974, the researchers found that by boosting this natural ratio to about 0.12 (i.e., by raising the level of nicotine in relation to the level of tar) they could make a low-delivery cigarette that was “comparable to the Marlboro in terms of both subjective acceptability and strength.”⁶⁰⁰ A follow-up study in 1975 also found “evidence that the optimum nicotine to tar (N/T) ratio for a [low-delivery] tar cigarette is somewhat higher than that occurring in smoke from the natural state of tobacco.”⁶⁰¹ Thus, Philip Morris’ research showed that for low-tar cigarettes, it was “optimal” to supply a higher proportion of nicotine than would occur naturally. The distribution lists accompanying both the 1974 study and the 1975 follow-up show these studies were distributed to senior officials at Philip Morris, including Helmut Wakeham, the vice president for research and development.

As Philip Morris enhanced its ability to reduce tar levels, it continued to research the optimum nicotine levels to accompany these ever-lower tar levels. It also conducted research on nicotine deliveries in its competitors’ low-tar brands. The Philip Morris researchers concluded that the nicotine-to-tar ratios in their competitors’ products “go up as tar goes down.”⁶⁰² They further stated that “the mechanics of cigarette engineering

⁵⁹⁹ Dunn WL, Johnston M, Ryan F, *et al.* (Philip Morris Inc.), *Plans for 1972* (Sep. 8, 1971), in 141 Cong. Rec. H8128 (daily ed. Aug. 1, 1995). See AR (Vol. 711 Ref. 6).

⁶⁰⁰ Philip Morris Research Center, *Behavioral Research Annual Report (Part II)*, distributed by Osdene TS (Nov. 1, 1974), in 141 Cong. Rec. H7659 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁶⁰¹ Jones B, Houck W, Martin P (Philip Morris Inc.), *Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication* (Oct. 1975), in 141 Cong. Rec. H8132 (daily ed. Aug. 1, 1995) (emphasis added). See AR (Vol. 711 Ref. 6).

⁶⁰² Dunn WL (Philip Morris Inc.), *Plans and Objectives—1979* (Dec. 6, 1978), in 141 Cong. Rec. H7670 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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and the deliberate decisions of our competitors are such as to suggest that *high* nicotine/tar ratios be used at ultra low tar levels.”⁶⁰³

This extensive research on deliberately altering nicotine/tar ratios shows that Philip Morris did not, in fact, want to allow nicotine to “follow the tar level” but instead wanted to supply an optimum nicotine level that required independent manipulation of the nicotine delivery of cigarettes. In addition to the research on optimal nicotine/tar ratios, Philip Morris scientists have conducted other product development research relating to the delivery of nicotine. In the 1980’s, Philip Morris conducted extensive research to find “nicotine analogues” that could replace nicotine in cigarettes. As described in section II.C.2.a.ii., above, this research was designed to find analogues that would specifically retain nicotine’s pharmacological effects on the brain, revealing both Philip Morris’ recognition of the pharmacological effects of nicotine and its intent to maintain these pharmacological effects even if compelled to cease the use of nicotine.

Philip Morris also conducted research to determine whether a second component of tobacco smoke, acetaldehyde, acted synergistically with nicotine to produce reinforcing effects on the brain. The culmination of this research was Philip Morris’ attempt to establish the “maximally reinforcing” ratio of acetaldehyde to nicotine in cigarette smoke. This research demonstrates again Philip Morris’ objective of identifying pharmacologically active doses of nicotine and of enhancing those effects where possible. A 1982 Philip Morris report on research plans and objectives stated:

Since both acetaldehyde and nicotine are reinforcing agents and each are contained in smoke *it becomes important to determine ratio[s] of acetaldehyde to nicotine which produce maximal*

⁶⁰³ *Id.* at H7670 (emphasis added).

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*reinforcing effects . . . This will allow us to determine the optimum ratio of acetaldehyde to nicotine that maintains the most behavior.*⁶⁰⁴

Philip Morris' patents further reflect and corroborate its interest in developing methods of enhancing nicotine deliveries. For example, among other patents related to nicotine, Philip Morris holds patents to permit the "release in controlled amounts and when desired of nicotine"⁶⁰⁵ and for "releasing nicotine into tobacco smoke."⁶⁰⁶ The purpose of the patented method is to "[m]aintain[] the nicotine content at a sufficiently high level to provide the desired physiological activity, taste and odor which this material imparts."⁶⁰⁷

Collectively, the documents in the administrative record show that ensuring an adequate delivery of nicotine has been a dominant consideration in Philip Morris product research and development for nearly 30 years. As Project Table indicates, Philip Morris' research on the optimum way to deliver nicotine to smokers continues to this day.

See section II.C.2.a.iii., above.

⁶⁰⁴ DeNoble VJ (Philip Morris Inc.), *Project Number 1610 (Behavioral Pharmacology) Objectives and Plans—1982-1983* (Jul. 20, 1982), at 2 (emphasis added). See AR (Vol. 54 Ref. 1921).

⁶⁰⁵ U.S. Patent No. 3,280,823, Bavley A, Air B, Robb II EW, assigned to Philip Morris Inc., *Additive-Releasing Filter for Releasing Additives into Tobacco Smoke* (Oct. 25, 1966), at C2:39-40. See AR (Vol. 26 Ref. 352).

⁶⁰⁶ U.S. Patent No. 3,584,630, Inskeep GE, assigned to Philip Morris Inc., *Tobacco Product Having Low Nicotine Content Associated with a Release Agent Having Nicotine Weakly Absorbed Thereon* (Jun. 15, 1971), at C2:5-15. See AR (Vol. 27 Ref. 387).

⁶⁰⁷ *Id.* at C1:39-41 (emphasis added).

U.S. Patent No. 3,280,823, Bavley A, Air B, Robb II EW, assigned to Philip Morris Inc., *Additive-Releasing Filter for Releasing Additives into Tobacco Smoke* (Oct. 25, 1966), at C1:43-45. See AR (Vol. 26 Ref. 352).

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b. RJR's Product Research and Development Efforts

RJR has also conducted product research and development to ensure that its cigarettes deliver levels of nicotine to smokers that provide desired pharmacological effects. A presentation from RJR's researchers to its marketing department in approximately 1977, for example, reveals that RJR understood the importance of maintaining adequate nicotine deliveries as tar deliveries declined and had identified a range of nicotine delivery levels capable of producing pharmacological effects. According to this presentation, nicotine has two roles in cigarettes. First, it contributes to the "mouth taste" or "mouth satisfaction" derived from a cigarette.⁶⁰⁸ Second, and even more important, it "acts upon the central nervous system and produces in the average smoker a sensation one could describe as either stimulating or relaxing."⁶⁰⁹ Moreover, according to the presentation, "a confirmed smoker attempts to get a certain desired level of nicotine. About one half hour after smoking, after all the nicotine has been biologically or pharmacologically inactivated, the smoker experiences a need for nicotine and lights up another cigarette."⁶¹⁰ For these reasons, the researchers reported that "a zero nicotine cigarette . . . really has no potential to provide smoking satisfaction. It produces no taste in the mouth, but even more seriously *it fails to provide the ultimate satisfaction in the lungs.*"⁶¹¹

⁶⁰⁸ Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking*, (1976/1977), at 7-9. See AR (Vol. 700 Ref. 593).

⁶⁰⁹ *Id.* at 3.

⁶¹⁰ *Id.* at 5.

⁶¹¹ *Id.* at 9 (emphasis added).

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The researchers observed that RJR's competitors "*are fully aware of the advisability of maintaining a low tar value and also maintaining the nicotine as high as possible.*"⁶¹² They cited True, which is produced by Lorillard Tobacco Co., as an example of a cigarette in which tar levels had been reduced dramatically while nicotine levels had been left essentially unchanged, stating:

[T]he old True had 11 mg tar [and] .6 mg nicotine -- the new True is 5 mg tar [and] .5 mg nicotine. So although the tar was reduced 6 mg from 11 mg to 5 mg, *nicotine was dropped only .1 mg. . . .*⁶¹³

The researchers then recommended that RJR develop cigarettes that reduced tar but maintained nicotine at levels sufficient to provide "(1) mouth satisfaction—quality of nicotine" and "(2) ultimate physiological satisfaction—quantity of nicotine."⁶¹⁴ Specifically, RJR recommended that a new brand deliver 5 mg tar and 0.5 to 0.8 mg nicotine, stating that "*on inhalation into the lungs, 0.5 mg to 0.8 mg of nicotine would provide sufficient nicotine to the blood to produce the stimulation and relaxation effects desired by the smoker.*"⁶¹⁵ As discussed in section II.C.4.a.ii., below, RJR appears to have implemented these recommendations.

Similar recommendations were made by Claude Teague, Jr., RJR's assistant director for research. As noted in section II.C.2.b.i., above, a 1972 memorandum written by RJR's assistant director for research, Charles Teague, referred to efforts at RJR to

⁶¹² *Id.* at 10 (emphasis added).

⁶¹³ *Id.* (emphasis added).

⁶¹⁴ *Id.* at 11.

⁶¹⁵ *Id.* at 11-12 (emphasis added).

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*“reduc[e] the amount of ‘tar’ in cigarette smoke per unit of nicotine.”*⁶¹⁶ In its comments, RJR confirms that it has conducted research on cigarettes with enhanced nicotine-to-tar ratios.⁶¹⁷

In addition to developing low-tar cigarettes that maintain adequate nicotine deliveries, RJR has been particularly active in developing novel tobacco products that deliver nicotine but few other components of tobacco smoke. As noted in section II.C.2.b.i., above, Teague first recommended such a “futuristic” product in 1972, urging that “[t]here should be some simpler, ‘cleaner’, more efficient and direct way to provide the desired nicotine dosage than the present system involving combustion of tobacco.”⁶¹⁸

RJR actually developed and marketed such an alternative tobacco product, called Premier, in the late 1980’s. As described in section II.C.2.b.iii., above, RJR conducted comparative studies of the blood levels of nicotine produced by Premier and by conventional cigarettes to ensure that Premier delivered normal doses of nicotine to the user. However, because the tobacco in the product was heated rather than burned, it delivered the vapor recommended by Teague, with virtually no tar and other non-nicotine components of normal tobacco smoke.

Currently, RJR is test-marketing a similar product, “Eclipse.” As described in section II.C.2.b.iii., above, Eclipse, like Premier, is intended to rely primarily on heating

⁶¹⁶ Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 6 (emphasis added). See AR (Vol. 531 Ref. 125).

⁶¹⁷ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 3. See AR (Vol. 519 Ref. 103).

⁶¹⁸ Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 7 (emphasis added). See AR (Vol. 531 Ref. 125).

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rather than burning tobacco and to deliver levels of nicotine similar to a conventional ultra-low-tar cigarette, but much reduced levels of other cigarette smoke constituents.

RJR's extensive efforts to develop and market alternative cigarettes that deliver nicotine and little else show that it regards nicotine as the essential ingredient of tobacco. The efforts also show that RJR regards cigarettes as, in effect, devices for the delivery of nicotine.

Like Philip Morris, RJR also holds various patents on ways to manipulate nicotine deliveries, including patents intended to "provide a cigarette which delivers a larger amount of nicotine in the first few puffs than in the last few puffs"⁶¹⁹ and intended to mask the harsh flavor of cigarettes with increased levels of nicotine.⁶²⁰ Regardless of whether the patents have been actually used in commercial cigarettes, they are further evidence of RJR's interest in developing ways to control and manipulate nicotine deliveries.

c. Brown & Williamson's Product Research and Development Efforts

Like Philip Morris and RJR, Brown & Williamson and its parent BATCO have conducted research to identify the minimum and optimum doses of nicotine necessary to produce desired pharmacological effects and they have invested considerable resources to develop cigarettes that optimize the delivery of nicotine to smokers. In the case of Brown & Williamson and BATCO, these efforts have spanned over three decades and show a consistent focus on methods to maintain nicotine deliveries at levels sufficient to provide

⁶¹⁹ U.S. Patent No. 4,595,024, Greene TB, Townsend DE, Perfetti TA, assigned to R.J. Reynolds Tobacco Company, *Segmented Cigarette*, (Jun. 17, 1986), at C2:23-26. See AR (Vol. 26 Ref. 370).

⁶²⁰ U.S. Patent No. 4,830,028, Lawson JW, Bullings BR, Perfetti TA, assigned to R.J. Reynolds Tobacco Company, *Salts Provided from Nicotine and Organic Acid as Cigarette Additives* (May 16, 1989), at C1. See AR (Vol. 34 Ref. 593).

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pharmacological satisfaction while reducing tar deliveries. These product research and development efforts cover a wide variety of strategies to enhance nicotine deliveries, including the use of nicotine-rich tobacco blends, genetic manipulation of tobacco plants, chemical manipulation of tobacco blends, and novel filter designs.

i. Product Research and Development in the 1960's. BATCO's product research and development efforts to optimize nicotine delivery in the 1960's focused on three areas. According to an internal Brown & Williamson memorandum written in 1965, one goal of BATCO research was to "*find ways of obtaining maximum nicotine for minimum tar.*"⁶²¹ The approaches then under consideration for maximizing nicotine and minimizing tar included "alteration of blends," "addition of nicotine containing powders to tobacco," and "nicotine fortification of cigarette papers."⁶²² Similarly, at a 1967 BATCO conference, the researchers urged that "[t]he development of low TPM, normal nicotine cigarettes should continue."⁶²³

As part of its effort in the 1960's to maximize nicotine while minimizing tar, BATCO investigated whether nicotine delivery could be controlled by increasing the proportion of "extractable nicotine" (also known as "free nicotine") in the smoke through increases in the alkalinity or pH of tobacco smoke. By changing the chemical characteristics of the smoke, this technique would increase the amount of nicotine

⁶²¹ Griffith RB (Brown & Williamson), *Report to Executive Committee* (Jul. 1, 1965), at 2 (emphasis added). See AR (Vol. 27 Ref. 377).

⁶²² *Id.*

⁶²³ Minutes of BATCO Group R&D Conference at Montreal, Canada (Oct. 25, 1967), at 4 (emphasis added). See AR (Vol. 27 Ref. 378-1). A "low TPM" cigarette refers to a cigarette low in "total particulate matter" or "tar."

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absorbed by the smoker without raising the level of nicotine in the cigarette. A 1966 BATCO study confirmed that “the reaction of a smoker to the strength of the smoke from a cigarette could be correlated to *the amount of ‘extractable’ nicotine in the smoke, rather than to the total nicotine content,*” further explaining that “it would appear that the increased smoker response is associated with *nicotine reaching the brain more quickly.*”⁶²⁴ A 1967 BATCO study found that the addition of PEI (polyethyleneimine) to filters caused a significant increase in the delivery of “extractable nicotine” to the smoker.⁶²⁵ And a 1968 study reported a direct correlation between smoke pH and nicotine absorption in the mouth, stating that “[n]icotine retention appears to be *dependent principally on smoke pH and nicotine content.*”⁶²⁶

BATCO’s second objective was to develop an alternative tobacco product that delivered nicotine but not tar. In the 1960’s, BATCO’s Charles Ellis worked on Project ARIEL, an early Premier-like tobacco product that involved heating rather than burning nicotine-enriched tobacco. According to a 1967 patent, “the invention . . . seeks primarily to furnish *a smoking device which will yield nicotine in an acceptable form, both psychologically and physiologically,* but without the necessity for taking into the system so much of the products of combustion as is usual when smoking a conventional

⁶²⁴ BATCO, *Further Work on ‘Extractable’ Nicotine* (Sep. 30, 1966), at BW-W2-11617 (emphasis added). See AR (Vol. 62 Ref. 308).

⁶²⁵ BATCO, *Relation between ‘Extractable Nicotine’ Content of Smoke and Panel Response* (Mar. 17, 1967), at 2. See AR (Vol. 176 Ref. 2045).

⁶²⁶ BATCO, *The Retention of Nicotine and Phenols in the Human Mouth* (1968), at BW-W2-11691 (emphasis added). See AR (Vol. 445 Ref. 7593).

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cigarette.”⁶²⁷ Although ARIEL was never commercialized, Brown & Williamson continues to develop and patent similar tobacco products to this day.⁶²⁸ Like RJR’s development of Premier and Eclipse, Brown & Williamson and BATCO’s development of these alternative tobacco products that deliver little more than nicotine shows that the companies regard cigarettes as, in effect, devices for the delivery of nicotine.

Third, BATCO launched efforts to find a nicotine analogue. A 1968 conference of BATCO researchers recommended:

In view of its pre-eminent importance, the pharmacology of nicotine should continue to be kept under review and *attention paid to the possible discovery of other substances possessing the desired features of brain stimulation and stress-relief without direct effects on the circulatory system.*⁶²⁹

BATCO’s interest in nicotine analogues led to a 1972 BATCO report that “concluded that substances closely related to nicotine in structure (nicotine analogues) could be important” because “[s]hould nicotine become less attractive to smokers, the future of the tobacco industry would become less secure.”⁶³⁰ Thus, as with Philip Morris,

⁶²⁷ U.S. Patent No. 3,356,094, Ellis CD, Dean C, Hughes IW, assigned to Battelle Memorial Institute, *Smoking Devices* (Dec. 5, 1967), at C2:66-71 (emphasis added). See AR (Vol. 34 Ref. 571).

⁶²⁸ Philip Morris Inc., Draft Report Regarding a Proposal for a “Safer” Cigarette, Code-named *Table*, at 5 (stating that “[O]ther tobacco industry patent activity by . . . Brown & Williamson illustrates extensive interest in the development of a superior nicotine delivery device with or without a tobacco base”). See AR (Vol. 531 Ref. 122).

Slade J, Bero LA, Hanauer P, *et al.*, Nicotine and Addiction, the Brown & Williamson documents, *Journal of the American Medical Association* 1995;274(3):225-233, at 228. See AR (Vol. 528 Ref. 97).

⁶²⁹ Minutes of BATCO Research Conference at Hilton Head, SC (Sep. 24-30, 1968), at 3 (emphasis added). See AR (Vol. 31 Ref. 525-1).

⁶³⁰ Kilburn KD, Underwood JG (BATCO), *Preparation and Properties of Nicotine Analogues* (Nov. 9, 1972), at 1. See AR (Vol. 31 Ref. 524-1).

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Brown & Williamson's nicotine analogue research demonstrated the company's intention to preserve the effects of nicotine on the brain in new tobacco products.

Collectively, the three areas of product development research related to nicotine delivery in the 1960's show Brown & Williamson's long-standing focus on delivering pharmacologically active doses of nicotine to smokers.

ii. Product Research and Development to Maintain Pharmacologically Satisfying Doses of Nicotine while Lowering Tar. Documents in the administrative record indicate that BATCO's efforts in the 1970's coalesced around the objective of maintaining nicotine deliveries in lower-tar cigarettes. The minutes of a 1975 BATCO research conference, for instance, observed that “[o]nce again the need for normal nicotine low tar cigarettes which appeal to the consumer was identified.”⁶³¹ A year later, at a 1976 BATCO conference, the researchers predicted a “clear opportunity” for low-tar, normal-nicotine cigarettes “[p]rovided we can get smokers to dissociate tar from nicotine in their minds in terms of a possible health hazard.”⁶³² At another 1976 conference, the researchers stated:

[I]n that the ‘benefits’ of smoking appear to be related to nicotine, we can infer that the ‘benefits’ of smoking might disappear if cigarettes with low levels of nicotine became the norm . . .⁶³³

In conjunction with their efforts to develop cigarettes that were low in tar but maintained nicotine delivery, Brown & Williamson and BATCO conducted product

⁶³¹ Minutes of BATCO Group R&D Conference at Merano, Italy (Apr. 2-8, 1975), at 4 (emphasis added). See AR (Vol. 27 Ref. 379-1).

⁶³² Minutes of BATCO Group R&D Conference on Smoking Behaviour at Southampton, England (Oct. 11-12, 1976), at 8. See AR (Vol. 27 Ref. 379-2).

⁶³³ *Id.* at 4.

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development research in the 1970's and 1980's to determine the dose of nicotine required to produce satisfying pharmacological effects in smokers. Project Wheat was central to these efforts. The multiyear project had two parts. In Part 1, the attitudes of over 1,000 smokers were surveyed to assess their "inner need" to smoke.⁶³⁴ In Part 2, the smokers were asked to assess experimental cigarettes with different nicotine deliveries.⁶³⁵

According to BATCO:

The purpose of the survey was to classify smokers into a number of categories showing distinct patterns of motivation, and different levels of so-called Inner Need, as a first step towards testing the hypothesis that *a smoker's Inner Need level is related to his preferred nicotine delivery.*⁶³⁶

Project Wheat was thus designed to determine the optimum dose of nicotine delivered by cigarettes for individual smokers as a function of the strength of their "inner need" to smoke. BATCO researchers defined "inner need" as the smoker's use of cigarettes to relieve stress, aid concentration, control appetite, and relieve craving.⁶³⁷ These are the characteristic pharmacological effects of nicotine. See section II.B., above. They also described "the 'inner need' dimension" as correlating "with the extent of inhalation, with *the craving for cigarettes when these are not available*, and with *the*

⁶³⁴ Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and their General Smoking Habits* (Jul. 10, 1975), at 1. See AR (Vol. 20 Ref. 204-1).

⁶³⁵ Wood DJ (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976). See AR (Vol. 20 Ref. 204-2).

⁶³⁶ Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and their General Smoking Habits* (Jul. 10, 1975), at 1 (emphasis added). See AR (Vol. 20 Ref. 204-1).

⁶³⁷ Wood DJ (BATCO), *Project Wheat* (Jan. 10, 1974). See AR (Vol. 177 Ref. 2056).

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difficulty which consumers anticipate in giving up smoking."⁶³⁸ Thus, a nicotine level that satisfies "inner need" is one that provides desired pharmacological effects.

According to the BATCO researchers, the hypothesis that "inner need" is related to nicotine delivery should be "seen as part of a general approach to the problem of designing cigarettes of increased consumer acceptance."⁶³⁹ They further explained: "*In considering which product features are important in terms of consumer acceptance, the nicotine delivery is one of the more obvious candidates. . . . The importance of nicotine hardly needs to be stressed, as it is so widely recognised.*"⁶⁴⁰

Project Wheat found that "[a]s predicted by the hypothesis, *High Need clusters tend to prefer relatively high nicotine cigarettes*, their optimum nicotine delivery being higher than that of Low Need clusters."⁶⁴¹ Project Wheat also found that there was a conflict between smokers' concern for health, which led them to favor low-tar brands of cigarettes, and their "inner need" to smoke, which led them to seek higher nicotine levels. According to the project report:

Concern for the possible health risks of smoking influences consumers in the direction of trying low delivery brands. . . . However there is evidence of a conflict between concern for health and the desire for a satisfying cigarette, from which it follows that low tar brands would be much more widely accepted if their

⁶³⁸ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 438 (Jun. 21 and 23, 1994) (emphasis added). See AR (Vol. 709 Ref. 3).

⁶³⁹ Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and their General Smoking Habits* (Jul. 10, 1975), at 1. See AR (Vol. 20 Ref. 204-1).

⁶⁴⁰ *Id.* at 3 (emphasis added).

⁶⁴¹ Wood DJ (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 1 (emphasis added). See AR (Vol. 20 Ref. 204-2).

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nicotine deliveries could be brought within the range required by groups of consumer[s].⁶⁴²

Most important, the project developed a model of the cigarette market that showed a “substantial potential” for cigarettes that attract smokers concerned about both their health and satisfying their “inner need” for nicotine. According to the project report:

*A model of the market is now proposed in which two major determinants of the type of cigarette which best suits a smoker's requirements are Inner Need and concern for health. This model leads to the conclusion that there is a substantial potential for a range of cigarettes which at present is not available. These cigarettes range from some with low tar and medium nicotine deliveries to others with medium tar and high nicotine deliveries, and are visualised as attracting those smokers who combine above average Inner Need with above average concern for health.*⁶⁴³

A chart in the Project Wheat report showed the magnitude of this new potential market. According to the chart, over 40% of smokers want a cigarette with lower tar and higher nicotine than currently available.⁶⁴⁴

Project Wheat is persuasive evidence of the extensive product research and development by Brown & Williamson and BATCO to manipulate nicotine levels to provide pharmacologically active doses of nicotine. Project Wheat's “model of the market” showed the companies that there existed a significant market for cigarettes with low-tar levels but relatively enhanced nicotine levels.

Brown & Williamson and BATCO conducted additional research designed to correlate nicotine dose and pharmacological effects. For example, a 1980 BATCO Group

⁶⁴² *Id.* at 48.

⁶⁴³ *Id.* at 2 (emphasis added).

⁶⁴⁴ *Id.* at 50-51.

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R&D report describes BATCO's successful effort to develop an improved method for measuring nicotine and its metabolites in the body. The method was developed to study the pharmacological effects of nicotine and their relationship to nicotine dose.

The report states that in some cases:

the pharmacological response of smokers to nicotine is believed to be responsible for an individual's smoking behaviour, providing the motivation for and the degree of satisfaction required by the smoker.

[W]here the causal relationship between nicotine and individual biochemical physiological or psychological responses are to be investigated, accurate information regarding nicotine dose is essential.⁶⁴⁵

A related study was designed to provide an animal model that would allow BATCO to estimate human nicotine doses and to aid in understanding the relationship between the dose of nicotine delivered by cigarettes and smokers' choice of particular brands.⁶⁴⁶

A session on "Nicotine Dose Estimation" at BATCO's 1984 Smoking Behaviour-Marketing Conference was intended "to review the current status of plasma/urinary measures . . . of nicotine dose and to identify the significance for the smoker and product design."⁶⁴⁷ That same year, BATCO described its proposed research agenda for 1985-1987 as including studies "to establish the *minimum dose of smoke nicotine that can provide pharmacological satisfaction* for the smoker."⁶⁴⁸

⁶⁴⁵ Read GA, Anderson IGM (BATCO Group R&D), *Method for Nicotine and Cotinine in Blood and Urine* (May 21, 1980), at 2-3. See AR (Vol. 59 Ref. 235).

⁶⁴⁶ Read GA, Anderson IGM, Chapman RE (BATCO Group R&D), *Nicotine Studies: A Second Report. Estimation of Whole Body Nicotine Dose by Urinary Nicotine and Cotinine Measurement* (Mar. 3, 1981), at 9-10. See AR (Vol. 59 Ref. 234).

⁶⁴⁷ Proceedings of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session II, Montreal, Canada (Jul. 9-12, 1984) (slide), at BW-W2-02641. See AR (Vol. 23 Ref. 305).

⁶⁴⁸ BATCO Group R&D Research Programme, 1984: Proposed revisions for 1985-87, Research Conference, Southampton, England (Sep. 1984), at 2 (emphasis added). See AR (Vol. 22 Ref. 280).

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As described below, Brown & Williamson and BATCO pursued three different strategies in the late 1970's and 1980's for reducing tar deliveries in cigarettes while maintaining adequate nicotine deliveries.

iii. Blending and "Y-1." One approach to reducing tar levels while maintaining adequate nicotine levels is through blending. As noted above in section II.C.3.c.i., BATCO researchers first investigated this approach 30 years ago, when they recommended "alteration of blends" as one way to obtain "maximum nicotine for minimum tar."⁶⁴⁹ By 1976, they had concluded that "*there would appear to be a forthcoming demand for high nicotine tobaccos*" in view of the interest in increasing the nicotine/tar ratios in low tar cigarettes.⁶⁵⁰

By the late 1970's, Brown & Williamson had begun a decade-long effort to develop a high-nicotine flue-cured tobacco plant that came to be named "Y-1." As described in the Jurisdictional Analysis, the Agency found that the company used conventional and advanced genetic breeding techniques to develop a commercially viable plant that had almost twice the nicotine content of domestically grown varieties of flue cured tobacco. See 60 FR 41700–41702. Whereas typical domestic varieties of tobacco contain between 2.5% to 3.5% nicotine, Brown & Williamson's patent for Y-1 indicated that the company had succeeded in raising the nicotine level to about 6% by weight.⁶⁵¹ Brown & Williamson achieved this objective by cross-breeding commercial varieties of

⁶⁴⁹ Griffith RB (BATCO), *Report to Executive Committee* (Jul. 1, 1965), at 2. See AR (Vol. 27 Ref. 377).

⁶⁵⁰ Minutes of BATCO Group R&D Conference on Smoking and Behaviour at Southampton, England (Oct. 11-12, 1976) at BW-W2-02311 (emphasis added). See AR (Vol. 27 Ref. 381).

⁶⁵¹ U.S. Patent application, Fisher PR, Hardison HA, Bravo JE, *New Variety of Tobacco Plant*, assigned to Brown & Williamson Tobacco Corp. (1991), at 1. See AR (Vol. 68 Ref. 14).

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tobacco with *Nicotiana rustica*, a wild tobacco variety that is very high in nicotine but is not used in commercial cigarettes because of its harshness.

Brown & Williamson had Y-1 made into a male sterile plant, a technique that ensures that when the plant is grown it will not produce seeds that can be appropriated by others.⁶⁵² Brown & Williamson grew the plant in Brazil.⁶⁵³ The Agency further found, and the company does not dispute, that Y-1 was eventually used in five different brands of cigarettes in 1993, and that as of mid-1994 Brown & Williamson still had 3.5 million to 4 million pounds of additional Y-1 in storage.⁶⁵⁴

The purpose of Y-1 was to develop a high-nicotine tobacco that could be used as a “blending tool” so that products could be designed that were lower in tar but not lower in nicotine.⁶⁵⁵ Although Brown & Williamson asserts that it never used Y-1 in commercial cigarettes to raise nicotine/tar ratios, the company does not dispute that its goal was to deliberately alter the traditional relationship between tar and nicotine. Indeed, Brown & Williamson implicitly concedes that the company used Y-1 to develop “prototypes” with increased nicotine/tar ratios and tested them on consumer panels.⁶⁵⁶ The development of Y-1 thus provides direct evidence of Brown & Williamson’s intention to enhance nicotine deliveries.

⁶⁵² *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103 Cong., 2d Sess. 18 (Jun. 21, 1994) (testimony of David Kessler). See AR (Vol. 709 Ref. 3).

⁶⁵³ *Id.* at 142 (testimony of Thomas Sandefur, chairman and CEO, Brown & Williamson).

⁶⁵⁴ Transcript of FDA Meeting with Brown & Williamson (Jun. 17, 1994), at 124-125. See AR (Vol. 28 Ref. 414).

⁶⁵⁵ *Id.* at 85-86.

⁶⁵⁶ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 32. See AR (Vol. 529 Ref. 104).

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iv. Chemical Manipulation. Another approach to reducing tar while maintaining adequate nicotine for the smoker is to alter the chemistry of tobacco smoke in a manner that increases the transfer of nicotine to the smoker. As discussed above, BATCO did work in this area in the 1960's, which suggested that increasing the percentage of "extractable nicotine" delivered to the smoker resulted in "nicotine reaching the brain more quickly."⁶⁵⁷

BATCO's research and development efforts continued in the 1970's and 1980's. In a 1976 research conference, BATCO researchers discussed how the use of a filter additive PEI or "alkali treatment" could "maintain normal nicotine reaction for the smoker while actually reducing the amount of nicotine per cigarette":

A second approach . . . is to aim at a lower smoke production per cigarette (i.e. lower tar) while maintaining "normal" nicotine. Work along these lines is already going on. *A further modification of this approach is to maintain normal nicotine reaction for the smoker while actually reducing the total amount of nicotine per cigarette.* It is believed that this can be done, e.g. by the use of P.E.I. or by alkali treatment of tobacco stems.⁶⁵⁸

Similar observations were made at other research conferences. In 1978, for instance, BATCO researchers stated: "With conventional cigarettes, the transfer of nicotine to the smoker from the tobacco has very low efficiency. Potentially, therefore, *opportunities exist for very big savings in tobacco if this low efficiency can be greatly increased.*"⁶⁵⁹

⁶⁵⁷ BATCO, *Further Work on 'Extractable' Nicotine* (1966), at BW-W2-11621. See AR (Vol. 62 Ref. 308).

⁶⁵⁸ Morini HA (BATCO), *Cigarettes with Health Reassurance* (1976), at 1 (emphasis added). See AR (Vol. 27 Ref. 380).

⁶⁵⁹ Notes on BATCO Group R&D Conference at Sydney, Australia (Mar. 1978), at 4 (emphasis added). See AR (Vol. 26 Ref. 367).

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This would not be an “opportunity” if the company did not recognize that nicotine was the essential active ingredient intended to be delivered.

In 1982, BATCO researchers urged that a design objective for new products should be “to enhance or maximise sensory and pharmacological sensations, i.e., ‘to make the smoke work harder’ so as to achieve maximum sensation at a given delivery level.”⁶⁶⁰ And in 1984, BATCO researchers discussed a study in which “*experimental cigarettes . . . will . . . be used to improve the efficient use of smoke nicotine through pH modification.*”⁶⁶¹

v. “Elasticity” Technologies. A third approach to lowering tar while maintaining an adequate nicotine delivery is to increase the “elasticity” of cigarettes. “Elasticity” refers to the ability of a cigarette, whatever its nicotine yield as measured by a smoking machine, to deliver enough smoke to permit a smoker to obtain the nicotine the smoker needs. The elasticity of a cigarette can be increased, for instance, by placing ventilation holes in the filter. These holes allow fresh air to be pulled into the smoking machine during inhalation, thereby diluting the smoke and reducing the measured yields. However, the holes can be blocked by smokers’ fingers or lips, allowing the smoker to obtain more nicotine than the machine measured delivery. *See* 60 FR 41716–41718. Brown & Williamson and BATCO sought to develop elasticity technologies. During a 1983 BATCO conference, BATCO researchers observed that “[e]lasticity can be designed

⁶⁶⁰ Minutes of BATCO Research Conference at Montebello, Canada (Aug. 30-Sep. 3, 1982), at 3 (emphasis added). *See* AR (Vol. 179 Ref. 2082).

⁶⁶¹ BATCO, *Proposed Revisions for 1985-1987* (Sep. 1984), at 1-2 (emphasis added). *See* AR (Vol. 26 Ref. 369-1).

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into a cigarette using tobacco blend and pressure drop components.”⁶⁶² A year later, at a 1984 conference, BATCO researchers elaborated:

Compensation by modifying smoking regime . . . is a topic which is being explored . . . and *this includes designing products which aid smoker compensation.*

The marketing policy concerning this type of product is not clear but it is believed it will depend largely on the degree of elasticity in the design and how overtly this elasticity is achieved. *The consensus is that small improvements in elasticity which are less obvious, visually or otherwise is likely to be an acceptable route.*⁶⁶³

Taken together, Brown & Williamson and BATCO’s product research and development efforts exhibit a sustained focus on nicotine over the course of three decades. The companies recognized through their research that significant marketing opportunities existed for cigarettes that reduced tar deliveries but maintained nicotine deliveries at levels high enough to satisfy smokers’ “inner need” for nicotine. They then developed a broad range of techniques for enhancing nicotine deliveries. These extensive efforts are evidence of a “design” or “plan” to manipulate and control nicotine deliveries to provide a pharmacologically active dose of nicotine.

d. Other Cigarette Manufacturers’ Product Research and Development Efforts

i. American Tobacco Company. The American Tobacco Company

(American Tobacco) also conducted extensive research and development on ways to increase and optimize nicotine deliveries. In 1969, for instance, the company

⁶⁶² BATCO, *Smoking Behavior Conference: Overview* (1983), at BW-W2-03292. See AR (Vol. 27 Ref. 392).

⁶⁶³ Proceedings of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III (Jul. 9-12, 1984), at 55 (emphasis added). See AR (Vol. 27 Ref. 391).

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manufactured Lucky Strike cigarettes enriched with a nicotine salt (nicotine malate) and sold them in the Seattle market.⁶⁶⁴

In 1974, the company's manager of new products, R. M. Irby, wrote to the vice president of manufacture and leaf, J. B. McCarthy, to summarize "our current knowledge regarding increasing the nicotine content of reconstituted tobacco."⁶⁶⁵ Irby's memorandum stated that nicotine in reconstituted tobacco could be increased either by adding "Compound W," a code name for nicotine, to the reconstituted tobacco or by replacing "the lower nicotine-containing leaf components such as Turkish . . . with high nicotine tobacco such as Malawi sun-cured scrap (5% nicotine)."⁶⁶⁶

Three years later, American Tobacco researchers wrote a memorandum describing "suggested" ways of increasing the nicotine/tar ratio in cigarettes. The methods included the "addition of ammonia salts . . . to tobacco, which on smoking would free the ammonia and thereby cause an increase in nicotine transfer to the smoke."⁶⁶⁷

By 1980, American Tobacco was conducting experiments on this idea by adding a salt (potassium carbonate) to its Tareyton blend. According to the research memorandum describing the experiment, "[s]ince most nicotine in tobacco is a non-volatile salt, *it was*

⁶⁶⁴ Letter to Waxman HA, on behalf of the American Tobacco Company (Oct. 14, 1994), at 3. See AR (Vol. 26 Ref. 355).

⁶⁶⁵ Irby RM Jr. (American Tobacco), *Nicotine Content of Reconstituted Tobacco* (Jun. 5, 1974), at 1. See AR (Vol. 26 Ref. 357-3).

⁶⁶⁶ *Id.* at 1-2.

⁶⁶⁷ Pederson PM (American Tobacco), *A Study of the Nicotine to Tar Ratio* (Apr. 18, 1977), at 4. See AR (Vol. 26 Ref. 365).

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*thought that a greater transfer would take place if the tobacco was made basic causing the nicotine to volatilize when the cigarette is smoked.”*⁶⁶⁸

Other efforts by American Tobacco to increase the amount of nicotine delivered by its cigarettes are described in the Jurisdictional Analysis. *See* 60 FR 41675–41677. These efforts show that like Philip Morris, RJR, and Brown & Williamson, American Tobacco has designed and planned ways to enhance nicotine deliveries to smokers.

ii. Lorillard Tobacco Company. Like the other cigarette manufacturers, the Lorillard Tobacco Company developed knowledge about numerous ways to manipulate and control nicotine deliveries. For instance, in a 1975 presentation, Alexander Spears, the vice chairman and chief operating officer of Lorillard, stated that “[t]hrough [a] combination of . . . variables, . . . it is possible to manipulate the yield of nicotine from about .1 mg to 4 mg per cigarette.”⁶⁶⁹ The variables cited by Spears as controlling nicotine deliveries included “the nicotine content of the tobacco”; “[the] porosity of the wrapper and/or ventilation at the filter”; “the affinity of the filter material for nicotine, particularly as a function of smoke pH”; and “plant genetics.”⁶⁷⁰

In a 1981 paper on tobacco leaf blending, Spears further described “*the ways in which higher nicotine levels can be achieved.*”⁶⁷¹ Spears explained that nicotine

⁶⁶⁸ Bodenhamer NL (American Tobacco), *Leaf Services Monthly Report for June* (Jun. 30, 1980) (emphasis added). *See* AR (Vol. 27 Ref. 385)

⁶⁶⁹ Spears AW (Lorillard Tobacco Co.), *Factors Affecting Smoke Delivery of Nicotine and Carbon Monoxide*, presented at the 1975 Symposium-Nicotine and Carbon Dioxide (Nov. 17-18, 1975), in *Symposium Proceedings-1*, at 13 (emphasis added). *See* AR (Vol. 27 Ref. 395a).

⁶⁷⁰ *Id.*

⁶⁷¹ Spears AW, Jones ST (Lorillard Tobacco Co.), *Chemical and Physical Criterias for Tobacco Leaf of Modern Day Cigarettes*, *Recent Advances in Tobacco Science*, Oct. 6-9, 1981;7:19-39, at 23. *See* AR (Vol. 26 Ref. 373-1).

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concentrations of tobaccos vary widely, from 3.65% nicotine in upper-stalk Burley tobacco and 3.26% in upper-stalk flue-cured tobacco to 0.95% in Oriental tobacco and 0.85% in stem-sheet or reconstituted tobacco. According to Spears, “[h]igher nicotine levels can be achieved by decreasing Oriental and the stem and tobacco sheet and increasing the Burley and upper stalk positions of both the Flue-cured and the Burley tobacco.”⁶⁷² He further observed that “current research is directed toward increasing the nicotine levels while maintaining or marginally reducing the ‘tar’ deliveries.”⁶⁷³

The administrative record thus reveals that the cigarette manufacturers have consistently focused their product research and development efforts on developing methods to maintain or enhance nicotine deliveries. These activities are remarkable for their sustained duration and for the fact that each cigarette manufacturer independently acquired similar capabilities to manipulate and control nicotine deliveries. This again demonstrates the central role of nicotine delivery in the design of cigarettes.

e. Filter and Paper Suppliers’ Product Research and Development Efforts

The filter and paper suppliers for cigarette manufacturers also developed products to enhance nicotine deliveries, including methods for “increasing nicotine delivery *without* changing tar delivery”⁶⁷⁴ and for “alter[ing] cigarette nicotine delivery *independently* of tar

⁶⁷² *Id.* at 24 (emphasis added).

⁶⁷³ *Id.* at 31 (emphasis added).

⁶⁷⁴ Selke WA, Making the cigarette do just what you want it to do, *Journal Tobacco International*, 1983:12 (emphasis added). See AR (Vol. 102 Ref. 896).

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delivery.”⁶⁷⁵ These efforts are not direct evidence of the manufacturers’ intent, because the product development was conducted by suppliers, rather than the manufacturers themselves. Nevertheless, the suppliers’ efforts corroborate the Agency’s finding that the cigarette manufacturers seek the capability to enhance nicotine deliveries in low-tar cigarettes. They show that the suppliers understood manufacturers to be interested in acquiring products that would enable the manufacturers to selectively remove more tar than nicotine from cigarette smoke.

To develop products with enhanced nicotine deliveries, the filter and paper suppliers altered the filtration and ventilation systems in cigarettes. Filters are used to trap smoke particles before they enter the mouths of smokers. Ventilation technologies draw air into the cigarette through holes in the filter or through porous cigarette paper, diluting the smoke. The suppliers found that these systems could be manipulated to selectively remove more tar than nicotine, thereby increasing the nicotine/tar ratio in the smoke.

Documents in the administrative record describe several of the methods developed for increasing nicotine delivery relative to tar. According to one report, “[s]imply changing the location of the vents in a . . . filter has a measurable effect on the cigarette performance,” with “the nicotine content [being]. . . greatest when the vents were positioned where the tobacco and filter were joined.”⁶⁷⁶ The same effect could be achieved by perforating the cigarette paper. One report found that “[i]ncreasingly porous

⁶⁷⁵ Lee BM (Eastman Kodak Company), *Modification of Nicotine to Tar Ratio in Cigarette Smoke*, 42nd Tobacco Chemists’ Research Conference, Lexington, Kentucky (Oct. 2-5, 1988), at 33 (emphasis added). See AR (Vol. 639 Ref. 2).

⁶⁷⁶ Kiefer JE, *Ventilated Filters and Their Effect on Smoke Composition*, *Recent Advances in Tobacco Science* (1979), at 79. See AR (Vol. 28 Ref. 465).

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perforated papers . . . *selectively increase nicotine*. . . .”⁶⁷⁷ Research by a tobacco company confirmed the influence of paper design on tar and nicotine deliveries, finding that “tar/nicotine ratios are determined primarily by paper permeability; high permeability produces the lowest tar/nicotine ratios.”⁶⁷⁸ A low tar/nicotine ratio is mathematically equivalent to a high nicotine/tar ratio.

Other reports have shown that cigarettes designed with increased ventilation and less filtration will “increas[e] nicotine delivery without changing tar delivery;”⁶⁷⁹ and that the use of additives to increase the pH of the filter will alter cigarette nicotine delivery independently of tar delivery, increasing the nicotine/tar ratio by up to 15%.⁶⁸⁰

f. These Product Research and Development Efforts Were Undertaken for Commercial Reasons

The cigarette manufacturers do not generally dispute that they engaged in the product research and development activities described above. Instead, they argue that their research on increasing or maintaining nicotine delivery while lowering tar was largely in response to “government” initiatives. In support of this claim, these comments refer to

⁶⁷⁷ Owens Jr. WF (Ecusta Paper and Film Group), *Effect of Cigarette Paper on Smoke Yield and Composition*, 32d Tobacco Chemists’ Research Conference, Montreal, Canada (1978) (*emphasis added*). See AR (Vol. 639 Ref. 2).

⁶⁷⁸ McMurtrie A, Littringer EF, and Wu DT, *Cigarette Paper Effects on Tar/Nicotine and CO/Tar Ratios*, 35th Tobacco Chemists’ Research Conference, Winston-Salem, North Carolina (1981). See AR (Vol. 639 Ref. 2).

⁶⁷⁹ Selke WA, Making the cigarette do just what you want it to do, *Journal Tobacco International* 1983:12. See AR (Vol. 102 Ref. 896).

Browne CL (Hoechst Celanese), *The Design of Cigarettes*, at 72. See AR (Vol. 27 Ref. 399).

⁶⁸⁰ Lee BM (Eastman Kodak Company), *Modification of Nicotine to Tar Ratio in Cigarette Smoke*, 42nd Tobacco Chemists’ Research Conference, Lexington, Kentucky (Oct. 2-5, 1988), at 33. See AR (Vol. 639 Ref. 2).

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a few sentences in a 1981 report of the U.S. Surgeon General, the recommendation of a scientist at NIH in 1976, and a few scattered articles from nongovernment researchers beginning in 1973. The comments offer no evidence from company documents to show that any part of the industry's extensive research on increasing nicotine delivery from low-tar cigarettes was actually motivated by the cited "initiatives."

The evidence in the administrative record also fails to support the industry's claims. The large number of internal tobacco company documents available to FDA indicates that the companies' product research and development was conducted for commercial reasons. Philip Morris, for instance, stated that "the rationale" for its research and development efforts "rests on the premise that such knowledge will strengthen Philip Morris R&D capability in developing new and improved smoking products."⁶⁸¹

The driving force behind the efforts to enhance nicotine delivery in low-tar products was the industry's knowledge that people use tobacco for nicotine and that below a certain nicotine level, the motivation for tobacco use, and the market for tobacco products will disappear. RJR researchers knew in the 1970's that "a zero nicotine cigarette . . . fails to provide the ultimate satisfaction in the lungs;" hence they recommended "*maintaining the nicotine as high as possible*" in low-tar cigarettes.⁶⁸² Similarly, a 1976 BATCO "Smoking Behaviour" conference report shows that BATCO was aware of the need to maintain adequate nicotine deliveries, stating that "the 'benefits' of smoking appear to be related to nicotine, [and] we can infer that the 'benefits' of

⁶⁸¹ Dunn WL, *Plans and Objectives—1979* (Dec. 6, 1978), in 141 Cong. Rec. H7669 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁶⁸² Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 9, 10 (emphasis added). See AR (Vol. 700 Ref. 593).

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smoking might disappear if cigarettes with low levels of nicotine became the norm.”⁶⁸³

Likewise, a 1972 Philip Morris presentation indicates that Philip Morris knew that cigarettes with inadequate levels of nicotine would not be purchased by smokers.⁶⁸⁴

Moreover, the industry’s research on selectively increasing or maintaining nicotine while lowering tar cannot be attributed to government initiatives because it began before the earliest government “initiative” cited by the comments. For example, as noted in section II.C.3.c.i. above, Brown & Williamson was developing “ways of obtaining maximum nicotine for minimum tar” at least as early as 1965⁶⁸⁵—well before the 1976 NIH and the 1981 Surgeon’s General documents cited by the industry. Similarly, Philip Morris was working on increasing nicotine levels in relation to tar as early as 1970, when it began experimentally altering the nicotine/tar ratio of Marlboro cigarettes by “reduc[ing] the tar delivery incrementally . . . and increas[ing] the nicotine delivery incrementally by adding a nicotine salt.”⁶⁸⁶ Thus, the industry was plainly developing low-tar, enhanced-nicotine products before any of the cited “government initiatives.”

Finally, FDA notes that to the extent that the industry accepted the recommendations of outside researchers who suggested the development of low-tar, high-nicotine products, those recommendations were based on the researchers’ conclusion that

⁶⁸³ Minutes of BATCO Group R&D Conference on Smoking and Behaviour at Southampton, England (Oct. 11-12, 1976), at 4. See AR (Vol. 27 Ref. 376).

⁶⁸⁴ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 4 (emphasis added). See AR (Vol. 12 Ref. 133).

⁶⁸⁵ Griffith RB (BATCO), *Report to Executive Committee* (Jul. 1, 1965), at 2. See AR (Vol. 27 Ref. 377).

⁶⁸⁶ Eichorn PA, Dunn WL (Philip Morris Inc.), *Quarterly Report of Projects 1600 and 2302—Oct. 1-Dec. 31, 1970* (Dec. 31, 1970), in 141 Cong. Rec. H8128 (daily ed. Aug. 1, 1995). See AR (Vol. 27 Ref. 376).

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smokers seek adequate doses of nicotine to satisfy dependence and will compensate to achieve those doses when given a low-nicotine cigarette.⁶⁸⁷ The cigarette industry, in contrast, denies that smokers compensate for nicotine to any significant extent. It is not credible that the industry would have accepted and acted on outsiders' recommendations while rejecting the fundamental premises on which the recommendations were based. Moreover, the Surgeon General, while suggesting that cigarettes with a lower tar-to-nicotine ratio should be investigated, specifically cautioned against achieving this goal through strategies that reduced tar while maintaining a normal nicotine yield:

[F]actors of "smoker compensation" must be considered in the evaluation of lower "tar" and nicotine cigarettes. Filtered, lower "tar" and nicotine cigarettes that are less vulnerable to increasing the smoke and nicotine deliveries are needed. . . . Attempting to minimize smoker compensation by selectively reducing "tar" and other smoke compounds while maintaining nicotine yield may carry serious disadvantages. First, maintaining nicotine delivery may reinforce physiologic habituation, and interfere with smoking cessation attempts. Second, nicotine gives rise to the tobacco-specific carcinogenic N-nitrosamines . . . Finally, nicotine is suspected to be a major smoke constituent correlated with the increased risk of cardiovascular disease among cigarette smokers.⁶⁸⁸

Accordingly, the evidence establishes that the industry researched and developed methods to increase relative nicotine deliveries while decreasing tar deliveries for a commercial purpose—to ensure that cigarettes provide pharmacologically satisfying doses of nicotine.

⁶⁸⁷ See, e.g., Russell MAH, *et al.*, Comparison of effect on tobacco consumption and carbon monoxide absorption of changing to high and low nicotine cigarettes, *British Medical Journal* 1973;4:512-516. See AR (Vol. 89 Ref. 485).

Gori G, Low risk cigarettes: a prescription, *Science* 1976;94(4271):1243-1246. See AR (Vol. 535 Ref. 96, vol. IV.D, at 1-5).

⁶⁸⁸ Department of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette, A Report of the Surgeon General, 1981*, at 98 (citation omitted). See AR (Vol. 123 Ref. 1586).

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4. The Cigarette Manufacturers Design Commercially Marketed Cigarettes to Provide a Pharmacologically Active Dose of Nicotine

The evidence summarized in section II.C.3. that the manufacturers have conducted product research and development to establish the doses of nicotine needed to produce pharmacological effects and to optimize nicotine deliveries to consumers establishes that the manufacturers have the capacity to design cigarettes that provide pharmacologically active doses of nicotine. In this section, the Agency evaluates the evidence in the record regarding the manipulation and control of nicotine in commercial cigarettes.⁶⁸⁹

As discussed below, the evidence in the administrative record establishes that many of the product research and development efforts described in section II.C.3. are used in important ways in the commercial cigarettes marketed today. The available evidence shows that the cigarette manufacturers pay careful attention to nicotine in all phases of cigarette manufacture. As described in the Jurisdictional Analysis, the focus on nicotine is apparent at each step—from the growing and purchasing of tobacco leaves, to the blending of different tobacco varieties, to the design and manufacture of the finished cigarette. *See* 60 FR 41693–41733.

The evidence in the record further demonstrates that the final products—the finished cigarettes sold to consumers—reflect the manufacturers' careful attention to

⁶⁸⁹ The evidence in section II.C.2., supported by the evidence in section II.C.3. that the manufacturers "have in mind" that these products will have and be used for pharmacological effects, is sufficient by itself to establish intended pharmacological use. It is thus not necessary for the Agency to establish that commercial cigarettes have been affirmatively designed to provide a pharmacologically active dose of nicotine to show that the manufacturers "intend" the pharmacological effects and uses of cigarettes. For example, a manufacturer of a traditional full-strength cigarette may not need to take any specific design steps to insure that the cigarette provides a pharmacologically active dose of nicotine. Nevertheless, this manufacturer's understanding and expectation that the full-strength cigarette will be used by consumers for drug purposes would be sufficient to establish the cigarette's intended pharmacological use.

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nicotine. Manufacturers of commercially marketed cigarettes commonly manipulate nicotine deliveries to provide remarkably precise, pharmacologically active doses of nicotine to consumers. The principal techniques that are used to control and manipulate nicotine deliveries include: (1) the use of nicotine-rich tobacco blends in low-tar cigarettes; (2) the use of filtration and ventilation technologies that selectively remove more tar from smoke than nicotine; and (3) the use of chemical additives that increase the percentage of "free" nicotine in cigarette smoke. Control is also achieved as a result of extensive attention to nicotine in tobacco breeding, leaf purchasing, leaf blending, and the manufacture of reconstituted tobacco.

Indeed, the evidence in the record establishes that cigarette designs in recent decades have been driven by the manufacturers' desire to maintain nicotine deliveries at pharmacologically active levels. As consumer awareness of the health effects of smoking has increased, the cigarette manufacturers have responded by adding filters and using ventilation to reduce tar deliveries. However, the manufacturers have not reduced nicotine deliveries proportionately. Rather, the evidence available to the Agency indicates that they have strived to ensure that nicotine deliveries remain at a pharmacologically active level.⁶⁹⁰

**a. The Manufacturers Use Nicotine-Rich Tobacco Blends
in Low-Tar Cigarettes**

Perhaps the clearest example of deliberate manipulation and control to maintain nicotine deliveries at levels sufficient to provide pharmacological satisfaction occurs in the

⁶⁹⁰ RJR's Eclipse, the new tobacco product that is being test-marketed, carries this effort to close to its logical conclusion—maintaining nicotine deliveries at the level of conventional ultra-low-tar cigarettes while allegedly reducing many of the tar components of tobacco smoke substantially below these levels. Eclipse is discussed further in section II.C.3.b., above (product research and development).

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manufacture of low-tar cigarettes. The evidence in the administrative record indicates that cigarette manufacturers commonly use nicotine-rich tobacco blends in these products. Approximately 80% of the cigarettes on the market today are either low-tar (6 to 15 mg tar) or ultra-low-tar (less than 6 mg tar).⁶⁹¹

i. The Use of Nicotine-Rich Tobacco Blends in the 1950's. The evidence in the record indicates that the use of richer nicotine blends first occurred in the 1950's, when filters were first added to cigarettes. Documents provided to the Agency by the tobacco industry show that a shift to higher nicotine blends occurred to offset the reductions in nicotine deliveries caused by the use of filters. According to one 1956 document: "*With the increase in production of filter tip cigarettes, . . . demand has increased for heavier-bodied [tobacco] types that have full aroma and flavor and a relatively high nicotine content.*"⁶⁹²

As early as 1957, the U.S. Department of Agriculture (USDA) recognized that the introduction of filters was causing increased demand for higher nicotine tobacco. That year, the director of the tobacco division of USDA's Agricultural Marketing Service, Stephen E. Wrather, testified before Congress that the industry had "moved up the stalk"

⁶⁹¹ Federal Trade Commission, *Report of "Tar," Nicotine, and Carbon Monoxide of the Smoke of 1107 Varieties of Domestic Cigarettes* (1995). See AR (Vol. 535 Ref. 96, vol. IV.B).

⁶⁹² Jones GL, Collins WK, *Measured Crop Performance Tobacco 1956*, Department of Field Crops, N.C., State College, Raleigh N.C., Research Report No. 4 (Dec. 1956), at 1 (emphasis added). See AR (Vol. 535 Ref. 96, vol. IV.K).

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in blending tobacco for use in filter cigarettes.⁶⁹³ “Moving up the stalk” is a reference to the higher nicotine content in the upper leaves of tobacco plants.⁶⁹⁴

Wrather also indicated that using this higher nicotine tobacco in the blend for filtered cigarettes enabled manufacturers to maintain the same “strength” levels in the smoke that existed in unfiltered cigarettes.⁶⁹⁵ A 1957 *Consumer Reports* analysis of nicotine levels in filtered and unfiltered cigarettes placed in the record of the hearing showed that the average nicotine content in regular-size cigarettes with filters was higher than in regular-size cigarettes without filters.⁶⁹⁶ This could only have been accomplished through the use of higher nicotine tobacco leaves in the blend for filtered cigarettes.

ii. The Use of Nicotine-Rich Tobacco Blends Today. During the 1960’s and 1970’s, the demand of consumers for “healthier” cigarettes led to further declines in tar yields. As described above in section II.C.3., this caused the cigarette manufacturers to develop methods to ensure that the nicotine levels in cigarettes did not drop below acceptable levels.⁶⁹⁷

⁶⁹³ *False and Misleading Advertising (Filter-tip Cigarettes): Hearings Before the Subcommittee of the Committee on Government Operations, U.S. House of Representatives, 85th Cong., 1st Sess. 189 (1957) (testimony of Stephen E. Wrather). See AR (Vol. 172, Ref. 2035).*

⁶⁹⁴ *See, e.g., Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 10 (“Higher stalk tobacco leaves do have more nicotine than lower stalk leaves on the same plant”). See AR (Vol. 529 Ref. 104).*

⁶⁹⁵ *False and Misleading Advertising (Filter-tip Cigarettes): Hearings Before the Subcommittee of the Committee on Government Operations, U.S. House of Representatives, 85th Cong., 1st Sess. 196 (1957) (testimony of Stephen E. Wrather). See AR (Vol. 172, Ref. 2035).*

⁶⁹⁶ *Id.* at 662 (exhibit 15c).

⁶⁹⁷ Philip Morris USA, Research and Development Five Year Plan, 1974-1978 (May 1973), in 141 Cong. Rec. H8130-8131 (daily ed. Aug. 1, 1995). *See AR (Vol. 711 Ref. 6).*

See also Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication (Oct. 1975), in 141 Cong. Rec. H8009 (daily ed. Jul. 31, 1995). See AR (Vol. 27 Ref. 376a).

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The evidence in the record indicates that the low-tar cigarettes on the market today reflect the industry's concerns with providing an acceptable nicotine level. As numerous documents in the record reveal, low-tar cigarettes are specifically blended to increase their nicotine concentrations. For instance, the administrative record includes the following descriptions of the use of blending to control and manipulate nicotine:

- William Farone, the former director of applied research at Philip Morris, stated that “[t]he industry employs two principal means of controlling the nicotine levels.”⁶⁹⁸ One of these is “*modification and control of the tobacco blend*, i.e., the ratio of Burley (air-cured), Bright (flue-cured), Oriental, stems, expanded tobacco products, and reprocessed tobacco products such as tobacco sheet made from stems and waste leaf.”⁶⁹⁹ According to Farone:

Product developers and blend and leaf specialists were responsible for manipulating and controlling the design and production of cigarettes in order to satisfy the consumer's need for nicotine in lower yield products.

*Blend changes were an especially important tool used to ensure desired nicotine levels. Tar is a function of tobacco weight. However, an all-burley cigarette will produce a higher nicotine level than an all-bright cigarette of the same weight. The industry knew that by using a higher percentage of higher nicotine tobacco in their low tar cigarettes they could achieve an increase of their nicotine levels.*⁷⁰⁰

Jones B, Houck W, Martin P (Philip Morris Inc.), *Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication* (Oct. 1975), in 141 Cong. Rec. H8132 (daily ed. Aug. 1, 1995). See AR (Vol. 711 Ref. 6).

Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 2. See AR (Vol. 20 Ref. 204-2).

⁶⁹⁸ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 5. See AR (Vol. 638 Ref. 2).

⁶⁹⁹ *Id.* at 5 (emphasis added).

⁷⁰⁰ *Id.* at 10 (emphasis added).

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- Ian Uydess, the former Philip Morris scientist, stated that:

Nicotine levels were routinely targeted and adjusted by Philip Morris in its various products at least in part, through blend changes

. . . .

When Philip Morris designed a new or modified blend, they used their stored tobacco inventories much like a scientist would use a chemical stockroom to select the ingredients needed to synthesize a new material. . . .

. . . *Philip Morris routinely applied this knowledge of selective tobacco blending to achieve desired nicotine . . . levels in the products that it designed and marketed.*⁷⁰¹

- Alexander Spears, the vice chairman and chief operating officer of Lorillard Tobacco Co., wrote that “*the lowest ‘tar’ segment is composed of cigarettes utilizing a tobacco blend which is significantly higher in nicotine.*”⁷⁰² According to Spears, the nicotine concentration in the lowest tar cigarettes in 1981 was 22% greater than the concentration in regular cigarettes (2.2% versus 1.8%).⁷⁰³ Spears further explains that “[h]igher nicotine levels can be achieved by decreasing Oriental and the stem and tobacco sheet and increasing the Burley and upper stalk positions of both the flue-cured and the Burley tobacco.”⁷⁰⁴
- Another Lorillard researcher, Vello Norman, has explained that the shift to tobacco blends with more nicotine-rich burley tobacco was motivated by a desire “to impart

⁷⁰¹ Declaration of Uydess IL (Feb. 29, 1996), at 8, 10 (emphasis added). See AR (Vol. 638 Ref. 1).

⁷⁰² Spears AW, Jones ST (Lorillard Tobacco Co.), Chemical and Physical Criteria for Tobacco Leaf of Modern Day Cigarettes, *Recent Advances in Tobacco Science*, Oct. 6-9, 1981;7:19, at 22 (emphasis added). See AR (Vol. 26 Ref. 373).

⁷⁰³ *Id.* at 21.

⁷⁰⁴ *Id.* at 24.

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more impact to smoke” to offset the effects of “gradually lower cigarette smoke yields”:

As various means were used to gradually lower cigarette smoke yields there has been a tendency to use more Burley in order to impart more impact to smoke. Thus, while total smoke yields of cigarettes have diminished, the relative composition of smoke has, in the case of many cigarettes, shifted slightly towards what is more characteristic of Burley.⁷⁰⁵

“Impact” is a term used by the tobacco industry to describe effects that are associated with nicotine delivery. *See, e.g.,* Jurisdictional Analysis, 60 FR 41776–41777.

- Similarly, a scientist at Brown & Williamson reported that “[u]ltra low tar cigarettes . . . use blends which contain about 20% more nicotine.”⁷⁰⁶

Brown & Williamson’s development of the high-nicotine Y-1 variety of tobacco, which is discussed above in section II.C.3.c.iii., was an attempt to use breeding and blending to increase nicotine concentrations in low-tar cigarettes. An example in which blending has been used to increase nicotine concentrations in commercial low-tar cigarettes is Philip Morris’ Merit cigarettes. FDA has analyzed the relative nicotine concentrations in the regular, low-tar, and ultra-low-tar versions of Merit cigarettes. FDA’s analysis revealed that Merit Filter 100’s contained 1.46% nicotine, but that Merit Ultra Lights 100’s contained 1.67% nicotine, and Merit Ultima 100’s (the lowest-tar product) contained 1.99% nicotine. *See* 60 FR 41723–41724. These findings, which

⁷⁰⁵ Norman V (Lorillard Research Center), *Changes in Smoke Chemistry of Modern Day Cigarettes*, Greensboro, NC (1982), at 168. *See* AR (Vol. 99 Ref. 813).

⁷⁰⁶ Reynolds ML (Brown & Williamson), *Symposium Summary*, presented at Winston Salem, NC, at 179 (Oct. 6-9, 1981) (emphasis added). *See* AR (Vol. 99 Ref. 823).

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show nicotine concentrations increasing as reported tar yields drop, are unchallenged by Philip Morris.

A similar pattern of higher nicotine concentrations in lower tar products exists in other brands. For instance, in 1981, Brown & Williamson launched a new ultra-low-tar brand called Barclay. Tests of Barclay and fourteen other cigarettes in 1982 showed that the tobacco in the Barclay blend had a nicotine concentration of 2.69%—higher than any other brand tested. In fact, Barclay's nicotine concentration was over 90% higher than the regular-strength Lucky Strike cigarette tested.⁷⁰⁷ Other brands show the same pattern of higher nicotine concentrations in the lowest-tar cigarettes.

These industry blending practices facilitate the use of low-tar products for pharmaceutical purposes. The enhanced nicotine concentrations in the lowest tar cigarettes result in higher nicotine deliveries than would otherwise occur, allowing consumers to more readily satisfy their addiction to nicotine and obtain other pharmacological effects of nicotine from low-tar cigarettes.

iii. The Use of Nicotine-Rich Tobacco Blends Is Not Due to Accident or Taste. In the Jurisdictional Analysis, FDA summarized the evidence then available to the Agency regarding the use of nicotine-rich blends in low-tar cigarettes, concluding that “[s]ignificant evidence also demonstrates that tobacco manufacturers have used blending techniques to increase nicotine concentrations in low-tar cigarettes and thereby maintain nicotine delivery while reducing tar delivery.” 60 FR 41708. The public comment period

⁷⁰⁷ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment, House Energy and Commerce Committee, U.S. House of Representatives, 103d Cong., 2d Sess. 173 (Jun. 23, 1994). See AR (Vol. 709 Ref. 3).*

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provided the cigarette manufacturers with an opportunity to provide an alternative explanation of this evidence of nicotine manipulation. As explained below, however, the industry does not effectively rebut the evidence that the manufacturers use nicotine-rich blends to enhance nicotine deliveries. The industry's failure to provide a convincing counter-explanation for its actions is further support for the Agency's finding that the manufacturers design low-tar cigarettes with nicotine-rich blends to maintain adequate nicotine deliveries.

The cigarette manufacturers make two conflicting arguments in response to the evidence that they manipulate tobacco blends to enhance nicotine content in low-tar products. First, they categorically assert that they "do not independently 'control' for or 'manipulate' the nicotine content in any of their blends."⁷⁰⁸

Second, they maintain that, to the extent they do control and manipulate nicotine content, they do so strictly for taste. Thus, they contend that (1) they "blend their tobaccos for flavor"⁷⁰⁹ and (2) "nicotine plays an important role in the taste and flavor of cigarette smoke."⁷¹⁰ During his appearance before Congress, for instance, William Campbell, the president of Philip Morris, conceded that the ultra-light Merit Ultima cigarette uses a tobacco blend with a higher concentration of nicotine than the regular Merit cigarette, but insisted that "it's there for taste."⁷¹¹ Similarly, Thomas Sandefur, then

⁷⁰⁸ Joint Comment of Cigarette Manufacturers (Jan. 2, 1996), Vol. IV, at 66. See AR (Vol. 535 Ref. 96).

⁷⁰⁹ *Id.*

⁷¹⁰ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 50. See AR (Vol. 519 Ref. 103).

⁷¹¹ *Regulation of Tobacco Products (Part 1): Hearings Before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, 103d Cong., 2d Sess. 764 (Apr. 14, 1994) (testimony of W.I. Campbell). See AR (Vol. 707 Ref. 1).*

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CEO of Brown & Williamson, conceded under questioning that Brown & Williamson uses high-nicotine blends in low-tar products, but asserted that “[w]hat we were trying to do was maintain a certain amount of nicotine which gives us better taste.”⁷¹²

Based on the evidence in the record, the Agency finds the manufacturers’ contention that they do not control and manipulate nicotine levels in blends not to be credible. The high nicotine content in the blends of low-tar cigarettes is not an accident. It necessarily reflects the deliberate design choices of the manufacturers. Moreover, the manufacturers’ argument that they do not control and manipulate the nicotine content of blends is in fundamental conflict with their assertions that they manipulate nicotine for taste.

For several reasons, the Agency also does not regard the manufacturers’ assertion that they control and manipulate nicotine only for taste to be credible. First, the manufacturers’ assertion is contradicted by numerous internal statements of senior researchers and officials in the tobacco industry, made public during the Agency’s investigation. As discussed above in section II.C.2., many senior researchers and officials within the industry explicitly acknowledge that nicotine provides desired pharmacological effects to consumers, and refer to cigarettes as a “dispenser for a dose unit of nicotine,”⁷¹³ a “nicotine delivery device,”⁷¹⁴ “a vehicle for delivery of nicotine,”⁷¹⁵ “the means of

⁷¹² *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Congress, 2d Sess. 227 (Jun. 23, 1994) (statement of Thomas Sandefur) (emphasis added). See AR (Vol. 709 Ref. 3).

⁷¹³ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5. See AR (Vol. 12 Ref. 133).

⁷¹⁴ Philip Morris Inc., Draft Report Regarding a Proposal for a “Safer” Cigarette, Code-named *Table*, at 5. See AR (Vol. 531 Ref. 122).

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providing nicotine dose in a metered fashion,”⁷¹⁶ and a device that provides the smoker “very flexible control over titrating his desired dose of nicotine.”⁷¹⁷ Other senior executives have stated that the cigarette industry is “in the business of selling nicotine, an addictive drug . . .”⁷¹⁸ and that “a good part of the tobacco industry is concerned with the administration of nicotine to consumers.”⁷¹⁹ The industry’s argument that high-nicotine blends are used in cigarettes only for taste cannot be reconciled with the industry’s own internal statements that cigarettes are intended to deliver pharmacological doses of nicotine to consumers. Indeed, one Philip Morris document quoted by the company in its comments calls nicotine a “*tasteless*” constituent of tobacco.⁷²⁰

Second, the manufacturers’ position on nicotine and taste cannot be reconciled with the industry’s record of extensive research into nicotine pharmacology. In contrast, very little of the industry’s research has examined the role of nicotine in taste. In their comments the cigarette manufacturers cite only a handful of industry studies on this subject. FDA has reviewed all of these studies and finds that they do not substantiate the industry’s claim that nicotine’s effects on taste are the reason consumers smoke. *See*

⁷¹⁵ Teague, CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1. *See* AR (Vol. 531 Ref. 125).

⁷¹⁶ Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference, Session I, slides (Jul. 9-12, 1984), at BW-W2-03242. *See* AR (Vol. 24 Ref. 315).

⁷¹⁷ *Transdermal Nicotine Patches*, at 2. *See* AR (Vol. 531 Ref. 124).

⁷¹⁸ Yeaman A (Brown & Williamson), *Implications of Battelle Hippo I and II and the Griffith Filter* (Jul. 17, 1963), at 4. *See* AR (Vol. 21 Ref. 221).

⁷¹⁹ Green SJ (BATCO), *BAT Group Research* (Sep. 4, 1968), at 2. *See* AR (Vol. 15 Ref. 192).

⁷²⁰ Philip Morris Inc., Comment (Apr. 19, 1996), at 64-65 (emphasis added), citing, “Merit Team Second Speaker” (Jan. 14, 1976). *See* AR (Vol. 700 Ref. 226).

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section II.B.2.c., above. Philip Morris's comments do state that Philip Morris conducted sophisticated investigations into flavor using an EEG-assisted "olfactometer." Yet according to Philip Morris, "[n]one of that 'olfactometer' work involved nicotine at all"⁷²¹—an omission that conflicts with the industry's assertion that nicotine has an important role in flavor.

By contrast, the industry has conducted or funded hundreds of studies on nicotine pharmacology, focused primarily on nicotine's effects on brain function. Manufacturers have learned through this research that nicotine has the hallmark characteristics of an addictive drug, *see* section II.C.3., above, and "abuse liability";⁷²² that nicotine changes patterns of human brain waves in a manner associated with anxiety relief;⁷²³ and that "[n]icotine is an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses."⁷²⁴

The research conducted by several companies to find "nicotine analogues" to replace nicotine in cigarettes provides an especially clear illustration that the industry regarded nicotine's primary effects as pharmacological, not flavor-related. The goal of this research was to develop a molecule that would "mimic nicotine's effect in the

⁷²¹ *Id.* at 47 (emphasis added).

⁷²² *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 33 (Apr. 28, 1994) (testimony of Victor DeNoble). *See* AR (Vol. 708 Ref. 2).

⁷²³ Pritchard WS (R.J. Reynolds Tobacco Co.), Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490. *See* AR (Vol. 3 Ref. 23-2).

⁷²⁴ BATCO, *Method for Nicotine and Cotinine in Blood and Urine* (May 21, 1980), at 2. *See* AR (Vol. 23 Ref. 300-1).

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brain”⁷²⁵ and “possess[] the desired features of brain stimulation and stress-relief”⁷²⁶ not to find substitute compounds with the same flavor characteristics as nicotine.

Third, the manufacturers’ contention that they blend for taste and not for pharmacological effects conflicts with their assertions that they blend and design their products to meet consumer preferences. As discussed above in sections II.A. and II.B., the primary reason consumers smoke is to satisfy their addiction and obtain the other pharmacological effects of nicotine, such as sedation and stimulation. This fact is widely accepted by both the scientific community and researchers and officials within the tobacco industry. Cigarette manufacturers that strive to satisfy smokers’ demands must necessarily design and blend cigarettes that produce pharmacological effects, including satisfying the needs of addicted smokers. This issue is further discussed in section II.C.4.f., below.

The Agency does not find that flavor is irrelevant in the blending process. To the contrary, the Agency agrees that one of the objectives in tobacco blending is to provide flavorful cigarette smoke. In the competitive cigarette marketplace, a cigarette that satisfied consumers’ pharmacological demands for nicotine but did not taste good would be unlikely to be a commercial success. RJR’s experience with Premier may, in fact, confirm this point.

⁷²⁵ *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 33 (Apr. 28, 1994) (testimony of Victor DeNoble). See AR (Vol. 708 Ref. 2).

⁷²⁶ Minutes of BATCO Research Conference at Hilton Head, SC (Sep. 24-30, 1968), at 3. See AR (Vol. 14 Ref. 172-2).

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The Agency finds, however, that a cigarette that tasted good but did not satisfy consumers' pharmacological demands for nicotine would be even more unlikely to be a commercial success. As Ian Uydess, the former Philip Morris scientist, states:

[A] cigarette having satisfactory ('high enough') nicotine levels but marginal flavor, stood a better chance of being 'accepted' in the market place than a somewhat better tasting product with zero or ultra-low levels of nicotine ('not enough').

*... Tobacco companies like Philip Morris learned a long time ago that it was hard to get people to stay with a good tasting product if the nicotine level was too low.*⁷²⁷

In other words, to produce a cigarette that smokers will find acceptable, the cigarette manufacturer must use tobacco blends that provide consumers the desired pharmacological effects of nicotine.

For these reasons, FDA concludes that cigarette manufacturers use nicotine-rich blends in low-tar cigarettes to ensure that these cigarettes deliver pharmacologically active doses of nicotine.

b. The Manufacturers Use Filtration and Ventilation Technologies That Selectively Remove More Tar than Nicotine and That Allow Smokers To Inhale More Nicotine than the Measured Levels

The evidence before the Agency also supports a finding that cigarette manufacturers use cigarette filters and ventilation to manipulate nicotine deliveries. Especially in low-tar products, the available evidence indicates that cigarette manufacturers and their filter suppliers have engineered filtration and ventilation systems to bring about greater reductions in tar than in nicotine, thereby increasing the nicotine/tar ratio. According to William Farone of Philip Morris, "modification of the construction of

⁷²⁷ Declaration of Uydess IL (Feb. 29, 1996), at 11, 13 (emphasis added). See AR (Vol. 638 Ref. 1).

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the cigarette such as filter type, the type of filter material used, the number and placement of ventilation holes, [and] the density, composition and porosity of the cigarette paper” is the second principal means of controlling nicotine used by the industry.⁷²⁸

The effect of filtration and ventilation on nicotine deliveries is recognized in the technical tobacco literature. According to an article by a researcher at Lorillard Tobacco Co.:

[V]entilated filters caused a significant drop in the amount of nicotine retained on the filter.

. . . *[S]moke from ventilated cigarettes is relatively enriched in nicotine.*⁷²⁹

Similarly, scientists at Eastman Kodak Co., a manufacturer of cigarette filters, have observed that “[a]s ventilation is increased, the nicotine content . . . increases markedly.”⁷³⁰

Indeed, some filter manufacturers have openly promoted the ability of their filters to increase nicotine/tar ratios. For instance, Filtrona Ltd.’s Filtrona Ratio filter was promoted as “a new option available to cigarette designers which allows management of the yield ratios of important smoke components relative to tar, [including] . . . nicotine.”⁷³¹

⁷²⁸ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 5. See AR (Vol. 638 Ref. 2).

⁷²⁹ Norman V, Ihrig AM, Shoffner RA (Lorillard Tobacco Co.), The effect of tip dilution on the filtration efficiency of upstream and downstream segments of cigarette filters, *Beitrage zur Tabakforschung International*, Jul. 1984;12(4):178-185, at 184 (emphasis added). See AR (Vol. 103 Ref. 923).

⁷³⁰ Kiefer JE (Eastman Kodak Co.), Ventilated filters and their effect on smoke composition, *Recent Advances in Tobacco Science* (1979), at 78. See AR (Vol. 28 Ref. 465).

⁷³¹ Papers, filters, and tipping, *Tobacco Reporter*, Apr. 1985;112(4):32. See AR (Vol. 351 Ref. 5624).

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When applied to commercial brands, this filter increased nicotine deliveries by over 25%, while leaving tar deliveries virtually unchanged.⁷³²

In their comments on the Jurisdictional Analysis, the cigarette manufacturers acknowledge that filtration and ventilation in low-tar cigarettes produce enhanced nicotine/tar ratios, but they argue that this is strictly an unavoidable physical phenomenon—not a design feature. The administrative record does not support their position.

Contrary to the cigarette manufacturers' contention, the filter manufacturers describe the role of filters and ventilation as not simply removing tar and nicotine according to immutable proportions determined by the laws of physics. Filters are highly engineered products that are "*designed exclusively to yield the maximum satisfaction from a carefully chosen tobacco blend.*"⁷³³ The object of filters and ventilation is to "control the yield of the many constituents that the smoker receives" and to "*act[] more as a smoke modifier* than as an absolute filter which removes all particles of a known size."⁷³⁴

As described above in section II.C.3.e., the administrative record indicates that filter manufacturers have developed numerous strategies for independently changing tar and nicotine deliveries. When the cigarette manufacturer selects a filter and ventilation design, therefore, the cigarette manufacturer's choices necessarily affect the relative

⁷³² *Id.*

⁷³³ Philips JA (Filtrona International Ltd.), Filters for cigarettes: an integral part of the cigarette, *Tobacco Reporter* (Oct. 1981), at 34 (emphasis added). See AR (Vol. 351 Ref. 5624).

⁷³⁴ *Id.* at 34 (emphasis added).

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nicotine and tar deliveries. A decision to place the ventilation holes close to the tobacco rod will increase relative nicotine deliveries,⁷³⁵ as will a decision to increase the porosity of the cigarette paper.⁷³⁶ The use of increasingly porous perforated cigarette paper will “selectively increase nicotine.”⁷³⁷ A decision to rely on relatively more ventilation and relatively less filtration is another “tool[]” that “increas[es] nicotine delivery without changing tar delivery.”⁷³⁸ Likewise, when manufacturers decide to increase the pH of the filter through use of an additive, this increases cigarette nicotine delivery “independently” of tar delivery.⁷³⁹ Thus, contrary to the position of the cigarette manufacturers, there are many technical choices that manufacturers make in filtration and ventilation design that determine the extent to which the cigarette filter and ventilation will increase nicotine deliveries relative to tar deliveries.

The statement of William Farone corroborates the evidence showing that deliberate design decisions have caused the selective filtration and ventilation observed in

⁷³⁵ Kiefer JE (Eastman Kodak Co.), Ventilated filters and their effect on smoke composition, *Recent Advances in Tobacco Science* (1979), at 79. See AR (Vol. 28 Ref. 465).

⁷³⁶ McMurtrie A, Litinger EF, Wu DT (Brown & Williamson), *Cigarette Paper Effects on Tar/Nicotine and CO/Tar Ratios*, 35th Tobacco Chemists' Research Conference, Winston-Salem, North Carolina (Oct. 6-9, 1981). See AR (Vol. 639 Ref. 2).

⁷³⁷ Owens WF Jr. (Ecusta Paper and Film Group), *Effect of Cigarette Paper on Smoke Yield Composition*, 32d Tobacco Chemists' Research Conference, Montreal, Canada (1978) (emphasis added). See AR (Vol. 639 Ref. 10).

⁷³⁸ Selke WA, Making the cigarette do just what you want it to do, *Journal Tobacco International* 1983:12. See AR (Vol. 102 Ref. 896).

⁷³⁹ Lee BM (Eastman Kodak Co.), *Modification of Nicotine to Tar Ratio in Cigarette Smoke*, 42d Tobacco Chemists' Research Conference, Lexington, Kentucky (Oct. 2-5, 1988), at 33. See AR (Vol. 639 Ref. 2).

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low-tar cigarettes. According to Farone, “[t]he cigarette industry . . . *altered the cigarette filter in order to increase nicotine delivery.*”⁷⁴⁰ Specifically, he states:

*Filter design and ventilation allowed the design and manufacture of cigarettes that removed a higher percentage of tar than nicotine. Selective filtration was accomplished by altering the technical specifications for a filter, e.g. by selecting different filter tow combinations, varying the denier per filament, and deciding whether or not to use additives in the filter. . . . [A]ppropriate filters were identified to attain a predetermined nicotine/tar ratio.*⁷⁴¹

The example of the regular-length Benson & Hedges filtered cigarettes that Congressman Henry A. Waxman described on the floor of the U.S. House of Representatives in July 1995 also contradicts the position of the cigarette industry.⁷⁴² The cigarette industry maintains that high nicotine/tar ratios are unavoidable in ultra-low-tar cigarettes because the high levels of filtration and ventilation in these cigarettes inevitably remove more tar than nicotine. The Benson & Hedges example, however, shows that (1) ultra-low-tar and nicotine levels can be achieved without increasing the ratio of nicotine to tar and (2) the high nicotine/tar ratios typically observed in cigarettes with ultra-low tar levels are therefore the result of deliberate design choices of manufacturers.

The Benson & Hedges cigarette was marketed as an ultra-low-tar cigarette from 1978 to 1985, with tar levels consistently below or near 1 milligram.⁷⁴³ In three of those

⁷⁴⁰ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 11 (emphasis added). See AR (Vol. 638 Ref. 2).

⁷⁴¹ *Id.* (emphasis added).

⁷⁴² Remarks of Waxman HA, 141 Cong. Rec. H8009-8010 (daily ed. Jul. 31, 1995). See AR (Vol. 27 Ref. 376a).

⁷⁴³ *Id.*

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years (1978, 1984, and 1985), the nicotine levels were also proportionately low, producing a normal nicotine/tar ratio.⁷⁴⁴ Thus, in these years, the filtration and ventilation technologies used by the manufacturer to reduce tar deliveries did not selectively increase nicotine deliveries. In contrast, from 1979 to 1983, the nicotine levels were elevated relative to the tar levels, producing a high nicotine/tar ratio.⁷⁴⁵ These changes in the nicotine/tar ratio were not due to chance.⁷⁴⁶ These facts thus establish that the manufacturer, in this case Philip Morris, had the technical ability to achieve ultra-low-tar levels without causing nicotine levels to be relatively enhanced.

The evidence also indicates that cigarette manufacturers also use “elasticity” technologies, principally ventilation techniques that can be readily blocked, to allow smokers to increase their nicotine intakes above the levels measured on smoking machines. One example is Brown & Williamson’s Barclay cigarette. This cigarette was first introduced as an ultra-low-tar cigarette in 1981. As noted above in section II.C.4.a.ii., tests in 1982 showed that the tobacco in the Barclay blend had a higher nicotine concentration than any other cigarette brand tested. Barclay also had more total nicotine in the tobacco rod than any other cigarette tested. For instance, Barclay had *over 60% more total nicotine* in the cigarette rod (12.80 mg per cigarette) than regular-strength Lucky Strike (7.92 mg per cigarette). Yet despite its high nicotine levels, Barclay had the second lowest nicotine yields of any cigarette tested, as measured by the FTC smoking machine method. Thus, even though, as noted, Barclay had over 60% more nicotine in

⁷⁴⁴ *Id.*

⁷⁴⁵ *Id.*

⁷⁴⁶ *Id.*

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the cigarette rod than the regular-strength Lucky Strike, its nicotine yield on the FTC smoking machine (0.15 mg per cigarette) was *90% lower* than the yield of the Lucky Strike (1.46 mg per cigarette).

Barclay was able to combine the highest total nicotine content with the second-lowest measured nicotine yield by relying on a "channel-ventilated" filter system. An investigation commenced by FTC in 1981 found that air flow through these channels is compromised during actual smoking and that, as a result, Barclay actually delivered considerably more nicotine and tar to the smoker than is obtained using the FTC's testing method. In 1983, the FTC successfully sued to enjoin Brown & Williamson from using nicotine, tar, and carbon monoxide results obtained from the FTC's smoking machines in Barclay advertising. *See* 60 FR 41718.

While Barclay is a striking example of a filter that delivers more nicotine to its smokers than to a smoking machine, the use of ventilation systems that can be blocked by smokers is common. As FDA reported in the Jurisdictional Analysis, the evidence in the record indicates that 32% to 69% of smokers of low-tar cigarettes block ventilation holes. *See* 60 FR 41717.

In sum, the evidence in the record supports a finding that the increase in nicotine deliveries relative to tar deliveries produced by selective filtration and ventilation result from the deliberate design choices of the manufacturers. The manufacturers do not persuasively refute this finding. Accordingly, the Agency finds that the manufacturers use filtration and ventilation technologies that are designed to selectively remove more tar than nicotine.

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c. The Manufacturers Use Chemical Additives to Increase the Delivery of “Free” Nicotine

The evidence in the record also supports a finding that the cigarette manufacturers control and manipulate nicotine deliveries through chemical manipulation. One way they do this is through the use of ammonia technologies that increase the delivery of “free” nicotine to smokers by raising the alkalinity or pH of tobacco smoke. “Free” nicotine is also sometimes referred to as “volatile,” “extractable,” or “non-ionized” nicotine. The use of ammonia compounds to increase pH is an outgrowth of the industry’s product development research to improve the efficient use of smoke nicotine through pH modification. *See* section II.C.3., above.

The use of ammonia compounds is common in the cigarette industry. Ammonia compounds have been regularly identified in the list of cigarette ingredients submitted by the industry to the Department of Health and Human Services.⁷⁴⁷ Indeed, the comments of the cigarette manufacturers concede that several ammonia-related compounds are used in the manufacture of cigarettes.⁷⁴⁸

An article in the *Wall Street Journal* describes the extent of the industry’s reliance on ammonia technology.⁷⁴⁹ According to the article, which is based on two major Brown & Williamson internal reports, Brown & Williamson adds ammonia compounds to “almost all” of its nonmenthol brands; Brown & Williamson views ammonia technology as “the

⁷⁴⁷ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 84. *See* AR (Vol. 535 Ref. 96).

⁷⁴⁸ *Id.*

⁷⁴⁹ Freedman AM, Impact booster tobacco firm shows how ammonia spurs delivery of nicotine, *Wall Street Journal* (Oct. 18, 1995). *See* AR (Vol. 639 Ref. 2).

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soul of Marlboro” and “the key factor” that “makes Marlboro a Marlboro”; and Brown & Williamson found that ammonia technology was also used by RJR, Lorillard, and American Tobacco Co.⁷⁵⁰ In congressional testimony, Thomas Sandefur, the CEO of Brown & Williamson, confirmed the widespread use of ammonia within the cigarette industry.⁷⁵¹

It is well established that the addition of ammonia compounds to tobacco increases pH. This increase transforms nicotine that is “bound” in nicotine salts to “free” nicotine.⁷⁵² This effect is described in Brown & Williamson’s 1991 “Handbook for Leaf Blenders and Product Developers,” which states that “[a]mmonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine.”⁷⁵³

Changing the chemical form of nicotine from a bound nicotine salt to free nicotine has several significant consequences, according to the evidence in the administrative record. First, it increases the quantity of nicotine that is transferred from the cigarette to

⁷⁵⁰ *Id.*

⁷⁵¹ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 224-225 (Jun. 23, 1994) (statement of Thomas Sandefur). *See* AR (Vol. 709 Ref. 3).

⁷⁵² *See, e.g.,* Armitage AK, Turner DM, Absorption of nicotine in cigarette and cigar smoke through the oral mucosa, *Nature*, Jun. 27, 1970;226:1231-1232. *See* AR (Vol. 45 Ref. 25).

Surgeon General’s Report, 1988, at 29. *See* AR (Vol. 129 Ref. 1592).

⁷⁵³ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 21 (Jun. 21, 1994) (statement of David Kessler) (emphasis added). *See* AR (Vol. 709 Ref. 3).

Brown & Williamson has acknowledged in its comment that the Handbook is a Brown & Williamson document. Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 37. *See* AR (Vol. 529 Ref. 104).

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the smoke. According to William Farone, the former director of applied research at Philip

Morris:

*The use of ammonia chemistry was important to the industry in maintaining adequate nicotine delivery to satisfy smokers. The industry was able to deliver more of the available nicotine in the blend to the smoker by using ammonia compounds. . . . In the complex world of tobacco smoke chemistry, by increasing the pH of the aerosol in the mainstream smoke, more of the aerosol would be in the vapor phase and less in the liquid (or condensed) phase. By increasing the ratio of vapor phase to liquid phase, one increases the total nicotine delivery since the condensed phase is less likely to survive the filter and the trip to the lungs.*⁷⁵⁴

Similarly, documents from the American Tobacco Company state:

*There has been an interest in increasing the amount of nicotine that is transferred from the tobacco to the mainstream smoke while leaving the "tar" level unchanged. Since most of the nicotine in tobacco is a non-volatile salt, it was thought that a greater transfer would take place if the tobacco was made basic causing the nicotine to volatilize when the cigarette is smoked.*⁷⁵⁵

The second effect of increasing the free nicotine is to increase the amount of nicotine absorption that takes place in the mouth. It is well-established that free nicotine is significantly more absorbable than bound nicotine.⁷⁵⁶ As early as 1968, researchers at BATCO, Brown & Williamson's parent, reported that there is a direct correlation between smoke pH and nicotine absorption in the mouth, stating that "[n]icotine retention appears

⁷⁵⁴ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 13 (emphasis added). See AR (Vol. 638 Ref. 2).

⁷⁵⁵ Bodenhamer NL (American Tobacco), Leaf Services Monthly Report for June (Jun. 30, 1980) (emphasis added). See AR (Vol. 27 Ref. 385).

⁷⁵⁶ See, e.g., Armitage AK, Turner DM, Absorption of nicotine in cigarette and cigar smoke through the oral mucosa, *Nature*, Jun. 27, 1970;226:1231-1232. See AR (Vol. 45 Ref. 25).

Surgeon General's Report, 1988, at 29. See AR (Vol. 129 Ref. 1592).

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to be dependent principally on smoke pH and nicotine content.”⁷⁵⁷ Similarly, RJR researchers have reported that:

[B]y raising pH . . . from 6.0 to 6.5 [in a low-tar cigarette] you raise the level of nicotine that is transferred to the taste buds and body fluids in the mouth to the same level as with the higher tar cigarette. *And hence, even though the tar level has been dropped from 25 mg to 10 mg, by raising the pH from 6.0 to 6.5, you increase the nicotine transfer in the mouth. . . .*⁷⁵⁸

This effect of increased nicotine absorption in the mouth appears to be related to what some cigarette manufacturers describe as smoke “impact.” For example, Brown & Williamson’s Handbook for Leaf Blenders states that by adding ammonia:

the ratio of extractable nicotine to bound nicotine in the smoke may be altered in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in cigarette smoke and this is how ammonia can act as an impact booster.⁷⁵⁹

RJR describes this effect as “mouth satisfaction,” which it distinguishes from “the ultimate satisfaction” which “comes from the nicotine which is extracted . . . in the lungs.”⁷⁶⁰

The third effect of increasing free nicotine appears to be to increase the rate of transfer of nicotine to the brain. This effect is discussed in a BATCO research paper

⁷⁵⁷ BATCO, *The Retention of Nicotine and Phenols in the Human Mouth* (1968), at BW-W2-11691. See AR (Vol. 445 Ref. 7593).

⁷⁵⁸ Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 7 (emphasis added). See AR (Vol. 700 Ref. 593).

⁷⁵⁹ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 21 (Jun. 21, 1994) (statement of David Kessler). See AR (Vol. 709 Ref. 3).

⁷⁶⁰ Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 7, 9. See AR (Vol. 700 Ref. 593).

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entitled "Further Work on Extractable Nicotine."⁷⁶¹ According to this report, when smoke is inhaled into the lungs, there is virtually complete retention of the nicotine, regardless of whether the nicotine is in its free or bound form. However, the report hypothesizes that the speed of absorption is different when free or extractable nicotine is increased and that "*with a higher 'extractable' nicotine, nicotine reaches the brain more quickly.*"⁷⁶² RJR researchers have also recognized that pH adjustments affect the speed of nicotine absorption, recommending that in designing cigarettes for new smokers "[t]he *rate* of absorption of nicotine should be kept low *by holding pH down*, probably below 6."⁷⁶³

FDA notes that the use of chemical manipulation to boost free nicotine levels may raise the amount of nicotine delivered to the smoker without a corresponding increase in nicotine yield, as measured by the FTC smoking machine. Thus, the actual nicotine delivery to the smoker from some brands may be higher than the FTC yield because of the addition of ammonia or similar compounds to increase free nicotine.

Based on this evidence, the Agency finds that cigarette manufacturers manipulate and control nicotine deliveries through the use of ammonia compounds. These compounds transform bound nicotine to free nicotine. According to the industry's own documents, this transformation facilitates consumer use of cigarettes for pharmacological

⁷⁶¹ BATCO, *Further Work on 'Extractable' Nicotine* (1966), at BW-W2-11615 (emphasis added). See AR (Vol. 62 Ref. 308).

⁷⁶² *Id.* at 7 (emphasis added).

⁷⁶³ Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on Some Thoughts About New Brands of Cigarettes for the Youth Market* (Feb. 2, 1973), at 4 (emphasis added). See AR (Vol. 531 Ref. 125).

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purposes by: (1) increasing the amount of nicotine that is transferred from the tobacco to the smoke; (2) increasing the absorption of nicotine in the mouth; and (3) possibly increasing the speed of nicotine transfer to the brain.

d. Nicotine Deliveries Have Increased in Recent Years by Design, Especially in Low-Tar Cigarettes

The use of the methods described above, especially the use of nicotine-rich tobacco blends and selective filtration and ventilation, have increased nicotine deliveries to consumers. In the Jurisdictional Analysis, FDA found that nicotine deliveries as measured by the FTC smoking machine have been increasing since 1982, with the greatest increases occurring in the ultra-low-tar category. *See* 60 FR 41727–41730. These increases have been occurring without parallel increases in tar deliveries, thus indicating an industry-wide trend of designing cigarettes with enhanced nicotine deliveries.

The nicotine/tar ratios in low-tar cigarettes reflect these changes. The Agency's statistical analysis shows that, according to 1994 Federal Trade Commission data, the lowest-tar products had a markedly higher ratio of nicotine to tar than that found in higher-tar products. None of the 153 products with 14 or more milligrams of tar (the high-tar segment of the market) had a nicotine/tar ratio greater than 1 to 12. By contrast, 88 of the 93 products with 6 or fewer milligrams of tar (the ultra-low-tar segment) had a nicotine/tar ratio greater than 1 to 12. *See* 60 FR 41724. The industry did not challenge these figures in their comments.

The increase in nicotine/tar ratios has occurred primarily in the last two decades. In comparison with the 1994 results, only 2 of the 142 marketed cigarettes included in the FTC's report for 1972 had a nicotine/tar ratio greater than 1 to 12. Thus, the evidence

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from the reported nicotine and tar deliveries supports the conclusion that as the market for lower tar cigarettes grew over the last 25 years, manufacturers deliberately altered what had been the traditional ratio of nicotine to tar, increasing nicotine levels in relation to tar levels.⁷⁶⁴

This increase in the nicotine/tar ratios is persuasive evidence that the manufacturers design cigarettes to increase their relative nicotine deliveries. Without manufacturer intervention, nicotine levels tend to follow tar levels, because methods that reduce tar deliveries tend to reduce nicotine deliveries as well. As one industry executive testified before Congress, “[n]icotine levels follow the tar level. . . . The correlation . . . is essentially perfect correlation between tar and nicotine.”⁷⁶⁵ The increase in nicotine deliveries relative to tar deliveries indicates that the manufacturers have taken affirmative steps to enhance nicotine deliveries.

The manufacturers dispute this finding. Although they first asserted that nicotine deliveries fall proportionately with tar deliveries, they now assert that the increase in nicotine/tar ratios is due to the unavoidable effects of filtration and ventilation—not any intentional actions of the manufacturers. The record does not support the industry’s assertion, however. First, as discussed in section II.C.4.a.ii., above, the cigarette

⁷⁶⁴ Federal Trade Commission, *Report of the “Tar” and Nicotine Content of 142 Varieties of Cigarettes* (Jul. 1972). See AR (Vol. 314 Ref. 4856). On a percentage basis, only 1.4% of the 1972 products had a nicotine/tar ratio greater than 1 to 12. In 1994, that figure grew to 26.3% overall, and rose to 95% for the 93 products in the lowest tar category. *Id.*; Federal Trade Commission, *Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes* (1994). See AR (Vol. 29 Ref. 485).

⁷⁶⁵ *Regulation of Tobacco Products (Part 1): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 143, 378 (Mar. 25, 1994) (statement of Alexander Spears). See AR (Vol. 707 Ref. 1).

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manufacturers deliberately use tobacco blends with the highest nicotine concentrations in the lowest tar cigarettes.

Second, the record contradicts the industry's contention that they do not control the extent to which filtration and ventilation selectively reduce tar more than nicotine. Indeed, the record indicates that the manufacturers affirmatively use filtration and ventilation to enhance nicotine/tar ratios. *See* section II.C.4.b., above.

Moreover, as the Agency reported in the Jurisdictional Analysis, increases in nicotine deliveries relative to tar deliveries have occurred in all categories of cigarettes. Although the increases in nicotine delivery are largest among the ultra-low-tar cigarettes, relative nicotine deliveries have also been increasing in low-tar and high-tar cigarettes. *See* 60 FR 41727–41731. The manufacturers' theory regarding the unavoidable effects of filtration and ventilation in ultra-low-tar cigarettes cannot explain these other increases in relative nicotine deliveries.

The evidence in the record provides specific examples where manufacturers appear to have designed cigarettes to achieve enhanced nicotine deliveries. As discussed in section II.C.3.b., above, for example, RJR researchers in the mid-1970's recommended "*maintaining the nicotine as high as possible*" in low-tar cigarettes.⁷⁶⁶ Researchers specifically recommended that RJR develop a new brand that would deliver 5 mg tar and 0.5 to 0.8 mg nicotine, stating that "*on inhalation into the lungs, 0.5 to 0.8 mg of nicotine*

⁷⁶⁶ Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 10 (emphasis added). *See* AR (Vol. 700 Ref. 593).

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*would provide sufficient nicotine to the blood to produce the stimulation and relaxation effects desired by the smoker.”*⁷⁶⁷

In the late 1970's and 1980's, RJR began to market ultra-low-tar cigarettes that met these specifications. For instance, RJR first introduced an ultra-light version of its Winston brand in 1981. That year, the Winston Ultra Lights 100's had a tar delivery of 5 mg and a nicotine delivery of 0.5 mg—exactly the deliveries recommended by its researchers as providing the sufficient nicotine to provide the pharmacological effects sought by consumers.⁷⁶⁸ As recently as 1994, both the king-size Winston Ultra Lights (hard pack) and the Winston Ultra Lights 100's (hard pack) continued to have these recommended deliveries of 5 mg tar and 0.5 mg. nicotine, as did king-size Camel Ultra Lights and several other RJR ultra-low-tar brands.⁷⁶⁹

Another example of deliberate design to achieve relatively enhanced nicotine deliveries appears to be the Merit Ultra Lights by Philip Morris. Philip Morris researchers conducted extensive research in the 1970's to determine “what combinations of tar and nicotine make for optimal acceptability in a low delivery cigarette.”⁷⁷⁰ This research concluded that a higher nicotine/tar ratio (at least 0.09), compared to the natural ratio of

⁷⁶⁷ *Id.* at 11-12 (emphasis added).

⁷⁶⁸ Federal Trade Commission, “*Tar, Nicotine and Carbon Monoxide of the Smoke of 200 Varieties of Cigarettes*” (1981). See AR (Vol. 535 Ref. 96, vol. III.D).

⁷⁶⁹ Federal Trade Commission, *Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes* (1994). See AR (Vol. 29 Ref. 485).

⁷⁷⁰ Dunn WL, Johnston M, Ryan F (Philip Morris Inc.), *Plans for 1972* (Sep. 8, 1971), in 141 Cong. Rec. H8128 (daily ed. Aug. 1, 1995). See AR (Vol. 711 Ref. 6).

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0.07, was optimal.⁷⁷¹ Similarly, shortly thereafter, Philip Morris introduced the king-size Merit Ultra Lights with an elevated nicotine/tar ratio of approximately 0.10.⁷⁷² The king-size Merit Ultra Lights (hard pack) continued to have an elevated nicotine/tar ratio of 0.10 as recently in 1994.⁷⁷³ According to William Farone, the former director of applied research at Philip Morris, the Merit Ultra Lights is an example of “a blend change incorporating the greater use of higher nicotine tobacco . . . [to] produce a *low tar cigarette with the desired pharmacologically active level of nicotine*.”⁷⁷⁴

These brands do not appear to be isolated examples. The evidence in the record indicates that the design of cigarettes to achieve specific nicotine deliveries is a common practice within the cigarette industry. According to Farone, cigarettes are designed to “attain a *predetermined nicotine/tar ratio*.”⁷⁷⁵ Likewise, Ian Uydess, the former Philip Morris scientist, states that “[n]icotine levels were routinely targeted and adjusted by Philip Morris.”⁷⁷⁶

⁷⁷¹ Jones B, Houck W, Martin P (Philip Morris Inc.), *Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication* (Oct. 1975), in 141 Cong. Rec. H8132 (daily ed. Aug. 1, 1995) (emphasis added). See AR (Vol. 711 Ref. 6).

⁷⁷² Federal Trade Commission, “Tar,” Nicotine, and Carbon Monoxide of the Smoke of 200 Varieties of Cigarettes (1981). See AR (Vol. 535 Ref. 96, vol. III.D).

⁷⁷³ Federal Trade Commission, *Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes* (1994). See AR (Vol. 29 Ref. 485).

⁷⁷⁴ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 10 (emphasis added). See AR (Vol. 638 Ref. 2).

⁷⁷⁵ *Id.* at 11 (emphasis added).

⁷⁷⁶ Declaration of Uydess IL (Feb. 29, 1996), at 8 (emphasis added). See AR (Vol. 638 Ref. 1).

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e. The Manufacturers Precisely Control Nicotine Deliveries

A principal feature of all marketed cigarettes is the precise control over nicotine delivery achieved by the manufacturers. Annual variations in the nicotine content of raw tobacco leaves originating in the same geographical area can be as high as 100%.⁷⁷⁷ Nevertheless, the nicotine deliveries in commercial cigarettes are consistent to a tenth of 1%. *See* 60 FR 41694. This is a high degree of control even for a conventional pharmaceutical company. It does not occur by chance, and the industry does not pretend that it does. The precise control ensures that smokers receive a consistent nicotine dosage within a brand from cigarette to cigarette, pack to pack, and year to year.

The evidence in the record supports a finding that the manufacturers' precise control over nicotine levels reflects the central role of nicotine in cigarette manufacturing. According to the statement of William Farone of Philip Morris, the cigarette industry even developed "complex computer models to help determine nicotine and tar deliveries."⁷⁷⁸ These models "allowed blend ingredients, filter and paper components, and numerous other variables to be considered simultaneously" and "enabled product developers to identify which components were required to produce specific nicotine and tar deliveries."⁷⁷⁹

The administrative record demonstrates that the industry pays careful attention to nicotine throughout the manufacturing process. In particular, as described below, nicotine

⁷⁷⁷ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 32. *See* AR (Vol. 535 Ref. 96).

⁷⁷⁸ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 13. *See* AR (Vol. 638 Ref. 2).

⁷⁷⁹ *Id.* at 13-14.

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plays an essential role in tobacco growing, leaf purchasing, leaf blending, and the manufacture of reconstituted tobacco. This control provides smokers seeking the pharmacological effects of nicotine with a remarkably consistent dose of nicotine from cigarette to cigarette.

i. Tobacco Growing. Cigarette manufacturers' ability to control nicotine delivery begins with tobacco growing. Although cigarette manufacturers do not directly control what tobacco farmers grow, they have successfully influenced the characteristics of tobacco crops, including their nicotine content.

As discussed in the Jurisdictional Analysis, cigarette manufacturers were influential in establishing the Minimum Standards Program (MSP) administered by the USDA. This program began in the 1960's in response to the emergence of so-called "discount" varieties of tobacco that had low nicotine contents. The MSP eliminated the discount varieties and helped control the variation in the nicotine content of the tobacco crop by setting minimum and maximum permissible levels of nicotine. *See* 60 FR 41697-41698.

Moreover, tobacco leaf experts have reported that the nicotine level in certain varieties of tobacco rose in response to the needs of cigarette manufacturers. For instance, an expert with a U.S. leaf company observed in 1983 that "[o]nce the manufacturer has expressed a preference for a certain style of leaf, cultural practices can be implemented on the farm to try to fulfill his requirements."⁷⁸⁰ According to this expert,

⁷⁸⁰ Glass JM, Production and leaf chemistry of burley tobacco in Latin America, in *Recent Advances in Tobacco Science*, 37th Tobacco Chemists' Research Conference (1983), at 81. *See* AR (Vol. 528 Ref. 97, appendix 19).

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“a noticeable change has occurred in leaf chemistry” of burley tobacco imported into the United States—“*especially the increase in nicotine levels.*”⁷⁸¹

ii. Leaf Purchasing. The industry’s direct control over nicotine delivery starts with its leaf purchasing decisions. As described in the Jurisdictional Analysis, *see* 60 FR 41703–41706, and as the industry comments themselves confirm, important leaf characteristics in purchasing include “stalk position,” “impact,” and “smoke quality.” These characteristics correlate closely with the nicotine content in the tobacco leaves.

The industry acknowledges that, as a general rule, the relative position of a tobacco leaf on the stalk of the plant will determine the nicotine content in that leaf.⁷⁸² The nicotine level usually goes up from the bottom to the top of the stalk. According to Brown & Williamson’s comment, “[h]igher stalk tobacco leaves do have more nicotine than lower stalk leaves on the same plant.”⁷⁸³

The Agency has found that stalk position plays a key role in the leaf purchasing practices of cigarette manufacturers. The industry does not dispute the significance of stalk position. For example, Brown & Williamson does not dispute the Agency’s finding that stalk position is the “first thing” Brown & Williamson looks for during leaf purchasing. *See* 60 FR 41705. Similarly, RJR concedes that stalk position is one of the three primary “quality determinants” used by RJR in leaf purchasing.⁷⁸⁴ Because of the

⁷⁸¹ *Id.* at 77 (emphasis added).

⁷⁸² R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 44. *See* AR (Vol. 519 Ref. 103).

Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 10. *See* AR (Vol. 529 Ref. 104).

⁷⁸³ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 10 (emphasis added). *See* AR (Vol. 529 Ref. 104).

⁷⁸⁴ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 44. *See* AR (Vol. 519 Ref. 103).

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relationship between stalk position and nicotine content, when manufacturers select tobacco leaves based on stalk position, they are in effect controlling the nicotine content of the leaves they purchase.

It is also undisputed that “impact” is associated with the nicotine level in a tobacco leaf and that “impact” plays a role in leaf purchasing. RJR, for instance, admits that “impact is . . . an element of any smoking of tobacco, including smoking of samples purchased during the auction season;” and that “nicotine is reported to be a factor” in “impact.”⁷⁸⁵

Cigarette manufacturers deny that nicotine plays a role in leaf selection. In their words, “nicotine content is not a principal criterion in the purchase of leaf.”⁷⁸⁶ The Agency does not find this assertion to be credible. Finished cigarettes have highly consistent nicotine deliveries. This control could not be achieved without taking into account nicotine content in the purchase of tobacco leaves. If nicotine content was not a critical purchasing factor, manufacturers would have no assurance that they were purchasing leaves that could be blended together to provide consistent nicotine deliveries in the finished cigarettes.

iii. Leaf Blending. Leaf blending is one of the primary means the industry uses to control nicotine levels in cigarettes. This is acknowledged by the industry, which states in its joint comment that “[t]obacco is blended for consistency and uniformity. . . .”⁷⁸⁷ At

⁷⁸⁵ *Id.* at 43-44.

⁷⁸⁶ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 58. *See* AR (Vol. 535 Ref. 96).

⁷⁸⁷ *Id.* at 66.

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a minimum, therefore, the industry has conceded one of the Agency's points in its Jurisdictional Analysis: blending to ensure "consistency and uniformity" enables the industry to overcome naturally occurring variations in nicotine associated with genetics and soil and climatic conditions. *See* 60 FR 41706.

The joint industry comment provides a graphic representation of the naturally occurring variations in nicotine levels in raw tobacco. The industry's submission shows the rising but substantially fluctuating nicotine levels in flue-cured tobacco from the early 1950's through the early 1990's.⁷⁸⁸ Through blending, tobacco manufacturers are able to overcome these variations and produce a remarkably consistent product with uniform nicotine levels.

The central role of blending in ensuring consistent nicotine yields is acknowledged in the industry comments. As Brown & Williamson observes, "the manufacturing challenge is to maintain constancy of product composition not only from day to day, but month to month and year to year despite variation in the raw material."⁷⁸⁹

iv. Reconstituted Tobacco. The tobacco industry also pays careful attention to nicotine during the manufacture of reconstituted tobacco, which makes up about 15% to 25% of the tobacco in cigarettes.⁷⁹⁰ The process of manufacturing reconstituted tobacco is described in detail in the Jurisdictional Analysis. *See* 60 FR 41719–41721. The careful management of nicotine in this process allows the manufacturers to control precisely the level of nicotine in reconstituted tobacco.

⁷⁸⁸ *Id.* at Vol. IV, Fig. 1.

⁷⁸⁹ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 17. *See* AR (Vol. 529 Ref. 104).

⁷⁹⁰ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 72. *See* AR (Vol. 535 Ref. 96).

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The statement of William Farone, the former Philip Morris director of applied research, describes how “the industry has used reconstituted tobacco products to assist in controlling the nicotine delivery in cigarettes.”⁷⁹¹ According to Farone:

By controlling the ingredients that go into making reconstituted tobacco, the industry controls the chemical and physical properties of the finished sheet, *including its nicotine content*. . . . The reconstituted tobacco blend destined for a low tar cigarette can be made with a higher concentration of [high-nicotine] burley tobacco scraps than the blend of reconstituted tobacco designated for a full flavor brand.⁷⁹²

Farone also describes how cigarette manufacturers monitor nicotine levels in reconstituted tobacco, stating that “[q]uality control checks involving the use of a gas or liquid chromatography to ascertain the exact nicotine amounts are routinely employed during the process.”⁷⁹³ In its comments, Philip Morris confirms that it regularly measures nicotine levels in reconstituted tobacco. According to Philip Morris’ comments:

Representative periodic sampling is done with respect to all tobacco materials that go into the cigarette manufacturing process—natural leaf tobacco, expanded tobacco, as well as blended and reconstituted leaf. *Such periodic sampling includes measurements of . . . alkaloids or nicotine.*⁷⁹⁴

⁷⁹¹ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 12. See AR (Vol. 638 Ref. 2).

⁷⁹² *Id.*

⁷⁹³ *Id.*

⁷⁹⁴ Philip Morris Inc., Comment (Apr. 19, 1996), at 56 (emphasis added). See AR (Vol. 700 Ref. 226).

The Agency also received a declaration relating to reconstituted tobacco from Jerome Rivers, a former supervisor in Philip Morris’ Blended Leaf Plant, Declaration of Rivers J (Mar. 7, 1996). See AR (Vol. 640 Ref. 3), as well as two affidavits from current Philip Morris employees denying some of Rivers’ assertions (Philip Morris Inc., Comment (Apr. 19, 1996), Appendix 3. See AR (Vol. 700 Ref. 226)), and supplemental comments relating to Rivers’ declaration submitted by Philip Morris after the close of the comment period. Philip Morris Inc., Supplemental Comments (May 30, 1996). See AR (Vol. 700 Ref. 1331). After considering Rivers’ declaration, the two affidavits, and Philip Morris’ original and supplemental comments, the Agency has determined that it will not rely on the Rivers declaration or the two affidavits.

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There is also evidence that reconstituted tobacco is used by cigarette manufacturers as a vehicle for the addition of ammonia compounds. An article in the *Wall Street Journal* reports that Philip Morris, Brown & Williamson, and R.J. Reynolds add ammonia to their reconstituted tobacco.⁷⁹⁵ According to the article, internal Brown & Williamson documents describe the “nicotine pick-up potential” of ammonia in reconstituted tobacco. The tobacco company documents described in the article state that ammonia added to reconstituted tobacco can scavenge nicotine from the tobacco in the rest of the cigarette, significantly increasing the level of “free nicotine” in the cigarette. One of the documents, a Brown & Williamson competitive analysis of Marlboro, states that ammonia-treated reconstituted tobacco is “the soul of Marlboro.”⁷⁹⁶

As a result of the industry’s focus on nicotine in the areas described above, as well as in other areas described in the Jurisdictional Analysis, cigarette manufacturers provide smokers seeking the pharmacological effects of nicotine with a remarkably consistent dose of nicotine from cigarette to cigarette.

f. Satisfying Consumer Preferences Requires Controlling and Manipulating Nicotine Deliveries to Satisfy Addiction and Provide Other Pharmacological Effects

The cigarette industry maintains that it does not control and manipulate nicotine deliveries because its sole objective is to design cigarettes that meet consumer preferences.

Brown & Williamson, for example, asserts that:

[I]ts intent is to design, manufacture and market its cigarettes to meet the preferences of adult smokers over competing brands, not to create and maintain addiction. . . . Consumer demand determines

⁷⁹⁵ Freedman AM, Tobacco firm shows how ammonia spurs delivery of nicotine, *Wall Street Journal* (Oct. 18, 1995). See AR (Vol. 639 Ref. 2).

⁷⁹⁶ *Id.*

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the content of the tobacco blends used in marketed B&W cigarettes.⁷⁹⁷

Similarly, RJR asserts that it “designs, manufactures, and markets a broad range of cigarette products in response to the . . . demands of adult smokers” and “not . . . to provide smokers with pharmacologically active ‘doses’ of nicotine.”⁷⁹⁸

The Agency agrees that cigarette manufacturers, like other manufacturers of consumer products, design their products to meet consumer demand. The Agency disagrees, however, that this establishes that cigarette manufacturers do not control and manipulate nicotine levels for pharmacological purposes. The unstated premise of the manufacturers’ argument is that the consumer demands they seek to satisfy do *not* include a desire for the pharmacological effects of nicotine. This is simply not credible. To the contrary, the Agency finds that what the cigarette manufacturers describe as satisfying consumer preferences is, in reality, providing consumers with cigarettes that sustain consumers’ addiction and offer other desired pharmacological effects of nicotine.

It is beyond reasonable dispute that consumers of cigarettes smoke for the pharmacological effects of nicotine, including satisfaction of their addiction. As discussed in sections II.A. and II.B., above, this fact is widely accepted in the scientific community. As discussed in section II.C.2. and 3., above, this fact is also accepted by the cigarette manufacturers’ own scientists. The implication of this fact for cigarette design is clear: to compete in the marketplace, cigarette manufacturers must produce cigarettes that sustain

⁷⁹⁷ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 3, 12 (emphasis added). *See* AR (Vol. 529 Ref. 104).

⁷⁹⁸ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 3-4. *See* AR (Vol. 519 Ref. 103).

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smokers' addiction and provide the other pharmacological effects of nicotine sought by smokers. Any cigarette manufacturer that failed to provide these pharmacological effects would soon find itself out of business, because addicted smokers and other smokers seeking the pharmacological effects of nicotine would switch to other brands.

Brown & Williamson provides an example of how meeting consumer preferences compels cigarette manufacturers to control and manipulate nicotine. As noted above, Brown & Williamson's comments assert that Brown & Williamson designs its cigarettes to meet "consumer demands." As discussed above in section II.C.2.c., however, the documents in the record from Brown & Williamson and its parent, BATCO, also acknowledge that "*a considerable proportion of smokers depend on the pharmacological action of nicotine for their motivation to continue smoking*"⁷⁹⁹ and that "*nicotine plays a predominant role for many smokers.*"⁸⁰⁰ Indeed, as recently as 1992, company researchers stated that what "*the smoker clearly wants*" is "*[t]he rapid, peaking intake of nicotine.*"⁸⁰¹ Both Brown & Williamson's assertion that it designs cigarettes to meet "consumer demands" and its acknowledgment that smokers seek "the pharmacological action of nicotine" leads to an obvious conclusion: Brown & Williamson's efforts to meet consumer preferences necessarily require the company to design cigarettes that provide consumers with the pharmacological effects of nicotine.

⁷⁹⁹ Kilburn KD, Underwood JG (BATCO), *Preparation and Properties of Nicotine Analogues* (Nov. 9, 1972), at 2 (emphasis added). See AR (Vol. 31 Ref. 524-1).

⁸⁰⁰ Green SJ (BATCO), *BAT Group Research* (Sep. 4, 1968), at 2 (emphasis added). See AR (Vol. 15 Ref. 192).

⁸⁰¹ *Transdermal Nicotine*, Research and Development/Quality, at 3 (emphasis added). See AR (Vol. 531 Ref. 125).

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Documents in the administrative record confirm that in designing cigarettes to meet “consumer demands,” the cigarette manufacturers carefully take into account consumers’ pharmacological need for nicotine. One example is Project Wheat. As discussed above in section II.C.3.c.ii., BATCO conducted Project Wheat in the mid-1970’s to determine smokers’ “Inner Need” for nicotine.⁸⁰² BATCO undertook this research for the express purpose of improving its ability to meet consumer demands. As the BATCO researchers stated, Project Wheat was “*seen as a part of a general approach to the problem of designing cigarettes of increased consumer acceptance*” because “[i]n considering which product features are important in terms of consumer acceptance, the nicotine delivery is one of the more obvious candidates.”⁸⁰³

Project Wheat found that no cigarettes then on the market provided the “low tar and medium nicotine deliveries” sought by smokers who had an average “Inner Need” for nicotine, but “an above average concern for health.”⁸⁰⁴ According to a “model of the market” developed in Project Wheat, over 40% of smokers wanted cigarettes with a higher ratio of nicotine to tar than was then available.⁸⁰⁵ Shortly thereafter, ultra-low-tar cigarettes made with nicotine-rich tobacco blends were introduced into the market, including a Brown & Williamson cigarette called Barclay. See section II.C.4.a.ii., above.

⁸⁰² Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and Their General Smoking Habits* (Jul. 10, 1975), at 1. See AR (Vol. 20 Ref. 204-1).

⁸⁰³ *Id.* at 1, 3 (emphasis added).

⁸⁰⁴ Wood DJ (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 2. See AR (Vol. 20 Ref. 204-2).

⁸⁰⁵ BATCO Group R&D Conference on Smoking Behaviour at Southampton, England (Oct. 11-12, 1976), at BW-W2-02308. See AR (Vol. 178 Ref. 2074).

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The process of “consumer preference testing,” which is described in the comments of the cigarette manufacturers, is one of the ways the manufacturers refine nicotine deliveries. In its comments, Brown & Williamson explains that it asks consumers to rate prototype cigarettes to determine if its tobacco blends produce “satisfaction,” “strength,” and other desirable attributes to consumers. According to Brown & Williamson, “satisfaction,” as used in consumer preference testing, “reflects the consumer’s total reaction to the total smoking experience delivered by the cigarettes.”⁸⁰⁶ If consumer testing shows that a Brown & Williamson cigarette produces insufficient satisfaction, Brown & Williamson says its product developers will “adjust product recipes and designs to improve or maintain product preference.”⁸⁰⁷

In reality, however, Brown & Williamson knows that nicotine’s pharmacological effects play the primary role in consumer “satisfaction.” For instance, in 1983, BATCO researchers reported their “basic assumption” that “*nicotine, . . . is almost certainly the key smoke component for satisfaction.*”⁸⁰⁸ Likewise, in a 1984 conference, the BATCO researchers reported that “‘*satisfaction*’ must be related to nicotine. Many people believe it [is] a ‘whole body response’ and *involves the action of nicotine in the brain.*”⁸⁰⁹ Thus, Brown & Williamson understands that reports of inadequate satisfaction in consumer preference testing can signal a need to enhance nicotine deliveries.

⁸⁰⁶ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 8. See AR (Vol. 529 Ref. 104).

⁸⁰⁷ *Id.* at 9.

⁸⁰⁸ Minutes of BATCO Research Conference at Rio de Janeiro (Aug. 22-26, 1983), at 10 (emphasis added). See AR (Vol. 22 Ref. 287-5).

⁸⁰⁹ BATCO, *Conference Outline* (Jun. 6-8, 1984), at BW-W2-01977 (citation omitted) (emphasis added). See AR (Vol. 22 Ref. 287-6).

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The statements of William Farone, the former Philip Morris director of applied research, and Ian Uydess, the former Philip Morris scientist, make precisely this point. They confirm that product developers for the cigarette manufacturers do in fact adjust nicotine levels during consumer testing. According to Farone:

*This concept of nicotine delivery being essential to consumer satisfaction was common knowledge within Philip Morris and the rest of the industry. When consumer testing indicated that a product was lacking in "impact" or some similar descriptor that could be associated with nicotine, experienced market researchers and product developers would compensate by increasing nicotine levels*⁸¹⁰

Similarly, Ian Uydess states:

In the case of nicotine, specific levels of nicotine would be targeted in the test products (test 'articles') in a range that extended from 'ultra-low' (or even zero) nicotine deliveries, to deliveries equal to, or slightly above that found in some of their own (or a competitor's) 'full-flavor' or 'full-bodied' products. This was done to examine how the smoker would react to various nicotine levels as a predictor of how well these products might do in the market with specific regard to: "not enough nicotine", "an acceptable level of nicotine", or "too much nicotine."⁸¹¹

Thus, the Agency concludes that the manufacturers' explanation for their actions does not withstand scrutiny. Overwhelming evidence establishes that smokers seek the pharmacological effects of nicotine from cigarettes. See section II.A. and II.B., above. Overwhelming evidence also establishes that the manufacturers know that. See section II.C.2., above. Manufacturers that design their products to meet consumer demands that

⁸¹⁰ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 8 (emphasis added). See AR (Vol. 638 Ref. 2).

⁸¹¹ Declaration of Uydess IL (Feb. 29, 1996), at 11. See AR (Vol. 638 Ref. 1).

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they know are pharmacological in nature are necessarily engaged in designing products to provide pharmacological effects.

In sum, the evidence discussed in this section discloses that the manufacturers use several methods to control and manipulate nicotine deliveries in commercial cigarettes. These design features include: (1) the use of various tobacco blends with varying nicotine levels; (2) filter ventilation and related technologies that selectively remove more tar than nicotine and allow smokers to obtain more nicotine than the measured FTC yields; and (3) the use of ammonia technologies that increase the delivery of “free” nicotine. In addition, the evidence shows that the manufacturers control nicotine levels in virtually all aspects of cigarette manufacture, thereby ensuring that smokers receive a consistent nicotine delivery in each cigarette. Combined with the evidence regarding product research and development in section II.C.3., this evidence shows that the manufacturers “design” cigarettes to provide a consistent, pharmacologically active dose of nicotine to smokers, thereby establishing that cigarettes are “intended” to affect the structure and function of the body.

5. Conclusion

The Agency’s role in determining intended use through the statements, research, and actions of the manufacturer is to be a fact finder. In this case, after careful consideration of the evidence and the comments, the Agency finds that the evidence of cigarette manufacturers’ statements, research, and actions demonstrates that cigarettes are intended to cause significant pharmacological effects in smokers. The Agency makes this finding for three principal reasons.

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First, as described in section II.C.2., above, the evidence shows that the cigarette manufacturers are aware of and have exhaustively studied the pharmacological effects and uses of nicotine. In the case of Philip Morris, RJR, and Brown & Williamson, the manufacturers conducted extensive in-house research on the pharmacological effects and uses of nicotine. Their researchers and officials repeatedly expressed the view that nicotine causes pharmacological effects, that consumers smoke cigarettes to obtain these effects, and that cigarettes are delivery devices for nicotine. The evidence further shows that the cigarette manufacturers as a group funded extensive research into nicotine pharmacology through the Council for Tobacco Research. This evidence establishes that the manufacturers “have in mind” that cigarettes will be used for the particular purpose of delivering the pharmacological effects of nicotine to smokers.

Second, the evidence in sections II.C.3. and II.C.4. shows that the cigarette manufacturers “design” cigarettes to have pharmacological effects. This evidence reveals that the manufacturers have conducted extensive product research and development to identify pharmacologically active doses of nicotine and to optimize the delivery of nicotine to smokers and that company researchers repeatedly recommended the development of cigarettes that maintain adequate nicotine deliveries.

This evidence also shows that the cigarette manufacturers carefully control and manipulate the nicotine delivery of their commercially marketed cigarettes to provide smokers with a pharmacologically active dose of nicotine. Among other practices, the manufacturers use high-nicotine blends that increase nicotine deliveries in their lowest-tar products; rely on filtration and ventilation technologies that selectively remove more tar than nicotine; add ammonia compounds that increase the delivery of “free” nicotine; and

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carefully control the nicotine level in all cigarettes. Through the use of these practices, the cigarette manufacturers are able to deliver sufficient nicotine to satisfy consumers. An inevitable consequence of these practices is to keep consumers smoking by sustaining their addiction.

Third, the manufacturers have been unable to provide a convincing explanation that refutes either the evidence showing that they have in mind the pharmacological effects and uses of cigarettes or the evidence showing that they have designed cigarettes to provide these effects. This failure is significant because the manufacturers alone have access to the company documents and other information that would provide a complete explanation of their knowledge and design practices. The absence of a credible counter-explanation by the persons best situated to explain the evidence before the Agency adds additional support for the Agency's findings.

Under the legal standards described in section II.C.1., above, the evidence that the manufacturers (1) "have in mind" that cigarettes will be used for pharmacological purposes and (2) "design" cigarettes to deliver a pharmacologically active dose of nicotine each provides an independent basis for establishing intended use. Taken together, the two categories of evidence are consistent with each other and mutually reinforcing. Taken as a whole, therefore, the evidence from the statements, research, and actions of the manufacturers amply supports the finding that the effects of cigarettes on the structure and function of the body are "intended" by the cigarette manufacturers.

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6. Response to Comments**a. Comments on Statements and Research on Nicotine's Drug Effects****i. Comments on Specific Philip Morris Statements and Research Projects.** In

July 1995, a large number of Philip Morris internal documents reflecting over a decade of its research on smoking motivation were published in the *Congressional Record*. A smaller number of documents from Philip Morris became available as a result of a lawsuit brought against Philip Morris by a smoker.⁸¹² In its Jurisdictional Analysis, FDA reproduced statements from those documents as evidence that company officials believed that consumers use cigarettes to obtain the pharmacological effects of nicotine.

A comment submitted by Philip Morris argues that the documents do not provide such evidence because FDA allegedly mischaracterized or took out of context some of the quotes from the documents. Philip Morris argues that: (1) other statements in the documents show that Philip Morris researchers were actually uncertain why people smoke; (2) in addition to studies on the pharmacological motivations for smoking, Philip Morris conducted studies on other motives for smoking, demonstrating that Philip Morris did not believe that pharmacological motives for smoking were primary; (3) FDA omitted passages from the documents that would have cast them in a different light; and (4) some of the statements cited by FDA were actually only hypotheses of Philip Morris researchers, or the hypotheses of outside researchers, which were not ultimately supported by the results of their studies.

⁸¹² *Cipollone v. Liggett Group Inc.*, No. 83-2864 (D.N.J. dismissed Nov. 3, 1992).

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FDA has reviewed all of the publicly available documents written by Philip Morris officials. The Agency has concluded that, both individually and as a whole, they demonstrate that Philip Morris conducted extensive, sophisticated research on the pharmacological effects of nicotine in cigarettes and the pharmacological motives for smoking, and that officials responsible for research and development at all levels of the company expressed consistent beliefs throughout the period covered by the documents that the pharmacological effects of nicotine were the primary reason people smoke. The documents also demonstrate that these beliefs, and the data supporting them, were held by and communicated to company executives, including the board of directors. Below, FDA addresses each of Philip Morris' arguments, with examples from individual documents claimed by Philip Morris to have been mischaracterized. In every case, the documents speak for themselves.

1. Philip Morris argues that it conducted studies on other motives for smoking, demonstrating that Philip Morris did not believe that pharmacological motives for smoking were primary. Philip Morris cites a single document from 1970 for this premise.

FDA has reviewed the studies on smoking motivation referred to in the publicly available Philip Morris documents. The relative importance Philip Morris placed on pharmacological motives for smoking compared to other motives is clear from these studies. The vast majority of the company's studies were conducted to assess the pharmacological effects of, and motives for, smoking. A small minority of the studies were intended to assess other reasons for smoking. Indeed, the research documents show that Philip Morris' focus on the pharmacological effects of nicotine increased over time.

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By the early 1980's, when the large collection of documents made public by Congress end, Philip Morris' research on smoking motivation was overwhelmingly dominated by research on the pharmacological effects of nicotine. A 1980 report, for instance, describes fifteen major studies—eleven of which examined various aspects of nicotine's pharmacological effects on smokers and on dose-regulating behavior by smokers.⁸¹³ The nicotine-related studies included:

- (1) Studies on the effects of cigarettes and nicotine on electrical and chemical activity in the human brain. The objectives of this program are described as follows:

It is our belief that the reinforcing properties of cigarette smoking are directly relatable to the effects that smoking has on electrical and chemical events within the central nervous system. Therefore, the goals of the electrophysiology program are to: (I) Determine how cigarette smoking affects the electrical activity of the brain, and (II) Identify, as far as possible, the neural elements which mediate cigarette smoking's reinforcing actions.⁸¹⁴

- (2) Studies on rats demonstrating that nicotine is “reinforcing” (causes animals to “self-administ[er]” nicotine, i.e., seek repeated doses), tests positive in drug discrimination tests which can predict whether a substance has mood-altering effects in humans, and acts centrally in the brain. The objectives of this program include “(I) To develop a better understanding of the behavioral pharmacological actions of nicotine, particularly the action which reinforces smoking behavior.”⁸¹⁵

⁸¹³ Dunn WL (Philip Morris Inc.), *Plans and Objectives—1981* (Nov. 26, 1980), in 141 Cong. Rec. H7681–7683 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸¹⁴ *Id.* at H7681.

⁸¹⁵ *Id.* at H7682.

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- (3) Studies on the level of nicotine in saliva over time, and on the correlation of salivary nicotine levels to blood nicotine levels, to answer the question, "Does a low systemic level of nicotine trigger the smoking response?"⁸¹⁶

Philip Morris provides no additional or later documents that would suggest that these studies are not representative. Thus, the extensive and sustained investigation into nicotine pharmacology reflected in Philip Morris' documents demonstrates that its researchers believed that the pharmacological effects of nicotine were the primary reason for smoking. Moreover, as detailed in section II.C.2.a.iii., above, a 1992 Philip Morris document shows that the views expressed by Philip Morris officials in the 1970's and 1980's are still held by Philip Morris employees.⁸¹⁷

Moreover, even if Philip Morris had significantly researched other motives for smoking, this could not render Philip Morris' research into the pharmacological motives for smoking irrelevant. Neither FDA nor the courts have suggested that a product with pharmacological uses must not have any other uses if it is to be regulated as a drug or device. When it has been established that a manufacturer intends that its product be used for a pharmacological purpose, FDA's jurisdiction is not defeated by a showing that the

⁸¹⁶ *Id.* at H7682.

See also Dunn WL (Philip Morris Inc.), *Plans and Objectives—1979* (Dec. 6, 1978) ("All of the effort of the Behavioral Research Laboratory is aimed at achieving this objective: To understand the psychological reward the smoker gets from smoking, to understand the psychophysiology underlying this reward, and to relate this reward to the constituents in smoke"), in 141 Cong. Rec. H7668–7670 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

Dunn WL (Philip Morris Inc.), *Plans and Objectives—1980* (Jan. 7, 1980), in 141 Cong. Rec. H7670–7672 (daily ed. Jul. 25, 1995). *See* AR (Vol. 14 Ref. 175a).

⁸¹⁷ Philip Morris Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table*. *See* AR (Vol. 531 Ref. 122).

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manufacturer also intends the product to be used for other, nonpharmacological purposes. *See, e.g., United States v. Guardian Chemical Corp.*, 410 F.2d 157, 162-163 (2d Cir. 1969) (solvent intended both to dissolve kidney stones and to clean medical instruments was properly regulated as a “drug”). Thus, if there is evidence that nicotine-containing tobacco products are intended to produce significant drug effects in consumers, the fact that manufacturers may also intend them to provide “flavor” or other nonpharmacological effects would not defeat a finding that such products are “drugs” within the meaning of the Act.

2. Philip Morris also contends that in reproducing certain quotes from Philip Morris documents, FDA omitted portions of the documents that would have shown that the author did not believe that people smoke to obtain the pharmacological effects of nicotine. Philip Morris cites four examples. FDA has reviewed each of the documents in question and has concluded that each of the statements quoted in the Jurisdictional Analysis has been fairly presented and has not been taken out of context.

First, FDA reproduced in the Jurisdictional Analysis a number of quotes from memoranda, presentations, and letters by William Dunn, a senior scientist at Philip Morris, who was responsible for a large number of research projects on smoking motivation. The quotes demonstrated that Dunn believed people smoke to obtain the pharmacological effects of nicotine. *See* 60 FR 41591, 41596–41599, 41682, 41756, 41761. Philip Morris claims that several quotes were taken out of context, and that the full context demonstrates that Dunn did not believe the pharmacological effects of nicotine are the primary reason people smoke, and in fact did not know why people smoke. Philip Morris

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also contends that the quotes attributed to Dunn were in fact the views of other scientists that Dunn was simply describing.

The collected writings of William Dunn could not be clearer. As is fully demonstrated in the Jurisdictional Analysis, he made repeated statements throughout his career reflecting a consistent belief that people smoke primarily to obtain the psychopharmacological effects of nicotine. As recently as 1994, when Dunn was visited by FDA investigators, he told them that people smoke for the nicotine.⁸¹⁸ At a conference in 1972, Dunn explained his "conviction" that consumers smoke for the pharmacological effects of nicotine. This quote also refutes Philip Morris' claim that Dunn was merely describing the views of other scientists:

Let me explain *my conviction*.

The cigarette should be conceived not as a product but as a package. The product is nicotine. The cigarette is but one of many package layers The smoker must strip off all these package layers to get to that which he seeks Think of the cigarette pack as a storage container for a day's supply of nicotine Think of the cigarette as a dispenser for a dose unit of nicotine Think of a puff of smoke as the vehicle of nicotine:

- 1) A convenient 35 cc mouthful contains approximately the right amount of nicotine
- 2) The smoker has wide latitude in further calibration: puff volume, puff interval, depth and duration of inhalation . . .
- 3) Highly absorbable: 97% nicotine retention
- 4) Rapid transfer: nicotine delivered to blood stream in 1 to 3 minutes

Smoke is beyond question the most optimized vehicle of nicotine.⁸¹⁹

⁸¹⁸ See notes summarizing May 10, 1994 meeting between FDA and Dunn WL. See AR (Vol. 21 Ref. 231).

⁸¹⁹ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5-6 (emphasis added). See AR (Vol. 12 Ref. 133).

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Dunn further explained how he and other Philip Morris officials could both express uncertainty about “why people smoke” and believe that they smoke for the pharmacological effects of nicotine: “If we accept the premise that nicotine is what the smoker seeks, we’ve still not answered the question ‘Why do people smoke’? We’ve merely reformulated it to read ‘Why does the smoker take nicotine into his system?’”⁸²⁰

Thus, it was Dunn’s “conviction” that people smoke to obtain a systemic dose of nicotine. What remained to be determined was precisely why the pharmacological effects of nicotine were reinforcing to smokers and what biochemical mechanisms were triggered by nicotine in the central nervous system. In fact, the records of Philip Morris research between the 1960’s and the 1980’s demonstrate that Philip Morris spent those decades conducting exhaustive research to determine the physiological and psychoactive effects of nicotine inhalation that cause smokers to repeatedly seek nicotine, and to ascertain the “dose-regulating” mechanisms through which smokers obtain an adequate amount of nicotine to achieve those effects.⁸²¹ See Jurisdictional Analysis, 60 FR 41599.

Accordingly, FDA concludes that it has appropriately represented the words of William Dunn.

The second document is a 1969 speech to the board of directors of Philip Morris by Helmut Wakeham, vice president for research and development. The speech begins with the statement that scientists cannot yet give a definitive explanation of why people smoke “backed up by fact.” The speech nevertheless attempts to answer the question by

⁸²⁰ *Id.* at 6-7.

⁸²¹ See documents printed in 141 Cong. Rec. H7646-7683 (daily ed. Jul. 25, 1995), and 141 Cong. Rec. H8127-8135 (daily ed. Aug. 1, 1995). See AR (Vol. 14 Ref. 175a and Vol. 711 Ref. 6).

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marshaling three types of available evidence: what smokers say about why they smoke, what differences in personality characterize smokers and nonsmokers, and what the “immediate effects of smoke inhalation upon . . . human body function” are.⁸²² In the latter category, the speech provides a long list of nicotine’s effects on human body function, including “arousal center in brain stem excited.”⁸²³ Following this discussion of the evidence, the speech concludes with the quote cited by FDA in the Jurisdictional Analysis: “We are of the conviction, in view of the foregoing, that the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker, the effect being most rewarding to the individual under stress.”⁸²⁴

This document speaks for itself. It is beyond question that the quoted statement reflects the “conviction” of the author of the speech that people continue to smoke to obtain the pharmacological effects of nicotine, and that this conviction existed as a result of the available data.

The third document cited by Philip Morris provides equally weak support for the claim that Philip Morris researchers were uncertain whether people smoke to obtain nicotine. From an internal Philip Morris document entitled “Why People Start to Smoke,” FDA printed a quote from the end of the document describing the results of a “special

⁸²² Wakeham H (Philip Morris Inc.), *Smoker Psychology Research* (Nov. 26, 1969), at 9. See AR (Vol. 11 Ref. 142).

⁸²³ *Id.* at 10.

⁸²⁴ *Id.* at 11.

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study done for Philip Morris” on “the motivation that leads to a *continuation* of smoking”.⁸²⁵

[T]he circumstances in which smoking occurs may be generalized as follows:

1. As a narcotic, tranquilizer, or sedative. Smokers regularly cigarettes at times of stress.
2. At the beginning or ending of a basic activity. . . .
3. Automatic smoking behavior.⁸²⁶

Philip Morris points to a statement, from the portion of the document on why people *start* smoking, that “[t]here are surprisingly few hard facts on the question of the *initiation* of smoking,”⁸²⁷ claiming that this somehow shows that the author is unsure of why people *continue* to smoke. As the document itself demonstrates, the author describes no uncertainty on the question of why people continue to smoke.

The fourth document cited by Philip Morris is the first of several Philip Morris reports on research conducted by the company to test its hypothesis that smoking is used in times of stress as an “anxiety reducer.”⁸²⁸ The proposed study involved administering shocks to college students and determining whether stress caused the students to smoke more. According to Philip Morris, the research proposal expresses uncertainty about whether smoking mitigates stress, and therefore cannot support FDA’s conclusion that Philip Morris officials believed that nicotine’s pharmacological effects motivate smoking behavior.

⁸²⁵ Udow A (Philip Morris Inc.), *Why People Start to Smoke* (Jun. 2, 1976), in 141 Cong. Rec. H7663-H7664 (daily ed. Jul. 25, 1995) (emphasis added). See AR (Vol. 14 Ref. 175a).

⁸²⁶ *Id.* at H7664.

⁸²⁷ *Id.* at H7663 (emphasis added).

⁸²⁸ Ryan FJ (Philip Morris Inc.), *Proposed Research Project: Smoking and Anxiety* (Dec. 23, 1969), in 141 Cong. Rec. H7648 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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FDA disagrees that this document can be used to demonstrate that Philip Morris is uncertain about the relationship of smoking and stress. Because the document in question merely proposes the research to test the hypothesis that smoking reduces anxiety, it does not attempt to answer the question posed. What Philip Morris fails to point out is that this research, once begun, showed a “very high” correlation between personality factors, “particularly the Anxiety factor,” and puff rate and that the researchers were “very much encouraged by the trend of these findings.”⁸²⁹ In fact, this study design appears to have been abandoned in favor of other designs only because “fear of shock is scaring away some of our more valuable subjects.”⁸³⁰ Subsequent research reports show that Philip Morris researchers continued to obtain results showing a correlation between anxiety and both puffing and nicotine intake,⁸³¹ and subsequent statements by Philip Morris researchers continue to show that they believed that one of the primary motives for smoking is to relieve stress.⁸³²

⁸²⁹ Dunn WL (Philip Morris Inc.), *Consumer Psychology* (Sep.16-Oct. 15,1971) (discussing projects entitled, “Shock I, II, III, IV”), in 141 Cong. Rec. H7648-7649 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸³⁰ Dunn WL (Philip Morris Inc.), *Quarterly Report-Projects 1600 and 2302* (Oct. 5, 1972) in 141 Cong. Rec. H7649 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸³¹ Dunn WL (Philip Morris Inc.), *1600 Objectives for 1973* (Nov. 14, 1972) (subjects show differential heart rate when threatened with shock on days when they are allowed to smoke compared to days when they are not), in 141 Cong. Rec. H8130 (daily ed. Aug. 1, 1995) See AR (Vol. 711 Ref. 6).

Philip Morris Research Center, *Behavioral Research Annual Report* (Jul. 18, 1975), in 141 Cong. Rec. H7652, H7654 (daily ed. Jul. 25, 1995). See AR (Vol. 21 Ref. 240a-2).

⁸³² Udow A (Philip Morris Inc.), *Why People Start to Smoke* (Jun. 2, 1976) (“the circumstances in which smoking occurs may be generalized as follows: 1. As a narcotic, tranquilizer, or sedative. Smokers regularly use cigarettes at times of stress. . . .”), in 141 Cong. Rec. H7664 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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Not only do the documents discussed immediately above contradict Philip Morris' assertion that its employees do not know why people smoke, but the available Philip Morris documents contain overwhelming support for the finding that Philip Morris officials believe that the major reason people smoke is to obtain the pharmacological effects of nicotine. Expressions of this belief are repeated frequently and consistently over the period of years reflected in these documents. *See, e.g.*, Jurisdictional Analysis, 60 FR 41595–41599, 41608, 41613–41615, 41650–41652.

3. Philip Morris contends that in reproducing William Dunn's statement of his "conviction" that cigarettes are the "most optimized vehicle" for delivering nicotine, *see* comment 2, above, FDA omitted a subsequent paragraph in which the scientist attempted to defuse concern about his "drug-like conceptualization of the cigarette":

Lest anyone be made unduly apprehensive about this drug-like conceptualization of the cigarette, let me hasten to point out that there are many other vehicles of sought-after agents which dispense in dose units: wine is the vehicle and dispenser of alcohol, tea and coffee are the vehicles and dispensers of caffeine, matches dispense dose units of heat, and money is the storage container, vehicle and dose-dispenser of many things.⁸³³

Philip Morris claims that this paragraph demonstrates that the earlier part of the quote cannot be used as evidence that Philip Morris intends cigarettes as nicotine delivery systems.

FDA disagrees. The paragraph quoted by Philip Morris illustrates that tobacco company officials were aware of the potential consequences of admitting that cigarettes are "drug-like." Moreover, the paragraph does not in any way undercut the fundamental

⁸³³ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 6. *See* AR (Vol. 12 Ref. 133).

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point made by Dunn: that cigarettes are *nicotine* delivery systems. The fact that other items can also be conceptualized as delivery systems for various things cannot alter what it was that Dunn believed was the essential ingredient delivered by cigarettes: *doses of nicotine*. He did not conceptualize cigarettes as delivery systems for flavor, or taste, or something to occupy one's hands. Rather, he conceptualized cigarettes as delivery systems for "a dose unit of nicotine," which is "delivered to [the] blood stream in 1 to 3 minutes."⁸³⁴

4. Philip Morris also contends that in reproducing certain quotes from Philip Morris documents, FDA omitted portions of the documents that were inconsistent with the quoted portion.

First, Philip Morris contends that FDA omitted a significant passage from a quote on a proposed Philip Morris study on smoking and hyperactivity. The full quote with the omitted passages follows:

Some children are so active (or "hyperkinetic") that they are unable to sit quietly in school and concentrate on what is being taught. In recent years it has been found that amphetamines, which are strong stimulants, have the anomalous effect of quieting these children down and enabling them to concentrate in the face of distractions which otherwise would have disrupted their attention. Many children are therefore regularly administered amphetamines throughout grade school years. The wisdom of such prescription is open to question and some published reports have suggested that caffeine, in the form of coffee or tea for breakfast would produce the same end result. We wonder whether such children may not eventually become cigarette smokers in their teenage years as they discover the advantage of self-stimulation via nicotine. We have already collaborated with a local school system in identifying some such children presently in the third grade; we are reviewing the available literature on the topic; and we may propose a prospective study of this relationship. It would be good to show that smoking is an advantage to at least one

⁸³⁴ *Id.* at 5-6.

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subgroup of the population. Needless to say, we will not propose giving cigarettes to children.⁸³⁵

The full quote demonstrates that Philip Morris researchers regarded nicotine as a stimulant and proposed to study whether hyperactive youths use cigarettes, not for flavor or taste, but to self-medicate an attentional disorder. It is completely consistent with FDA's finding that Philip Morris officials believe that nicotine in cigarettes has pharmacological effects and that consumers use cigarettes to obtain those effects.

Philip Morris claims that the researchers were equating nicotine and caffeine. It is clear from this and later references to this study that Philip Morris was interested in whether nicotine is used to self-medicate hyperactivity by smokers who as children were "known to have their hyperactive or impulsive behaviors reduced by drugs (e.g., Ritalin)."⁸³⁶ If the researchers equated nicotine and caffeine, they regarded both substances as stimulant drugs that could be used to treat hyperactivity through their pharmacological effects. It is unlikely that they did equate them, however, since the same researchers had 2 years earlier demonstrated that nicotine produces a much more pronounced stimulant effect than caffeine.⁸³⁷

Philip Morris also claims that this document proposed a study on hyperkinetic adults, rather than children. Nothing in the available documents supports this claim. The documents mention only a study of hyperkinetic "children," whom Philip Morris

⁸³⁵ Dunn WL (Philip Morris Inc.), *Smoker Psychology/May 1-31, 1974* (Jun. 10, 1974), in 141 Cong. Rec. H7651 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸³⁶ Dunn WL (Philip Morris Inc.), *Smoker Psychology/April 1-30, 1977* (May 13, 1977), in 141 Cong. Rec. H7657 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸³⁷ Memorandum from Schori TR to Dunn WL, *Smoking and Caffeine: A Comparison of Physiological Arousal Effects* (May 17, 1992), at 1-2. See AR (Vol. 15 Ref. 189-7).

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researchers propose to identify and follow to establish whether they become smokers in their “teenage years.”

Second, Philip Morris contends that the context of a statement made by Helmut Wakeham that “nicotine is believed essential to cigarette acceptability” refers to its role in taste and flavor.⁸³⁸ The full text of this document contradicts Philip Morris’ argument. As explained in the Jurisdictional Analysis, 60 FR 41595, earlier in Wakeham’s presentation, he described the pharmacological effects of nicotine on smokers:

- (a) Low nicotine doses stimulate, but high doses depress functions.
- (b) Continued usage develops tolerance. . . .

In contrast to those effects, it is also recognised that smoking produces pleasurable reactions or tranquility, and that this is due at least in part to nicotine, and not entirely to the physical manipulations involved in smoking.⁸³⁹

Three pages later, under the heading “Controlled Nicotine in Filler and Smoker,”

Wakeham says:

Even though nicotine is believed essential to cigarette acceptability, a reduction in level may be desirable for medical reasons.

Problems:

- 1. How much nicotine reduction will be acceptable to the smoker?
- 2. What taste difference will be tolerated?⁸⁴⁰

The document, on its face, demonstrates two things: (1) Wakeham believed that nicotine produced pharmacological effects in smokers; and (2) the problem of determining

⁸³⁸ Wakeham H (Philip Morris Inc.), *Tobacco and Health—R&D Approach* (Nov. 15, 1961), at 43. See AR (Vol. 125 Ref. 1314).

⁸³⁹ *Id.* at 40.

⁸⁴⁰ *Id.* at 43.

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the level of nicotine reduction that would be “acceptable to the smoker” is separate from the problem of determining what taste difference would be tolerated. Had Wakeham believed that nicotine is essential only for taste, only the second question would have been relevant. Instead, he recognized that a reduction in nicotine would not be acceptable to smokers for the additional reasons he had already spelled out: that nicotine produces mood-altering reactions that smokers seek. The plain language of the document thus fails to substantiate Philip Morris’ claim that Wakeham believed that nicotine is essential only for taste. As in many other tobacco company documents, nicotine’s role in taste, if it is mentioned at all, is seen as secondary to its pharmacological role. *See* Jurisdictional Analysis, 60 FR 41772–41778.

5. Philip Morris argues that some of the statements cited by FDA were only Philip Morris researchers’ “premises” and “working hypotheses” or even the hypotheses of outside researchers. According to Philip Morris, these statements are not “facts” or conclusions based on data and are therefore irrelevant to intended use.

FDA disagrees that these consistent statements of Philip Morris researchers that people smoke to obtain the pharmacological effects of nicotine are irrelevant to Philip Morris’ intent in manufacturing and marketing cigarettes. In establishing the intended use of Philip Morris’ tobacco products, the premises, hypotheses, and beliefs of the scientists whose job within the company is to understand the motives for smoking, and who regularly communicate those views to company executives, are highly relevant. Philip Morris and other tobacco companies contend that cigarettes are labeled for “pleasure,” not pharmacological effects, and that nicotine is present in cigarettes only for flavor. On this basis, the company argues that cigarettes are not intended as drugs or devices. Nowhere,

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however, in the publicly available Philip Morris documents, or in the documents produced by Philip Morris in this proceeding, do their scientists put forward a premise or hypothesis that people smoke primarily for nicotine's flavor and/or any other nonpharmacological motive—much less communicate such a view to company executives. The evidence in the administrative record demonstrates, instead, that during the entire period covered by those documents, Philip Morris scientists were communicating to their superiors their scientific opinion that nicotine's pharmacological effects are the primary motivator of smoking behavior.

6. Philip Morris also argues that its researchers' "hypotheses" were not ultimately supported by the results of their research.

FDA disagrees that the documents show that the major premises of Philip Morris scientists concerning the role of nicotine in tobacco use were disproven. These premises center on the scientists' often stated belief that cigarette smoking is reinforced by the pharmacological effects of nicotine on the brain. In fact, this premise continued to be repeated and even strengthened over the period of research reflected in the documents. For example, the major premise of a 1974 research report is that "the smoking habit is maintained by the reinforcing effects of the pharmacologically active components of smoke. A corollary to this premise is that the smoker will regulate his smoke intake so as to achieve his habitual quota of the pharmacological action."⁸⁴¹

Philip Morris attempts to use this research report in support of its claim that Philip Morris scientists failed to find support for their beliefs that people smoke to obtain the

⁸⁴¹ Philip Morris Research Center, *Behavioral Research Annual Report, Part II* (Nov. 1, 1974) (approved by Osdene TS), in 141 Cong. Rec. H7658, H7660 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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pharmacological effects of nicotine. According to Philip Morris, this report refuted the compensation theory.⁸⁴² Philip Morris' claim that its researchers refuted their major premises fails on two grounds. First, the document shows that Philip Morris researchers considered the compensation theory to be at most a "corollary" of their major premise that smoking is maintained by the reinforcing effects of nicotine. Philip Morris makes no attempt to show that the major premise was disproven. Nor could it. Philip Morris conducted one of the earliest definitive studies on nicotine's reinforcing effects in the early 1980's, well before similar research had been published by outside scientists. As William Dunn told T.S. Osdene, Philip Morris' director of research, the company's research made "it quite clear that nicotine can function as a positive reinforcer for rats."⁸⁴³ As described in section II.A.3.c.i., above, the ability of a substance to function as a "positive reinforcer" in animals is one of the most telling pieces of evidence that the substance will be addictive in humans.

Second, both the 1974 and subsequent research reports (through and including the last available report in 1980) show that Philip Morris continued to believe in, and test, the compensation theory, using ever more sophisticated and precise methods. Philip Morris relies on a statement from the 1974 report in which the researchers note that previous attempts to show compensation by analyzing the number and amount of cigarettes smoked had shown positive trends but not convincing evidence that the smoker regulates intake of

⁸⁴² "Compensation," as described in section II.A.7.i., above, describes the behavior of smokers who are given cigarettes with more or less nicotine than their usual brands. Data, including tobacco industry data, show that smokers "compensate" by altering their smoking behavior (e.g., by smoking more cigarettes or smoking each cigarette more intensely) to obtain their customary nicotine intake.

⁸⁴³ Dunn WL (Philip Morris Inc.), *Plans and Objectives—1981* (Nov. 26, 1980), in 141 Cong. Rec. H7681-7682 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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nicotine. Philip Morris omits subsequent statements demonstrating that the researchers have not “refuted” the compensation theory, but have merely decided to take a new approach to establishing compensation. Following the statement quoted by Philip Morris, the researchers state that they “question whether the indices of intake which have been investigated to date are, in fact, the appropriate indices to be measuring.”⁸⁴⁴ Instead, they believe that new evidence suggests that compensation may be accomplished through the inhalation patterns of smokers:

[O]bservations [concerning differences in how smoke is inhaled from smoker to smoker] have made us aware of a heretofore unnoticed mechanism that has the potential of affording the smoker a wide latitude of control over the amount of smoke he brings into contact with the absorption sites.⁸⁴⁵

The researchers go on to describe a new series of experiments designed “to systematically observe the inhalation patterns of smokers” and thereby determine whether compensation for nicotine is occurring.⁸⁴⁶ The researchers also developed, three years later, a new theoretical model to explain their inability up to that point to demonstrate compensation. Under this theory, some smoking is triggered by “deficits or surfeits of nicotine (or some unknown smoke components)” and some by external stimuli:

The adoption of this point of view by members of the staff will lead us to recognize that apparent failures of [the] nicotine compensation model may not in fact be failures at all and that *nicotine compensation is a real phenomenon which is masked by the fact that smokers smoke many cigarettes out of habit rather than need.*⁸⁴⁷

⁸⁴⁴ Philip Morris Research Center, *Behavioral Research Annual Report, Part II* (Nov. 1, 1994), in 141 Cong. Rec. H7658, 7660 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁸⁴⁵ *Id.*

⁸⁴⁶ *Id.*

⁸⁴⁷ Dunn WL (Philip Morris Inc.), *Behavioral Research Accomplishments—1977* (Dec. 19, 1977), in 141 Cong. Rec. H7666-7667 (daily ed. Jul. 25, 1995) (emphasis added). See AR (Vol. 14 Ref. 175a).

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The Philip Morris research reports demonstrate that Philip Morris continued to attempt to measure inhalation patterns throughout the period covered by the reports, and that the researchers continued to believe, and sometimes showed, that smokers compensate for nicotine.⁸⁴⁸

Finally, Philip Morris cites a small number of minor studies in the Philip Morris research documents in which the researchers did not find discernible effects due to smoking; it claims that these show that Philip Morris failed to find support for the belief that nicotine's pharmacological effects motivate smoking. The apparent failure of a small fraction of its studies to demonstrate particular pharmacological effects from nicotine cannot obscure what is evident from a fair reading of the publicly available research reports: the company's research on nicotine demonstrated that nicotine had many significant pharmacological effects on smokers. The record also shows that, through the period covered by the reports, Philip Morris' emphasis on the pharmacological motivations for smoking increased and its research on the pharmacological effects of nicotine grew in size and sophistication. By the end of that period, Philip Morris had successfully established that nicotine is a positive reinforcer in rats, that it produces psychoactive effects like other drugs of abuse, that it produces tolerance, and that it acts

⁸⁴⁸ See, e.g., Letter from Dunn WL to Schachter S (Sep. 8, 1975) (Philip Morris expects inhalation patterns "to be dose-regulating mechanisms of remarkable precision and sensitivity"), in 141 Cong. Rec. H7662 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

Dunn WL (Philip Morris Inc.), *Behavioral Research Accomplishments-1977* (Dec. 19, 1977) ("We have . . . [s]hown that we can distinguish between [nicotine] regulator and nonregulator smokers and that after being deprived, the regulators do indeed try to make up for lost intake"), in 141 Cong. Rec. H7666 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

Dunn WL (Philip Morris Inc.), *Plans and Objectives-1981* (Nov. 26, 1980), in 141 Cong. Rec. H7681, H7683 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

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centrally in the brain. These are the standard animal tests performed by pharmaceutical companies and public health organizations to establish that a substance is addictive. At this time, Philip Morris was also engaged in a broad-based study of the effects of smoking and nicotine on *human* brain wave patterns to “identify as far as possible the neural elements which mediate cigarette smoking’s reinforcing actions.”⁸⁴⁹ The record thus contradicts Philip Morris’ claim that its research failed to bear out the premise that people smoke to obtain nicotine.

7. Philip Morris argues that FDA has mischaracterized statements of Philip Morris officials in several company documents related to the addictive effects of nicotine and cigarettes. FDA has reviewed the statements and concluded that it has not mischaracterized the statements that it relied on.

First, in the Jurisdictional Analysis, 60 FR 41607–41608, FDA cited a Philip Morris study on a smoking cessation campaign in Greenfield, Iowa, in 1969 as evidence that Philip Morris researchers recognized that smoking cessation produces a withdrawal syndrome. Philip Morris claims that its study did not conclude that nicotine is “addictive” and that the study showed only that former smokers experienced “transient . . . common behavioral mannerisms such as eating more, tapping their fingers, twiddling their thumbs, biting their lips, chewing on matches, or feeling ill-tempered.”⁸⁵⁰ Philip Morris also argues that this study was published more than 20 years ago and therefore is not “new” evidence.

⁸⁴⁹ *Id.* at H7681.

⁸⁵⁰ Philip Morris Inc., Comment (Jan. 2, 1996), at 17. *See* AR (Vol. 519 Ref. 105).

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FDA believes that the Philip Morris study on the Iowa “cold turkey” campaign provides solid evidence that Philip Morris knows that abstinence from smoking produces a significant, long-term withdrawal syndrome. As discussed in section II.A.3., above, withdrawal is recognized as one of the characteristic features of drug dependence. Contrary to the comment’s claim that the study revealed only mild and “transient” symptoms, the study author, a Philip Morris researcher, summarizes the symptoms of those who quit smoking this way:

Even after *eight months* quitters were apt to report having neurotic symptoms, such as feeling depressed, being restless and tense, being ill-tempered, having loss of energy, being apt to doze off, etc. They were further troubled by constipation and weight gains which averaged about 5 lbs. per quitter.⁸⁵¹

The researcher later reports on the worsening of health symptoms among the quitters, observing that their “list of complaints is long and impressive.”⁸⁵² The author encapsulates the quitters’ experience as follows:

This is not the happy picture painted by the Cancer Society’s anti-smoking commercial which shows an exuberant couple leaping in the air and kicking their heels with joy because they’ve kicked the habit. A more appropriate commercial would show *a restless, nervous, constipated husband bickering viciously with his bitchy wife who is nagging him about his slothful behavior and growing waistline.*⁸⁵³

Accordingly, this study provides evidence that Philip Morris knows that smokers suffer significant, long-term withdrawal symptoms, a characteristic feature of addictive

⁸⁵¹ Ryan FJ (Philip Morris Inc.), *Bird-1: A Study of the Quit-Smoking Campaign in Greenfield, Iowa, in Conjunction with Movie, Cold Turkey* (Mar. 1971), at 1. (emphasis added). See AR (Vol. 390 Ref. 6394).

⁸⁵² *Id.* at 31.

⁸⁵³ *Id.* at 33 (emphasis added).

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substances. There is no support for Philip Morris' contention that the withdrawal symptoms reported in this study are not comparable to withdrawal symptoms from other drugs that produce physical dependence. The withdrawal symptoms reported by Philip Morris include many of the same changes in mood, behavior, and physical functioning identified as evidence of a withdrawal syndrome for all drugs that produce physical dependence. They are the same symptoms that have been recognized by the Surgeon General and other public health organizations as evidence that nicotine produces a withdrawal syndrome and physical dependence.⁸⁵⁴

Finally, Philip Morris' claim that this study was published 20 years ago is misleading. The material quoted in the Jurisdictional Analysis and here comes principally from an internal Philip Morris study report that was not published.⁸⁵⁵ Another version of the study was published, in which the quoted material was omitted.⁸⁵⁶

Philip Morris also argues that FDA "deliberately mischaracterize[d]" another Philip Morris document in which Philip Morris acknowledges both nicotine dependence and a withdrawal syndrome from cigarette deprivation. FDA notes that Philip Morris challenges only the use of the statement to show that Philip Morris acknowledges withdrawal; Philip Morris makes no claim that this statement does not acknowledge nicotine dependence.

⁸⁵⁴ Surgeon General's Report, 1988, at 198-221. See AR (Vol. 129 Ref. 1592).

American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 244. See AR (Vol. 5 Ref. 46-1).

⁸⁵⁵ Ryan FJ (Philip Morris Inc.), *Bird-1: A Study of the Quit-Smoking Campaign in Greenfield, Iowa, in Conjunction with Movie, Cold Turkey* (Mar. 1971). See AR (Vol. 21 Ref. 207).

⁸⁵⁶ Ryan FJ (Philip Morris Inc.), *Cold turkey in Greenfield, Iowa: a follow-up study*, in *Smoking Behavior: Motives and Incentives*, ed. Dunn WL (Washington DC: VH Winston & Sons, 1973). See AR (Vol. 8 Ref. 105).

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The document is a report from W. L. Dunn to T. S. Osdene, vice president for research and development, entitled, "Plans and Objectives-1980." In describing the company's "Experimental Psychology Program," the report states that the first objective of the program is to "gain better understanding of the role of nicotine in smoking." The report describes one of its approaches to this objective as follows:

Identification of two smoking population subgroups, one of which has greater nicotine needs than the other. We have described these people in the past as compensators and noncompensators, and attempted to define them by their consumption changes when nicotine deliveries were moderately shifted. However, we've had no great success in the identification to date. Now we may have two extra tools to use: Commercial PM cigarettes of ultra low tar and nicotine, and salivary nicotine concentrations. Others, principally at Columbia University, have suggested that shifts to ultra low nicotine cigarettes produce the same type of psychological stress behaviors as quitting. *We therefore propose a shift study in which smokers are shifted to an ultra low brand, and the key dependent variable becomes the presence or absence of the withdrawal syndrome. Those who show evidence of nicotine dependence and those who do not can then be used to test our hypotheses on the relationship of salivary concentration to smoking behavior.*⁸⁵⁷

Philip Morris claims that this statement contains no acknowledgment of a cigarette withdrawal syndrome, because the Philip Morris researchers: (1) found no support for their hypothesis that people compensate for changes in nicotine yield; (2) were merely testing hypotheses proposed by outside researchers; and (3) were referring to psychological stress behaviors, not physiological symptoms when they spoke of withdrawal.

The full text of this statement fails to support Philip Morris' strained construction. The obvious purpose of the statement is to explain that the researchers intended to try a

⁸⁵⁷ Dunn WL (Philip Morris Inc.), *Plans and Objectives-1980* (Jan. 7, 1980), in 141 Cong. Rec. H7670, H7672 (daily ed. Jul. 25, 1995) (emphasis added). See AR (Vol. 14 Ref. 175a).

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new approach to identifying “compensators” and “noncompensators,” relying on evidence of withdrawal/dependence. The researchers are clear that withdrawal is an established syndrome they will use to identify compensators and noncompensators, not the reverse. The only outside hypothesis mentioned in the statement is the notion that switching to ultra-low nicotine cigarettes can be used to induce the same stress behaviors as quitting. The more fundamental notion that quitting produces a withdrawal syndrome is not an outsider’s hypothesis but a clearly accepted premise of the entire approach. Nothing in the statement suggests that the researchers intend to test an “hypothesis” that quitting produces withdrawal; they intend to use this accepted fact to search for compensators and noncompensators. Finally, there is no evidence in the document to support Philip Morris’ assertion that the Philip Morris researchers were referring to psychological stress behaviors, not physiological symptoms.

Philip Morris also contends that FDA inappropriately characterized a Philip Morris memo, which FDA briefly cited in a footnote to the Jurisdictional Analysis, as indicating that people smoke to avoid “withdrawal.” According to Philip Morris, the memo merely placed cigarettes in the same category as alcohol, tea, coffee, chewing gum, overeating, and sex.

Philip Morris’ characterization focuses on the introduction of the memo, while ignoring its central purpose. The actual purpose of the memo is to propose to study the question of why people continue to smoke despite “compelling pressures upon the smoker to discontinue the behavior” and to “document the penalties imposed by discontinuation of

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cigarette smoking.”⁸⁵⁸ The memo offers the following rationale for documenting the “penalties” of discontinuation:

The literature on the subject cites body weight gains up to twenty pounds. Constipation has been cited as another sequelae (Ejrup, 1965), as well as blisters in the mouth. Chessick (1964) has warned against the “neurovegetative disequilibrium” that can result and Masoni (1963) contends that some may not be able to stabilize emotionally. There is anecdotal and lay observation of lowered efficiency and heightened irritability upon withdrawal. We know, too, that in periods of non-voluntary deprivation, as in concentration camps of World War II, the incentive value of the cigarette exceeds that of essential foodstuff.⁸⁵⁹

The actual text of the memo thus demonstrates clearly that Philip Morris has knowledge of significant withdrawal symptoms associated with smoking deprivation. The memo displays no skepticism about the existence of the cited withdrawal symptoms.

8. Philip Morris argues that reports of animal research conducted in its laboratories by Philip Morris researchers Victor DeNoble and Paul Mele do not conclude that nicotine is addictive.

The reports in question showed that Philip Morris had established that nicotine functions as a “positive reinforcer” in rats (causes them to seek repeated doses), and has other psychoactive effects characteristic of addictive substances. *See Jurisdictional Analysis*, 60 FR 41754–41758. These reports also showed that Philip Morris conducted research to find nicotine analogues (substitutes) that would have equal or greater reinforcing and psychoactive effects as nicotine. *Id.* These central nervous system effects were characterized by Philip Morris as “desirable properties” of nicotine that could be

⁸⁵⁸ Dunn WL (Philip Morris Inc.), *Stating the Risk Study Problem* (Jul. 29, 1969), at 3. *See AR* (Vol. 15 Ref. 189-6).

⁸⁵⁹ *Id.*

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“enhanced” as a result of nicotine analogue research.⁸⁶⁰ Finally, these research reports showed that Philip Morris conducted research to find an “optimum” combination of nicotine and acetaldehyde (another component of smoke) that had “maximal reinforcing effects.”⁸⁶¹

FDA disagrees that it inappropriately relied on these studies. FDA did not cite these documents for the proposition that Philip Morris acknowledged that nicotine is addictive. FDA cited them, appropriately, as evidence that Philip Morris: (1) had conducted research demonstrating that nicotine is a positive reinforcer, one of the characteristic features of addictive substances; and (2) understood that the pharmacological effects of nicotine were essential to the market for tobacco products and intended to offer products that affect the central nervous system. *See Jurisdictional Analysis*, 60 FR 41750–41762.

9. Philip Morris states that, during his tenure at Philip Morris, Victor DeNoble repeatedly advised his colleagues that the fact that a substance has positive reinforcement effects does not mean that the substance is “addictive.”

FDA agrees that animal self-administration does not alone demonstrate conclusively that a substance will be addictive in humans. As DeNoble stated in his testimony before Congress, however, “[t]he self-administration study is a classical hallmark to indicate that a solution or drug substance has . . . the potential to be a drug of

⁸⁶⁰ Charles JL (Philip Morris Inc.), *Nicotine Receptor Program—University of Rochester* (Mar. 18, 1980). *See AR* (Vol. 32 Ref. 532).

⁸⁶¹ DeNoble VJ (Philip Morris Inc.), *Project Number 1610 (Behavior Pharmacology) Objectives and Plans 1982-1983* (Jul. 20, 1982), at 2. *See AR* (Vol. 345 Ref. 5443).

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abuse in humans.”⁸⁶² As described earlier, a drug’s abuse liability refers to its potential to cause drug dependence/addiction.

As described in section II.A.3.c., above, a complete screen for abuse liability also includes studies that demonstrate that the drug’s reinforcing effects are caused by its actions in the central nervous system, that the drug has psychoactive effects, that the drug produces withdrawal and/or tolerance. Philip Morris research also demonstrated that nicotine has each of these properties.⁸⁶³ These results distinguish nicotine from such nonaddictive substances as saccharin, which are not psychoactive.

As described in section II.C.2.a.ii., above, corporate executives were informed that Philip Morris’ own research predicted that nicotine would be a drug of abuse in humans. A reasonable manufacturer with this information should have foreseen that nicotine was likely to be addictive in humans.

10. Tobacco industry comments challenge the reliability of a report submitted by William A. Farone, director of applied research at Philip Morris from 1976 to 1984, entitled “The Manipulation and Control of Nicotine and Tar in the Design and

⁸⁶² *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*. 103d Cong. 2d Sess. 18 (Apr. 28, 1994) (testimony of Victor J. DeNoble). See AR (Vol. 708 Ref. 2).

⁸⁶³ See, e.g., Dunn WL (Philip Morris Inc.), *Plans and Objectives—1980* (Jan. 7, 1980), in 141 Cong. Rec. H7668, H7669 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

DeNoble VJ (Philip Morris, Inc.) *Nicotine Program—Behavioral Research Laboratory* (Apr. 24, 1980), at 2. See AR (Vol. 345 Ref. 5446).

Ryan FJ (Philip Morris Inc.), *Bird-1: A Study of the Quit-Smoking Campaign in Greenfield, Iowa, in Conjunction with Movie, Cold Turkey* (Mar. 1971). See AR (Vol. 21 Ref. 207).

DeNoble VJ, Mele PC (Philip Morris Inc.), *Development of behavioral tolerance following chronic nicotine administration* (unpublished manuscript). See AR (Vol. 346 Ref. 5464).

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Manufacture of Cigarettes: A Scientific Perspective.” In this report, Farone describes the beliefs of Philip Morris, and, in some cases the tobacco industry, concerning: the essential role of nicotine in tobacco use; research conducted by the industry on nicotine’s pharmacological effects; and techniques used by the industry to reduce tar while maintaining an adequate level of nicotine. Farone bases his report on personal knowledge, as well as company documents and published literature. The tobacco industry argues generally that the information in Farone’s report should not be relied upon because: (1) many of his statements about Philip Morris or the industry are not supported by documentary evidence; and (2) Farone left Philip Morris in 1984 and therefore does not have personal knowledge of the current operations of the company.

Other comments argue that Farone’s report provides additional factual support for the conclusion that Philip Morris scientists and executives understand and intend that the primary role of nicotine in Philip Morris’ products is to provide nicotine’s pharmacological effects to consumers. These comments also argue that Victor DeNoble, former research scientist for Philip Morris, has publicly confirmed the accuracy of many of the statements made by Farone. Finally, these comments argue that the reliability of the information provided by Farone, is enhanced by its consistency with the sworn testimony of the former vice president for research and development for Brown & Williamson.

FDA disagrees with the tobacco industry comments that Farone’s report is not reliable evidence relevant to establishing the intended use of cigarettes. Farone was a high-ranking manager within Philip Morris, whose responsibilities gave him first-hand knowledge of the information presented in the report. As director of applied research, Farone supervised five research divisions with a total of 150 employees, mostly

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professionals. He reported directly to the vice president for research and development and regularly met with other senior management officials, including the CEO and president of Philip Morris, to discuss Philip Morris activities related to basic and applied research, product and process development, manufacturing, and results of test marketing of new products.⁸⁶⁴ He was thus in a position to have personal knowledge of the views and activities of Philip Morris concerning the topics discussed in his report. Thus, the fact that he does not cite documentary evidence to support each statement in the report is irrelevant to the weight to which the report is entitled.⁸⁶⁵

The fact that Farone left Philip Morris in 1984 also provides no basis to consider his report irrelevant. As discussed above in section II.C.2.e., the extensive collection of tobacco company statements relied on by the agency reflects a consistent pattern of tobacco industry views spanning three decades. These statements provide evidence of the long-standing knowledge and beliefs of tobacco company officials that cigarettes are primarily used by consumers for the pharmacological effects of nicotine. Farone's statements about the knowledge, beliefs, and actions of the tobacco industry are entirely consistent with the body of industry statements relied on by the agency, adding to their credibility. Moreover, Farone's statements are consistent with the recent Philip Morris

⁸⁶⁴ Declaration of Uydess IL (Feb. 29, 1996), at 23-24. See AR (Vol. 638 Ref. 1).

⁸⁶⁵ FDA notes that Philip Morris has submitted two affidavits from current employees which purport to provide, based on the personal knowledge of the affiants, information about the measurement of nicotine levels in reconstituted tobacco. Neither of these affidavits cites any documentary support. Thus, Philip Morris appears to believe that FDA is entitled to rely on information based on personal knowledge. Philip Morris Inc., Comment (Apr. 19, 1996), at appendix 3. See AR (Vol. 700 Ref. 226).

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document concerning Project Table,⁸⁶⁶ demonstrating that the company's views have not changed since Farone left the company.

11. Tobacco industry comments also challenge specific statements made in Farone's report. FDA addresses those comments that challenge statements cited by the Agency.

The tobacco industry contests Farone's statement that it is widely believed within the tobacco industry that nicotine is the primary reason people smoke. The industry argues that the documents cited by Farone do not support this statement, and that industry evidence shows that consumers do not smoke cigarettes "nearly exclusively" or "solely" for the pharmacological effects of nicotine.⁸⁶⁷

FDA disagrees with these comments. As described above and in sections II.C.6.a.ii. and iii., below, there is ample support, including the documents cited by Farone, for the conclusion that tobacco industry officials believe that people use tobacco primarily to obtain the pharmacological effects of nicotine. Moreover, as discussed above, Farone's position and responsibilities within Philip Morris were such that the statements based on his personal knowledge may be considered reliable evidence. Finally, Farone's statement is corroborated by the existence of dozens of similar statements by Philip Morris officials in other documents cited in section II.C.2.a.i., above, and in the Jurisdictional Analysis. *See* 60 FR 41584–41620.

⁸⁶⁶ Philip Morris, Inc., Draft Report Regarding a Proposal for a "Safer" Cigarette, Code-named *Table*. *See* AR (Vol. 531 Ref. 122).

⁸⁶⁷ Philip Morris Inc., Comment (Apr. 19, 1996), at 57. *See* AR (Vol. 700 Ref. 226).

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The tobacco industry comments present no contradictory statements or other evidence to demonstrate that tobacco industry officials do not believe that nicotine is the primary reason people smoke. Instead, the industry argues that there is evidence that, in fact, consumers do not smoke cigarettes “solely” or “nearly exclusively” for the pharmacological effects of nicotine. These comments misconstrue the nature of the evidence required to establish intended use. The statements of Farone and others are properly used by FDA to show that Philip Morris *knows* that consumers use cigarettes for the pharmacological effects of nicotine. This knowledge is relevant to establishing the company’s intent to affect the structure and function of the body. See 21 CFR 201.128 and 801.4. In establishing intended use through a manufacturer’s actual knowledge, it is not necessary for the Agency to show knowledge that consumers use tobacco nearly exclusively for its pharmacological effects. *Cf. Action on Smoking and Health v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980) (FDA must establish nearly exclusive consumer use for pharmacological effects only where there is no other evidence of manufacturer’s intent).

Moreover, as described in section II.B., above, the scientific evidence demonstrates that the pharmacological effects of nicotine are the primary motivation for tobacco use, and that other aspects of tobacco use, such as flavor, are secondary. Indeed, the data show that tobacco users enjoy the flavor of tobacco products because they have come to associate its flavor with obtaining the pharmacological effects of nicotine. Thus, contrary to Philip Morris’ comment, even though not necessary to establish “intended use,” the evidence shows that consumers do use tobacco products nearly exclusively for the pharmacological effects of nicotine.

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ii. Comments on Specific RJR Statements and Research Projects. Like Philip Morris, RJR argues that FDA misused statements and research reports by RJR officials that the Agency relied upon as evidence that RJR officials believe that consumers use cigarettes to obtain the pharmacological effects of nicotine. FDA has reviewed the statements and research reports in context and concluded that, with one minor exception, the Agency correctly relied upon them.

1. RJR argues that the 1972 memorandum by Claude Teague, assistant director for research at RJR,⁸⁶⁸ cited by FDA, does not provide evidence of the intended use of cigarettes because Teague was only presenting a “hypothesis” to stimulate discussion, and because the document does not reflect institutional intent. RJR focuses heavily on the fact that one of the quoted paragraphs and a few other phrases in the document begin with “if” or otherwise suggest uncertainty.

At the time the Jurisdictional Analysis was published, two paragraphs from the memorandum that had been published in the *New York Times*. The complete nine-page memorandum was subsequently submitted to the Agency in a comment and is discussed above in section II.C.2.b.i. The full document demonstrates that RJR’s assistant vice president for research asserted as fact, not hypothesis, that nicotine’s pharmacological effects are the primary reason people smoke and that cigarettes are nicotine delivery systems. Before the paragraph that begins “If nicotine is the *sine qua non* of tobacco products,” Teague says:

⁸⁶⁸ Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1-2. See AR (Vol. 531 Ref. 125).

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Nicotine is known to be a habit-forming alkaloid, hence the confirmed user of tobacco products is primarily seeking the physiological "satisfaction" derived from nicotine—and perhaps other compounds Thus a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form. Our industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine. . . .⁸⁶⁹

The actual text of the document thus flatly contradicts RJR's claim that Teague was making "suppositions" about nicotine that were "very tentative."⁸⁷⁰ He was, instead, stating as established fact that people smoke for the pharmacological effects of nicotine. The later statement, "If nicotine is the *sine qua non* of tobacco," is thus not an "hypothesis" but a rhetorical device to encapsulate the author's previously expressed position.

2. In the Jurisdictional Analysis, FDA relied upon the statements of RJR researchers in published papers that many of the most important effects of smoking cited by smokers as the reasons they smoke are the pharmacological effects of nicotine. RJR argues that none of the papers asserts that the pharmacological effects of nicotine are the most important reason for smoking, and that the papers also refer to the role of nonpharmacological effects in smoking behavior. RJR also contends that these papers do not show that consumers use tobacco nearly exclusively for its pharmacological effects.

FDA disagrees. A fair reading of these studies indicates that the authors view nicotine as playing a far more significant role in smoking motivation than other, nonpharmacological motives.

⁸⁶⁹ *Id.* at 1.

⁸⁷⁰ R.J. Reynolds Tobacco Co., Comment (Jan 2, 1996), at 30. See AR (Vol. 519 Ref. 103).

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For example, a paper published in 1991 refers to the fact that some smokers report that they smoke to increase their mental alertness, while others smoke to calm their moods; the paper attempts to prove that both sets of motives can be attributed to the effects of nicotine on different hemispheres of the brain.⁸⁷¹ The study demonstrated that smoking produced EEG effects in different hemispheres of the brain, depending on the depth of inhalation, leading the researchers to conclude that “light inhaling . . . smokers may smoke primarily for purposes of mental activation and performance enhancement” while “an important motive for deep inhaling smokers might be anxiety reduction.”⁸⁷² Nonpharmacological motives for smoking are not mentioned at all. In studies where they are mentioned, RJR researchers never claim that nonpharmacological motives are more important to the smoker than nicotine.

RJR’s contention that its published studies do not demonstrate “nearly exclusive consumer use” of cigarettes for pharmacological effects does not diminish their relevance to establishing intended use. These studies were designed by RJR to examine the effects of smoking on the human brain and on behavior, not to quantify consumer use. These studies are properly used by FDA to show that RJR knows that consumers use cigarettes for the pharmacological effects of nicotine. A manufacturer’s actual knowledge is relevant to establishing the intended use of these products to affect the structure and function of the body. See 21 CFR 201.128 and 801.4. Moreover, when the evidence of tobacco manufacturer’s statements, research, and actions demonstrates that their products are

⁸⁷¹ Pritchard WS (R.J. Reynolds Tobacco Co.), *Electroencephalographic effects of cigarette smoking*, *Psychopharmacology* 1991;104:485-490. See AR (Vol. 3 Ref. 23-2).

⁸⁷² *Id.* at 488.

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actually intended to affect the structure or function of the body, it is not necessary for the Agency to show that consumers use tobacco nearly exclusively for its pharmacological effects. Some courts have suggested such a showing could be required, but only where there is no other evidence of the intended use and FDA is relying exclusively on actual consumer use. *Action on Smoking and Health v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980). The “nearly exclusive” consumer use standard is inapplicable in the context of direct evidence of manufacturers intent. See sections II.B.1., above, and II.E.1., below.

3. In the Jurisdictional Analysis, 60 FR 41601, FDA stated that attorneys for RJR had, in a court filing, described the following pharmacological “benefits” of smoking: “satisfaction; stress reduction; relaxation; stimulation; aided concentration; increased memory retention; alleviation of boredom and fatigue; avoidance of loss of vigilance in repetitive and sustained tasks.”⁸⁷³ RJR argues that FDA’s use of this litigation response was misleading because: (1) the listed benefits were only those reported by smokers or the literature, and were not subscribed to by RJR; (2) FDA omitted from the quote benefits that were not pharmacological; and (3) the listed benefits were not characterized by RJR as “pharmacological” or “significant,” and are likely due to other aspects of smoking, including the sensory aspects. RJR also states that even if some of the benefits quoted by FDA “are in some sense pharmacological,” the litigation response is not evidence of intended use.

⁸⁷³ Reply to Interrogatories, *Gilboy v. American Tobacco Co. et al.*, No. 314002 (La. Dist. Ct.). See AR (Vol. 15 Ref. 194-1). FDA notes that Lorillard has not contested FDA’s reliance on a similar court filing by Lorillard in *Covert v. Lorillard et al.*, No. 88-1018-B (M.D.La.). See AR (Vol. 15 Ref. 194-2).

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FDA disagrees that its use of the company's statements in litigation was misleading or that the statements fail to provide evidence of intended use. The statement filed in court by RJR was used as evidence that RJR, *speaking as a corporation*, knows that consumers use tobacco for its pharmacological effects. The knowledge of a manufacturer that its product is used for pharmacological effects provides objective evidence of intent to affect the structure and function of the body. The fact that RJR was repeating benefits reported by consumers does not in any way undercut FDA's reliance on the quote: RJR's awareness of how consumers use its product is highly relevant. The fact that the original quote included two nonpharmacological "benefits" of smoking similarly fails to diminish the relevance of the quote. When it has been established that a manufacturer intends that its product be used for a pharmacological purpose, FDA's jurisdiction is not defeated by a showing that the manufacturer also intends the product to be used for other, nonpharmacological purposes. *Guardian Chemical Corp.*, 410 F.2d at 162-163.

Finally, while RJR did not explicitly characterize the benefits as pharmacological in this particular filing, RJR scientists have published reports demonstrating that the company knows that these "benefits" of tobacco are due to the pharmacological effects of nicotine. In one paper, for example, RJR scientists reported on a study whose purpose was to isolate the psychopharmacological effects of nicotine from the effects of other aspects of the cigarette:

Anxiety relief and improved mental alertness are two of the benefits of smoking commonly reported by smokers as their reason for smoking [The study results] indicate that *the beneficial effects*

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*of smoking on cognitive performance . . . are a function of nicotine absorbed from cigarette smoke upon inhalation.*⁸⁷⁴

Thus, RJR scientists characterize the very effects that the corporation listed in the pleading as nicotine's pharmacological effects.

4. RJR challenges FDA's use in the Jurisdictional Analysis of the statement of its former CEO, F. Ross Johnson, in response to a question from a reporter about whether tobacco is addictive: "Of course it's addictive. That's why you smoke the stuff."⁸⁷⁵ RJR argues that this statement is not evidence of intent because, as Johnson "explained" in a subsequent letter to the reporter, he used the term "addictive" not in the "technical" sense, but as an expression of the "common experience that some people find it hard to quit smoking, and so continue to smoke."⁸⁷⁶ RJR also argues that Johnson's statement should not be attributed to RJR because, at the time he made it, he was no longer employed by RJR, and "there is no indication that Johnson's comment reflected anything he learned or observed" at RJR.⁸⁷⁷

The arguments put forward by RJR for discounting the statement of its former CEO are not persuasive. It is doubtful that the former CEO of a tobacco company would

⁸⁷⁴ Robinson JH, Pritchard WS, Davis RA (R.J. Reynolds Tobacco Co.), Psychopharmacological effects of smoking a cigarette with typical "tar" and carbon monoxide yields but minimal nicotine, *Psychopharmacology* 1992;108:466-472, at 471 (emphasis added). See AR (Vol. 11 Ref. 129-3).

See also Pritchard WS (R.J. Reynolds Tobacco Co.), Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490 (presenting evidence that both mental alertness and anxiety reduction are a function of nicotine's effects on different parts of the brain). See AR (Vol. 3 Ref. 23-1).

⁸⁷⁵ Shapiro E, Big spender finds new place to spend, *Wall Street Journal* (Oct. 6, 1994). See AR (Vol. 21 Ref. 230).

⁸⁷⁶ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 21. See AR (Vol. 519 Ref. 103).

⁸⁷⁷ *Id.*

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state that tobacco is “addictive” without foreseeing that he would be understood to mean the term in its “technical” sense. The further suggestion that the statement did not reflect Johnson’s knowledge while at RJR is similarly unconvincing.

5. RJR argues that FDA incorrectly stated that a particular research article⁸⁷⁸ found that tobacco users report “craving.” FDA has reviewed the article in question and agrees with the comment that it does not clearly find that smokers report craving.

iii. Comments on Specific Brown & Williamson Statements and Research Projects. In the Jurisdictional Analysis, FDA cited over 75 Brown & Williamson and BATCO documents to demonstrate the cigarette manufacturer’s knowledge that cigarettes produce significant pharmacological effects, including causing and sustaining addiction, and are used by smokers for these effects. FDA also cited a substantial number of documents from Brown & Williamson’s affiliate, Imperial Tobacco, and from American Tobacco, a company with which Brown & Williamson recently merged. Although Brown & Williamson makes a general assertion that the Agency has mischaracterized these documents, the company makes no attempt to refute FDA’s specific characterizations of the vast majority of the Brown & Williamson documents cited by FDA. The Agency believes that these documents speak for themselves and fully support its conclusion that Brown & Williamson intends cigarettes to affect the structure and function of the body.

With respect to the few Brown & Williamson documents regarding nicotine pharmacology that the company does specifically address, FDA has reviewed the company’s comments and concludes that the company’s statements and research were

⁸⁷⁸ Robinson JH, Pritchard W, The role of nicotine in tobacco use, *Psychopharmacology* 1992;108:395-405. See AR (Vol. 14 Ref. 175).

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properly characterized in the Jurisdictional Analysis. These comments and FDA's responses are presented below.

1. FDA relied on a large number of statements from researchers and high-ranking officials of Brown & Williamson and BATCO acknowledging that nicotine is addictive. Brown & Williamson makes a general argument that none of the statements by BATCO employees about addiction is attributable to Brown & Williamson, because their employees were merely reciting language from government and other external sources. The company provides only one example to support this contention. FDA quoted from a speech by Charles Ellis, the science advisor to BATCO's Board of Directors, in which he told an audience of tobacco industry officials: "smoking is a habit of addiction"⁸⁷⁹ According to the comment, Ellis' "terminology mirrored virtually identical phrases used by the Royal College of Physicians three months earlier . . . [and] does not support any conclusion about his own views."⁸⁸⁰ Brown & Williamson also makes a baffling argument that the Surgeon General two years later determined that smoking was a "habit" rather than an "addiction" and that the Surgeon General's determination "clearly trumps the earlier imprecise language quoted by FDA."

FDA has reviewed the full text of Ellis' speech and finds no support for Brown & Williamson's contention that Ellis was merely reciting the views of the Royal College; in the quoted passage, Ellis is clearly stating his own views. FDA is similarly unable to conclude that the 1964 determination of the U.S. Surgeon General transformed Ellis' assertion two years

⁸⁷⁹ Ellis C (BATCO), The smoking and health problem, in *Smoking and Health—Policy on Research*, Research Conference, Southampton, England (1962), at 4. See AR (Vol. 21 Ref. 220).

⁸⁸⁰ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 27. See AR (Vol. 529 Ref. 104).

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earlier that “smoking is a habit of addiction” into the statement that it is simply a habit.

Because Brown & Williamson provides no evidence that other statements of its officials concerning the addictive properties of nicotine were not their own views, and the documents themselves do not support such a conclusion, FDA finds no basis to disregard those statements.

2. Brown & Williamson also challenges FDA’s reliance on a report entitled, “A Tentative Hypothesis on Nicotine Addiction,” arguing that it was not written by tobacco company researchers, reports no data, and is “nothing more than speculation.”⁸⁸¹

The report in question was sent to BATCO by the Battelle scientists who were doing contract work for BATCO on nicotine pharmacology, among other things, and contains their hypothesis of the mechanism by which smokers become addicted to nicotine. While the document hypothesizes as to the *mechanism* of addiction, it treats the existence of nicotine addiction as a fact, not hypothesis. For example, after hypothesizing that when smokers are deprived of nicotine, their endocrine systems become unbalanced, the report says: “[a] body left in this unbalanced status craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine.”⁸⁸²

A copy of the report was sent by Charles Ellis to Addison Yeaman, the general counsel of Brown & Williamson. Accordingly, this document provides evidence that

⁸⁸¹ *Id.* at 29.

⁸⁸² Haselbach C, Libert O, *A Tentative Hypothesis on Nicotine Addiction* (May 30, 1963), at 2. See AR (Vol. 20 Ref. 197-1).

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company executives had knowledge that nicotine is addictive.⁸⁸³ Indeed, shortly thereafter, Yeaman wrote a memo in which he accepted the view that nicotine is addictive, and concluded, “[w]e are, then, in the business of selling nicotine, an addictive drug.”⁸⁸⁴

3. A comment from Brown & Williamson argues that FDA has distorted its nicotine research by not recognizing that the research failed to confirm the hypotheses of its researchers. In support of this argument, Brown & Williamson offers only one example. According to the comment, the results of “Project HIPPO” failed to support its hypotheses.

The example put forward by Brown & Williamson does not establish that FDA distorted Brown & Williamson nicotine research. First, Brown & Williamson fails in its attempt to show misuse of the research project. Second, FDA relied on dozens of Brown & Williamson documents reflecting over thirty years of research, the vast majority of which Brown & Williamson does not challenge.

Project HIPPO consisted of a series of studies commissioned in the early 1960’s by BATCO to investigate the role of nicotine in why people smoke, and specifically to compare the effects of nicotine with those of tranquilizers, which were perceived as marketplace competition for tobacco:

The aim of the whole research “HIPPO” was to understand some of the activities of nicotine—those activities that could explain why

⁸⁸³ Letter from Ellis C to Yeaman A (Brown & Williamson) (Jun. 28, 1963). See AR (Vol. 14 Ref. 165-2).

⁸⁸⁴ Yeaman A (Brown & Williamson), *Implications of Battelle Hippo I and II and the Griffith Filter* (Jul. 17, 1963), at 4. See AR (Vol. 21 Ref. 221). Brown & Williamson protests FDA’s use of this document, claiming that it was stolen from Brown & Williamson and is privileged. FDA does not believe that this document can be considered confidential, having been published in newspapers and other media throughout the United States and made available to the public without limitation by the University of California.

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cigarette smokers are so fond of their habit. It was also our purpose to compare these effects of the new drugs called “tranquillizers” which might supersede tobacco habits in the near future.⁸⁸⁵

Contrary to the position taken by Brown & Williamson, Project HIPPO’s authors reported that they were successful in demonstrating that nicotine was superior to tranquilizers in certain ways:

Our investigation definitely shows that *both kinds of drugs* act quite differently, and that nicotine may be considered . . . as more “beneficial”—or less noxious—than the new tranquilizers, from some very important points of view.

The so-called “*beneficial*” *effects of nicotine* are of two kinds:

1. Enhancing effect on the pituitary-adrenal response to stress;
2. Regulation of body weight.”⁸⁸⁶

Although the researchers did not show that nicotine acted through certain hypothesized biochemical mechanisms, the documents demonstrate that this was not the central purpose of the research. Thus, Project HIPPO successfully demonstrated to BATCO that nicotine has two significant pharmacological effects on tobacco users: it acts like tranquilizers in helping them respond to stress, and it regulates body weight.

4. A comment from a public health organization pointed out a number of additional statements in BATCO and Brown & Williamson internal documents acknowledging the importance of nicotine’s pharmacological effects to use of tobacco products.⁸⁸⁷ For example, the comment provided a copy of a handwritten note by S. J. Green, the long-time director of research and a board member at BATCO, in which Green

⁸⁸⁵ Haselbach CH, Libert O, *Final Report on Project HIPPO II* (Mar. 1963), at 1. See AR (Vol. 64 Ref. 321).

⁸⁸⁶ *Id.* at 2 (emphasis added).

⁸⁸⁷ American Society of Addiction Medicine, Comment (Dec. 29, 1995), at 3. See AR (Vol. 528 Ref. 97).

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says that “[t]he strong addiction to cigarette[s] removes freedom of choice from many individuals.”⁸⁸⁸ The comment also provided a copy of a 1978 BATCO document that forecast developments in technology that could be used to produce current cigarette products. The author defined “a finished smoking material” as having the following purposes: “[t]o generate smoke, taste, and pharmacological effect.”⁸⁸⁹

FDA agrees that many of the statements to which the comment draws attention provide additional support for the determination that Brown & Williamson knows that tobacco produces pharmacological effects on consumers, including addiction, and that consumers smoke cigarettes to sustain addiction and for other pharmacological effects.

iv. Other Comments.

1. Tobacco industry comments argue that the evidence compiled by FDA of a massive industry research enterprise on nicotine pharmacology is irrelevant to the intended use of the industry’s products. The comments contend that the industry conducted this research to understand and improve its products, to compare the pharmacology of new cigarettes with that of other cigarettes, to be prepared for government restrictions on tobacco products, and to respond to consumer preferences. The comments also argue that the kind of research conducted by the industry was also being done by outside researchers and reported in the public domain. Thus, according to the comments, such research need not be related to the interests of manufacturers. For these reasons,

⁸⁸⁸ Notes of Green SJ (1978). See AR (Vol. 528 Ref. 97, appendix 18).

⁸⁸⁹ Kilburn KD (BATCO), *A Technological Forecast of the Future of Tobacco Processing* (Oct. 16, 1978), at 60. See AR (Vol. 258 Ref. 3524).

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according to the comments, the industry's research is not evidence of intent to affect the structure and function of the body.

FDA disagrees that the industry's extensive and sophisticated research into nicotine's pharmacological effects is irrelevant to the intended use of the products. This research establishes that the industry has actual knowledge that nicotine has powerful pharmacological effects and that consumers use tobacco to obtain those effects.

"Objective intent" to affect the structure or function of the body may be established by a manufacturer's "knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it." 21 CFR 201.128 and 801.4.

The argument that other researchers conducted and published nicotine research similar to that conducted by the tobacco industry fails to provide an adequate basis to disregard the industry's research as evidence of intent. Although there may undoubtedly be other motives for this kind of research, the industry's own documents establishes that their motive is directly related to providing an adequate dose of nicotine the pharmacologically active ingredient in tobacco.

In its comments, Brown & Williamson even acknowledges that some of BATCO's most significant nicotine research was conducted, not because of outside pressure, but because Charles Ellis, senior scientific advisor to BATCO, believed that an alternative cigarette that provided only a nicotine aerosol could satisfy smokers and because he wanted to identify the "beneficial properties of nicotine."⁸⁹⁰ Indeed, as described in the

⁸⁹⁰ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 23. See AR (Vol. 529 Ref. 104).

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Jurisdictional Analysis, Ellis believed that the research was critical “to elucidate the effects of nicotine as a beneficent alkaloid drug”⁸⁹¹ and because “we are in a nicotine rather than a tobacco industry.”⁸⁹² See also Jurisdictional Analysis, 60 FR 41621–41640. Industry documents further show that the research was not merely exploratory, but was intended to be used in product development.⁸⁹³

None of the additional motives claimed by the industry for its nicotine research are inconsistent with FDA’s finding that the research was conducted because the industry believes people use tobacco to obtain the pharmacological effects of nicotine, and wanted to gather information about nicotine how to ensure that tobacco products provide an adequate dose of nicotine. Each of the motives listed by the industry logically coexist with the industry’s belief that consumers use tobacco for its pharmacological effects. Indeed, most of the proffered explanations themselves strongly suggest that the industry believes that the pharmacological effects of nicotine are central to the success of its products. For example, the most obvious explanation for a company’s decision to compare the nicotine pharmacokinetics of a new cigarette with that of existing cigarettes is that the company believes that the pharmacological effects of nicotine are important to the success of the new product.

⁸⁹¹ Ellis C (BATCO), The smoking and health problem in *Smoking and Health—Policy on Research*, Research Conference, Southampton, England (1962), at 16. See AR (Vol. 21 Ref. 232).

⁸⁹² Johnson RR (BATCO), *Comments on Nicotine* (Jun. 30, 1963), at 10–11. See AR (Vol. 21 Ref. 242).

⁸⁹³ Dunn WL (Philip Morris Inc.), *Plans and Objectives—1979* (Dec. 6, 1978), in 141 Cong. Rec. H7668–7669 (daily ed. Jul. 25, 1995) (nicotine pharmacology research would be used to “strengthen Philip Morris R&D capability in developing new and improved smoking products”). See AR (Vol. 14 Ref. 175a).

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Similarly, the claim that the research on nicotine pharmacology was conducted to be prepared for government restrictions is consistent with the industry's belief that it must understand and preserve the pharmacological effects of nicotine to ensure the continued success of tobacco. This explanation for the industry's nicotine research was presented by the companies as the rationale for their nicotine analogue research. Internal documents show that the companies wanted to develop substitutes for nicotine that would mimic nicotine's pharmacological effects on the central nervous systems of smokers should restrictions prevent their continued use of nicotine.⁸⁹⁴

The industry's claim that it conducted research on maintaining and increasing nicotine deliveries from low-tar cigarettes because government officials "published concerns that smokers switching to lower 'tar' delivery cigarettes might change their smoking patterns if nicotine levels were too low"⁸⁹⁵ similarly suggests that the industry believes that smokers smoke to obtain an adequate dose of nicotine. As discussed in section II.C.3.f., above, the small number of recommendations that low-tar, high-nicotine cigarettes be investigated were premised on the view that smokers use cigarettes to satisfy their dependence on nicotine and will compensate when given low nicotine cigarettes by smoking more intensely or more cigarettes to obtain an adequate dose of nicotine. It is not credible that the cigarette industry would develop cigarettes whose avowed purpose is to avoid smoker compensation, unless they share the view that smokers use cigarettes to obtain an adequate dose of nicotine.

⁸⁹⁴ See, e.g., Kilburn KD, Underwood JG (BATCO), *Preparation and Properties of Nicotine Analogues* (Nov. 9, 1972), at 1-2. See AR (Vol. 31 Ref. 524-1).

⁸⁹⁵ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 30. See AR (Vol. 529 Ref. 104).

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Finally, the claim that the research was conducted to respond to consumer preferences strongly suggests that the tobacco companies understand that consumers prefer products that deliver the pharmacological effects of nicotine. Where, as here, the tobacco industry is marketing a product to which most of its consumers are addicted, satisfying consumer preferences requires the company to understand the consumer's need for nicotine in order to supply a sufficient dose of nicotine. If, on the other hand, consumer preferences were limited to taste and flavor, research on nicotine pharmacology would be irrelevant to satisfying those preferences.

Even if the record supported the industry's claim that its research was *initiated* for some purpose other than its belief that people use tobacco for nicotine's pharmacological effects (which it does not), this would not alter the fact that the research *results* demonstrated to the industry that consumers use tobacco primarily for nicotine's pharmacological effects.

2. Tobacco company comments argue that the tobacco industry's nicotine research does not establish that adults smoke solely or "nearly exclusively" to obtain nicotine. One company, while acknowledging that its parent "explored the effects of nicotine and the role it played in smoking," contends that its research "generally has concluded that the presence and effects of nicotine do not alone account for smoking enjoyment."⁸⁹⁶

First, the industry's contention that its research shows that nicotine does not "alone" account for tobacco use is not in any way inconsistent with FDA's conclusion that

⁸⁹⁶ *Id.* at 22-23.

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the industry's research demonstrates that nicotine plays a central role in tobacco use.

Indeed, throughout its comments, the tobacco industry implicitly acknowledges that its research demonstrates that nicotine does play a critical role in tobacco use.

Second, this research is persuasive evidence that the manufacturers intend cigarettes and smokeless tobacco products to affect the structure or function of the body of tobacco users. As described elsewhere in this notice, FDA's regulations provide that whether a product is "intended to affect the structure or any function of the body" may be established by, among other things, evidence that the vendor has knowledge that its product is being used for a pharmacological purpose, even though the product is not promoted for that purpose. 21 CFR 201.128 and 801.4. These regulations do not require the manufacturer to have knowledge that consumers use the product solely or nearly exclusively for a pharmacological purpose.

The industry's own research establishes that it has actual knowledge that consumers use tobacco products primarily for their pharmacological effects. This is persuasive and sufficient evidence that the manufacturers intend to affect the structure or function of the body. Furthermore, the tobacco industry's nicotine research, together with the other evidence in the record on consumer use, demonstrates that consumers use tobacco overwhelmingly for nicotine's pharmacological effects.

3. In the Jurisdictional Analysis, FDA reviewed the industry research and statements demonstrating that tobacco companies are aware of the high percentage of smokers who have made unsuccessful attempts to quit. This evidence demonstrates that a large proportion of tobacco users display one of the characteristic features of addiction: continued use despite attempts to quit. *See Jurisdictional Analysis*, 60 FR 41667-41673.

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One tobacco company argued that it had never determined that smokers cannot quit and that its research was not directed at control of smokers' ability to quit. Another tobacco company cited evidence that it knows many smokers would like to quit smoking, but that this is irrelevant to whether they are actually unable to quit. This company contends that the fact that many people do quit shows that tobacco is not addictive.

Both companies' comments rely on a false assumption about the relationship of the ability to quit and addiction. As described above in section II.A.3., "addiction" is not a condition that can be demonstrated only if no user is ever able to quit. Substantial percentages of users of such addictive substances as heroin and cocaine are eventually able to quit without formal treatment.⁸⁹⁷ In fact, more than half of people seeking treatment for alcohol or drug abuse who also smoke cigarettes report that quitting smoking would be harder than giving up their other drug of abuse.⁸⁹⁸

The characteristic feature of all addictive substances is that it is very difficult (not impossible) to quit and that addicted users often fail despite serious attempts to do so. See section II.A.3., above. Tobacco company data bear this out. For example, a BATCO researcher presented data at a major BATCO conference showing that, although 40% of Canadian smokers have tried to quit, fewer than 4% were able to quit permanently within

⁸⁹⁷ Kleber HD, Conney D, Don't you believe that nicotine isn't addictive, *New York Times*, Apr. 4, 1994. See AR (Vol. 196 Ref. 2497).

⁸⁹⁸ Kozlowski LT, Wilkinson A, Skinner W, *et al.*, Comparing tobacco cigarette dependence with other drug dependencies, *Journal of the American Medical Association* 1989;261(6):898-901. See AR (Vol. 41 Ref. 92).

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the past year.⁸⁹⁹ Similarly, a Philip Morris researcher reported that of smokers who made an attempt to quit in Greenfield, Iowa, only 28% were still abstaining after 7 months.⁹⁰⁰

The argument that tobacco companies do not have knowledge of the low success rates experienced by tobacco users who attempt to quit defies credibility. Not only is this a matter of common knowledge, but the Council for Tobacco Research (of which every major tobacco company is or has been a member) sponsored a book on tobacco research in which the authors review, among many topics, a wealth of data on the difficulty of quitting.⁹⁰¹ Indeed, the very company that argued that its knowledge was limited to the fact that some smokers want to quit has argued in court that consumers should be held to the knowledge that it is very difficult to quit.⁹⁰²

4. One comment provided additional tobacco industry-funded research on nicotine pharmacology that had not been included in the Jurisdictional Analysis. FDA has confirmed that the following studies submitted with the comment are additional tobacco industry-funded studies on nicotine pharmacology and the relationship of nicotine to tobacco use:

(1) Knapp PH, Bliss CM, Wells H, "Addictive aspects in heavy cigarette smoking," *American Journal of Psychiatry* 1963;119:966-972 (supported by the Tobacco Industry Research Committee);

⁸⁹⁹ Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III (Jul. 9-12, 1984), at BW-W2-02790. See AR (Vol. 25 Ref. 337-1).

⁹⁰⁰ Ryan FJ (Philip Morris Inc.), Cold Turkey in Greenfield Iowa: a follow-up study in *Smoking Behavior: Motives and Incentives*, ed. Dunn WL (Washington DC: VH Winston & Sons, 1973), at 233 (table 1). See AR (Vol. 8 Ref. 105).

⁹⁰¹ Larson PS, Silvette H, *Tobacco—Experimental and Clinical Studies: A Comprehensive Account of the World Literature* (1968), Supplement I at 300-302. See AR (Vol. 50 Ref. 151).

⁹⁰² Appellees brief in reply to appellants' opposition to petition for transfer, *Rogers v. R.J. Reynolds et al.*, No. 49A02-8904 CV 164 (Sup. Ct. Ind. 1990), at 7-8. See AR (Vol. 21 Ref. 229).

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- (2) Ague C, "Nicotine content of cigarettes and the smoking habit: their relevance to subjective ratings of preferences in smokers," *Psychopharmacologia* 1972;24:326-330 (supported by the Tobacco Research Council);
- (3) Beckett AH, Triggs EJ, "Enzyme induction in man caused by smoking," *Nature* 1967;216:587 (supported by the Tobacco Research Council); and
- (4) Bowman ER, Turnbull LB, McKennis H, "Metabolism of Nicotine in the Human and Excretion of Pyridine Compounds by Smokers," *Journal of Pharmacology and Experimental Therapeutics* 1959; 127:92-95 (supported by the Tobacco Industry Research Committee and the American Tobacco Company).⁹⁰³

The study by Knapp, Bliss, and Wells, which was funded by the Tobacco Industry

Research Committee, the predecessor to the Council for Tobacco Research, concluded that nicotine produces addiction in some tobacco users.

b. Comments on Product Research and Development To Optimize and Manipulate Nicotine Delivery

i. Comments on Specific Philip Morris Product Research and Development Projects.

1. A comment from Philip Morris argues that FDA has mischaracterized its nicotine analogue research. The comment concedes that Philip Morris conducted research in which the company developed a "behavioral, peripheral and central nervous system profile of nicotine" and compared nicotine analogues to this profile.⁹⁰⁴ The comment asserts, however, that the company's research on nicotine analogues is not evidence of intended use because outside researchers were also investigating nicotine analogues, Philip

⁹⁰³ American Society of Addiction Medicine, Comment (Dec. 29, 1995), at appendix 9. See AR (Vol. 528 Ref. 97).

⁹⁰⁴ Philip Morris Inc., Comment (Jan. 2, 1996), at 25. See AR (Vol. 519 Ref. 105).

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Morris provided analogues to outside researchers, and the research did not result in development of a commercial product.⁹⁰⁵

Philip Morris appears to be arguing that if outside researchers were also interested in nicotine analogues for unspecified reasons, then Philip Morris' own intent in conducting this research is irrelevant. FDA disagrees. Philip Morris' purpose in conducting nicotine analogue research provides evidence of the company's knowledge that nicotine's psychoactive and reinforcing effects are central to the market for tobacco. The purposes of outside researchers do not diminish or alter Philip Morris' motives in any way.

Philip Morris' internal documents and the statements of former Philip Morris employees reveal that the purpose of its nicotine analogue research was to find chemicals that mimic nicotine's effects on the central nervous system, but not its adverse effects on the cardiovascular system, that could be substituted for nicotine in cigarettes to produce a safer cigarette.⁹⁰⁶ Specifically, Philip Morris sought to identify, through sophisticated laboratory studies in rats, whether nicotine produces discriminative stimulus effects (which predict whether a substance has mood-altering effects in humans) and reinforcing effects

⁹⁰⁵ Additional comments alleging that FDA misrepresented the results of Philip Morris' studies on nicotine's reinforcing properties and invalidly equated reinforcement with addiction are addressed in section II.C.6.a.i., above.

⁹⁰⁶ See, e.g., *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. (Apr. 28, 1994), at 5, 35 (testimony of Victor DeNoble) See AR (Vol. 708 Ref. 2).

See also, Charles JL (Philip Morris Inc.), *Nicotine Receptor Program—University of Rochester* (Mar. 18, 1980) ("The original charge of the nicotine program was (1) to ascertain if the central and peripheral effects could be 'separated' and (2) to design a nicotine analogue which would have CNS activity equivalent to nicotine with little or no peripheral effect"). See AR (Vol. 32 Ref. 532).

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(which predict whether a substance will induce repeated compulsive use in humans), and then find analogues that could produce the same effects, for use in future cigarettes.⁹⁰⁷

Philip Morris' nicotine analogue research thus demonstrates that Philip Morris knows that nicotine's psychoactive and reinforcing effects are critical to the success of existing tobacco products.

2. In the Jurisdictional Analysis, FDA presented evidence that Philip Morris conducted research on acetaldehyde, another component of cigarette smoke that was hypothesized to contribute to tobacco's reinforcing effects. According to Philip Morris research reports, the objective of this research was to find the "maximally reinforcing" combination of nicotine and acetaldehyde.⁹⁰⁸ Philip Morris argues that its research to find the maximally reinforcing combination of acetaldehyde and nicotine is not relevant to the intended use of cigarettes because the mean level of acetaldehyde in cigarettes is declining and is commonly found in proportions far from those found to be maximally reinforcing. Philip Morris also argues that its research does not establish that acetaldehyde is addictive.

Regardless of whether Philip Morris has increased the acetaldehyde levels in its cigarettes, its research on acetaldehyde is further evidence of the company's understanding of the reinforcing properties of cigarettes and the steps it has taken to exploit those properties. In fact, there is some evidence that acetaldehyde levels in Philip Morris products have increased since 1982, the year that Philip Morris conducted its

⁹⁰⁷ DeNoble VJ, Carron L (Philip Morris Inc.), *Progress in Behavior Pharmacology Laboratory* (Mar. 27, 1981), at 1-32. See AR (Vol. 32 Ref. 541). There is no evidence that Philip Morris tested these analogues to ensure that they produced the same "taste" as nicotine.

⁹⁰⁸ DeNoble VJ (Philip Morris Inc.), *Project Number 1610 (Behavior Pharmacology) Objectives and Plans 1982-1983* (Jul. 20, 1982), at 2. See AR (Vol. 345 Ref. 5443).

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reinforcement research. According to a report in the *Wall Street Journal*, a competing tobacco company that analyzed Marlboro King Size cigarettes found that acetaldehyde levels in that brand had increased 40% between 1982 and 1991.⁹⁰⁹

Although a determination that acetaldehyde is a positive reinforcer is not equivalent to a finding that it is addictive, it is one of the most critical pieces of evidence that a substance is addictive. For a complete description of the role of reinforcement in addiction, see section II.A.3.c., above. Philip Morris' research into acetaldehyde's use as a multiplier of the reinforcing effects of nicotine provides evidence of Philip Morris' intent to deliver a reinforcing drug.

3. Philip Morris disputes William Farone's statement that designing cigarettes with reduced tar but an acceptable level of nicotine was a key objective of the tobacco industry. Philip Morris makes a series of arguments that purport to explain why the tar and nicotine levels in marketed cigarettes have not been reduced proportionately. The company argues that the "physics" of the filter technologies used to reduce tar and nicotine do not reduce these two constituents to the same degree, resulting in a slight increase in the nicotine-to-tar ratio, and that the Merit Ultra Lights brand of cigarettes is not an example of manipulation of nicotine-to-tar ratios.⁹¹⁰

Neither of these arguments challenges Farone's statement that the tobacco industry conducted extensive product development *research* on how to reduce tar while maintaining a level of nicotine that provides the consumer with the same "pharmacological

⁹⁰⁹ Freedman AM, Fine tuning Marlboro, *Wall Street Journal*, (Oct. 18, 1995). See AR (Vol. 533 Ref. 102).

⁹¹⁰ Philip Morris Inc., Comment (Apr. 19, 1996), at 61-62. See AR (Vol. 700 Ref. 226).

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satisfaction” as full strength cigarettes.⁹¹¹ Philip Morris’ arguments with respect to the methods used to control nicotine-to-tar ratios are addressed in sections II.C.4., above, and section II.C.6.c.ii., below.

Tobacco industry comments also state that Farone fails to acknowledge that, beginning in the 1970’s, outside scientists recommended that research be conducted on the development of a high nicotine/low tar cigarette. This argument has already been addressed above in section II.C.3.f. In this context, FDA notes that Farone is reporting on the tobacco industry’s *internal* reasons for conducting the research, and these reasons are relevant to establishing the companies’ intent to affect the structure or function of the body.

4. Philip Morris challenges the reliability of statements made in a declaration submitted to FDA by Ian L. Uydess, a research scientist who worked for Philip Morris from 1977 to 1981, and from 1982 to 1989. Uydess’ declaration is based on his own participation in research and development projects at Philip Morris; his personal observations of activities in other parts of the company; his attendance at meetings and discussions held among the scientists, engineers and management at Philip Morris; and his close association with other scientists and senior management at Philip Morris.⁹¹² Philip Morris argues that the information provided by Uydess is unreliable because: (1) he left Philip Morris seven years ago; (2) he did not work on the development of commercial cigarettes; and (3) his declaration reports, in part, on information relayed to him informally

⁹¹¹ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 7. See AR (Vol. 638 Ref. 2).

⁹¹² Declaration of Uydess IL (Feb. 29, 1996), at 5. See AR (Vol. 638 Ref. 1).

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by colleagues. In contrast, other comments argue that the reliability of Uydess' statement is shown by its consistency with the statement of other former tobacco company officials.

FDA disagrees that Uydess' declaration is unreliable or irrelevant to establishing the knowledge and actions of Philip Morris. His position and tenure at the company gave him personal knowledge of the views of Philip Morris officials on the role of nicotine in cigarettes, and of the company's research and actions in developing new products. Moreover, like Farone, Uydess' statements about the knowledge, views, and actions of Philip Morris are consistent with a large body of Philip Morris documents and statements, covering over three decades. Uydess' statements are also consistent with the recent Philip Morris document concerning Project Table, demonstrating that the company's views have not changed since Uydess left the company. The information he provided is thus corroborated by evidence already gathered by FDA.

5. Philip Morris also challenges particular statements made by Uydess in his declaration. FDA addresses those comments that challenge statements relied on by the Agency.

Philip Morris argues that Uydess' statement that Philip Morris conducted exhaustive research on nicotine chemistry in tobacco leaf and tobacco smoke is true but irrelevant because: (1) any manufacturer in the business of selling an agricultural product develops expertise in the product; (2) tobacco chemistry is widely studied outside Philip Morris; and (3) the company's research was not used to increase artificially the nicotine yield of its commercial cigarettes.

FDA disagrees that extensive research by a tobacco manufacturer into the amount of nicotine in tobacco leaf and tobacco smoke—using highly sophisticated equipment

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developed, in part, by the company—is irrelevant to the manufacturer’s intent in selling cigarettes. Philip Morris’ arguments suggest that Uydess’ statement relates to the company’s research on tobacco chemistry in general, rather than to any specific component in tobacco. Uydess says, however, that Philip Morris’ exhaustive research related specifically to nicotine and that Philip Morris “wanted to know everything there was to know about nicotine.”⁹¹³ The intensity of Philip Morris’ focus on nicotine provides evidence that the company knows that nicotine is central to the success of its products.

Philip Morris’ public position is that if nicotine is important, it is important, like flavorants, only for its sensory appeal. The company, however, offers no evidence or argument that its exhaustive research on nicotine pharmacology is matched by its research on any other flavor or sensory aspects of nicotine. Moreover, as described in section II.C.2.a., above, Philip Morris’ public position is contradicted by the views of its scientists, who have repeatedly stated that the primary reason for smoking is nicotine’s pharmacological effects. FDA concludes that the extent of Philip Morris’ research on nicotine is relevant to establishing its intent to affect the structure or function of the body.

ii. Comments on Specific RJR Product Research and Development Projects.

1. RJR contends that Premier and Eclipse are not “alternative cigarettes” but conventional cigarettes, and that they were created to address public criticisms of cigarettes. RJR also disputes FDA’s findings that Premier contained very little tobacco and that the nicotine in blood studies conducted on Premier show that RJR intended Premier to deliver nicotine to the smoker’s blood and brain.

⁹¹³ *Id.* at 14.

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RJR's arguments concerning Premier and Eclipse are not persuasive. RJR now claims that Premier was a conventional cigarettes because it was a "roll of tobacco wrapped in paper"; "contained sugars, humectants, flavorings, tobacco paper, and a filter"; was "taxed as a cigarette"; and was "marketed for smoking taste and pleasure."⁹¹⁴ In fact, Premier resembled a conventional cigarette in outward appearance only. It contained a carbon tip that served as the heat source. A nicotine source had been combined with glycerol and adsorbed within alpha-alumina spheres contained within an aluminum cylinder positioned directly behind the carbon heat source. RJR informed FDA that at least 70% of the nicotine delivered by Premier was provided from spray-dried tobacco. The remaining nicotine was provided from the cut tobacco leaf surrounding this cylinder and the tobacco extract-treated paper filter positioned in front of the cellulose acetate filter.⁹¹⁵ Although there was a small amount of tobacco in Premier, it was not burned; the only component of Premier that was burned was the carbon heat source and some paper, to "simulate[] the ash of other cigarettes."⁹¹⁶

The critical aspect of Premier is the fact that the major constituents of its smoke differed from those in the smoke of conventional cigarettes in almost every way except nicotine content.⁹¹⁷ In other words, virtually the only constituent of tobacco smoke that RJR designed Premier to preserve was nicotine.

⁹¹⁴ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), 35. See AR (Vol. 519 Ref. 103).

⁹¹⁵ Letter with enclosures from Hutt PB, outside counsel for RJR, to Budich KM, FDA (Jan. 26, 1988). See AR (Vol. 34 Ref. 556).

⁹¹⁶ R.J. Reynolds Tobacco Co., *Chemical and Biological Studies on New Cigarette Prototypes That Heat Instead of Burn Tobacco* (Winston-Salem NC, 1988), at 4. See AR (Vol. 107 Ref. 980).

⁹¹⁷ *Id.* at 134-136.

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FDA does not contest that Premier was developed to address criticisms of cigarettes; undoubtedly, Premier was an attempt to make a safer cigarette. However, making a safer cigarette would not require the company to maintain a near-normal nicotine delivery, or to ensure that the nicotine was actually delivered to the smoker's blood in the same quantity as from conventional cigarettes, unless the company believed that ensuring near-normal nicotine blood levels was an essential feature of a profitable cigarette. RJR's argument that its pharmacokinetic comparisons of the nicotine levels delivered by Premier and a conventional cigarette were intended simply as comparisons of the two products, apparently without any further purpose, is unpersuasive. According to RJR's publication summarizing the studies conducted on Premier, RJR did not conduct similar pharmacokinetic studies on the delivery of any other smoke constituent to the smoker's blood.⁹¹⁸ This fact demonstrates that RJR believes that nicotine is the defining ingredient of cigarettes and that delivery of an adequate level of nicotine to the smoker's blood is central to the success of its products.

The RJR nicotine blood level study is also directly at odds with the company's public position that nicotine's role is limited to providing taste or flavor. The amount of nicotine delivered into a smoker's bloodstream is irrelevant to nicotine's ability to function as a flavoring agent. Nicotine absorption into the bloodstream is relevant only if the company believes that nicotine delivers pharmacological effects to the smoker and that these effects are important to the use of the product. RJR's reliance on a Surgeon General recommendation that cigarettes with low tar-to-nicotine ratios be evaluated for their

⁹¹⁸ *Id.* at 457-557.

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pharmacological properties and effects on compensation⁹¹⁹ merely underscores RJR's understanding that the nicotine in cigarettes delivers pharmacological effects and that consumers use cigarettes for these effects.

RJR's last argument, that its study was necessary because an FDA representative later asked whether nicotine was delivered by Premier in amounts comparable to conventional cigarettes, is similarly unavailing. As RJR acknowledges in its comment, the study had already been conducted at the time FDA asked the question. Moreover, FDA asked this question because FDA saw the delivery of nicotine to the blood of smokers as relevant to whether Premier should be regulated as a drug or device.

2. RJR also argues that FDA has misused an RJR book on tobacco flavors in the Jurisdictional Analysis. FDA noted that the book, which contains over one thousand flavorants for tobacco, does not list nicotine as a flavorant.⁹²⁰ RJR contends that the book describes only flavors that could be added to tobacco, and nicotine is not listed because RJR does not add nicotine.

FDA does not find RJR's argument persuasive. Even if the book were limited to flavors that "could be added" to tobacco (a limitation that is not stated in the book itself), the claim that RJR does not use it as an additive would not logically exclude it from the category of substances that "could" be added. The book does not purport to list only those substances that are actually added by RJR to its tobacco products.

⁹¹⁹ Department of Health and Human Services, *The Health Consequences of Smoking: The Changing Cigarette, A Report of the Surgeon General*, 1981, at 58. See AR (Vol. 123 Ref. 1586).

⁹²⁰ Leffingwell JC, Yound HJ (R.J. Reynolds Tobacco Co.), *Tobacco Flavoring for Smoking Products* (Winston-Salem NC: R.J. Reynolds Tobacco Co., 1972). See AR (Vol. 34 Ref. 591).

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Moreover, RJR's claim that it does not add nicotine raises an inconsistency. If it is the company's position that nicotine is benignly used (and controlled) in tobacco solely for its effects on flavor, and is an extremely important flavorant in tobacco, why have a policy—as RJR claims⁹²¹—of not adding it when appropriate? The book does list many other naturally occurring components of tobacco and tobacco smoke as flavorants, apparently contemplating their addition to tobacco. That RJR policy in itself therefore seems at odds with the claim that nicotine is used for flavor.

3. RJR also maintains that FDA's reliance on an RJR patent was misplaced. In the Jurisdictional Analysis, FDA cited an RJR patent for a process that increases the nicotine content of a cigarette but masks the resulting harsh taste of the cigarette.⁹²² FDA used the patent to show that the tobacco industry wanted to increase nicotine in some cigarettes *despite* its harsh flavor. RJR dismisses the significance of this patent, arguing that FDA has ignored "basic principles of flavor" and that people like harsh flavors. RJR also argues that the patent is irrelevant because the process it described for increasing nicotine and masking the resulting flavor was not used in commercial cigarettes.

RJR's argument is contradicted by its own patent and by the statements of a flavor specialist employed by the company. Both acknowledge that nicotine's harsh flavor can be unpleasant to the smoker and must be masked by the addition of sugars or other chemicals. The patent itself demonstrates that the company, as the assignee of the patent, knows that increasing nicotine past a certain point in low-tar cigarettes produces a harshness that leads to

⁹²¹ R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 50. See AR (Vol. 519 Ref. 103).

⁹²² U.S. Patent No. 4,830,028. Lawson JW, Bullings BR, Perfetti TA, R.J. Reynolds Tobacco Company, *Salts Provided from Nicotine and Organic Acid as Cigarette Additives* (May 16, 1989), at C1. See AR (Vol. 34 Ref. 593).

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rejection by consumers. Rather than simply keep nicotine below that point, as a company would do if nicotine were present solely for flavor, the patent describes a process for increasing nicotine and simultaneously masking its harshness. The claim that the processes in the patent were not used does not in any way undercut FDA's conclusion that the patent demonstrates RJR's knowledge that nicotine's effects on taste are sometimes negatively related to product acceptance, and RJR's desire to increase nicotine content even beyond the point where nicotine has a demonstrably negative effect on taste.

Moreover, an RJR flavor specialist has written that although nicotine is necessary for "satisfaction," its flavor in some tobacco blends is "a 'harshness' which can be choking and unpleasant," requiring that steps be taken to mask nicotine's flavor.⁹²³

Thus, it is clear that RJR officials recognize that nicotine's flavor is sometimes a liability that must be masked to permit nicotine to fulfill its pharmacological functions.

4. RJR comments that a document that refers to "physiological satisfaction," which FDA cited as an RJR Marketing Report, is in fact an Imperial Tobacco Co. document.⁹²⁴

FDA agrees that this document is an Imperial Tobacco Co. document rather than an RJR document. The document is one of dozens of tobacco industry documents in which the term "satisfaction" is used to describe a pharmacological effect. It is therefore relevant to establishing the industry's understanding and use of that term.

⁹²³ Leffingwell JC (R.J. Reynolds Tobacco Co.), Nitrogen components of leaf and their relationship to smoking quality and aroma, presented at the 30th Tobacco Chemists' Research Conference, at 9. See AR (Vol. 28 Ref. 450).

⁹²⁴ Imperial Tobacco Ltd., *Matinee Marketing Strategy* (1971) ("A cigarette that delivers physiological satisfaction, yet is low in tar and nicotine, must surely be a major objective"), quoted in Memorandum to File from Joyal C (Dec. 27, 1992), at 11. See AR (Vol. 27 Ref. 384).

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iii. Comments on Specific Brown & Williamson Product Research and Development Projects.

1. A comment from Brown & Williamson argues that FDA has distorted its nicotine research by not recognizing that the research was not commercialized. According to the comment, Project ARIEL was never commercialized.

ARIEL was an alternative cigarette, developed by Charles Ellis, and referred to by BATCO researchers as a “device[] for the controlled administration of nicotine.”⁹²⁵ ARIEL eliminated almost every ingredient of conventional cigarettes other than nicotine. Its purpose was to provide “the same benefits, pleasure and satisfaction without the disadvantages” of a conventional cigarette.⁹²⁶ The relevance of this product to intent is that it demonstrates that BATCO regarded nicotine as the essential ingredient in, and the source of the pleasure and satisfaction from, cigarettes. ARIEL’s development demonstrates Brown & Williamson’s knowledge of and belief in nicotine’s central role in cigarettes, regardless of its ultimate failure to be accepted by consumers, or Brown & Williamson’s decision not to market it.

2. As described above, a BATCO study entitled “Project Wheat” was conducted to determine the level of nicotine preferred by smokers and correlate it with the extent to which the smoker relies on cigarettes to meet “inner needs.”⁹²⁷ A smoker’s inner need level was defined by the extent to which the smoker used nicotine to relieve stress,

⁹²⁵ Minutes of BATCO Research Conference at Hilton Head Island, SC (Sep. 24–30, 1968), at 3. See AR (Vol. 31 Ref. 525).

⁹²⁶ U.S. Patent No. 3,258,015. Ellis CD, Dean C, Schachner H, *et al.*, Battelle Memorial Institute, *Smoking Device* (Jun. 28, 1966). See AR (Vol. 34 Ref. 569).

⁹²⁷ Wood DJ, Wilkes EB (BATCO), *Project Wheat - Part 1: Cluster Profiles of U.K. Male Smokers and their General Smoking Habits* (Jul. 10, 1975), at 1. See AR (Vol. 20 Ref. 204-1).

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aid concentration, avoid weight gain, or reduce craving. BATCO hypothesized that “the inner need dimension was probably defining a requirement for nicotine.”⁹²⁸ FDA pointed out that inner need therefore correlated with the extent to which a smoker used cigarettes for pharmacological effects. Project Wheat was intended to allow BATCO to market cigarettes with different nicotine levels designed to satisfy identified groups of consumers. Brown & Williamson argues that FDA had no basis for concluding that a smoker’s inner need was defined by the extent to which the smoker used cigarettes for the drug effects of nicotine, that Project Wheat failed to find any significant correlation between inner need levels and preferred nicotine delivery, that the term “inner need” came from an outside researcher, not BATCO, and that FDA falsely suggested that Project Wheat identified an allegedly “addictive” dose of nicotine.

Brown & Williamson’s attempts to discredit FDA’s characterization of Project Wheat are not persuasive. FDA relied on the study as evidence that Brown & Williamson had conducted research on the dose of nicotine required by consumers with the purpose of designing cigarettes to satisfy their nicotine requirements. Brown & Williamson acknowledges that Project Wheat was designed to determine whether smokers who smoked to satisfy an “Inner Need” had preferred nicotine delivery levels, and that this information was to be used to design cigarettes to meet their needs.⁹²⁹ These facts alone demonstrate that it was the tobacco company’s intention to produce cigarettes with satisfying doses of nicotine. (Nowhere did FDA state that the study was intended to establish “addictive” doses of nicotine.)

⁹²⁸ *Id.* at 5.

⁹²⁹ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 43–44. *See* AR (Vol. 529 Ref. 104).

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Moreover, both Project Wheat and other Brown & Williamson research demonstrate that the company knew that "Inner Need" level corresponded to the smoker's use of cigarettes for pharmacological effects. Project Wheat researchers concluded that future studies to design cigarettes with acceptable nicotine levels should classify smokers along a single dimension of inner need that might correspond to "pharmacological addiction":

[I]t would be preferable to position respondents along the single dimension of Inner Need. . . . the suggestion is very much in line with that made by Russell . . . who . . . concluded that *it might prove more useful to classify smokers according to their position on a single dimension of pharmacological addiction* rather than in terms of their profiles on the six types of smoking.⁹³⁰

Brown & Williamson's assertion that stress relief, aided concentration, and weight control are not among the principal pharmacological effects of nicotine is not credible. In fact, as early as 1962, Project HIPPO concluded that nicotine's most significant pharmacological benefits were its ability to relieve stress and to control weight gain.⁹³¹

Contrary to Brown & Williamson's argument, Project Wheat found a correlation between inner need level and preferred nicotine delivery.⁹³² Thus, the Project Wheat researchers concluded that inner need correlated with preferred nicotine delivery and agreed with Russell that inner need is related to pharmacological addiction.

⁹³⁰ Wood DJ (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 49 (citation omitted) (emphasis added). See AR (Vol. 20 Ref. 204-2).

⁹³¹ Haselbach CH, Libert O, *Final Report on Project HIPPO II* (Mar. 1963), at 2. See AR (Vol. 14 Ref. 163-1).

⁹³² Wood DJ (BATCO), *Project Wheat - Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Delivery as Influenced by Inner Need* (Jan. 30, 1976), at 47-48 ("High Need clusters tend to prefer relatively high nicotine cigarettes, and . . . their optimum nicotine delivery is certainly higher than is that of the Low Need clusters.") See AR (Vol. 20 Ref. 204-2).

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3. A comment from Brown & Williamson claims that the company has never marketed a product that used “elasticity” to enable smokers to compensate for lowered nicotine yields. The company concedes that internal documents show that “BATCO explored the possibility of using its knowledge of compensation in the development of low ‘tar’ products” but claims that these were only theoretical discussions.⁹³³

FDA relied, in part, on the industry’s product development research on increasing nicotine as evidence that the industry understands that tobacco satisfaction is a function of the pharmacological effects of nicotine and of the industry’s attempts, successful or not, to ensure that tobacco users receive sufficient nicotine to achieve those effects. FDA did not rely on this research as evidence that the researched products were marketed.

In fact, however, there is good reason to believe that Brown & Williamson, as well as other tobacco companies, have incorporated “elasticity” into their marketed products. For example, Brown & Williamson’s Barclay cigarettes were promoted as ultra-low cigarettes, with advertised deliveries of 1 mg tar and .02 mg nicotine, as measured by the FTC method. *Federal Trade Commission v. Brown & Williamson*, 778 F.2d 35, 37 (D.C. Cir. 1985). Philip Morris and RJR complained to the FTC that Barclay’s channel-ventilated filter system allowed the cigarette to produce low tar and nicotine yields when measured by the FTC (smoking machine) method, but to actually deliver far more tar and nicotine to the smoker. According to the complaint, the FTC smoking machine is able to “smoke” the cigarette without obstructing Barclay’s unique ventilation system, but “when the cigarette is smoked between human lips its air ventilation system is inevitably

⁹³³ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 42. See AR (Vol. 529 Ref. 104).

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obstructed and the cigarette delivers disproportionately more tar and nicotine than other comparably rated cigarettes.” *Id.* at 37.

The FTC brought an enforcement proceeding to enjoin Brown & Williamson from using the FTC tar and nicotine figures in Barclay advertisements. *Federal Trade Commission v. Brown & Williamson*, 580 F. Supp. 981 (D.D.C. 1983), *aff’d in part, rev’d in part*, 778 F.2d 35 (D.C. Cir. 1985). The district court found, and the Court of Appeals agreed, that use of the FTC tar and nicotine figures for Barclay was false and misleading, because—primarily as a result of its channel-ventilated filter system—Barclay delivers significantly more tar and nicotine to the smoker than indicated by the FTC yields. 580 F. Supp. at 989; 778 F.2d at 41-42. Thus, Barclay represents a clear example of the use of filter technology to provide elasticity, i.e., to enable the smoker to extract more nicotine from the smoke than the advertised yield.

Brown & Williamson argues that Barclay is not an example of a product designed to provide elasticity, and that there is no evidence to support FDA’s claim that the channel-ventilated filter boosts nicotine delivery. FDA disagrees. The district court opinion in *Federal Trade Commission v. Brown & Williamson* demonstrates that Barclay cigarettes deliver substantially more nicotine than their advertised yields and that this increase in nicotine delivery over the machine-tested yield is due to compromising the channel-ventilated filter during human smoking. The district court cited a study submitted by Brown & Williamson, which found that “smokers who smoked Barclay received approximately 1-1/2 to 2 times as much nicotine into their systems as smokers of the other cigarettes [with comparable FTC ratings] tested.” 580 F. Supp. at 988. The court also

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found that the increase in nicotine and tar deliveries was due to compromising the ventilation system under actual smoking conditions. 580 F. Supp. at 989.

The conclusion that Barclay was designed to provide elasticity is also supported by evidence that Barclay was reported to contain significantly more nicotine than comparable cigarettes. As described above in section II.C.4., an independent study conducted in 1982 showed that Barclay had both the highest nicotine concentration and the most total nicotine in the rod of all the cigarette brands tested, including regular strength (high tar/high nicotine) cigarettes.⁹³⁴ Compared to the other cigarettes with comparable FTC nicotine ratings (≤ 0.2 mg nicotine, as published in 1981 FTC Report) that were tested, Barclay contained a tobacco blend with a 50% to 95% higher nicotine concentration, and 20% to 85% more total nicotine. Thus, while Barclay had among the lowest FTC yields, it delivered a significantly higher level of nicotine during human smoking because (1) it contained more nicotine than any comparable cigarette, and (2) the nature of the filter permitted smokers to defeat the ventilation system and obtain substantially more nicotine than the advertised yield (1-1/2 to 2 times the nicotine of comparable cigarettes, according to Brown & Williamson's own study).

iv. Other Comments.

1. Comments from the tobacco industry argue that the tobacco company studies cited by FDA do not support the finding that smokers compensate. One comment argues that Brown & Williamson and BATCO researchers did not acknowledge that

⁹³⁴ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives, 103d Cong., 2d Sess. 173 (Jun. 23, 1994) (data from Neal Benowitz). See AR (Vol. 709 Ref. 3).*

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smokers compensate to obtain a dose of nicotine that satisfies a physiological need. This comment does concede, however, that it is “hardly news” that “the phenomenon of compensation was internally ‘recognized’ or ‘acknowledged’ by tobacco manufacturers.”⁹³⁵ This comment also argues that reductions in tar and nicotine yields have resulted in reductions of the amount of nicotine obtained by smokers. On the other hand, a comment from a public health organization provided additional examples of industry statements and research on compensation.⁹³⁶

FDA has reviewed the studies relied on in this section of the Jurisdictional Analysis and concludes that they provide a wealth of evidence that the tobacco industry understands that smokers compensate to obtain a desired dose of nicotine. The contention that these studies fail to demonstrate compensation cannot be supported. For example, BATCO researchers stated in 1984 that “it is accepted that nicotine is both the driving force and the signal (as impact) for compensation in human smoking behavior.”⁹³⁷

A large number of additional industry studies cited by FDA found that compensation occurred to one degree or another. *See* Jurisdictional Analysis, 60 FR 41659–41666. Throughout these studies and conference reports, tobacco company officials consistently recognize that compensation behaviors occur to adjust nicotine dose. The public health organization comment provided several additional examples of tobacco industry acknowledgment that compensation occurs because smokers are attempting to

⁹³⁵ Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 40. *See* AR (Vol. 529 Ref. 104).

⁹³⁶ American Society of Addiction Medicine, Comment (Dec. 29, 1995), Table 6. *See* AR (Vol. 528 Ref. 97).

⁹³⁷ Minutes of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III (Jul. 9-12, 1984), at 56. *See* AR (Vol. 25 Ref. 325-1).

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maintain their customary nicotine dose. For example, a 1981 monograph on nicotine published by the Tobacco Advisory Council (an industry organization of which BATCO was a member) reviewed the evidence on compensation and concluded that while regulation of nicotine intake is not consistently seen in every study:

Human subjects appear to modify their smoking behaviour to maintain the total dosage of nicotine when they smoke cigarettes of varying nicotine content. . . . Studies of nicotine antagonists indicate that smokers seek an effective brain level of nicotine when modifying their smoking behaviour.⁹³⁸

Accordingly, the industry's research amply supports FDA's conclusion that the tobacco industry knows that smokers use cigarettes to "compensate"—to obtain desired doses of nicotine.

2. One comment from a tobacco manufacturer argues that "much" of the nicotine-related research did not result in alterations to marketed products, and a comment from another cigarette manufacturer argues that its product development research did not result in the addition of "extraneous nicotine."

The claim that some of the industry's research did not result in changes to commercial-marketed products does not alter the relevance of the industry's research to establishing manufacturers' awareness of the pharmacological effects of nicotine. As noted above, the knowledge produced by the research is evidence of intended use. Moreover, there is a great deal of evidence that the knowledge was acted upon. Even the industry comments do not claim that none of the research was acted upon. For example, the brands of cigarettes advertised as lowest in tar and nicotine have the highest

⁹³⁸ Cohen AJ, Roe JC (Tobacco Advisory Council), *Monograph on the 'Pharmacology and Toxicology of Nicotine'* (1981), at 38 (citation omitted). See AR (Vol. 34 Ref. 583).

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concentrations of nicotine on the market, reflecting industry to ensure that nicotine levels in low-yield products do not fall below minimum levels that consumers will accept. *See* section II.C.4.a., above.

Finally, the argument that none of the product development research resulted in the addition of “extraneous nicotine” to commercial cigarettes is irrelevant to establishing intended use. Whether or not this statement is true, the research, in and of itself, establishes the knowledge of tobacco manufacturers that nicotine delivery is essential to the success of their products. In addition, the evidence shows that nicotine has actually been manipulated in commercial cigarettes, demonstrating that tobacco manufacturers have not merely researched but have taken affirmative steps to ensure the delivery of an adequate dose of nicotine. *See* Jurisdictional Analysis, 60 FR 41693–41733. It is the fact that the industry has manipulated nicotine delivery, rather than the manner in which it is accomplished, that is relevant to establishing the intended use of these products.

c. Comments on Nicotine Manipulation and Control

i. Comments on the Use of High-Nicotine Blends in Low-Yield Cigarettes.

1. The cigarette manufacturers contend that the use of high-nicotine blends in low-tar cigarettes does not affect the nicotine delivery of these cigarettes. According to the manufacturers, the increase in nicotine from the use of high-yield blends is more than offset by other design features, such as a reduction in the total mass of tobacco in the cigarette and increased filtration and ventilation.

The Agency disagrees. It is beyond reasonable dispute that the use of high-nicotine blends does affect nicotine deliveries. Indeed, the joint comment of the manufacturers acknowledge this point. The comment concedes that “nicotine content of

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the leaf” is one of the “*factors that determine the nicotine yield in the cigarette smoke.*”⁹³⁹

Of the four factors that the comment lists as determining nicotine yield, two of the factors —“the blend itself” and “the percentage of processed tobaccos”⁹⁴⁰—relate directly to the concentration of nicotine in the cigarette rod. Similarly, Alexander Spears, the vice chairman and chief operating officer of Lorillard, has acknowledged that among other factors, “*the nicotine yield of a cigarette is determined by the nicotine content of the tobacco.*”⁹⁴¹

Although it may be true that other design features of low-tar cigarettes reduce nicotine deliveries, the use of high-nicotine blends is designed to *offset* those reductions. Thus, high-nicotine blends result in higher nicotine deliveries than would be provided by a low-tar cigarette that did not use such blends.

Moreover, the nicotine yields measured on an FTC smoking machine do not accurately predict the amount of nicotine that will be inhaled and absorbed by smokers because smokers of low-yield products frequently compensate for the low nicotine deliveries by inhaling more deeply or puffing more frequently. *See Jurisdictional Analysis*, 60 FR 41573–41574. The use of higher nicotine blends in low-yield cigarettes increases the total amount of nicotine that is available to be extracted by smokers.

⁹³⁹ Joint Comment of Cigarette Manufacturers, Comment, (Jan. 2, 1996), Vol. IV, at 69 (emphasis added). *See* AR (Vol. 535 Ref. 96).

⁹⁴⁰ *Id.* at 70.

⁹⁴¹ Spears AW (Lorillard Tobacco Co.), *Factors Affecting Smoke Delivery of Nicotine and Carbon Monoxide*, presented at the 1975 Symposium-Nicotine and Carbon Dioxide (Nov. 17-18, 1975), in *Symposium Proceedings-1*, 12-18, at 13 (emphasis added). *See* AR (Vol. 27 Ref. 395a).

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2. Brown & Williamson's comments concede that it used Y-1, a high-nicotine tobacco, in marketed cigarettes. The comments assert, however, that Y-1 "was never used by B&W for the purpose of altering the ratio of nicotine to tar in the smoke of any commercialized brands."⁹⁴² What is beyond dispute, however, is the original purpose of the creation of Y-1. As described in section II.C.3.c.iii., Brown & Williamson developed Y-1 as a "blending tool" so that it could maintain nicotine levels while tar levels dropped. Y-1 is thus a central example of product research and development to enhance nicotine deliveries.

ii. Comments on Nicotine Deliveries and Nicotine-to-Tar Ratios.

1. The cigarette industry asserts in its comments that the reduction in the nicotine delivery of cigarettes over the last 40 years demonstrates that the industry has not sought to control or manipulate nicotine. According to the industry, nicotine deliveries have dropped by 60% over the last 40 years. The industry maintains that the fact that cigarette manufacturers have reduced nicotine deliveries shows that the manufacturers do not control or manipulate nicotine deliveries to provide a pharmacologically active dose of nicotine.

The Agency agrees that nicotine deliveries as measured by smoking machines have declined over the last 40 years. This comparison is misleading, however. The recent trends show that nicotine deliveries have stopped declining and are, in fact, *increasing* — especially in low-tar cigarettes. From 1982 to 1991, the nicotine deliveries in the lowest-tar category of cigarettes increased approximately 15%. *See* Jurisdictional Analysis, 60

⁹⁴² Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 32. *See* AR (Vol. 529 Ref. 104).

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FR 41731. Although the industry maintains that “[n]icotine levels follow the tar level” in “essentially perfect correlation”⁹⁴³ and that this correlation shows that the industry does not manipulate nicotine,⁹⁴⁴ nicotine deliveries did not follow tar deliveries during this period. Rather, while nicotine deliveries were increasing from 1982 to 1991, tar deliveries declined or remained essentially flat.⁹⁴⁵

The recent trend of increasing nicotine deliveries in low-tar cigarettes supports the Agency’s finding that the cigarette manufacturers have controlled and manipulated nicotine to maintain a pharmacologically active dose. The trend is evidence that as tar deliveries dropped to low and ultra-low levels in the late 1970’s and the 1980’s, the manufacturers took steps to maintain a pharmacologically active nicotine dose by enhancing nicotine deliveries.

The overall trend in nicotine deliveries is also fully consistent with—and indeed corroborates—the Agency’s position. Forty years ago, cigarettes delivered over 2.5 mg of nicotine per cigarette.⁹⁴⁶ According to tobacco industry documents, however, nicotine deliveries as low as 0.5 to 0.8 mg per cigarette “provide sufficient nicotine to the blood to produce the stimulation and relaxation effects desired by the smoker.”⁹⁴⁷ Thus, nicotine

⁹⁴³ *Regulation of Tobacco Products (Part I), Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 378 (Mar. 25, 1994) (statement of Alexander Spears). See AR (Vol. 707 Ref. 1).

⁹⁴⁴ *Id.*

⁹⁴⁵ From 1982 to 1991, nicotine deliveries increased in ultra-low-tar, low-tar, and high-tar cigarettes. Tar deliveries, however, decreased in the high-tar and low-tar categories and increased only marginally (approximately 3%) in the ultra-low-tar category. See Jurisdictional Analysis, 60 FR 41728-41731.

⁹⁴⁶ Joint Comment of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. III, “Sales Weighted Average ‘Tar’ and Smoke Nicotine” Graph. See AR (Vol. 535 Ref. 96).

⁹⁴⁷ Senkus M (R. J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 12 (emphasis added). See AR (Vol. 700 Ref. 593).

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deliveries could be reduced significantly from 1956 levels without interfering with the ability of cigarettes to satisfy smokers' addiction and to provide other desired pharmacological effects of nicotine.

Once nicotine deliveries neared the minimum thresholds identified by the cigarette manufacturers, however, the manufacturers reversed course and began to enhance nicotine deliveries. As the tobacco industry documents in the record indicate, the industry feared that at these low levels, cigarettes might not deliver sufficient nicotine to smokers. *See* section II.C.3., above. Consequently, the cigarette manufacturers began to take measures to raise nicotine deliveries, such as using nicotine-rich tobacco blends in ultra-low tar cigarettes. *See* section II.C.4., above. The trend of increasing nicotine deliveries since 1982 reflects these actions.

Moreover, the Agency disagrees with the manufacturers that efforts to enhance nicotine deliveries will necessarily be reflected in the nicotine deliveries measured by smoking machines. To the contrary, the evidence in the record indicates that some of the methods used by the cigarette manufacturers to enhance nicotine deliveries are *not* reflected in the measured nicotine deliveries. The use of "elasticity" technologies, such as ventilation systems that can be blocked by smokers, is one example. As described in section II.C.4.b, these technologies are designed to allow smokers to inhale more nicotine than would be measured by a smoking machine. Similarly, the use of ammonia technologies to liberate "free" nicotine, which is described in section II.C.4.c., has effects

BATCO and Philip Morris researchers reached similar conclusions. According to one BATCO research study, a smoker's "nicotine requirement" is "about 0.8 mg per cigarette." Notes on the BATCO Group R&D Conference at Duck Key, FL (Jan. 12-18, 1974), at 2. *See* AR (Vol. 25 Ref. 327). Likewise, Philip Morris researchers recognized that "[t]he physiological response to nicotine can readily be elicited by cigarettes delivering in the range of 1 mg of nicotine." Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 4. *See* AR (Vol. 12 Ref. 133).

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on nicotine absorption that are not reflected in the nicotine levels measured by a smoking machine.

2. The cigarette industry criticizes various aspects of FDA's methodology in calculating nicotine deliveries. The industry's comments assert that these alleged methodological problems make FDA's findings of increased nicotine deliveries unreliable.

The Agency disagrees with these comments. The industry itself acknowledges in its comments that nicotine deliveries have increased among the lowest-tar cigarettes.⁹⁴⁸ This acknowledgment renders most of the industry's specific methodological objections irrelevant because it confirms the Agency's finding that nicotine deliveries have increased in the ultra-low-delivery category.

Moreover, the specific methodological comments of the cigarette industry are not well founded, as discussed below.

First, the cigarette industry is mistaken when it argues that FDA chose to use 1982 as its reference year to distort the trends in nicotine deliveries. FDA did not calculate these deliveries. Rather, these figures were calculated by the Federal Trade Commission (FTC), which annually reports tar and nicotine data for cigarettes. The FTC began its analysis in 1982 because this was the first year in which computer-readable data was available in the FTC files.

Second, the cigarette industry is mistaken when it suggests that the FTC did not follow the approach recommended by the Surgeon General for calculating sales-weighted tar and nicotine deliveries. In fact, the FTC followed this approach.

⁹⁴⁸ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. III, at 206. See AR (Vol. 535 Ref. 96).

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Third, FDA disagrees that brand shifting accounts for the increase in nicotine deliveries observed in the data. Brand shifting is unlikely to significantly affect reported average deliveries because brand shifts can occur in both directions (and so tend to cancel each other out) and because no single variety of cigarettes has a sufficient proportion of the sales to affect category averages.

Moreover, the data are inconsistent with the industry's brand-shifting theory. The data show that tar deliveries have either declined slightly (high- and low-tar categories) or increased slightly (ultra-low-tar category), while nicotine deliveries have increased significantly in these categories. If brand shifting was in fact causing the rise in nicotine deliveries in the three categories, tar deliveries should have risen similarly, which they did not. Most significantly, brand shifting cannot explain the increase in nicotine deliveries that was observed when all brands (from all three categories) were averaged together.

Fourth, FDA disagrees that normal analytical variation explains the observed increases in nicotine deliveries. The statistical chance that analytical variation could explain the results is vanishingly small. To begin with, the laboratory equipment used to measure nicotine and tar yields produces generally consistent results. The equipment has 20 ports, four of which are dedicated to measuring the tar and nicotine content of "monitor cigarettes" to guard against any "drifting" of the equipment.

Moreover, the trends reported by FDA from the FTC data reflect the results of literally tens of thousands of individual measurements of cigarettes. The reported tar and nicotine yield for any specific cigarette variety in a given year is the average of the test results of 100 individual cigarettes. The average tar and nicotine yields for all cigarette varieties in a given yield category, such as low-yield cigarettes, is the average of the

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reported tar and nicotine yields for each cigarette variety in the category. Any analytical variation in the testing of individual cigarettes will have at most a very small effect on the averages reported from so large a sample size.

Fifth, the questions raised by the industry regarding the origin of the sales-weighted data are groundless. The data for 1984, 1985, and 1986 came from the FTC. Although the FTC may not have issued a report on tar and nicotine deliveries for each of those years, the FTC informed the Agency that it did nonetheless collect tar and nicotine data for these years. The 1991 and 1992 data do use information from slightly fewer brands than the brands listed in the FTC's published reports for those years; however, the explanation is that the FTC did not have tar, nicotine, and sales data for every single brand listed in the published reports. Only those brands for which data were missing were eliminated by the FTC in calculating the sales-weighted averages. The sales data used by the FTC to calculate the sales-weighted averages came from the tobacco manufacturers.

Finally, contrary to the industry's assertion, FDA did put the data and analysis it relied upon in the administrative record.⁹⁴⁹

Thus, contrary to the comments of the industry, FDA finds that a reasonable methodology was used to calculate nicotine deliveries.

3. Philip Morris asserts that it has few cigarettes with an enhanced nicotine/tar ratio of 0.10, compared to the naturally occurring ratio of 0.07. The company argues that this is evidence that it does not design its cigarettes to enhance nicotine deliveries. Philip Morris further asserts that two Philip Morris brands with nicotine/tar ratios of

⁹⁴⁹ See Letter from Schultz WB (FDA), to Merrill R (Covington & Burling) (Dec. 27, 1995). See AR (Vol. 711 Ref. 7).

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approximately 0.10 analyzed by Rep. Henry A. Waxman and cited by FDA (Merit Ultima and regular Benson & Hedges filtered cigarettes) do not reflect intentional nicotine manipulation.

The Agency disagrees that cigarettes with an elevated nicotine/tar ratio of 0.10 are uncommon. In 1995, for instance, over 90 varieties of cigarettes had a nicotine/tar ratio of 0.10 or higher.⁹⁵⁰ Particularly among ultra-low-tar cigarettes, there are many examples of cigarettes with relatively enhanced nicotine deliveries and nicotine/tar ratios. Over 40% of cigarettes with tar deliveries of 5 mg or less have an enhanced nicotine/tar ratio of 0.10 or greater.⁹⁵¹ One example is the Merit Ultima, which is manufactured by Philip Morris and has a nicotine/tar ratio of 0.10.⁹⁵² Other examples are RJR's Winston Ultra Lights 100's and king-size Camel Ultra Lights, which have tar deliveries of 0.5 mg and nicotine deliveries of 0.5 mg, resulting in a nicotine/tar ratio of 0.10.⁹⁵³ The deliveries of nicotine and tar in the Winston Ultra Lights 100's and the king-size Camel Ultra Lights are exactly the deliveries that RJR researchers recommended to produce "a low tar value" while "maintaining the nicotine as high as possible."⁹⁵⁴ The existence of low-tar cigarettes with relatively elevated nicotine deliveries is compelling evidence that cigarette manufacturers design these cigarettes to provide enhanced nicotine deliveries.

⁹⁵⁰ Federal Trade Commission, *Report of "Tar," Nicotine, and Carbon Monoxide of the Smoke of 1107 Varieties of Domestic Cigarettes* (1995). See AR (Vol. 535 Ref. 96, vol. IV.B).

⁹⁵¹ *Id.*

⁹⁵² *Id.*

⁹⁵³ *Id.*

⁹⁵⁴ Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 10. See AR (Vol. 700 Ref. 593).

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Moreover, even if no ultra-low-tar cigarettes had a nicotine/tar ratio of precisely 0.10, this would prove very little. As discussed in section II.C.3.a., Philip Morris' product development efforts concluded that "the optimum nicotine to tar . . . ratio for a [low-delivery] cigarette is *somewhat higher* than that occurring in smoke from the natural state of tobacco."⁹⁵⁵ This research did not conclude that the "somewhat higher" ratio had to be a ratio of 0.10 (which is more than 40% higher than the "natural ratio" of 0.07) or greater. Consistent with Philip Morris' product development recommendations, most of the lowest-yield cigarettes do in fact have "somewhat higher" nicotine/tar ratios of 0.08 or greater. *See* Jurisdictional Analysis, 60 FR 41724.

The Agency rejects Philip Morris' claim that the enhanced nicotine/tar ratio of 0.10 in Merit Ultima can be explained by "the physics of low-yield filtration and ventilation."⁹⁵⁶ FDA's own analysis has shown that the Merit Ultima uses a blend richer in nicotine than the blends used in either the Merit Filter 100's or the Merit Ultra Lights. *See* Jurisdictional Analysis, 60 FR 41723–41724. This deliberately chosen nicotine-rich blend contributes to the elevated nicotine/tar ratio in the Merit Ultima—apart from any effects of filtration or ventilation. *See* section II.C.4.a.ii. Moreover, to the extent that filtration and ventilation contribute to the elevated nicotine/tar ratio, this effect is the result of deliberate design decisions. *See* section II.C.4.b.

The Agency is also not persuaded that the enhanced nicotine/tar ratios in the regular Benson & Hedges filtered cigarettes can be dismissed as "minuscule variations" in

⁹⁵⁵ Jones B, Houck W, Martin P (Philip Morris Inc.), *Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication* (Oct. 1975), in 141 Cong. Rec. H8132 (daily ed. Aug. 1, 1995) (emphasis added). *See* AR (Vol. 711 Ref. 6).

⁹⁵⁶ Philip Morris Inc., Comment (Jan. 2, 1996), at 43. *See* AR (Vol. 519 Ref. 105).

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tar and nicotine deliveries. A statistical analysis of the cigarettes prepared for and released by Rep. Waxman concluded that the possibility that the cigarette's enhanced nicotine/tar ratio could be explained by random fluctuations in tar and nicotine levels was virtually zero.⁹⁵⁷

iii. Comments on Chemical Manipulation.

1. Comments from the tobacco industry acknowledge that cigarette manufacturers add ammonia compounds to tobacco. However, the comments argue that the addition of ammonia does not have pharmacological significance because virtually all nicotine in cigarette smoke is absorbed into the bloodstream regardless of the pH of the smoke; because substantial amounts of ammonia would be required to raise smoke pH from 6.0 to 7.5 or 8.0; and because ammonia compounds do not increase the efficiency of the transfer of nicotine from the tobacco to the smoke.

The Agency disagrees with these comments. They conflict with the evidence from the cigarette industry documents in the record, as well as with basic scientific principles.

The evidence in the record demonstrates that the cigarette manufacturers add ammonia compounds to cigarettes to produce several pharmacological effects. As described in the industry documents, the pharmacologically significant effects of adding ammonia compounds to tobacco are (1) to increase the transfer of nicotine from the cigarette to the smoke; (2) to increase the rate of nicotine absorption in the mouth; and (3) possibly to increase the speed of nicotine absorption in the lungs. *See* section II.C.4.c.

⁹⁵⁷ Statement of Waxman HA, 141 Cong. Rec. H8009 (daily ed. Jul. 31, 1995). *See* AR (Vol. 27 Ref. 376a).

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Each of these three effects of adding ammonia compounds is significant even if the industry were correct that the lungs absorb virtually all of the nicotine that is inhaled.⁹⁵⁸ The first effect—increasing the transfer of nicotine from the cigarette to the smoke—is significant because it increases the quantity of nicotine *delivered* to the lungs. Most of the nicotine in a cigarette never enters the mouth of a smoker. Rather, it is trapped in the filter; lost to the atmosphere; or destroyed or decomposed by the heat of the cigarette.⁹⁵⁹ According to the statement of Dr. Farone, the former Philip Morris Director of Applied Research, however, the effect of adding ammonia compounds is “to deliver more of the available nicotine in the blend to the smoker.”⁹⁶⁰ Documents from the American Tobacco Company make a similar point, asserting that the use of alkaline compounds will “increas[e] the amount of nicotine that is transferred from the tobacco to the mainstream smoke.”⁹⁶¹

The second effect is likewise significant regardless of the efficiency of nicotine absorption in the lungs. This effect is to increase the amount of nicotine that the smoker

⁹⁵⁸ In fact, it is not clear that the lungs absorb virtually all the nicotine that is inhaled. According to one researcher, “[d]epending on inhalation patterns, retention times, and related factors, smokers may retain anywhere from 30% or less up to 90% or more of the total nicotine generated and delivered via the inhaled smoke.” Huber GL, Physical, chemical, and biological properties of tobacco, cigarette smoke, and other tobacco products, *Seminars in Respiratory Medicine* 1989;10:297-332, at 304. See AR (Vol. 333 Ref. 5045).

⁹⁵⁹ Armitage AK, Dollery CT, George CF, *et al.*, Absorption and metabolism of nicotine from cigarettes, *British Medical Journal*, 1975:313-316, at 315 (“[N]o more than 25% of the total nicotine content of the cigarette is likely to appear in the mainstream smoke. Most of the nicotine is lost into the surrounding air and sidestream smoke or is retained in the butt”). See AR (Vol. 131 Ref. 1462).

⁹⁶⁰ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 13. See AR (Vol. 638 Ref. 2).

⁹⁶¹ Bodenhamer NL (American Tobacco), Leaf Services Monthly Report for June (Jun. 30, 1980). See AR (Vol. 27 Ref. 385).

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absorbs through the *mouth*—not the lungs. Adding ammonia compounds raises the pH of the tobacco smoke. *See* section II.C.4.c. According to RJR researchers, by raising pH in a low-tar cigarette from just 6.0 to 6.5, “*you increase the nicotine transfer in the mouth.*”⁹⁶²

The third effect is a possible increase in the speed of nicotine absorption in the lungs. The increase in pH caused by the addition of ammonia compounds increases the proportion of “free” or “extractable” nicotine in the smoke. *See* section II.C.4.c. According to documents from BATCO, Brown & Williamson’s parent company hypothesized that “with a higher ‘extractable’ nicotine, nicotine reaches the brain more quickly.”⁹⁶³ The BATCO researchers further postulate that “in human smoking a difference in the time of nicotine absorption of tenths of a second may be important.”⁹⁶⁴

In light of this evidence from former cigarette industry employees and the industry’s own documents, the industry’s assertion that adding ammonia compounds has no pharmacological significance is not credible.

The tobacco industry comment also asserts that significant quantities of ammonia compounds are needed to raise the pH of smoke from 6.0 to 7.5 or 8.0. However, no scientific support is provided for this assertion. Moreover, even if the assertion were correct, it would be largely irrelevant. Significantly smaller increases in smoke pH are likely to have the pharmacological effects described above. As noted above, for instance,

⁹⁶² Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 7 (emphasis added). *See* AR (Vol. 700 Ref. 593).

⁹⁶³ BATCO, *Further Work on ‘Extractable’ Nicotine*, Southampton, England (1966), at 7. *See* AR (Vol. 62 Ref. 308).

⁹⁶⁴ *Id.* at 9.

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documents from RJR conclude that simply increasing the pH of smoke from 6.0 to 6.5 is sufficient to increase the absorption of nicotine in the mouth.⁹⁶⁵

The Agency further disagrees with the tobacco industry comment that the pH of cigarette tobacco has no bearing on the efficiency of nicotine transfer from the tobacco to the smoke. It is a basic scientific principle that compounds in free or unbound forms are vaporized more readily than compounds bound together in salts.⁹⁶⁶ Studies of cocaine, for instance, show that when cocaine is bound as a salt (as in cocaine hydrochloride), much of the cocaine is degraded during pyrolysis; in contrast, when the cocaine is converted to “free” form, the transfer of the cocaine to the smoke is much greater.⁹⁶⁷ The tobacco industry comment provides no evidence to refute these basic scientific principles or to rebut the evidence in the record showing that the conversion of nicotine from its bound form to its free form increases the transfer of nicotine to smoke.⁹⁶⁸

⁹⁶⁵ Senkus M (R. J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 7 (emphasis added). See AR (Vol. 700 Ref. 593).

⁹⁶⁶ Morrison RT, Boyd RN, *Organic Chemistry*, 2d ed., 1966, in Barnett G, Chiang CN eds., *Pharmacokinetics and Pharmacodynamics of Psychoactive Drugs*, A Research Monograph, Biomedical Publications, 2d edition, 1985, at 26. See AR (Vol. 711 Ref. 19).

⁹⁶⁷ Cook CE, Jeffcoat AR, Perez-Reyes M, Pharmacokinetic studies of cocaine and phencyclidine in man, in Barnett G, Chiang CN eds., *Pharmacokinetics and Pharmacodynamics of Psychoactive Drugs*, A Research Monograph, Biomedical Publications, 2d edition, 1985, at 64-65. See AR (Vol. 711 Ref. 16).

⁹⁶⁸ After the close of the comment period, FDA received a series of RJR documents from the 1970's regarding the effect of pH adjustments on nicotine delivery. These documents had been made public in a lawsuit involving RJR. Although not necessary to FDA's analysis, these documents provide further confirmation that cigarette manufacturers raise the pH of cigarette smoke to increase the amount of “free nicotine” that is delivered to the smoker, and that this increase in “free nicotine” has a pharmacological effect. One of these documents describes RJR's finding that the pH level of Marlboro and Kool cigarettes had risen significantly, with corresponding increases in “free” nicotine deliveries, and in sales. Teague CE (RJR), *Implications and Activities Arising from Correlation of Smoke pH with Nicotine Impact, Other Smoke Qualities, and Cigarette Sales*, at 1-3. See AR (Vol. 711 Ref. 47). The document states:

In essence, a cigarette is a system for delivery of nicotine to the smoker in attractive, useful form. At “normal” smoke pH, at or below about 6.0, essentially all of the smoke nicotine is chemically combined with acidic

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substances hence is non-volatile and relatively slowly absorbed by the smoker. *As the smoke pH increases above about 6.0, an increasing proportion of the total smoke nicotine occurs in "free" form, which is volatile, rapidly absorbed by the smoker, and believed to be instantly perceived as nicotine "kick."*

Id. at 2 (emphasis added). The document continues:

As a result of its higher smoke pH, the current Marlboro, despite a two-thirds reduction in smoke "tar" and nicotine over the years, calculates to have essentially the same amount of "free" nicotine in its smoke as did the WINSTON. Over the same period, with some reduction in smoke pH and about two-thirds reductions in smoke "tar" and nicotine, the calculated amount of "free" nicotine in WINSTON smoke has decreased by about two-thirds. Thus, currently the calculated amount of "free" nicotine in Marlboro smoke is almost three times the amount in WINSTON smoke.

Id. (emphasis added; underscoring in original). This document goes on to describe methods of increasing smoke pH:

Methods which may be used to increase smoke pH and/or nicotine "kick" include: (1) increasing the amount of (strong) burley in the blend, (2) reduction of casing sugar used on the burley and/or blend, (3) use of alkaline additives, usually ammonia compounds, to the blend, (4) addition of nicotine to the blend, (5) removal of acids from the blend, (6) special filter systems to remove acids from or add alkaline materials to the smoke, and (7) use of high air dilution filter systems. Methods 1-3, in combination, represent the Philip Morris approach, and are under active investigation.

Id. at 4.

A document entitled "Outline for Smoke pH Presentation" presents further data on the increase in pH in Marlboro cigarettes and Kool cigarettes. Finding that, as compared to RJR's Winston brand, Marlboro cigarettes had several characteristics, including alkaline stem additives and ammonia-puffed leaf, "all combining to raise smoke pH," the presentation states:

We must conclude that the difference between Marlboro and Winston must be deliberate. . . . What we are seeing and measuring fits what we know about Philip Morris and Brown and Williamson product philosophies. They appear to design products primarily to deliver optimum nicotine impact and satisfaction--aiming also at a relatively bland smoke, letting flavor fall where it will.

Another document in the series is a memorandum to RJR's Director of Marketing and Planning recommending the development of a new "youth-appeal" brand with more tar and nicotine. Colby FG, *Cigarette Concept to Assure RJR a Larger Segment of the Youth Market* (Dec. 4, 1973). See AR (Vol. 711 Ref. 47). According to the memorandum, "any desired additional nicotine 'kick' could be easily obtained through pH regulation."

When these documents were made public, RJR officials responded that the documents are not important and that subsequent studies on Marlboro showed that pH levels between 1973 and 1988 declined, while sales remained steady or increased. Weinstein H, Documents tie nicotine levels, cigarette sales, *Los Angeles Times*, A1 (May 23, 1996). See AR (Vol. 711 Ref. 18).

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2. Comments from the tobacco industry argue that ammonia compounds are added to tobacco to enhance the flavor characteristics of cigarette smoke and bind the tobacco together, but not for their effect on nicotine. The Agency disagrees with this comment. The record contains numerous internal documents that indicate that the effect of adding ammonia compounds is to change the delivery or absorption of nicotine. For instance, the Brown & Williamson's 1991 leaf blending manual states that "[a]mmonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine."⁹⁶⁹ Similarly, William Farone, the former director of applied research at Philip Morris, states that "[t]he use of ammonia chemistry was important to the industry in maintaining adequate nicotine delivery to satisfy smokers."⁹⁷⁰ The industry's assertion that the use of ammonia is simply for taste and binding cannot be reconciled with this evidence. Even if ammonia does have a flavor component, this fact does not negate the evidence in the record regarding ammonia's effect on nicotine.

The tobacco industry cites the addition of ammonia compounds to foods as evidence of ammonia's role in flavor. The use of ammonia compounds in foods, however, is not dispositive evidence of the use of ammonia compounds in tobacco, because the ammonia compounds in cigarettes are burned and inhaled rather than ingested. Moreover, one of the recognized uses for ammonia compounds in foods is "pH control," 21 CFR

⁹⁶⁹Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives, 103d Cong., 2d Sess., 21 (Jun. 21, 1994) (statement of David Kessler) (emphasis added). See AR (Vol. 709 Ref. 3).

⁹⁷⁰Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 13 (emphasis added). See AR (Vol. 638 Ref. 2).

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184.1133–184.1143, which is the same use of ammonia compounds described in the internal tobacco company documents.

3. Comments from the tobacco industry argue that FDA has taken a contradictory position in the Jurisdictional Analysis by finding both that cigarette manufacturers add ammonia compounds to increase the pH of tobacco and that cigarette manufacturers add acids to reduce the harshness of smoke.

FDA's positions are not inconsistent. The Jurisdictional Analysis found, based on the evidence then available, that when manufacturers use tobaccos that produce naturally high pH levels in smoke or that have naturally high nicotine contents, the manufacturers sometimes face the problem that the cigarette smoke contains too much nicotine and is too harsh. In these situations, the record indicates that manufacturers have developed ways to reduce harshness, including lowering pH. *See* Jurisdictional Analysis, 60 FR 41711–41713. In other situations, manufacturers face the opposite problem of cigarette smoke that may not deliver enough nicotine. In these latter situations, the record indicates that manufacturers will enhance nicotine deliveries, including adding ammonia compounds to raise the pH of the tobacco and the smoke, which increases the delivery of free nicotine to the smoker. *See* section II.C.4.c.

4. Brown & Williamson makes two comments regarding chemical manipulation. First, Brown & Williamson asserts that its internal documents show its knowledge that pH level does not affect nicotine delivery. Second, Brown & Williamson asserts that its internal documents show that the addition of ammonia compounds is simply a booster of smoke “impact.”

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The Agency disagrees with Brown & Williamson's characterization of its documents. Contrary to Brown & Williamson's comment, the administrative record shows that researchers working for Brown & Williamson and Brown & Williamson's parent, BATCO, have consistently understood that pH levels affect nicotine delivery. As early as 1968, BATCO researchers wrote that "[n]icotine retention appears to be dependent principally on smoke pH and nicotine content."⁹⁷¹ See sections II.C.3.c.i., II.C.3.c.iv., II.C.4.c.

In fact, one of the documents cited by Brown & Williamson contradicts its assertion. In a passage not quoted by Brown & Williamson, the document refers to the "pH dependent effect of nicotine," further underscoring the company's understanding of the relationship between pH and nicotine.⁹⁷²

The Agency does agree with Brown & Williamson that the 1991 blenders handbook links the addition of ammonia compounds to the "impact" of smoke. However, the document makes it clear that "impact" is simply a surrogate term for nicotine delivery, stating that the ammonia compounds increase "the ratio of extractable nicotine to bound nicotine in the smoke"; that "extractable nicotine contributes to the impact in cigarette smoke"; and that "this is how ammonia can act as an impact booster."⁹⁷³

⁹⁷¹ BATCO, *The Retention of Nicotine and Phenols in the Mouth* (1968), at BW-W2-11691 (emphasis added). See AR (Vol. 445 Ref. 7593).

⁹⁷² Ayres CI (BATCO), Notes from the GR&DC Nicotine Conference, in Proceedings of the Smoking Behaviour-Marketing Conference, Session III (Jul. 9-12, 1984), at BW-W2-02642 (emphasis added). See AR (Vol. 14 Ref. 172).

⁹⁷³ *Regulation of Tobacco Products (Part 3): Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 21 (Jun. 21, 1994) (statement of David Kessler). See AR (Vol. 709 Ref. 3).

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iv. Comments on Flavorings and Casings.

1. The cigarette manufacturers dispute that flavorings and casings are sometimes used to mask the unpleasant sensory characteristics of nicotine in cigarettes. The tobacco industry claims that flavorings and casings are used solely to affect the flavor and aroma of the cigarette.

The Agency agrees that flavorings and casings influence flavor. Nevertheless, the record shows that these ingredients have another use—that of masking the flavor of harsh high-nicotine tobaccos. In the Jurisdictional Analysis, the Agency cited several pieces of evidence showing that flavorings and casings are used to mask nicotine. *See* 60 FR 41711–41714. For instance, a “flavorist” for RJR wrote that “in air-cured tobaccos (cigar, burley, Maryland), the pH of smoke is generally alkaline and the flavor effect of nicotine is a ‘harshness’ which can be choking and unpleasant.”⁹⁷⁴ In these tobaccos, according to the flavorist, “the effect of nicotine is greatly modified, and the harshness is dramatically reduced. . . . by addition of sugars . . . to ‘mellow’ the smoke.”⁹⁷⁵ None of this evidence is rebutted by the cigarette manufacturers.

In addition, the statement of William Farone, the former director of applied research at Philip Morris, confirms that flavorings are used to mask the harshness of nicotine. According to Farone’s statement:

The tobacco industry found that in the manipulation of the nicotine/tar ratio, the methods used to increase the nicotine to tar ratio sometimes resulted in a cigarette that was too harsh. With a standard nicotine/tar ratio in a traditional cigarette no flavor smoothing compounds are generally needed to produce a

⁹⁷⁴ Leffingwell JC, Nitrogen components of leaf and their relationship to smoking quality and aroma, *Recent Advances in Tobacco Science*, vol. 2, at 9. *See* AR (Vol. 28 Ref. 450).

⁹⁷⁵ *Id.*

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palatable cigarette. The higher tar levels in traditional cigarettes mask the harshness of nicotine and the associated compounds produced in higher nicotine to tar ratios. A low tar cigarette with a higher nicotine/tar ratio than a traditional cigarette could be very harsh due to the lack of sufficient specific tar components to mask the nicotine and related basic compounds. *To overcome the harshness due to the increased burley in the blend, the industry used flavor "smoothers."*⁹⁷⁶

Thus, the evidence in the record supports the finding in the Jurisdictional Analysis that the cigarette industry sometimes uses flavorings to mask the harshness of nicotine in cigarettes with nicotine-rich tobacco blends.

2. The cigarette manufacturers cite the use of menthol in cigarettes as evidence that they do not use flavorings to mask the effects of nicotine. According to the industry, menthol is not used to mask the effects of high-nicotine tobaccos because menthol cigarettes generally have nicotine yields that are lower than or equal to regular cigarettes.

The Agency rejects this argument. The evidence before the Agency indicates that flavorings like cocoa, sugars, and licorice, which produce acids in smoke, are used to mask the bitterness or harshness of nicotine. See Jurisdictional Analysis 60 FR 41711–41714. The evidence does not indicate that menthol is used to mask harshness of tobacco. Consequently, the data presented by the industry on menthol is irrelevant to whether other flavorants are used to mask nicotine.

v. Comments on the Consistency of Nicotine Deliveries.

1. The cigarette manufacturers argue that the ability to produce cigarettes with uniform and consistent levels of nicotine is not evidence of any "intended use." They

⁹⁷⁶ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 14-15 (emphasis added). See AR (Vol. 638 Ref. 2).

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assert that blending to achieve consistency is a common practice among manufacturers that make consumer goods from agricultural products.

However, the remarkable degree of consistency in nicotine deliveries achieved by the manufacturers is especially relevant to the issue of the manipulation and control of nicotine. As discussed in section II.C.4.e.iii., above, the manufacturers' precise control over nicotine deliveries refutes the manufacturers' assertion that "the companies do not independently 'control' for or 'manipulate' the nicotine content in any of their blends."⁹⁷⁷ Moreover, the manufacturers' precise control over nicotine deliveries is consistent with—and corroborates—the Agency's finding that manufacturers intend that cigarettes will be used for pharmacological purposes. As discussed in the Jurisdictional Analysis, an FDA laboratory study showed that nicotine delivery varies so little from lot to lot of cigarettes that it equals or exceeds the degree of control exercised by pharmaceutical companies over the active ingredients in prescription drugs.⁹⁷⁸ The manufacturers' precise control over nicotine deliveries enable the industry to ensure that consumers can use cigarettes to satisfy addiction or to obtain other pharmacological effects.

vi. Comments on Breeding.

The comments of the cigarette industry claim that the cigarette manufacturers do not manipulate nicotine through plant breeding or agronomic practices. While the comments make several valid points on tangential issues, they do not affect the basic conclusions made in the Jurisdictional Analysis.

⁹⁷⁷ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. V, at 66. See AR (Vol. 535 Ref. 96).

⁹⁷⁸ FDA, Center for Drug Evaluation and Research, Division of Drug Analysis, Memorandum on Analysis of Packages of Cigarettes (Apr. 4, 1994). See AR (Vol. 29 Ref. 487).

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1. Regarding FDA's contention that American-grown tobaccos have had increasingly high levels of nicotine since the mid 1950's, the comments fault FDA for singling out the years 1955 and 1980 for comparison.

The Agency reported in the Jurisdictional Analysis the change in nicotine content between 1955 and 1980 because those were the years analyzed in the paper by DeJong cited by the Agency.⁹⁷⁹ The Agency agrees that the more recent data from the North Carolina Official Variety Trials, as submitted by the comments, show that nicotine content of leaves from that area has leveled off since 1980, and that the last 17 years appear to show a decrease in nicotine levels.⁹⁸⁰ The Agency does not agree, however, that it should have compared nicotine levels in the 1950's to nicotine levels in 1989, as suggested by the cigarette manufacturers. Unusually low nicotine levels were recorded in 1989 when compared with the five years preceding and succeeding it.

Other articles and information support the Agency's contention that the nicotine content of domestic tobacco increased from the 1950's to 1980. For example, one study cited by a comment concluded that nicotine levels "changed dramatically" from the mid-1950's to the early 1980's and ascribed the increase to changes in production practices.⁹⁸¹

⁹⁷⁹ DeJong DW, The role of American tobacco leaf chemistry in low-yield cigarettes: an agricultural viewpoint. *Tabak Journal International*, May 1985;376-383. See AR (Vol. 27 Ref. 401).

⁹⁸⁰ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 18. See AR (Vol. 535 Ref. 96).

⁹⁸¹ Bowman DT, Wernsman EA, Corbin TC, *et al.*, Contribution of genetic and production technology to long-term yield and quality gains in flue-cured tobacco, *Tobacco Science* 1984;28:30-35, at 34-35. See AR (Vol. 535 Ref. 96, vol. IV.A).

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In addition, Earl Wernsman of North Carolina State University told the Agency that nicotine levels have increased over the past 30 years.⁹⁸²

The Agency, however, does not agree with the industry's claim, that "FDA's reliance on the DeJong data, together with the Agency's total failure to acknowledge contrary data from equally or more authoritative sources, reflects a general strategy of selective and biased citation from the scientific literature."⁹⁸³ In fact, both sets of data reflect rising nicotine levels in tobacco from the mid 1950's through 1980.

2. The cigarette industry comments assert that the manufacturers have rejected high-nicotine tobacco crops produced during drought years. According to the industry, this rejection of high-nicotine crops shows that the manufacturers do not seek to manipulate nicotine through breeding high-nicotine tobaccos.

The Agency does not agree that any reliable inference can be drawn from the rejection of tobacco crops in drought years. This evidence establishes only that nicotine content can on occasion rise too high for the manufacturers' use. The Agency has never maintained that nicotine levels could not reach excessive levels. To the contrary, as discussed in the Jurisdictional Analysis, the Agency recognizes that too much nicotine in a cigarette can make the cigarette too harsh, requiring the use of flavors and casings to mask the harshness. *See* 60 FR 41712–41713.

3. The cigarette industry comments raise a number of issues regarding FDA's discussion of the Minimum Standards Programs (MSP's). The comment claims that

⁹⁸² Memorandum of Mar. 22, 1994, teleconference, from Murray M, to Wernsman E (Mar. 23, 1994). *See* AR (Vol. 256 Ref. 3459).

⁹⁸³ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. IV, at 9. *See* AR (Vol. 535 Ref. 96).

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“FDA has mischaracterized the nature, purpose and effect of the . . . MSP’s by claiming that the MSP’s were designed to ensure that nicotine levels did not fall below a specified level,” and that by “minimizing the role of the USDA, tobacco breeders, and State Extension-Research Services, FDA mischaracterizes the tobacco industry’s participation in these programs as ‘controlling.’”⁹⁸⁴ The comment argued that the cigarette manufacturers do not control the MSP’s, that the MSP’s are not designed to maintain nicotine above a specified level, and that the MSP’s prevent the introduction of high-nicotine varieties into cultivation.

The Agency does not find compelling any of the arguments raised by the comment that were intended to dispute the two most significant findings of the Agency regarding MSP’s: that they are used to ensure that nicotine levels do not fall below a specified level, and that the cigarette manufacturers are active participants in the program.

The comment points out that there are a variety of purposes of the MSP’s, and argues that therefore it is incorrect for FDA to claim that their purpose is “to ensure that nicotine levels in marketed tobacco do not fall below specified levels.”⁹⁸⁵ FDA agrees that the MSP’s have purposes in addition to controlling nicotine levels. However, the fact remains that the MSP’s help ensure that nicotine levels in marketed tobacco do not fall below the level in acceptable tobacco varieties. DeJong made this point clear when he wrote that “the first minimum standards programme was initiated in 1964. . . . Discount or *low-nicotine cultivars had previously been declared outside the price support system.*”⁹⁸⁶

⁹⁸⁴ *Id.* at 18-19 (emphasis added).

⁹⁸⁵ *Id.* at 21-22.

⁹⁸⁶ DeJong DW, The role of American tobacco leaf chemistry in low-yield cigarettes: an agricultural viewpoint, *Tabak Journal International*, May 1985:382 (emphasis added). See AR (Vol. 27 Ref. 401).

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FDA's point, which is not disputed by the comment, is that the discount and MSP programs discourage the planting of varieties that accumulate unusually low levels of nicotine.

FDA believes that it appropriately characterized the industry's role in the MSP's. The agency noted that the MSP's are administered by the USDA. *See* Jurisdictional Analysis, 60 FR 41697. In stating that the manufacturers exert control over the MSP's, the Agency did not imply that they exert sole control over all aspects of the programs. The manufacturers do, however, each have a vote on the MSP committees that set up the rules and administer the programs. They also represent by far the largest economic bloc on those committees.

4. The cigarette industry asserts that the cigarette manufacturers do not control the agronomic practices used by tobacco farmers for the purpose of increasing the nicotine content of tobacco. The comment maintains that all of the agronomic practices cited by the Agency as raising nicotine levels provide significant advantages to the farmer completely independent of any nicotine-enhancing properties. The comment also notes that some agronomic practices, such as irrigation, decrease nicotine content, and that recommendations regarding other practices, such as decreasing the use of nitrogen from the very high levels that were used for a few years, also result in decreased nicotine levels.

The Agency generally agrees with the comment on these points. The Agency never stated, and did not mean to imply, that cigarette manufacturers exert direct control over tobacco farmers or breeders. The Agency also agrees that farmers do not use nicotine-elevating agricultural practices exclusively for the purpose of elevating nicotine levels. The Agency is aware that farmers choose the agricultural practices they use for a

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variety of purposes. Nevertheless, DeJong noted that “[h]eavy application of nitrogen fertilization, early topping and tight chemical sucker control all acted in concert to push alkaloid levels upward.”⁹⁸⁷

In any case, the Agency’s fundamental point regarding tobacco breeding and farming is that tobacco leaves sold in the U.S. contain adequate levels of nicotine to enable the manufacturers to maintain nicotine delivery in their products at the levels they choose. When, in the early and mid-1950’s, farmers grew a preponderance of low-nicotine tobaccos, programs were set up to ensure that farmers would no longer grow such tobaccos. Since that time, manufacturers have had no difficulty purchasing tobaccos that provide the levels of nicotine that they need for their products. And in at least one well-documented case, Brown & Williamson doubled the nicotine content of one variety of flue-covered tobacco as a “blending tool” for use in low-tar cigarettes. This “Y-1” tobacco was designed to enable the company to maintain nicotine levels while lowering the tar content of cigarettes. *See* section II.C.3.c.iii., above.

vii. Comments on Leaf Purchasing.

1. The cigarette manufacturers assert that over time there has been no increase in the nicotine content of the tobacco they purchase. The manufacturers argue this is evidence that they do not use nicotine content as a principal factor in leaf selection.

The Agency disagrees with the manufacturers’ factual assertion regarding trends in nicotine content. The evidence in the record indicates that the nicotine content has increased in the tobacco purchased by cigarette manufacturers. As pointed out in the

⁹⁸⁷ *Id.*

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Jurisdictional Analysis, the nicotine content in American tobaccos of all types has increased since the 1950's. 60 FR 41696-41697. Moreover, a 1978 article submitted by the Tobacco Institute and entitled "Genetic Manipulation for Tailoring the Tobacco Plant To Meet the Requirements of the Grower, Manufacturer, and Consumer" states that "[i]n the United States the demand for lower stalk flue-cured tobacco has decreased."⁹⁸⁸ This confirms the existence of a trend first described by USDA officials in congressional testimony in the late 1950's. See section II.C.4.a.i., above. At that time USDA indicated that the tobacco industry had "moved up the stalk" in blending tobaccos by using the higher nicotine leaves in the upper part of the tobacco plant.⁹⁸⁹

2. The cigarette manufacturers also assert that they have rejected high-nicotine tobaccos. Again, they claim that this is evidence that they do not use nicotine content as a principal factor in leaf selection.

The Agency disagrees with the manufacturers' argument. As noted above in section II.C.6.c.vi., the Agency recognizes that too much nicotine in a cigarette can make the cigarette too harsh.

3. In its comments, Brown & Williamson disputes that it regularly adjusts the stalk position of its leaf purchases during the buying season based upon the results of nicotine analyses. The company's response, however, conflicts with the information

⁹⁸⁸ Chaplin JF, Genetic manipulation for tailoring the tobacco plant to meet the requirements of the grower, manufacturer, and consumer, *Bulletin D'Information Coresta* 1978;17-32, at 21 (emphasis added). See AR (Vol. 535 Ref. 96).

⁹⁸⁹ *Hearings on False and Misleading Advertising (filter-tip cigarettes)*, Subcommittee on Government Operations, U.S. House of Representatives, 85th Cong. 1st Sess. 189 (Jul. 1957). See AR (Vol. 172 Ref. 2035).

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provided to FDA by company employees during FDA's May 1994 visit to Brown & Williamson. *See* Jurisdictional Analysis, 60 FR 41705. Moreover, Brown & Williamson provides no affidavits or other documentary evidence to support its comment.

viii. Comments on Reconstituted Tobacco.

1. The cigarette manufacturers assert that they do not use reconstituted tobacco to manipulate or control nicotine levels. As evidence of this point, they argue that nicotine levels in reconstituted tobacco are lower than those in most tobacco blends.

The Agency disagrees with the argument. Evidence in the record shows that reconstituted tobacco is used by cigarette manufacturers as a site for the addition of ammonia compounds. According to an article in the *Wall Street Journal*, an internal Brown & Williamson handbook describes the "nicotine pick-up potential" of ammonia in reconstituted tobacco.⁹⁹⁰ The article also states that ammonia added to reconstituted tobacco can scavenge nicotine from the tobacco in the rest of the cigarette, significantly increasing the level of "free nicotine" in the cigarette.

2. The cigarette manufacturers assert that they do not closely monitor and control the level of nicotine in reconstituted tobacco.

The Agency disagrees with this assertion. The record shows that finished cigarettes contain precisely controlled and consistent nicotine levels. *See* Jurisdictional Analysis, 60 FR 41732. Because reconstituted tobacco is a significant ingredient in finished cigarettes, the precise control over nicotine in the finished cigarettes could not be

⁹⁹⁰ Freedman AM, Tobacco firm shows how ammonia spurs delivery of nicotine, *Wall Street Journal* (Oct. 18, 1995), A1. *See* AR (Vol. 639 Ref. 2).

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achieved unless the manufacturer also precisely controlled the nicotine level in reconstituted tobacco. Without such precise control, the wide variations in the nicotine levels of the tobacco stems and other raw ingredients of reconstituted tobacco would produce significant variations in the nicotine content of reconstituted tobacco and the finished cigarettes.

ix. Other Comments.

1. The Agency found in the Jurisdictional Analysis, based on the evidence then available, that cigarette manufacturers sometimes increase the degree to which the “tipping paper,” which is wrapped around the filter, is extended over the tobacco rod. *See* 60 FR 41721. One study cited by the Agency reported that this increased “overwrap” reduced the nicotine deliveries reported by the FTC testing method (because the test protocol requires stopping the test when the cigarette is smoked to within 3 millimeters of the tipping paper), while allowing smokers to increase their nicotine intake above the reported levels (by smoking the tobacco under the overwrap).⁹⁹¹

The manufacturers raise a number of questions about the data on which FDA relied and seek to depict FDA’s discussion of the overwrap width as speculative. In most cases, however, the information that would answer the questions raised by the manufacturers is within their control, but is nevertheless not provided.

⁹⁹¹ Grunberg NE, Morse DE, Maycock VA, *et al.*, Changes in overwrap and butt length of American filter cigarettes, *NY State Journal of Medicine* Jul. 1985;310-312. *See* AR (Vol. 29 Ref. 478).

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For example, the manufacturers argue that smokers do not smoke the overwrap because it is unpalatable, but they do not provide evidence to support this assertion despite the fact that the extensive consumer testing conducted by the manufacturers undoubtedly provides the information necessary to resolve whether the overwrap is smoked and whether it is palatable. The manufacturers also argue that the increase in overwrap width found in many cigarettes would not increase the amount of nicotine available to smokers if the burn rate of the cigarette were simultaneously increased. The burn rate of cigarettes is information known to the cigarette manufacturers but not to FDA. Yet the manufacturers fail to provide information on burn rate that would permit resolution of the issue they raise.

Moreover, although the manufacturers deny that the overwrap has been widened to increase availability of nicotine, they offer no alternative explanation for the increase found in the study relied on by FDA. In light of the ease with which the manufacturers could have provided the information necessary to show that the overwrap is not used to provide elasticity, and their failure to provide it, FDA concludes that the evidence supports the finding made in the Jurisdictional Analysis. Nevertheless, only additional information can help determine whether an increase in the tipping paper reduces the accuracy of the FTC measurement.

2. The cigarette manufacturers assert that the fact that they may hold patents permitting them to carefully manipulate and control nicotine does not prove that they actually do so. They also argue that patents are submitted by individual employees and that, as such, they are not evidence of the company's intentions.

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FDA cited the multitude of patents held by tobacco manufacturers on methods of manipulating nicotine delivery as additional evidence that the manufacturers have engaged in extensive research to develop methods to optimize nicotine delivery. The fact that the manufacturers have invested considerable resources in developing means of manipulating and controlling nicotine deliveries, including developing and acquiring patents, demonstrates that the manufacturers seek to be able to manipulate and control nicotine deliveries and have in fact “designed” and “planned” methods of doing so. This evidence is relevant to establishing the manufacturers’ intentions. In light of the large number of patents held by the industry with the common goal of manipulating nicotine delivery, the argument that all of these patents were obtained by individual employees working without the direction of the manufacturers is not credible.

3. In the Jurisdictional Analysis, the Agency found that the failure of the cigarette manufacturers to remove nicotine from cigarettes was evidence that the manufacturers intend their products to provide the pharmacological effects of nicotine. *See* 60 FR 41779–41787. In their comments, however, the cigarette manufacturers assert that they do not have the capacity to manufacture an acceptable denicotinized cigarette and, even if they did, this would not establish that the manufacturers intend to affect the structure or function of the body.

In the Agency’s view, the failure of denicotinized cigarettes in the marketplace is further evidence of the essential role of nicotine in cigarettes. The fact that efforts to introduce denicotinized cigarettes have failed demonstrates that consumers smoke cigarettes primarily to obtain the pharmacological effects of nicotine. Moreover, evidence that a manufacturer has, but does not use, technology that could remove a

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pharmacologically active ingredient from its product is relevant evidence that the manufacturer intends that the product will have pharmacological effects upon consumers.

The manufacturers' assertion that denicotinized cigarettes have failed because of inadequacies in the denicotinizing technologies is not supported by the evidence in the record. To the contrary, the record contains abundant evidence that the reason a denicotinized cigarette will not succeed is because it fails to provide the pharmacological effects sought by consumers. For instance, an RJR document asserts that "*a zero nicotine cigarette . . . really has no potential to provide smoking satisfaction. It produces no taste in the mouth, but even more seriously it fails to provide the ultimate satisfaction in the lungs.*"⁹⁹²

4. The cigarette manufacturers argue that the evidence in the administrative record does not establish that they add "extraneous" nicotine to cigarettes. According to the manufacturers, the failure of the Agency to demonstrate that they add extraneous nicotine means that the Agency has not demonstrated that the manufacturers manipulate and control nicotine.

The Agency disagrees. The administrative record contains abundant evidence that tobacco manufacturers can manipulate and control nicotine deliveries without adding extraneous nicotine. The record before the Agency demonstrates that the manufacturers have developed and used many techniques to manipulate and control nicotine, and few of them involve the addition of extraneous nicotine. These techniques are discussed in detail in section II.C.4., above and include using nicotine-rich blends in low-yield cigarettes,

⁹⁹² Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 9 (emphasis added). See AR (Vol. 700 Ref. 593).

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using filtration and ventilation techniques that selectively remove more tar than nicotine, and chemical manipulation to increase free nicotine deliveries. All of these techniques manipulate and control nicotine deliveries; all of them facilitate consumer use of cigarettes for pharmacological purposes; and none of the techniques require the addition of extraneous nicotine.

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D. THE STATEMENTS, RESEARCH, AND ACTIONS OF THE SMOKELESS TOBACCO MANUFACTURERS SHOW THAT THE MANUFACTURERS INTEND THEIR PRODUCTS TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY

In sections II.A. and II.B., above, the Agency concluded that smokeless tobacco is “intended” to affect the structure and function of the body on the basis of the foreseeable pharmacological effects and uses of smokeless tobacco and its widespread actual use by consumers for pharmacological purposes. In this section, the Agency considers a third category of evidence of intended use: the statements, research, and actions of the smokeless tobacco manufacturers.

The administrative record includes considerable evidence of the smokeless tobacco manufacturers’ statements, research, and manufacturing practices. Much of this evidence has only recently become available as the result of the Agency’s investigation, congressional hearings, and other investigations and sources. As discussed in section II.C.1., above, this evidence of the statements, research, and actions of the manufacturers is part of the relevant objective evidence that the Agency may rely upon in determining a product’s “intended uses.” The Agency’s role in making these determinations is that of a fact finder. The Agency’s fact-finding task has been made more difficult by the manufacturers’ general refusal to cooperate with the Agency’s investigation. In particular, the manufacturers failed to provide FDA with information and documents requested by the Agency in July 1994 regarding the role of nicotine in smokeless tobacco.⁹⁹³ This lack of cooperation has made the Agency’s investigation more difficult. The limited number of company documents provided by the

⁹⁹³ See, e.g., Letter from Chesmore RG (FDA) to Gierer V (U.S. Tobacco Company) Jul. 19, 1994. See AR (Vol. 54 Ref. 619).

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manufacturers with their comments sheds little light on the role of nicotine in smokeless tobacco and does not significantly change the evidence in the record.

The Agency made extensive findings based on the evidence then before it regarding the statements, research, and actions of the smokeless tobacco manufacturers in the Jurisdictional Analysis. The Agency received comments on these findings from the tobacco industry, public health organizations and other groups and members of the public. After careful consideration of the evidence in the record and the public comments, the Agency finds that the evidence provides an independent basis for concluding that smokeless tobacco is in fact intended to affect the structure and function of the bodies of smokeless tobacco users.

As described in this section, the evidence from internal company documents and other sources shows that smokeless tobacco manufacturers: (1) know that nicotine has pharmacological effects and uses, including causing and sustaining addiction; and (2) manipulate and control the delivery of nicotine from smokeless tobacco in a manner that promotes tolerance and addiction in consumers. Indeed, in the case of the nation's largest smokeless tobacco manufacturer, the statements of senior officials and the company's marketing strategies reveal that the company relies on an explicit "graduation process," under which users of smokeless tobacco are encouraged to progress from "starter" products that deliver low levels of nicotine to products that deliver higher and more addictive levels of nicotine. The cumulative evidence shows that the manufacturers design smokeless tobacco with an intent to affect the structure and function of the body.⁹⁹⁴

⁹⁹⁴ The discussion of the statements, research, and actions of the manufacturers in this section cites many documents. It is the totality of the evidence from these documents that the Agency relies upon. No single document cited by the Agency is essential to the Agency's conclusion that the manufacturers intend their

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1. The Smokeless Tobacco Manufacturers Understand That Nicotine Has Addictive and Other Pharmacological Effects and That Consumers Use Smokeless Tobacco To Obtain these Effects

Extensive evidence in the administrative record, including statements and research of smokeless tobacco manufacturers, demonstrates that the manufacturers know that nicotine causes significant pharmacological effects, including addiction. These statements and research also demonstrate that the manufacturers understand that consumers use smokeless tobacco to obtain the pharmacological effects of nicotine.

For example, Brown & Williamson Tobacco Corporation, which is also a smokeless tobacco manufacturer,⁹⁹⁵ understands that nicotine is addictive; that nicotine has other significant pharmacological effects; and that consumers use tobacco products to obtain nicotine. *See* section II.C.2.c., above. Researchers for Brown & Williamson's parent corporation, BATCO, have long regarded "buccal administration of nicotine" through products such as chewing tobacco and wet snuff as alternatives to the delivery of nicotine through cigarettes.⁹⁹⁶ According to these researchers, these types of tobacco usage—smoking, chewing, and snuffing—allow nicotine to go directly into the blood and to the brain; they stated that "[t]he common factor in all the types of tobacco usage . . . is nicotine,

products to affect the structure and function of the body. In particular, none of the documents in the Agency's docket of confidential documents is essential to the Agency's determination. *See* AR (Vols. 505-518).

⁹⁹⁵ Valero G, Moist poised to overtake leaf; smokeless tobacco, *U.S. Distribution Journal*, Dec. 15, 1995; 222(12):12. *See* AR (Vol. 711 Ref. 22).

⁹⁹⁶ Minutes of B.A.T. Group Research Conference at St. Adele, Quebec (Nov. 9-13, 1970), at 3. *See* AR (Vol. 44 Ref. 15-2).

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either absorbed through the lungs *or the lining of the nose or mouth*. Taken in these ways *nicotine will quickly enter a direct route, in the blood, to the brain.*"⁹⁹⁷

Indeed, as recently as 1992, Brown & Williamson stated that "[t]he fact that people use snuff and chewing tobacco indicates that administration routes other than the inhalation route can deliver tobacco satisfaction."⁹⁹⁸ BATCO scientists use "satisfaction" as a euphemism for the pharmacological effects of nicotine, stating "[i]ntuitively it is felt that '*satisfaction*' must be related to nicotine. Many people believe it [is] a 'whole body response' and *involves the action of nicotine in the brain.*"⁹⁹⁹ See section II.E.2., below.

Similarly, a senior vice president for marketing for United States Tobacco Company (UST), the nation's largest smokeless tobacco manufacturer,¹⁰⁰⁰ wrote in a memo on new product development that "*virtually all tobacco usage is based upon nicotine, 'the kick,' satisfaction.*"¹⁰⁰¹ The executive further stated:

Nicotine gives the consumer satisfaction. Some would describe it as a pleasant feeling. Others would describe it as a kick. . . . Others would describe it as a relaxing feeling.¹⁰⁰²

⁹⁹⁷ BATCO Group R&D Conference on Smoking Behaviour at Southampton, England (Oct. 11-12, 1976), at BW-W2-02145 (emphasis added). See AR (Vol. 14 Ref. 180-2).

⁹⁹⁸ Transdermal Nicotine Patches, at 3. See AR (Vol. 531 Ref. 124).

⁹⁹⁹ BATCO Nicotine Conference at Southampton, England (Jun. 6-8, 1984) at BW-W2-01977 (emphasis added). See AR (Vol. 22 Ref. 287-7).

¹⁰⁰⁰ UST has 82% of the market for moist snuff products sold in the United States in 1994. It also has nearly 40% of the market for all smokeless tobacco sold in the United States. See Valero G, Moist poised to overtake leaf; smokeless tobacco, *U.S. Distribution Journal*, Dec. 15, 1995; 222(12):12. See AR (Vol. 711 Ref. 22).

¹⁰⁰¹ Deposition of Erik Lindqvist, transcript of jury trial proceedings at 1662 in *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986) (emphasis added). See AR (Vol. 22 Ref. 292).

¹⁰⁰² *Id.*

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Another UST document compares the nicotine delivery of one of its products, Skoal Bandits, with the nicotine delivery of cigarettes. This document states:

The nicotine contents are more or less equivalent to that of a good quality cigarette of average strength. The nicotine is absorbed, giv[ing] satisfaction to the smoker.¹⁰⁰³

Like the major cigarette manufacturers, UST has funded its own studies on nicotine pharmacology, including studies on the absorption of nicotine from snuff and chewing tobacco, the effects of smokeless tobacco on performance and psychophysiological response, and detection of nicotine in blood.¹⁰⁰⁴ Other UST studies were designed to compare routes of nicotine administration in snuff and cigarette smoking¹⁰⁰⁵ and to describe the pharmacokinetics of nicotine and its major metabolites in experienced and inexperienced snuff

¹⁰⁰³ Potential Questions and Answers, submitted in *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986), at 1. See AR (Vol. 30 Ref. 509).

¹⁰⁰⁴ Kyerematen, GA, Dvorchik, BH, Vesell, ES, Influence of different forms of tobacco intake on nicotine elimination in man, *Pharmacology* 1983;26:205-209. See AR (Vol. 119 Ref. 1102).

Landers DM, Crews DJ, Boutcher SH, *et al.*, The effects of smokeless tobacco on performance and psychophysiological response, *Medicine and Science in Sports & Exercise* 1992;24(8):895-903, as cited in *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 144 (Nov. 29, 1994). See AR (Vol. 710 Ref. 4).

Allen JK, Stern JR, Harris J, *Analysis of Nicotine in Blood by HPLC with Electrochemical Detection*, (Abstract), submitted for presentation at the 10th International Symposium on Column Liquid Chromatography, San Francisco, CA (May 18-23, 1986), as cited in *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 144 (Nov. 29, 1994). See AR (Vol. 710 Ref. 4).

Baldini FD, Skinner JS, Landers DM, *et al.*, Effects of varying doses of smokeless tobacco at rest and during brief, high-intensity exercise, *Military Medicine* 1992;157:51-55, as cited in *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 144 (Nov. 29, 1994). See AR (Vol. 710 Ref. 4).

¹⁰⁰⁵ U.S. Tobacco Company, Results of Comparison of Routes of Nicotine Administration. Plaintiff's exhibit 3.28 from *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986). See AR (Vol. 24 Ref. 318).

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takers.¹⁰⁰⁶ The study comparing routes of nicotine administration, for instance, found that smokeless tobacco can actually deliver more nicotine than cigarettes to new tobacco users, stating that “for naive tobacco users, bioavailability of nicotine is greater after snuff dipping than after cigarette smoking. . . .”¹⁰⁰⁷

UST is also a founding member of the Council for Tobacco Research (CTR).¹⁰⁰⁸ As discussed in section II.C.2.d., above, CTR has funded many studies on behalf of its members evaluating the pharmacological effects of nicotine on the body. At least one of these studies stated that nicotine in tobacco can cause “drug addiction.”¹⁰⁰⁹ As a member of the Council for Tobacco Research, UST thus had direct knowledge of the pharmacological effects and the consumer uses of nicotine.

¹⁰⁰⁶ U.S. Tobacco Company, Pharmacokinetics of Nicotine and Its Major Metabolites in Naive and Habituated Snuff Takers. Plaintiff’s exhibit 3.27 from *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986). See AR (Vol. 24 Ref. 317).

¹⁰⁰⁷ U.S. Tobacco Company, Results of Comparison of Routes of Nicotine Administration. Plaintiff’s exhibit 3.28 from *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986). See AR (Vol. 24 Ref. 318).

¹⁰⁰⁸ UST has been intimately connected with CTR since its inception. The minutes of the initial meeting in March 1954 of the Tobacco Industry Research Council, the predecessor of the Council for Tobacco Research, indicate that UST’s president was the first vice chairman of the Council. TIRC, Report on Meeting (Mar. 15, 1954). See AR (Vol. 301 Ref. 4393). Subsequently, UST’s president served as a director of CTR from 1976 to 1984. Organization and Function of CTR (summaries of CTR meetings, 1976-1984). See AR (Vol. 342 Ref. 5382). Prior to 1988, UST manufactured cigarettes and was a class A member of CTR. Since 1988, UST has been a class B member of CTR. *Health Effects of Smokeless Tobacco: Hearing Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 137 (Nov. 29, 1994). See AR (Vol. 710 Ref. 4).

¹⁰⁰⁹ See, e.g., Svensson TH, Grenhoff J, Engberg G, Effect of nicotine on dynamic function of brain catecholamine neurons, in *The Biology of Nicotine Dependence*, eds. Bock G, Marsh J, CIBA Foundation Symposium, 1990;152:169-180. See AR (Vol. 61 Ref. 273).

Tung CS, Ugedo L, Grenhoff J, *et al.*, Peripheral induction burst firing in locus coeruleus neurons by nicotine mediated via excitatory amino acids, *Synapse* 1989;4(4):313-318. See AR (Vol. 61 Ref. 278).

Rosecrans JA, Nicotine as a discriminative stimulus: a neurobehavioral approach to studying central cholinergic mechanisms, *J Subst Abuse* 1989;1(3):287-300. See AR (Vol. 59 Ref. 239).

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Nicotine's pharmacological effects are also understood by Procordia A.B., the parent of Pinkerton Tobacco Company, the nation's third largest smokeless tobacco manufacturer.¹⁰¹⁰ Through corporate subsidiaries, Procordia has extensively investigated the pharmacological effects of nicotine, including funding numerous studies on nicotine's effects on the brain.¹⁰¹¹

¹⁰¹⁰ Valero G, Moist poised to overtake leaf; smokeless tobacco, *U.S. Distribution Journal*, Dec. 15, 1995; 222(12):12. See AR (Vol. 711 Ref. 22).

¹⁰¹¹ Procordia owns two foreign smokeless tobacco manufacturers, Svenska Tobaks AB and Swedish Tobacco Co. Through Svenska Tobaks and Swedish Tobacco, Procordia funded the following studies on nicotine pharmacology:

Adem A, Jossan SS, d'Argy R, *et al.*, Distribution of nicotinic receptors in human thalamus as visualized by 3H-nicotine and 3H-acetylcholine receptor autoradiography, *J Neural Transm* 1988;73(1):77-83. See AR (Vol. 45 Ref. 10).

Adem A, Nordberg A, Jossan SS, *et al.*, Quantitative autoradiography of nicotinic receptors in large cryosections of human brain hemispheres, *Neurosci Lett* 1989;101(3):247-252. See AR (Vol. 45 Ref. 9).

Andersson K, Eneroth P, Agnati L, Nicotine-induced increases of noradrenaline turnover in discrete noradrenaline nerve terminal systems of the hypothalamus and the median eminence of the rat and their relationship to changes in the secretion of adenohipophyseal hormones, *Acta Physiol Scand* 1981;113:227-231. See AR (Vol. 273 Ref. 3784).

Andersson K, Fuxe K, Agnati LF, *et al.*, Effects of acute central and peripheral administration of nicotine on ascending dopamine pathways in the male rat brain. Evidence for nicotine induced increases of dopamine turnover in various telencephalic dopamine nerve terminal systems, *Med Biol* 1981;59(3):170-176. See AR (Vol. 45 Ref. 11).

Andersson K, Fuxe K, Eneroth P, *et al.*, Interactions of nicotine and pentobarbitone in the regulation of telencephalic and hypothalamic catecholamine levels and turnover and of adenohipophyseal hormone secretion in the normal male rat, *Naunyn Schmiedebergs Arch Pharmacol* 1982;321:287-292. See AR (Vol. 423 Ref. 7141).

Andersson K, Hockey GRJ, Effects of cigarette smoking on incidental memory, *Psychopharmacology* 1977;52:223-226. See AR (Vol. 125 Ref. 1300).

Biber A, Scherer G, Hoepfner I, *et al.*, Determination of nicotine and cotinine in human serum and urine: an interlaboratory study, *Toxicol Lett* 1987;35(1):45-52. See AR (Vol. 140 Ref. 1649).

Copeland JR, Adem A, Jacob P, *et al.*, A comparison of the binding of nicotine and normicotine stereoisomers to nicotinic binding sites in rat brain cortex, *Naunyn Schmiedebergs Arch Pharmacol* 1991;343(2):123-127. See AR (Vol. 152 Ref. 1887).

Falkeborn Y, Larsson C, Nordberg A, Chronic nicotine exposure in rat: a behavioral and biochemical study of tolerance, *Drug Alcohol Depend* 1981;8:51-60. See AR (Vol. 141 Ref. 1679).

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Fuxe K, Andersson K, Eneroth P, *et al.*, Neurochemical mechanisms underlying the neuroendocrine actions of nicotine: focus on the plasticity of central cholinergic nicotinic receptors, *Prog Brain Res* 1989;79:197-207. See AR (Vol. 47 Ref. 95).

Fuxe K, Everitt BJ, Hokfelt T, On the action of nicotine and cotinine on central 5-hydroxytryptamine neurons, *Pharmacol Biochem Behav* 1979;10(5):671-677. See AR (Vol. 152 Ref. 1869).

Fuxe K, von Euler G, Finnman UB, *et al.*, Reduction of [3 H]nicotine binding in hypothalamic and cortical membranes by dopamine D1 receptors, *Acta Physiol Scand* 1989;136(2):295-296. See AR (Vol. 127 Ref. 1351).

Fuxe K, Agnati LF, Jansson A, *et al.*, Regulation of endocrine function by the nicotinic cholinergic receptor, *CIBA Foundation Symposium* 1990;152:113-130. See AR (Vol. 131 Ref. 1450).

Grenhoff J, Aston Jones G, Svensson TH, Nicotinic effects on the firing pattern of midbrain dopamine neurons, *Acta Physiol Scand* 1986;128(3):351-358. See AR (Vol. 143 Ref. 1771).

Larsson C, Nordberg A, Comparative analysis of nicotine-like receptor-ligand interactions in rodent brain homogenate, *J Neurochem* 1985;45:24-31. See AR (Vol. 141 Ref. 1684).

Larsson C, Lundberg PA, Halen A, *et al.*, In vitro binding of 3H-acetylcholine to nicotinic receptors in rodent and human brain, *J Neural Transm* 1987;69:3-18. See AR (Vol. 137 Ref. 1586).

Larsson C, Nilsson L, Halen A, *et al.*, Subchronic treatment of rats with nicotine: effects on tolerance and on [3 H]acetylcholine and [3 H]nicotine binding in the brain, *Drug Alcohol Depend* 1986;17:37-45. See AR (Vol. 141 Ref. 1677).

Nisell M, Nomikos GG, Svensson TH, Systemic nicotine-induced dopamine release in the rat nucleus accumbens is regulated by nicotinic receptors in the ventral tegmental area, *Synapse* 1994;16:36-44. See AR (Vol. 276 Ref. 3870).

Nordberg A, Romanelli L, Sundwall A, *et al.*, Effect of acute and subchronic nicotine treatment on cortical acetylcholine release and on nicotinic receptors in rats and guinea-pigs, *British Journal of Pharmacology* 1989;98(1):71-78. See AR (Vol. 131 Ref. 1454).

Nordberg A, Wahlstrom G, Arnello U, *et al.*, Effect of long-term nicotine treatment on [3-H]nicotine binding sites in the rats brain, *Drug Alcohol Depend* 1985;16:9-17. See AR (Vol. 141 Ref. 1678).

Nordberg A, Bergh C, Effect of nicotine on passive avoidance behaviour and motoric activity in mice, *Acta Pharmacol Toxicol Copenh* 1985;56(4):337-341. See AR (Vol. 274 Ref. 3820).

Nordberg A, Sundwall A, Pharmacodynamic effects of nicotine and acetylcholine biosynthesis, in mouse brain, *Acta Pharmacol Toxicol Copenh* 1983;52(5):341-347. See AR (Vol. 133 Ref. 1503).

Nordberg A, Larsson C, Studies of muscarinic and nicotinic binding sites in brain, *Acta Physiol Scand Suppl* 1980;479:19-23. See AR (Vol. 137 Ref. 1590).

Piloti A, Enzell CR, McKennis H Jr, *et al.*, Studies on the identification of tobacco alkaloids, their mammalian metabolites and related compounds by gas chromatography- Mass Spectrometry, *Beitrage zur Tabakforschung* 1976;8(6):339-349. See AR (Vol. 96 Ref. 704).

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Furthermore, numerous studies of the pharmacological effects and chemistry of nicotine and the sites and mechanisms of nicotine receptors in the brain have been funded by the Smokeless Tobacco Research Council.¹⁰¹² The Smokeless Tobacco Research Council

Schievelbein H, Absorption of Nicotine Under Various Conditions (an introductory review), presented at the Nicotine Workshop (Nov. 1974), *Beitrage zur Tabakforschung* 1976;8(5):196-202. See AR (Vol. 60 Ref. 254).

Schmitterlow CG, Hansson E, Andersson G, *et al.*, Distribution of Nicotine in the Central Nervous System, *Annals of the New York Academy of Sciences* 1967;142:2-14. See AR (Vol. 152 Ref. 1859).

Schmitterlow CG, Hansson E, Tissue distribution of C 14-nicotine, in Von Euler US (ed.), *Tobacco Alkaloids and Related Compounds* 1965:75-86, ed. Von Euler US. See AR (Vol. 60 Ref. 256).

Siegel RA, Andersson K, Fuxe K, *et al.*, Rapid and discrete changes in hypothalamic catecholamine nerve terminal systems induced by audiogenic stress, and their modulation by nicotine-relationship to neuroendocrine function, *Eur J Pharmacol* 1983;91:49-56. See AR (Vol. 60 Ref. 262).

Svensson TH, Engberg G, Effect of nicotine on single cell activity in the noradrenergic nucleus locus coeruleus, *Acta Physiol Scand Suppl* 1980;479:31-34. See AR (Vol. 422 Ref. 7124).

Szuts T, Olsson S, Lindquist NG, *et al.*, Long-term fate of [¹⁴C]nicotine in the mouse: retention in the bronchi, melanin-containing tissues and urinary bladder wall, *Toxicology* 1978;10(3):207-220. See AR (Vol. 131 Ref. 1458).

¹⁰¹² Anand R, and Lindstrom J, Chromosomal localization of seven neuronal nicotinic acetylcholine receptor subunit genes in humans, in *Report of the Council for Tobacco Research - USA, Inc. 1992*, at 101. See AR (Vol. 465 Ref. 7874).

Bencherif M, Lukas RJ, Cytochalasin modulation of nicotinic cholinergic receptor expression and muscarinic receptor function in human TE671/RD cells: a possible functional role of the cytoskeleton, *Journal of Neurochemistry* 1993;61(3):852-864. See AR (Vol. 141 Ref. 1683).

Britto LRG, Keyser KT, Lindstrom JM, *et al.*, Immunohistochemical localization of nicotinic acetylcholine receptor subunits in the mesencephalon and diencephalon of the chick (*Gallus Gallus*), *The Journal of Comparative Neurology* 1992;317:325-340. See AR (Vol. 131 Ref. 1453).

Cholerton S, McCracken NW, Idle JR, Sources of inter-individual variability in nicotine pharmacokinetics, in *Nicotine and Related Alkaloids: Absorption, Distribution, Metabolism, and Excretion*, eds. Gorrod JW, and Wahren J (1993), at 219-253. See AR (Vol. 47 Ref. 70).

Gerzanich V, Anand R, Lindstrom J, Homomers of $\alpha 8$ and $\alpha 7$ subunits of nicotinic receptors exhibit similar channel but contrasting binding site properties, *Molecular Pharmacology* 1994;45(2):212-220. See AR (Vol. 276 Ref. 3861).

Hsu YN, Amin J, Weiss D, *et al.*, Chronic nicotine exposure decreases the activation of $\alpha 4\beta 2$ but not $\alpha 3\beta 2$ neuronal nicotinic receptors expressed in *xenopus* oocytes, in *International Symposium on Nicotine: The*

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Effects of Nicotine on Biological Systems II, eds. Clarke PBS *et al.* (Montreal: Jul. 21-24, 1994). See AR (Vol. 135 Ref. 1529).

Keyser KT, Britto LRG, Schoepfer R, *et al.*, Three subtypes of α -bungarotoxin - sensitive nicotinic acetylcholine receptors are expressed in chick retina, *Journal of Neuroscience*, Feb. 1993;13(2):442-454. See AR (Vol. 126 Ref. 1343).

Marks R, Lindstrom J, Schroder H, Cellular and subcellular visualization of the $\beta 2$ - subunit of the nicotinic acetylcholine receptor in the mouse cerebral cortex, in *International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II*, eds. Clarke, PBS, *et al.*, at session 1, 4 (Montreal: Jul. 21-24, 1994). See AR (Vol. 104 Ref. 952).

McFarland BJ, Seidler FJ, Slotkin TA, Inhibition of DNA synthesis in neonatal rat brain regions caused by acute nicotine administration, *Developmental Brain Research* 1991;58:223-229. See AR (Vol. 414 Ref. 6940).

McLane DE, Wu X, Schoepfer R, *et al.*, Identification of sequence segments forming the α -bungarotoxin binding sites on two nicotinic acetylcholine receptor α subunits from the avian brain, in *Report of the Council for Tobacco Research - USA, Inc. 1991*. See AR (Vol. 19 Ref. 195-22).

McLane DE, Wu X, Lindstrom JM, *et al.*, Epitope mapping of polyclonal and monoclonal antibodies against two α -bungarotoxin-binding α subunits from neuronal nicotinic receptors, in *Report of the Council for Tobacco Research - USA, Inc. 1992*. See AR (Vol. 19 Ref. 195-23).

Navarro HA, Seidler FJ, Schwartz RD, *et al.*, Prenatal exposure to nicotine impairs nervous system development at a dose which does not affect viability or growth, *Brain Research Bulletin* 1989;23:187-192. See AR (Vol. 137 Ref. 1585).

Nelson S, Shelton GD, Lei S, *et al.*, Epitope mapping of monoclonal antibodies to *torpedo* acetylcholine receptor γ subunits, which specifically recognize the ϵ subunit of mammalian muscle acetylcholine receptor, in *Report of the Council for Tobacco Research - USA, Inc. 1992*. See AR (Vol. 19 Ref. 195-23).

Seeman JJ, Secor HV, Armstrong DW, *et al.*, Enantiomeric resolution and chiral recognition of racemic nicotine and nicotine analogues by β -cyclodextrin complexation. Structure-enantiomeric resolution relationships in host-guest interactions, *Analytical Chemistry* 1988;60:2120-2127. See AR (Vol. 275 Ref. 3836).

Slotkin TA, Cho H, Whitmore WL, Effects of prenatal nicotine exposure on neuronal development: selective actions on central and peripheral catecholaminergic pathways, *Brain Research Bulletin* 1987;18(5):601-611. See AR (Vol. 137 Ref. 1573).

Slotkin TA, Navarro HA, McCook EC, *et al.*, Fetal nicotine exposure produces postnatal up-regulation of adenylate cyclase activity in peripheral tissues, *Life Sciences* 1990;47:1561-1567. See AR (Vol. 276 Ref. 3865).

Slotkin TA, Lappi SE, Tayyeb MI, *et al.*, Chronic prenatal nicotine exposure sensitizes rat brain to acute postnatal nicotine challenge as assessed with ornithine decarboxylase, *Life Sciences* 1991;49(9):665-670. See AR (Vol. 137 Ref. 1580).

Slotkin TA, Developmental effects of nicotine, in *International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II*, eds. Clarke PBS, *et al.*, at session 4, S15 (Montreal: Jul. 21-24, 1994). See AR (Vol. 60 Ref. 264).

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was formed by the major smokeless tobacco manufacturers to fund scientific studies on behalf of the manufacturers. One such study recognized that nicotine is “*the major pharmacologically active component of tobacco.*”¹⁰¹³

2. The Smokeless Tobacco Manufacturers Manipulate Nicotine Deliveries from Smokeless Tobacco in a Manner That Promotes Tolerance and Addiction in Users

The evidence in the record also demonstrates that smokeless tobacco manufacturers manipulate the nicotine delivery of their products to produce graduated deliveries of nicotine that promote tolerance and addiction. Specifically, the evidence shows that the nicotine deliveries of smokeless tobacco are manipulated so that products intended for new users deliver low amounts of nicotine, while products intended for experienced users deliver far higher amounts of nicotine. This manipulation of nicotine delivery is accomplished primarily

Slotkin TA, Lappi SE, Seidler FJ., Impact of fetal nicotine exposure on development of rat brain regions: critical sensitive periods or effects of withdrawal?, *Brain Research Bulletin* 1993;31:319-328. See AR (Vol. 137 Ref. 1571).

Wahlsten JL, Lindstrom JM, Conti-Tronconi BM, Amino acid residues within the sequence region α 55-74 of torpedo nicotinic acetylcholine receptor interacting with antibodies to the main immunogenic region and with snake α -neurotoxins, in *Report of the Council for Tobacco Research - USA, Inc. 1993*, at 166-167. See AR (Vol. 465 Ref. 7873).

Wahlsten JL, Lindstrom JM, Ostlie N, *et al.*, Myasthenia gravis: effect on antibody binding of conservative substitutions of amino acid residues forming the main immunogenic region of the nicotinic acetylcholine receptor, in *Report of the Council for Tobacco Research - USA, Inc. 1993*, at 166. See AR (Vol. 465 Ref. 7873).

Yu CI, Morgan DG, Wecker L, Northern blot analysis demonstrates the presence of three different transcripts of neuronal nicotinic acetylcholine receptor α 4 gene in rat brain, in *International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II*, eds. Clarke PBS, *et al.*, at session 2, P10 (Montreal: Jul. 21-24, 1994). See AR (Vol. 104 Ref. 952).

¹⁰¹³ Cholerton S, McCracken NW, Idle JR, Sources of inter-individual variability in nicotine pharmacokinetics, in *Nicotine and Related Alkaloids: Absorption, Distribution, Metabolism, and Excretion*, eds. Gorrod JW, Wahren J (1993):219-253, at 219 (emphasis added). See AR (Vol. 47 Ref. 70).

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through the use of chemicals that alter the pH (acidity or alkalinity) of the tobacco. The effect is to promote tolerance and addiction in users.

The evidence of nicotine manipulation in smokeless tobacco in a manner that promotes tolerance in addiction in users is extensive. First, evidence shows that products intended for new users deliver less nicotine than products intended for experienced users. These graduated nicotine deliveries lead to increased tolerance and addiction because they allow new users to avoid adverse reactions to nicotine by beginning with low-nicotine products, while allowing experienced users to obtain sufficient nicotine to sustain their addiction by progressing to high-nicotine products.

Second, governmental data on smokeless tobacco use confirms that the graduated nicotine deliveries promote tolerance and addiction. These data show that since the advent of smokeless tobacco products with graduated nicotine deliveries, the number of children and adolescents who use and are addicted to smokeless tobacco has risen substantially.

Third, evidence from internal company documents and marketing campaigns of the nation's largest smokeless tobacco manufacturer, UST, shows the conscious manipulation of nicotine deliveries. UST deliberately relies on an explicit "graduation process" that introduces new users to low-nicotine delivery products while providing experienced users with higher-nicotine delivery products.

In combination with the evidence that the manufacturers understand the pharmacological effects and uses of nicotine, this evidence of nicotine manipulation to promote pharmacological effects in users demonstrates that the effects of nicotine in

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smokeless tobacco on the structure and function of the body are “intended” by the manufacturers.

a. Evidence of Graduated Nicotine Deliveries

Absorption of a drug through the buccal mucosa in the mouth into the bloodstream can be increased or decreased by adjusting the pH of the drug. Pharmaceutical companies regularly alter pH by adding alkaline or acidic additives to drugs to increase or decrease their absorption into the bloodstream. Raising the pH converts many drugs from an ionized form into a non-ionized or “free” form that more readily crosses biological membranes.¹⁰¹⁴

Nicotine absorption is affected in this manner by pH levels. Increasing the pH of nicotine converts ionized nicotine into non-ionized nicotine, rendering it significantly more absorbable in the mouth.¹⁰¹⁵ For this reason, the manufacturer of nicotine gum adds sodium carbonate to increase pH and enhance the absorption of nicotine.¹⁰¹⁶ Tobacco industry-supported researchers have acknowledged that nicotine absorption in the mouth increases as a function of pH and that “the pharmacological response is clearly dependent on the amount of nicotine in the mouth as free base.”¹⁰¹⁷ Indeed, the senior vice president for marketing at

¹⁰¹⁴ Benet LZ, Steiner LB, Pharmacokinetics: The dynamics of drug absorption, distribution, and elimination in *Goodman and Gilman's The Pharmacological Basis of Therapeutics* (1990), 3-32, at 4-5. See AR (Vol. 711 Ref. 14).

¹⁰¹⁵ Surgeon General's Report, 1988, at 29. See AR (Vol. 129 Ref. 1592).

¹⁰¹⁶ Henningfield JE, Radzius A, Cooper TM, *et al.*, Drinking coffee and carbonated beverages blocks absorption of nicotine from nicotine polacrilex gum, *Journal of the American Medical Association*, 1990;264:1560-1564. See AR (Vol. 29 Ref. 491-2).

¹⁰¹⁷ Armitage AK, Turner DM, Absorption of nicotine in cigarette and cigar smoke through the oral mucosa, *Nature*, 1970;226:1231-1232, at 1232. See AR (Vol. 143 Ref. 1810).

Cholerton S, McCracken NW, Idle JR, Sources of inter-individual variability in nicotine pharmacokinetics, in *Nicotine and Related Alkaloids: Absorption, Distribution, Metabolism, and Excretion*, eds. Gorrod JW, Wahren J (1993), at 220-221 (“Absorption of nicotine from chewing tobacco and nicotine gum is facilitated by buffering of the preparations to an alkaline pH (approx. 8.5)”). See AR (Vol. 47 Ref. 70).

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UST conceded that it was his understanding that “if the pH of the snuff product is raised, . . . the rate of absorption of the nicotine would be increased in the user’s mouth.”¹⁰¹⁸

The data collected and analyzed by FDA¹⁰¹⁹ and others¹⁰²⁰ demonstrate that moist snuff products marketed as “starter” products have relatively low pH levels, while products for established users have significantly higher pH levels, resulting in a pattern of graduated delivery of free nicotine. UST’s principal line of starter products is its “Skoal Bandits” line. The pH levels for Skoal Bandits are low, ranging from 5.2 to 5.6 for Skoal Bandits Classic to 6.8 to 7.1 for Skoal Bandits Mint; the free nicotine provided by Skoal Bandits is also low, ranging from 0.2% to 0.4% for Skoal Bandits Classic to only 6.4% to 9.9% for Skoal Bandits Mint. *See* Jurisdictional Analysis, 60 FR 41737. Likewise, another UST starter product, “Happy Days,” has a pH of 6.0 and provides only 0.9% free nicotine. In contrast, UST’s principal product for established users, Copenhagen, has a pH of 7.7 to 8.1. Because pH is measured on a logarithmic scale, the alkalinity of Copenhagen is approximately two

¹⁰¹⁸ The exchange from the *Marsee* trial transcript on this point was:

Q: And correspondingly, if the pH of the snuff product is raised, then, the rate of absorption of the nicotine from the snuff product would be increased in the user’s mouth?

A: Although I am not an expert on this, that is to the best of my understanding correct.

Deposition of Erik Lindqvist, *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.R. Ok. 1986). Transcript of jury trial proceedings, at 1668. *See* AR (Vol. 29 Ref. 489-2). The relationship between ionized nicotine and nicotine in its free form is thus similar to the relationship between cocaine and “free-base” or “crack” cocaine. Increasing the pH of cocaine, through the addition of alkaline additives such as sodium bicarbonate and ammonia, converts cocaine salt into free-base or crack cocaine, thereby significantly increasing the rate at which the cocaine is absorbed into the bloodstream. Siegel RK, Part III cocaine free base use, *Journal of Psychoactive Drugs* 1982;14:311-318, 352-359. *See* AR (Vol. 711 Ref. 23).

¹⁰¹⁹ The table on the next page presents the results of the studies performed by the two FDA laboratories in St. Louis, Missouri, and Cincinnati, Ohio.

¹⁰²⁰ Djordjevic MV, Hoffmann D, Glynn T, *et al.*, US commercial brands of moist snuff, 1994, Assessment of nicotine, moisture, and pH, *Tobacco Control*, 1995;4:62-66. *See* AR (Vol. 528 Ref. 97, appendix 9).

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MANUFACTURER/ PRODUCT NAME	TOTAL NICOTINE					
	pH		%Free Nicotine*		Content(mg/gm)**	
	St.Louis	Cinc.	St.Louis	Cinc.	St. Louis	Cinc.
U.S. Tobacco Co.						
Skoal Key	-	8.22	-	61.3	-	12.4
Copenhagen Snuff	8.14	7.71	56.5	32.7	13.2	13.8
Skoal L.C. Class	8.04	7.92	51.1	44.5	12.7	13.8
Skoal L.C. Wint.	7.50	7.57	23.1	26.0	12.7	13.9
Skoal L.C. Mint	7.35	7.52	17.6	24.0	13.2	13.7
Skoal L.C. Spear.	7.20	7.50	14.0	23.3	12.5	13.8
Skoal Or.F.C. Wint.	-	7.41	-	19.7	-	13.6
Skoal L.C. Strai.	7.47	7.41	22.0	19.5	12.1	13.8
Skoal L.C. Cherry	7.15	7.38	12.3	18.5	12.5	13.6
Skoal Band. Mint	6.83	7.06	6.4	9.9	6.7	8.8
Skoal Band. Wint.	6.56	6.72	3.3	4.8	7.8	8.2
Happy Days L.C. Mint -	6.00	-	0.9	-	13.9	-
Skoal Band. Strai.	-	5.48	-	0.3	-	10.8
Skoal Band. Class.	5.61	5.23	0.39	0.2	10.4	9.9
Helme Tobacco Co.***						
Redwood Full Flavor	-	7.52	-	24.0	-	12.6
Silver Cr. L.C.	-	7.22	-	13.7	-	6.0
Cooper Wint. L.C.	-	6.99	-	8.5	-	5.7
Gold River L.C.	-	5.77	-	0.6	-	6.4
Conwood Co.						
Kodiak Wint.	8.20	8.22	59.9	61.0	11.4	11.7
Kodiak Choice Wint.	-	7.98	-	47.7	-	11.4
Kodiak Straight	7.39	7.82	19.0	38.4	10.6	10.4
Hawken Wint.	5.56	5.58	0.35	0.4	4.4	0.4
Pinkerton Tobacco Co.						
Redman F.C. Ex. Wint.	-	7.58	-	-	-	12.3
Renegade Wint.	6.81	7.17	5.8	-	13.2	11.8

L.C. = long cut

* Calculated using the Henderson-Hasselbach Equation for acid base equilibrium. This calculation strictly is dependent on the pH determination. Any error in the pH determination will affect the percent free nicotine calculation.

** Measured on wet basis

*** Now Swisher International, Inc.

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orders of magnitude higher than the alkalinity of Skoal Bandits Classic and Happy Days (as measured in hydrogen ion concentrations). The level of free nicotine provided by Copenhagen is 33% to 57%, also far higher than the levels provided by Skoal Bandits or Happy Days.¹⁰²¹

The same pattern of graduated nicotine deliveries is found in the smokeless tobacco products of other manufacturers. Conwood's principal line of moist snuff starter products, "Hawken," has a pH of 5.6 and provides 0.4% free nicotine, whereas Conwood's product marketed for established users, "Kodiak-Wintergreen," has a pH of 8.2 and provides about 60% free nicotine.¹⁰²² Similarly, the principal starter product of Swisher International, Inc. (formerly Helme Tobacco Co.), "Gold River L.C.," has a pH of 5.8 and provides 0.6% free nicotine, whereas its product marketed for established users, "Redwood Full Flavor," has a pH of 7.5 and provides 24% free nicotine.¹⁰²³

These graduated nicotine deliveries directly promote tolerance and addiction. New users of smokeless tobacco have not developed a tolerance to nicotine. As a result, as a UST study documented, too much nicotine causes adverse reactions such as nausea and vomiting in new users,¹⁰²⁴ discouraging future experimentation with smokeless tobacco. Once tolerance to nicotine is developed, however, increasing doses of nicotine are required to

¹⁰²¹ See Table of "Total Nicotine" above.

¹⁰²² *Id.*

¹⁰²³ *Id.*

¹⁰²⁴ U.S. Tobacco Company, Pharmacokinetics of Nicotine and Its Major Metabolites in Naive and Habituated Snuff Takers, Plaintiff's exhibit 3.27 from *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986), at 9. See AR (Vol. 24 Ref. 317).

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produce the desired pharmacological effects.¹⁰²⁵ Thus, if nicotine levels were kept uniformly low to accommodate new users, the experienced user would not obtain the higher level of nicotine delivery needed to satisfy the user's addiction and to provide other desired pharmacological effects.

Graduating nicotine deliveries avoid these consequences and lead to increased tolerance and addiction. The low levels of nicotine delivery in starter brands, such as Skoal Bandits, allow the new user to develop a tolerance to nicotine¹⁰²⁶ without nausea and other adverse reactions. Once this tolerance is developed, the high levels of nicotine delivery in brands such as Copenhagen provide the experienced user with the desired increase in nicotine dose. Nicotine addiction is the final result.

There are several techniques the smokeless manufacturers use to achieve control over pH levels in smokeless tobacco. According to one report, pH adjustment is "done through fermentation, by adding alkaline buffering agents such as sodium carbonate and ammonium carbonate, or by altering the moisture content."¹⁰²⁷ The Swedish Tobacco Company, which like Pinkerton Tobacco Company is owned by Procordia AB, has admitted that "[i]n order to release the nicotine from the tobacco, the snuff is made slightly alkaline—sodium carbonate is added. . . ."¹⁰²⁸ The Smokeless Tobacco Council has also reported that two alkaline

¹⁰²⁵ Surgeon General's Report, 1988, at 44-45. See AR (Vol. 129 Ref. 1592).

¹⁰²⁶ Connolly GN, Orleans CT, Blum A, Snuffing tobacco out of sport, *American Journal of Public Health* Mar. 1992;82(3):352. See AR (Vol. 94 Ref. 629).

¹⁰²⁷ Connolly GN, Marketing of Nicotine Addiction By One Oral Snuff Manufacturer, *Tobacco Control* 1995;4:73-79, at 74. See AR (Vol. 528 Ref. 97, appendix 9).

¹⁰²⁸ Swedish Tobacco Company, *Smokeless Tobacco from Gothenburg*, 1994, appendix B, quoted in statement of Gregory N. Connolly in *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 53 (Nov. 29, 1994) (emphasis added). See AR (Vol. 710 Ref. 4).

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buffering agents, sodium carbonate and ammonium carbonate, are used in smokeless tobacco sold in the U.S.¹⁰²⁹

Despite this evidence, the smokeless tobacco industry argues that the pattern of pH values in smokeless tobacco is not the result of intentional nicotine manipulation. The Agency disagrees. The pH values in the upper ranges seen in marketed smokeless tobacco for established users do not occur naturally in the tobacco used for the production of smokeless tobacco. Jack Henningfield, chief, clinical pharmacology branch of the Addiction Research Center at the National Institute on Drug Abuse, testified before Congress:

Naturally occurring tobacco . . . does not occur, at least in these kinds of tobaccos, at the high pH levels that we observed. Normal fermentation processes typically result in acidification, as anyone has found when they saw their wine turn into vinegar. But here we see very high [alkaline] pH levels in some of the products.¹⁰³⁰

Moreover, other product features reflect a consistent attempt to market products that deliver smaller amounts of nicotine to new users and products that deliver larger amounts to established users. For example, UST's Skoal Bandits and Pinkerton's starter product, Renegades, are packaged in teabag-like pouches, which both contain a much smaller amount of snuff (about 0.5g) than the usual standard size "pinch" of snuff (about 1.5g). The pouch system also delays the release of nicotine from the snuff.¹⁰³¹ Thus, FDA data show that,

¹⁰²⁹ Letter to Waxman HA and Bliley, Jr. TJ (U. S. House of Representatives) from Pape SM (Patton, Boggs & Blow) (May 3, 1994), with enclosure *Ingredients Added to Tobacco in the Manufacture of Smokeless Tobacco Products as of April 4, 1994*. See AR (Vol. 192 Ref. 2173).

¹⁰³⁰ *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 98 (Nov. 29, 1994) (statement of Jack Henningfield). See AR (Vol. 710 Ref. 4).

¹⁰³¹ Memorandum from Ciolino L, *Moist Snuff Nicotine Release Studies* (Sep. 28, 1994), at 1. See AR (Vol. 30 Ref. 500-2).

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under typical use conditions, a standard size “pinch” of Copenhagen releases *12 times as much nicotine* in the first 2 minutes as a pouch of Bandits.¹⁰³²

The evidence thus demonstrates that smokeless tobacco manufacturers intentionally manipulate the pH levels of smokeless tobacco, thereby controlling and adjusting the level of nicotine delivered to consumers. Products intended for new users have uniformly lower levels of pH and nicotine delivery than products intended for experienced users. The effect is to promote nicotine tolerance and addiction in users of smokeless tobacco.

b. Evidence that Teenage Users Graduate from Smokeless Tobacco with Low Nicotine Deliveries to Products with High Nicotine Deliveries

Data on teenage use of smokeless tobacco shows that the manufacturers’ graduated nicotine deliveries have increased addiction to smokeless tobacco among young people. These data show that: (1) children and adolescents begin smokeless tobacco use with low nicotine delivery starter products and then switch to products with higher nicotine deliveries; and (2) the number of children and adolescents addicted to smokeless tobacco has risen substantially since the introduction of smokeless tobacco products with graduated nicotine deliveries.

Before the introduction of starter brands with low levels of nicotine in the early 1970’s, virtually no teenagers and young adults used smokeless tobacco. According to the Centers for Disease Control and Prevention (CDC), “[i]n 1970, the use of smokeless tobacco

¹⁰³² *Id.* at 2. See AR (Vol. 30 Ref. 500-2).

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was a behavior primarily restricted to older men.”¹⁰³³ In that year, only 2.2% of young males used smokeless tobacco, compared with 12.7% of males age 65 or older.¹⁰³⁴

In the 1970’s, however, smokeless tobacco manufacturers began to market low-nicotine “starter” products.¹⁰³⁵ These products have proven extremely successful in attracting young new users. Use by adolescent males aged 18 to 19 has increased approximately 1,500% between 1971 and 1991.¹⁰³⁶ Overall, use of smokeless tobacco almost tripled between 1970 and 1991.¹⁰³⁷ As discussed in section II.B.2., above, it has been estimated that approximately 75% of the regular young users of smokeless tobacco are addicted to nicotine.

Although the majority of the industry’s advertising dollars are spent on promoting low- and medium-nicotine brands,¹⁰³⁸ these brands serve mainly as a stepping stone to the high-nicotine delivery products. Most of the increased sales of smokeless tobacco are sales of high-nicotine delivery brands, like Copenhagen.¹⁰³⁹

¹⁰³³ *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 34 (Nov. 29, 1994) (statement of Michael P. Eriksen). See AR (Vol. 710 Ref. 4).

¹⁰³⁴ *Id.*

¹⁰³⁵ Connolly GN, *In the search for a perfect starter product: manipulation of nicotine in oral snuff brands* (1994) (unpublished), at 3-4. See AR (Vol. 30 Ref. 511).

¹⁰³⁶ Centers for Disease Control and Prevention, Office of Smoking and Health, unpublished data from 1970 and 1991 National Household Interview Surveys (rate of snuff use among 18-19 year-old males was 0.5% in 1970 and 7.6% in 1991). See AR (Vol. 31 Ref. 521-1).

¹⁰³⁷ *Id.*

¹⁰³⁸ Connolly GN, *In the search for a perfect starter product: manipulation of nicotine in oral snuff brands* (1994) (unpublished), at 5. See AR (Vol. 30 Ref. 511).

¹⁰³⁹ *Id.* at 6.

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A study by CDC confirms the role of low-nicotine delivery brands as starter products. The study analyzes data from CDC's 1993 Teenage Attitudes and Practices Survey (TAPS) and from a follow-up study to the 1989 TAPS.¹⁰⁴⁰ The authors found that the percentage of beginning teenage snuff users who bought Skoal Bandits (low nicotine delivery) and Skoal (medium nicotine delivery) was higher than the percentage of experienced teenage snuff users who bought these products.¹⁰⁴¹ Similarly, the proportion of teenage snuff users who chose Copenhagen (high nicotine delivery) was about three times higher among those who used snuff for 4 years or more than among those who used snuff for 1 year or less.¹⁰⁴² Use of Copenhagen was also higher among those who used smokeless tobacco more frequently and with increased intensity.¹⁰⁴³ The study also included an analysis that found that of those who used Skoal Bandits or Skoal at the beginning of the study, nearly a third had switched to Copenhagen 4 years later.¹⁰⁴⁴ However, among those who used Copenhagen at the beginning of the study, 83% were still using it 4 years later. Thus, teenage moist snuff users were significantly more likely to graduate to a higher nicotine delivery product than to switch down to a lower nicotine delivery product.¹⁰⁴⁵

The CDC report concluded that these findings "support the hypothesis that snuff users in earlier stages of tobacco use and nicotine addiction, use brands with low levels of

¹⁰⁴⁰ Tomar S, Giovino G, Eriksen M, Smokeless tobacco brand preference and switching among U.S. adolescents and young adults, *Tobacco Control* 1995;4:67-72. See AR (Vol. 528 Ref. 97, appendix 9).

¹⁰⁴¹ *Id.* at 69.

¹⁰⁴² *Id.* at 71.

¹⁰⁴³ *Id.*

¹⁰⁴⁴ *Id.*

¹⁰⁴⁵ *Id.*

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free nicotine, and then 'graduate' to brands with high levels."¹⁰⁴⁶ The report further stated that "[t]his pattern of brand preference probably reflects a progression of nicotine addiction and the need to increase nicotine intake to maintain the same physiological and psychological effects (chronic tolerance)."¹⁰⁴⁷

More frequent smokeless tobacco use, and use of products with higher amounts of free nicotine, result in greater difficulty in quitting, which is one of the characteristic features of addiction. *See* section II.A.3.b., above. CDC has found that 74% of young people who use smokeless tobacco daily report that "it's really hard to quit," compared with only 11% of those who use smokeless tobacco infrequently.¹⁰⁴⁸ When CDC evaluated the data by brand, it found that, of young people who used smokeless tobacco only infrequently, 22% of infrequent Copenhagen users reported that it was very difficult to quit, compared with only 7% of infrequent Skoal or Skoal Bandits users.¹⁰⁴⁹

Thus, empirical evidence indicates that the manufacturers' manipulation of nicotine deliveries has led to increased tolerance and addiction to nicotine among young smokeless tobacco users. Combined with the evidence of the manufacturers' understanding of the pharmacological effects of nicotine, and the laboratory evidence of graduated nicotine deliveries, this evidence shows that (1) the manufacturers manipulate nicotine in a manner that encourages new users to become tolerant and addicted to nicotine; and (2) there has

¹⁰⁴⁶ *Id.* at 72.

¹⁰⁴⁷ *Id.* at 71.

¹⁰⁴⁸ *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 40 (Nov. 29, 1994) (statement of Michael P. Eriksen). *See* AR (Vol. 710 Ref. 4).

¹⁰⁴⁹ *Id.*

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been a significant increase in smokeless tobacco use and nicotine tolerance and addiction among young smokeless tobacco users since the manufacturers began manipulating nicotine deliveries. This evidence provides a sufficient basis for the Agency's conclusion that the manufacturers intend to affect the structure and function of the body.

c. Documentary Evidence of UST's Deliberate "Graduation Process"

Although further evidence is unnecessary to establish that smokeless tobacco is intended to affect the structure and function of the body, evidence from the major moist snuff producer, UST, provides striking confirmation of an intentional plan to cause tolerance and addiction in users of smokeless tobacco. This evidence shows that UST intentionally manufactures products that deliver low, medium, and high amounts of nicotine; markets the lower nicotine delivery products to new users; and encourages established users to select higher nicotine delivery products. UST documents explicitly describe the company's strategy as a "graduation process," which the company exploits through marketing and advertising techniques.

UST's development of products offering graduated nicotine deliveries began in the late 1960's or early 1970's. The company initiated the "Lotus Project." A 1972 memorandum describing the project states that the "aim" was "[t]o make it easier for a new user to use tobacco in the mouth"; that the "target group" was "[n]ew users . . . age group 15-35"; and that the "product" should provide "[n]icotine satisfaction" that was "[m]ild" and "[i]nstant but not shocking."¹⁰⁵⁰ In another document discussing the Lotus Project, the president of UST's foreign subsidiary, United Scandia International, wrote to the president of UST to describe the graduated nicotine deliveries that should be offered:

¹⁰⁵⁰ *The Lotus Project*, from *Marsee v. U.S. Tobacco*, trial exhibit 159. See AR (Vol. 30 Ref. 505-3).

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There should be three products of three different tastes and strengths of nicotine.

a. High nicotine, strong tobacco flavor . . .

b. Medium strength of nicotine . . .

*c. Low nicotine, sweet product.*¹⁰⁵¹

Shortly after these Lotus Project documents were written, UST began aggressively to market low-nicotine starter products to new users. An advertisement for "Happy Days," one of the first low-nicotine products, targeted the product "for You Guys Just Starting Out."¹⁰⁵² In addition, UST's low-nicotine delivery products were marketed as starter products through free sampling on college campuses and at sports events.¹⁰⁵³

A brochure for Skoal Bandits contained instructions on how to use the products, a marketing approach tailored to the new user.¹⁰⁵⁴ In contrast, advertisements for UST's high-nicotine delivery product, Copenhagen, do not contain instructions or suggestions that they be tried by new users. Rather, Copenhagen's advertisements emphasize "satisfaction," an implied drug claim. See section II.E.2., below. They also seem to encourage graduation, using the slogan "Sooner or Later, It's Copenhagen."¹⁰⁵⁵

¹⁰⁵¹ Intracompany correspondence from Watson WW, president, United Scandia Internationals, to Bantle LA, president, U.S. Tobacco Company (Jun. 2, 1972) at 2, from *Marsee v. U.S. Tobacco*, trial exhibit 158 (emphasis added). See AR (Vol. 30 Ref. 505-2).

¹⁰⁵² Connolly GN, *In search for a perfect starter product: manipulation of nicotine in oral snuff brands* (1994) (unpublished). See AR (Vol. 30 Ref. 511).

¹⁰⁵³ U.S. Tobacco Company, *College Representative Manual, Introduction* (Jul. 31, 1985). See AR (Vol. 30 Ref. 512).

Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives, 103d Cong., 2d Sess. 108 (Nov. 29, 1994). See AR (Vol. 710 Ref. 4).

¹⁰⁵⁴ Connolly GN, *In search for a perfect starter product: manipulation of nicotine in oral snuff brands* (1994) (unpublished), at 5. See AR (Vol. 30 Ref. 511).

¹⁰⁵⁵ *Id.*

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In its comment, UST denies that it ever used a graduation strategy. However, documents presented to a congressional subcommittee in 1994, and other evidence, indicate that by the 1980's senior UST officials were explicitly describing their marketing approach as a "graduation process." For example:

- An executive vice-president of UST stated in a 1986 interview published in a UST newsletter:

for each market there is a set of criteria which have been established, and must be met. Skoal Bandits is the introductory product, and then *we look towards establishing a normal graduation process.*¹⁰⁵⁶

- Similarly, Ken Carlsen, a division manager in UST's sales department from 1979 to 1986, stated in an interview in the *Wall Street Journal*:

They talked about graduation all the time—in sales meetings, memos and manuals for the college program. *It was a mantra.*¹⁰⁵⁷

There are numerous other statements in the record from UST officials that refer expressly to UST's "graduation process."¹⁰⁵⁸ Indeed, two UST documents illustrate the company's

¹⁰⁵⁶ Interview of Jack Africk, executive vice president of U.S. Tobacco Company and president of the international division, *Up to Snuff*, 1986, at 2 (emphasis added). See AR (Vol. 196 Ref. 2496).

¹⁰⁵⁷ Freedman AM, Juiced up: how a tobacco giant doctors snuff brands to boost their "kick," *Wall Street Journal*, Oct. 26, 1994 (emphasis added). See AR (Vol. 20 Ref. 201).

¹⁰⁵⁸ See UST statements on nicotine manipulation, use of starter brands and graduation strategy, as cited in statement of Gregory N. Connolly in *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 58-64 (Nov. 29, 1994). See AR (Vol. 710 Ref. 4). These statements include the following:

"For people who haven't tasted (snuff) you'd of course begin them on a product that had a little tobacco taste, but wouldn't turn them off. . . . The *graduation* is to a more tobacco-y product . . . to a stronger product(s)." Source: Barry Nova, former president, U.S. Tobacco Company, *Wall Street Journal*, Oct. 26, 1994 (emphasis added).

"*Product Graduation Process.* . . . The Smokeless Consumer Marketing Representative must be aware of the importance of developing new users on a continuing basis and the importance of developing basis and the *graduation*

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strategy graphically. The first, a chart depicting a “graduation process,” displays a hierarchy of UST products.¹⁰⁵⁹ Arrows labeled “graduation process” represent the progression envisioned in this process, from the starter products, Skoal Bandits, at the bottom, past Skoal Long Cuts, which delivers an intermediate level of nicotine, to Copenhagen at the top of the chart.

The second document, another chart, depicts the graduation process as a bullseye.¹⁰⁶⁰ “Prospective new users” is printed just outside the outermost ring of the chart, “Bandits” is printed in the outer ring, “Long Cut” and “Skoal” are printed in successive inner rings, and “Cope” is printed in the bullseye. The rings of the chart thus progress from the lowest nicotine delivery products on the outside to the highest nicotine delivery products in the center of the bullseye. Marketing strategies for each circle are listed outside the bullseye and further demonstrate the company’s intention to sell low-nicotine delivery products to new

sampling brands and competitive brands.” Source: U.S. Tobacco Company Document no. 2215172, *Marsee* Court Transcript at 114, vol. 4, read into the record by Mr. Braly (emphasis added).

“Sampling Skoal Bandits often and intensively in and around the retail account create[s] new customers and feed[s] the *graduation* process.” Source: U.S. Tobacco Company Document no. 2101576, *Marsee* Court Transcript at 115, vol. 4, read into the record by Mr. Braly (emphasis added).

Skoal Bandits “will continue to fuel the new user base to assure *graduation* to our priority moist brands.” Source: U.S. Tobacco Company Document no. 2077832, *Marsee* Court Transcript at 112, vol. 4, read into the record by Mr. Braly (emphasis added).

“This brand (Happy Days) has been clearly positioned as a *starter product*.” Source: U.S. Tobacco Document no. 2143461, *Marsee* Court Transcript at 114, vol. 4, read into the record by Mr. Braly (emphasis added).

¹⁰⁵⁹ *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 62 (Nov. 29, 1994). See AR (Vol. 710 Ref. 4).

¹⁰⁶⁰ *Id.* at 101.

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users and high-nicotine delivery products to established users. For example, “mass” free sampling is planned for Bandits, “quality 1 on 1” sampling for Skoal Long Cut, and *no* sampling for Copenhagen. Similarly, while “mass” advertising is planned for Bandits, only “focused” advertising to “[r]einforce image among current users” is planned for Copenhagen. And while public relations efforts for Bandits and Long Cut are to be “[e]ducational,” public relations efforts for Skoal and Copenhagen are to “[e]mphasize tradition and heritage.”¹⁰⁶¹

The UST documents show further that the company’s manipulation of nicotine was deliberate. A senior vice president for marketing at UST, for example, has conceded that one UST product under development in the early 1980’s was intended to deliver less nicotine by design by lowering pH.¹⁰⁶²

These UST documents provide persuasive confirmation that UST produces smokeless tobacco brands with a range of nicotine deliveries in order to allow users to progress from low-nicotine delivery products to high-nicotine delivery products. Low-nicotine delivery products, which avoid overdosing new users who have not yet developed a tolerance to nicotine, are deliberately marketed to “you guys just starting out.” Once these new users develop a tolerance to nicotine, UST provides them with high-nicotine delivery products that

¹⁰⁶¹ U.S. Tobacco Company, *Expanding User Base* (undated). This document was disclosed during discovery in *Marsee v. U.S. Tobacco*. See AR (Vol. 30 Ref. 518)

¹⁰⁶² The exchange from the *Marsee* trial transcript on this point was:

Q: So this Red Seal menthol product was *intended to deliver less nicotine by design by lowering the pH*; is that correct?

A: That is correct.

Deposition of Erik Lindqvist, transcript of jury trial proceedings at 1668 *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986) (emphasis added). See AR (Vol. 22 Ref. 292).

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satisfy their addiction to nicotine. This is strong evidence that smokeless tobacco is intended to affect the structure and function of the body.

3. Conclusion

After careful consideration of the evidence in the administrative record and the comments on the Jurisdictional Analysis, the Agency finds that smokeless tobacco manufacturers intend that their products cause significant pharmacological effects in smokeless tobacco users. The Agency bases this finding primarily on two grounds.

First, the evidence shows that smokeless tobacco manufacturers understand that nicotine, one of the principal ingredients in smokeless tobacco, has pharmacological effects and uses, including causing and sustaining addiction.

Second, the evidence shows that the major smokeless tobacco manufacturers carefully manipulate the delivery of this pharmacologically active and addictive drug in a manner that promotes tolerance and addiction. Specifically, they manufacture low-nicotine delivery products for new users, who have not yet developed a tolerance to nicotine, and high-nicotine delivery products for experienced users, who need higher nicotine doses to sustain their addiction. In the case of UST, the company's internal documents explicitly acknowledge this "graduation process." The effect of this nicotine manipulation has been to increase addiction to smokeless tobacco among young people.

Based on the cumulative evidence, the Agency finds that smokeless tobacco manufacturers intend to market smokeless tobacco that produces tolerance and addiction in smokeless tobacco users. The Agency therefore concludes that smokeless tobacco is intended to affect the structure and function of the body within the meaning of the Federal Food, Drug, and Cosmetic Act.

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4. Response to Comments**a. Comments on pH Manipulation**

Comments submitted by the smokeless tobacco industry challenge the Agency's assertion that manufacturers produce graduated nicotine deliveries in their products primarily by manipulating the pH of the tobacco. The comments claim that the Agency presented no evidence of pH manipulation, that pH is not a determinant of nicotine absorption, that other factors determine nicotine absorption, and that FDA's data shows that smokeless tobacco has a low capacity to alter salivary pH, negating the possibility that the tobacco pH is relevant to absorption. None of these comments, however, present a persuasive rebuttal to the Agency's analysis.

1. The smokeless tobacco industry comments contend that the data presented by the Agency demonstrate that pH levels vary widely within products and little across product lines, making implausible the claim that companies manipulate and control pH as a way of controlling nicotine delivery from smokeless tobacco. Specifically, regarding the FDA laboratory data, one comment questions FDA's assertion that smokeless tobacco manufacturers control the delivery of nicotine, as measured by free nicotine calculations based on smokeless tobacco pH, when those values can vary up to 300% for the same product.

The Agency disagrees with this comment. Review of the data presented by four laboratories (two FDA laboratories, the laboratory of the National Institute for Drug Abuse (NIDA), and the laboratory of the American Health Foundation) shows that despite some variation within product brands, there is a remarkably consistent pattern of pH manipulation across product lines. For example, all of the laboratories found that for UST products,

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Copenhagen has the highest average pH, the Long Cut brands have intermediate pH's, and most flavors of Skoal Bandits have the lowest average pH's. The FDA laboratories and the American Health Foundation laboratory found that Conwood's starter product (Hawken) had pH levels less than 6, while its product for experienced users (Kodiak Wintergreen) had pH levels greater than 8. FDA also examined various products of Swisher International and found the same pattern of pH and nicotine dose graduation.

FDA agrees that there is some variation within products, in part due to storage conditions and storage duration. The fact that there is variation within products may also reflect the natural variation one would expect in an organic product that is marketed in a biologically active state. For example, processes occur during the shelf life of the product that could alter pH over time.¹⁰⁶³ Nonetheless, the evidence demonstrates that there is a consistent pattern in which products marketed as "starter products" are substantially lower in pH than are products marketed to experienced users.

There is no basis in the administrative record to conclude that these patterns of pH graduation could occur naturally or would be induced by the manufacturer for any reason other than to alter nicotine delivery. The high pH levels observed in the moist snuff products with high nicotine deliveries does not occur naturally.¹⁰⁶⁴

2. Smokeless tobacco industry comments state that FDA relies upon laboratory (in vitro) pH data, which the comments claim are not relevant to consumer (in vivo)

¹⁰⁶³ Djordjevic MV, Hoffman D, Glynn T, *et al.*, US commercial brands of moist snuff, 1994, assessment of nicotine, moisture, and pH, *Tobacco Control* 1995;4:62-66, at 63-64. See AR (Vol. 528 Ref. 97, appendix 9).

¹⁰⁶⁴ *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong., 2d Sess. 98 (Nov. 29, 1994) (testimony of Jack Henningfield). See AR (Vol. 710 Ref. 4).

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absorption of nicotine from smokeless tobacco. Specifically, these comments state that the Agency failed to present any data demonstrating a connection between smokeless tobacco pH, measured in vitro, and the actual rate and extent of nicotine absorbed in smokeless tobacco users.

FDA disagrees that in vitro data on smokeless tobacco pH are irrelevant to nicotine absorption in humans. Basic scientific principles, experience with nicotine gum and patches, and FDA laboratory data, demonstrate that the effect of increasing pH is to increase the amount of free nicotine available for absorption.

As described in section II.D.2.a., above, it is well established that the absorption of drugs into the bloodstream can be increased by adjusting pH levels, and that increasing the pH of nicotine converts nicotine salts into free nicotine, rendering it significantly more absorbable. Researchers funded by the tobacco industry have confirmed this point, stating that nicotine absorption in the mouth increases as a function of pH and that “the pharmacological response is clearly dependent on the amount of nicotine in the mouth as free base.”¹⁰⁶⁵

The nicotine polacrilex gum (Nicorette), which is approved for treatment of nicotine addiction by providing relief from withdrawal symptoms, provides further evidence of the relationship between pH and nicotine absorption. The gum is formulated to provide a pH of approximately 8, and the nicotine in the gum is well-absorbed at this pH. Versions of the nicotine gum that had lower pH levels, however, provided insufficient nicotine absorption.¹⁰⁶⁶

¹⁰⁶⁵ Armitage AK, Turner DM, Absorption of nicotine in cigarette and cigar smoke through the oral mucosa, *Nature* 1970;226:1231-1232. See AR (Vol. 143 Ref. 1810).

¹⁰⁶⁶ Henningfield JE, Radzius A, Cooper TM, *et al.*, Drinking coffee and carbonated beverages blocks absorption of nicotine from nicotine polacrilex gum, *Journal of the American Medical Association* 1990; 264:1560-1564. See AR (Vol. 29 Ref. 491-2).

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One of the principal effects of pH adjustment is to alter the rate of drug delivery to the target receptors in the body. The rate of drug delivery is well known to affect a wide range of pharmacological effects for numerous drug products. For example, a slow rate of absorption is the critical reason that nicotine patches do not produce mood-altering effects.¹⁰⁶⁷ These effects occur only when nicotine is absorbed quickly into the body.

FDA conducted tests to assess the speed of nicotine transfer across the membranes using smokeless tobacco with different pH levels. The results showed that, consistent with scientific theory, pH levels affected nicotine transfer: nicotine from the high-pH product was transferred across membranes more quickly than was nicotine from the low-pH product. In fact, in the first 2 minutes, the amount of nicotine released from a typical size pinch of Copenhagen, a product with a high pH, was 12 times higher than the amount of nicotine released from a Skoal Bandit pouch, a product with a low pH.¹⁰⁶⁸

For these reasons, FDA finds that there is an adequate scientific basis to conclude that in vitro pH values predict changes in nicotine delivery.

3. One smokeless tobacco industry comment presents a study performed by Andersson,¹⁰⁶⁹ which it claims refutes FDA's reliance on in vitro pH data. The comment states that the Andersson study demonstrated higher levels of nicotine in users of lower pH chewing tobacco than in users of higher pH moist snuff. According to the comment,

¹⁰⁶⁷ Benowitz NL, Pharmacodynamics of nicotine: implications for rational treatment of nicotine addiction, *British Journal of Addiction* 1991;86:495-499, at 496. See AR (Vol. 71 Ref. 52).

¹⁰⁶⁸ See Ciolino L, *Moist Snuff Nicotine Release Studies* (Sep. 28, 1994), at 2. See AR (Vol. 30 Ref. 500-2).

¹⁰⁶⁹ Andersson G, Bjornberg G, Curvall M, Oral mucosal changes and nicotine disposition in users of Swedish smokeless tobacco products: a comparative study, *J Oral Pathol Med* 1994:161-167. See AR (Vol. 526 Ref. 95, vol. VII).

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Andersson's data demonstrate that the smokeless tobacco product with the highest pH (8.5 to 8.6) had the poorest buccal absorption of nicotine. The comment argues that these data support the contention that smokeless tobacco pH is irrelevant to nicotine absorption in the smokeless tobacco user.

FDA disagrees with this comment. In fact, the Andersson study found that the degree of nicotine extraction was "significantly higher" among users of loose moist snuff than among users of moist snuff in pouches.¹⁰⁷⁰ This finding is consistent with FDA's analysis, because the loose moist snuff had a higher pH than the moist snuff in pouches.¹⁰⁷¹

Moreover, the comment mischaracterizes the Andersson findings in other ways as well. First, the study did not compare absorption characteristics on a gram-for-gram basis across products differing in pH. For example, the smokeless tobacco product with the highest absorption, a type of chewing tobacco, had over twice as much nicotine in it as any of the moist snuff products used in this study and subjects in the study used varying amounts of smokeless tobacco. Thus, nicotine absorption in the study could have been affected by the uncontrolled variation in the amount of nicotine consumed, confounding the effects of pH on nicotine absorption.

Second, the study measured nicotine blood levels at only one time point, which is inadequate to determine nicotine absorption (rate or extent). Third, the authors did not claim that the study demonstrated anything about the effects of pH on absorption.

¹⁰⁷⁰ *Id.* at 164.

¹⁰⁷¹ *Id.*

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Thus, the Andersson study provides no support for the argument that in vitro data are inadequate to describe the amount of nicotine available for absorption.

4. The comments from the smokeless tobacco industry state that a variety of biological and behavioral factors are stronger determinants of nicotine absorption than the pH of the product. The comments cite such factors as the length of time the smokeless tobacco is left in the mouth, the extent to which the smokeless tobacco is “worked” by the user, the rate and volume of expectorate, and the frequency and amount of swallowing, as well as salivary pH.

FDA agrees that other factors can influence nicotine absorption besides pH levels. Moreover, some of these additional factors are within the control of the manufacturer, including the use of pouches for some products; additives, such as humectants; the cut of the tobacco; and the use of various binding agents. Nonetheless, the role of these other factors appears to be less significant. The UST report entitled “Pharmacokinetics of Nicotine and its Major Metabolites in Naive and Habituated Snuff Takers,” for instance, concluded, that after using identical portions of snuff there “appears to be no differences” in plasma nicotine levels between inexperienced and experienced smokeless tobacco users.¹⁰⁷² One would expect many of the factors cited by the comment, including rate and volume of expectorating, and frequency and amount of swallowing, to differ between inexperienced and experienced users, but these differences apparently did *not* affect amount of nicotine absorption in the two groups.

¹⁰⁷² U.S. Tobacco, *Pharmacokinetics of Nicotine and its Major Metabolites in Naive and Habituated Snuff Takers*, UST document from *Marsee*, plaintiff’s exhibit 3.27 at 13. See AR (Vol. 344 Ref. 5436).

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Similarly, the final results from a preliminary study cited by the smokeless tobacco industry concluded that "buccal nicotine absorption was *not* affected by saliva discharge rate."¹⁰⁷³ These results are similar to those of a companion study by Nemeth-Coslett *et al.*, which studied the effect of the chewing rate on nicotine absorption from nicotine gum.¹⁰⁷⁴ In another study by these researchers, pH was varied, producing a strong effect on nicotine absorption from nicotine gum. In this companion study, there was minimal absorption under acidic conditions and significant absorption under alkaline conditions.¹⁰⁷⁵ Taken together, these studies show that the effects of pH on nicotine absorption are more significant than the effects of oral manipulation.

Moreover, behavioral factors should have a minor impact when comparing the effect of a series of smokeless tobacco on a given user, because the habits of the user should be relatively constant. Therefore, for any individual smokeless tobacco user, a product line with graduated pH levels will produce graduated nicotine deliveries.

In conclusion, although the Agency agrees that biological and behavioral factors can influence absorption of nicotine, the Agency finds that product pH has an established and significant role in controlling the absorption of nicotine.

5. A smokeless tobacco industry comment emphasizes the role of saliva and states that the pH levels of smokeless tobacco do not influence nicotine absorption. The

¹⁰⁷³ Cohen C, Radzius A, Simmons E, *et al.*, *Time course of buccal nicotine absorption* (NIDA unpublished report, 1994) (emphasis added). See AR (Vol. 711 Ref. 15).

¹⁰⁷⁴ Nemeth-Coslett R, Benowitz NL, Robinson N, *et al.*, Nicotine gum: chew rate, subjective effects and plasma nicotine, *Pharmacology, Biochemistry, & Behavior* 1988;29:747-751. See AR (Vol. 711 Ref. 10).

¹⁰⁷⁵ Henningfield JE, Radzius A, Cooper TM, *et al.*, Drinking coffee and carbonated beverages blocks absorption of nicotine from nicotine polacrilex gum, *Journal of the American Medical Association* 1990; 264:1560-1564. See AR (Vol. 29 Ref. 491-2).

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comment argues that FDA data show that the buffering capacity of saliva is greater than that of smokeless tobacco. Thus, according to the comment, when the smokeless tobacco and saliva mix in the mouth, the resultant pH of the mixture is determined by the saliva and not the tobacco.

FDA disagrees with this comment. FDA assessed the buffering capacity of saliva in a report entitled "Relative Buffering Capacity of Saliva and Moist Snuff."¹⁰⁷⁶ This study tested 1-ml, 2.5-ml, 5-ml, and 10-ml volumes of saliva.¹⁰⁷⁷ For each brand of smokeless tobacco tested, the product pH was measured and a 1.5g quantity of tobacco, representing a typical pinch, was selected. The effect of saliva volume on the resultant pH of saliva/moist snuff mixtures was then evaluated. Contrary to the comments of the smokeless tobacco manufacturers, the results of this study indicate that the saliva pH was altered by addition of the smokeless tobacco at all saliva volumes tested, demonstrating that product pH will influence the amount of free nicotine available for absorption.

FDA's Artificial Saliva Study, which is cited by the comment, does not conflict with these results. As clearly stated in the FDA memorandum summarizing the study, the Artificial Saliva Study was designed to measure and compare the rate of nicotine release from smokeless tobacco. The study did not measure smokeless tobacco effects on the pH of the artificial saliva.¹⁰⁷⁸

¹⁰⁷⁶ Memorandum from Ciolino L, *Relative Buffering Capacity of Saliva and Moist Snuff*. (Sep. 28, 1994). See AR (Vol. 29 Ref. 499).

¹⁰⁷⁷ *Id.* at 2.

¹⁰⁷⁸ Memorandum from Ciolino L, *Moist Snuff Nicotine Release Studies* (Sep. 28, 1994), at table IV.B. See AR (Vol. 30 Ref. 500-2).

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Moreover, there are several reasons why the Artificial Saliva Study cannot be used to answer the question of whether saliva pH or product pH dominates in the absorption process for nicotine from smokeless tobacco. First, the experiments in the Artificial Saliva Study were conducted for all of the products using only 0.5g of smokeless tobacco. This amount (0.5g) was used because this is the net tobacco weight in the Skoal Bandits pouch and because the purpose of this study was to make a controlled comparison among products. As stated in the FDA memo, however, 1.5g of tobacco more closely represents a typical “pinch” for Copenhagen, as well as for Skoal Long Cut Wintergreen and Skoal Original Fine Cut Wintergreen.¹⁰⁷⁹ Thus, the amount of product used in the experiments is three times lower than in typical use conditions for the latter three products, and certainly no conclusion can be drawn from this study as to whether salivary pH or product pH would dominate under typical use conditions.

Second, the experiments in the Artificial Saliva Study were conducted using 10 ml of saliva. Although there is about 10 ml of saliva in the human mouth, the volume of saliva that contacts the plug of moist snuff when it is initially placed in the mouth and used as directed is much less than 10 ml. When used as directed by the manufacturers, moist snuff is intended to stay in one place in the mouth, limiting mixing with saliva. Its use does not require the active oral manipulation and accompanying salivary saturation of chewing tobacco products. A pinch or a pouch of moist snuff is a self-contained dosing unit that is wedged between the gum and cheek in such a manner that it would be relatively protected from rapid saturation by saliva.

¹⁰⁷⁹ *Id.* at 1.

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Indeed, the industry's own instructions to users are to lodge the product between the cheek and gum to minimize such mixing or float. In direct marketing and advertising campaigns, new users are specifically instructed on how to use moist snuff products to minimize mixing with saliva. For example, in a UST advertisement entitled "Walt Garrison answers your questions about smokeless tobacco," the advertising copy states: "Just take a small pinch between your thumb and forefinger, put it between your cheek and gum, and leave it there. The tobacco will slowly release its great flavor to give you real tobacco satisfaction."¹⁰⁸⁰ In another UST advertisement, the instructions are consistent: "How do I use Skoal Bandits? Simply take a pouch and place it between your upper lip and gum. Leave it there, but DON'T CHEW IT. The pouch works like a teabag, holding the tobacco in, but letting the flavour out."¹⁰⁸¹ These instructions to consumers minimize salivary mixing and oral dissolution of the products. The less saliva contacts the product, the more the product pH controls absorption.

Third, the product pH's of the particular tins of smokeless tobacco used in the Artificial Saliva Study were not determined. Without knowing the product pH levels, the relative effects of saliva and product on the net solution pH after addition of the product cannot be evaluated. When discussing FDA's Artificial Saliva Study, the comment misrepresented pH levels that were measured as part of the Reproducibility Study portion of this work as the product pH levels. The measurements in the Reproducibility Study were made on different lots of smokeless tobacco than were used in the Artificial Saliva Study.

¹⁰⁸⁰ Ernster VL, Advertising and promotion of smokeless tobacco products, *Monographs/National Cancer Institute* 1989:87-94, at 90. See AR (Vol. 65 Ref. 853).

¹⁰⁸¹ Advertisement: "Introducing Skoal Bandits, The new way to enjoy tobacco." See AR (Vol. 241 Ref. 3260).

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The smokeless tobacco manufacturers themselves argue that there is lot-to-lot variability for product pH. Accordingly, the products' pH from the Reproducibility Study were not necessarily the same as the pH of the products tested in the Artificial Saliva Study.

In conclusion, the comment mischaracterized the Agency's laboratory data and drew erroneous conclusions from the data presented. In fact, FDA's analyses shows that the pH of smokeless tobacco affects the pH levels of the saliva in contact with the smokeless tobacco, thereby controlling the level of nicotine absorption.

6. One smokeless tobacco industry comment states that solids, such as tobacco, cannot have a pH value.

Solid materials must mix with a liquid before the product's pH is measured. When using the terms "tobacco pH" or "product pH," the Agency and other laboratories that have conducted studies on smokeless tobacco pH are referring to the measured pH when the smokeless tobacco product is allowed to contact an aqueous environment such as water or saliva, as the product does when it is placed in the tobacco user's mouth. The studies on smokeless tobacco pH are designed to determine whether various brands of smokeless tobacco are designed, formulated, processed, or otherwise manipulated to control the pH of the product after contact with the aqueous environment in the user's mouth.

7. Smokeless tobacco industry comments cite two reports written by Jeffrey R. Idle criticizing smokeless tobacco pH studies and reports and FDA laboratory data. The comments also claim that Idle's analysis was sent to the Centers for Disease Control and Prevention (CDC) by the UST and was shared with "interested parties." The comments assume that CDC shared this analysis with FDA and question why the analysis is not in the

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administrative record. Idle's analysis was not placed in the administrative record when the Jurisdictional Analysis was issued because the Agency was not aware of the document.

The Agency has reviewed the memorandum of Jeffrey Idle to UST entitled "FDA Proposed Rule: FDA Memoranda," dated December 13, 1995, and relevant portions of Idle's memorandum to UST dated February 9, 1995.¹⁰⁸² For several reasons, some of which are described below, FDA concludes that Idle and the commenters either misunderstood or mischaracterized FDA's results and analyses. Moreover, Idle's review selects certain data favorable to his position, while ignoring data contrary to his position.

a. Idle's analysis asserts that FDA's reliance on the laboratory data showing graduated nicotine deliveries is not valid because the analytic methods used by the laboratories were not standardized.

FDA acknowledges that the four laboratories involved conducted independent analyses, using slightly different methods, to compare the nicotine deliveries of various brands of smokeless tobacco. Nonetheless, all four laboratories found a remarkably similar trend of graduated nicotine delivery across product lines. Contrary to Idle's comment, the fact that different laboratories, using different methods, reach the same conclusion increases—rather than diminishes—the reliability of the conclusion.

b. Idle's analysis asserts that the fact that a range of pH levels and free nicotine deliveries were observed for individual brands in the laboratory data shows that the manufacturers do not control pH or free nicotine. According to Idle's analysis, if pH levels

¹⁰⁸² Memorandum from Idle JR to U.S. Tobacco Company (Dec. 13, 1995). See AR (Vol. 529 Ref. 98, appendix 6).

Statement of Jeffrey R. Idle (Feb. 9, 1995). See AR (Vol. 526 Ref. 95, vol. VI).

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and free nicotine delivery were controlled, the pH levels and free nicotine deliveries would never vary within a brand.

FDA disagrees with this comment. There are many explanations for the range of pH and free nicotine values observed within individual brands, including product fermentation during storage, natural variation in nicotine content and pH levels in tobacco leaves, and normal variation in laboratory analysis. Despite these variations, the data reveal a clear pattern of graduated pH levels and free nicotine delivery. It would have been surprising if no variations were measured by the laboratories.

c. Idle's analysis states that the majority of nicotine in all tobacco products is trapped inside the leaf particles and that acidic (low pH) conditions, not alkali (high pH) conditions, are necessary to leach nicotine out of smokeless tobacco. These assertions, however, are contradicted by the evidence in the administrative record. As discussed above, studies by FDA and other researchers, including researchers funded by the smokeless tobacco manufacturers, provide direct evidence that the release and absorption of nicotine increases as pH levels increase.

d. Idle's analysis states that the Skoal Long Cuts and Copenhagen are indistinguishable in terms of their nicotine content, rates of nicotine release, and pH levels. This assertion, however, is contradicted by the data measured in FDA laboratories. While the total nicotine content in Skoal Long Cuts and Copenhagen are similar, the products' pH and delivery of free nicotine differ substantially. For instance, FDA's data shows that Skoal Long Cut Cherry has a pH of 7.15 to 7.38 and a free nicotine delivery of 12.3% to 18.5%. These levels are substantially lower than Copenhagen, which has a pH of 7.71 to 8.14 and a free nicotine delivery of 32.7% to 56.5%. *See* section II.D.2.a., above.

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8. One comment states that there is no evidence in the administrative record that smokeless tobacco manufacturers add compounds for the purpose of affecting nicotine absorption into the bloodstream.

The Agency disagrees with this comment. As discussed in section II.D.2.a., above, there is substantial evidence in the record that the manufacturers add buffering agents to raise the pH levels in smokeless tobacco, which has the effect of increasing nicotine absorption.

9. In the Jurisdictional Analysis, FDA reported that smokeless tobacco delivers nicotine at its most rapid rate within 5 minutes after placing the product in the mouth.¹⁰⁸³ Blood levels then continue to rise while the smokeless tobacco product is kept in the mouth.¹⁰⁸⁴ One smokeless tobacco industry comment contends that this FDA finding is false and misleading. According to the comment, the Agency relied on in vitro data that do not purport to simulate bioavailability in users. In addition, the comment states that the Agency did not cite any evidentiary support for its statement that the bolus dose results in peak pharmacological concentrations in users, maintained by slow continued release of nicotine from the product.

The Agency disagrees that its statement concerning the bolus dose of nicotine delivered by smokeless tobacco is false or misleading. The administrative record contains in vitro data demonstrating that when smokeless tobacco was placed in simulated saliva, a significant amount of nicotine was released from the products within the first 5 seconds.¹⁰⁸⁵

¹⁰⁸³ Benowitz N, Porchet H, Sheiner L, et al., Nicotine absorption and cardiovascular effects with smokeless tobacco use: comparison with cigarettes and nicotine gum, *Clinical Pharmacology and Therapeutics* 1988;44:23-28, at 25. See AR (Vol. 12 Ref. 134).

¹⁰⁸⁴ *Id.* at 24, fig. 1.

¹⁰⁸⁵ Memorandum from Ciolino L, *Moist Snuff Nicotine Release Studies* (Sep. 28, 1994), at table IV.A. See AR (Vol. 30 Ref. 500-2).

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This study provides strong evidence that a significant amount of nicotine is available for absorption within the first 5 seconds of use.

Additionally, the administrative record includes an *in vivo* pharmacokinetic study consistent with these *in vitro* results. This study concluded that rate of nicotine absorption peaks about 5 minutes after placing oral snuff and chewing tobacco in the mouth.¹⁰⁸⁶

Thus, the Agency provided both *in vivo* and *in vitro* data independently demonstrating that peak pharmacologic concentrations of nicotine are delivered within 5 minutes of placing smokeless tobacco in the mouth. The comment provided no evidence to rebut this conclusion.

b. Comments on the Graduation Process

1. Two smokeless tobacco industry comments contend that persuasive evidence of a graduation process would have come from a survey of smokeless tobacco users showing that switching is unidirectional (i.e., that when a user switches, he always switches from a pouch to a loose tobacco product and from a lower to a higher pH product), but that FDA failed to present such evidence. The comments claim that consumer demographic data demonstrate that there is “significant brand loyalty” and that many smokeless tobacco users stay with the brand they first choose. Furthermore, the comments claim that any switching that does occur does not indicate any patterns, and that social and other factors cause smokeless tobacco users to choose their own brands.

¹⁰⁸⁶ Benowitz N, Porchet H, Sheiner L, *et al.*, Nicotine absorption and cardiovascular effects with smokeless tobacco use: comparison with cigarettes and nicotine gum, *Clinical Pharmacology and Therapeutics* 1988;44:23-28, at 26. See AR (Vol. 12 Ref. 134).

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Contrary to the comments, the evidence in the record does in fact demonstrate a clear pattern of switching from brands of smokeless tobacco that deliver low levels of nicotine to brands that deliver higher levels of nicotine. As discussed in section II.D.2., above, an analysis of data from CDC's 1993 Teenage Attitudes and Practices Survey (TAPS) and a follow-up study from the 1989 TAPS shows that most brand switching involves switching from products with low nicotine delivery to products with higher nicotine delivery.

The comments do not provide data or any other documentation to the Agency to support the claim that there is no pattern to brand switching. Without any such evidence to support its claim, the smokeless tobacco industry has not provided an adequate basis to rebut the Agency's findings.

2. UST denies that it uses a graduation strategy in the manufacture and marketing of its products. Specifically, the UST comment states:

As best as U.S. Tobacco can now determine, the term "graduation process" as used in the early 1980s (1) did not relate to increasing levels of nicotine and pH; (2) did not drive the company's marketing strategies; and (3) is contradicted by consumer behavior in the marketplace.¹⁰⁸⁷

The Agency does not find UST's position to be credible. Contrary to UST's assertions, its products do deliver graduated levels of nicotine, *see* section II.D.2.a., above; UST's marketing strategies do target low-nicotine products for new users and high-nicotine products for experienced users, *see* section II.D.2.c., above; and consumers do shift from low-nicotine products to high-nicotine products. *See* section II.D.2.b., above. Moreover, senior UST officials, including the president of UST, and other UST documents do use the

¹⁰⁸⁷ U.S. Tobacco Company, Comment (Jan. 2, 1996), at 32. *See* AR (Vol. 529 Ref. 98).

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phrase “graduation process” to describe UST’s marketing approach. *See* section II.D.2.c., above.

3. UST alleges that FDA’s reliance on various UST documents and statements made by UST executives is ill-founded. UST claims that, among other things, the Agency took statements out of context; the statements were not representative of UST’s position; and the Agency improperly relied on statements, documents, and offers of proof from the plaintiff’s attorneys in a product liability suit.

The Agency believes that all of the documents and statements speak for themselves and fully support the position taken in the Jurisdictional Analysis. A summary of those comments and the Agency’s response follows:

a. In the Jurisdictional Analysis, the Agency referred to several statements made by a UST senior vice-president for marketing which demonstrate that UST understands the relationship between the pH of its products and nicotine delivery. UST states that the Agency mischaracterized the comments and failed to mention that the marketing executive disclaimed his expertise with respect to pH and nicotine in a prior exchange within the cited deposition.

While the Agency did not mention the prior exchange in the Jurisdictional Analysis, this omission does not affect the meaning of the relevant passages. As the record shows, this senior vice-president for marketing acknowledged his understanding that as the pH of the smokeless tobacco product is lowered, the rate of nicotine absorption by the user is also lowered:

Q. Mr. Lindqvist, is it your understanding that as the pH of the product is lowered, that the rate of absorption of nicotine by the user is also lowered?

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A. That would be my understanding, yes.¹⁰⁸⁸

The record also shows that this senior vice president participated in discussions with other senior level executives within the company about product development and specifically made suggestions for pH levels for those products that reflect his knowledge of the relationship of pH to the nicotine strength of the product. For instance, in discussing the specifications for a “premium project,” he recommended that UST set “*pH at the level of Copenhagen or higher.*”¹⁰⁸⁹ These statements demonstrate knowledge of the relationship of pH and nicotine delivery.

b. In the Jurisdictional Analysis and in section II.D.2.c., above, the Agency cites several UST documents that referred to the “Lotus Project.” These documents disclosed the company’s intent to produce products with varying amounts of nicotine and to develop a low nicotine product especially for new users. UST states that some of the comments referred to were just “one individual’s preliminary thoughts”¹⁰⁹⁰ about a low-nicotine product. Further, UST states that the Lotus Project documents refer to a Swedish marketing campaign by a foreign smokeless tobacco manufacturer, not a project planned for the United States or any other market by U.S. Tobacco.

The UST documents in question speak for themselves. The “one individual’s preliminary thoughts” were those of the president of UST’s smokeless tobacco foreign

¹⁰⁸⁸ Deposition of Erik Lindqvist, *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986) Transcript of jury trial proceedings at 1668. See AR (Vol. 29 Ref. 489-2).

¹⁰⁸⁹ U.S. Tobacco Company memo from Erik Lindqvist (Sep. 22, 1981) (emphasis added). This document was discussed in the trial transcript in *Marsee v. U.S. Tobacco* at 1668-1669. See AR (Vol. 29 Ref. 489-2).

¹⁰⁹⁰ Joint Comments of the Smokeless Tobacco Manufacturers (Jan. 2, 1996), at 24. See AR (Vol. 526 Ref. 95).

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subsidiary and were made to the president of UST in a memorandum written on UST letterhead and labeled "Intra-Company Correspondence."¹⁰⁹¹ Contrary to UST's comment, the president of UST expressly stated that the Swedish smokeless tobacco company and UST were "cooperat[ing] on this project" and that "he wanted a Lotus product for the U.S. market."¹⁰⁹² Suggestions for product development made by corporate executives carry significant weight and cannot be dismissed as one individual's preliminary thoughts. *See Ezold v. Wolf*, 983 F.2d 509, 546 (3d. Cir. 1992). Furthermore, UST acknowledges that "[s]uch a portion pack product, intended to appeal to cigarette smokers, was ultimately marketed in the U.S. under the brand name Skoal Bandits."¹⁰⁹³

c. In the Jurisdictional Analysis and in section II.D.1. above, the Agency cited as a UST document that posed "Potential Questions and Answers" about UST's introduction of Skoal Bandits in a foreign market.¹⁰⁹⁴ One question the company assumes consumers will ask is, "How much nicotine does it contain? Is it absorbed?"¹⁰⁹⁵ The company replies that the product contains about as much nicotine as an average cigarette and that "[t]he nicotine is absorbed, giv[ing] satisfaction to the smoker."¹⁰⁹⁶ The Agency stated that the document

¹⁰⁹¹ Intra-company correspondence from Watson WW (president, Scandia Internationals) to Bantle LA (president, U.S. Tobacco Company) (Jun. 2, 1972), from *Marsee v. U.S. Tobacco*, trial exhibit 158. *See* AR (Vol. 30 Ref. 505-2).

¹⁰⁹² Minutes from meeting in Greenwich at Bantle LA's office (Jul. 18, 1972), at 1, from *Marsee v. U.S. Tobacco*, trial exhibit 159. *See* AR (Vol. 30 Ref. 505-3).

¹⁰⁹³ Joint Comments of the Smokeless Tobacco Manufacturers (Jan. 2, 1996), at 24. *See* AR (Vol. 526 Ref. 95).

¹⁰⁹⁴ Potential Questions and Answers, submitted in *Marsee v. U.S. Tobacco*, at 1. *See* AR (Vol. 30 Ref. 509).

¹⁰⁹⁵ *Id.*

¹⁰⁹⁶ *Id.*

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demonstrates the manufacturer's intent to provide nicotine for absorption and thereby provide "satisfaction" to the smokeless tobacco user. UST argues that there is no suggestion by FDA that any of the statements contained in the document were ever communicated to the public, within or outside of the United States, and therefore that this document is irrelevant to establishing intended use.

FDA disagrees. This document is relevant to establishing the intent of the manufacturer, whether or not the information within the document was ultimately communicated to the public. The evidence relevant to establishing intended use is discussed in greater detail in sections II.C.1. and II.C.2.e., above, and II.E., below. As described therein, the manufacturer's intent may be demonstrated by company documents, regardless of whether the documents are disclosed to the public. In this case, the questions and answers on nicotine content and absorption demonstrate UST's knowledge of nicotine's effects on users of smokeless tobacco and the company's awareness of users' desire for satisfying doses of nicotine.

d. UST states that FDA relies on documents from a product liability lawsuit (*Marsee v. UST*), as well as sections of the trial transcript, and contends that these are distortions and mischaracterizations from plaintiff's attorneys. The comments also state that FDA relied on unsubstantiated statements made by the plaintiff's attorney in that case as part of an offer of proof.

In several instances, the Agency cited portions of a trial transcript that recorded the questioning of a senior UST official. The statements relied on by FDA were made by the UST official for a deposition or as part of the trial proceedings under penalty of perjury. The

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Agency does not have any reason to believe that the testimony was fraudulent, nor has the comment suggested that it was.

The Agency agrees that some of the quotes cited in the Jurisdictional Analysis and in this document were entered into the trial record of *Marsee* as an offer of proof. None of these quotes, however, are essential to FDA's analysis. Moreover, the Agency does not have any reason to believe that the attorneys mischaracterized the statements made in the documents, nor has the comment offered any such reason. The comment has thus provided no persuasive basis on which to reject this evidence.

e. UST argues that the Agency misinterprets the use of the terms "strength" and "nicotine satisfaction," as used in UST internal company documents. The company states that there is no evidence to support FDA's contention that "strength" refers to the delivery of nicotine. The comment further states that "satisfaction" is highly subjective and means something different to different people and that "nicotine satisfaction," as used in the smokeless tobacco company documents, refers to "taste."

The evidence shows that "strength," as used in various UST company documents, refers to nicotine delivery. Express statements made by UST officials refer to "strength" of nicotine and differentiate both "strength" and "satisfaction" from "taste" of the product.¹⁰⁹⁷ As described in section II.D.2.c., above, for instance, one UST document specifically urged UST to develop products with "three different . . . strengths of nicotine."¹⁰⁹⁸ Another UST

¹⁰⁹⁷ *The Lotus Project*, attached to minutes from a meeting in Greenwich at Bantle LA's office (Jul. 18, 1972), from *Marsee v. U.S. Tobacco*, trial exhibit 159. See AR (Vol. 30 Ref. 505-3).

¹⁰⁹⁸ Intra-company correspondence from Watson WW (president, Scandia Internationals) to Bantle LA (president, U.S. Tobacco Company) (Jun. 2, 1972), at 2, from *Marsee v. U.S. Tobacco*, trial exhibit 158. See AR (Vol. 30 Ref. 505-2).

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document states: “Our sales and marketing groups have asked for a W.B. type chew with *less strength* saying the present product contains *too much nicotine* for the type chewer to whom they would like to direct the sale of such a product.”¹⁰⁹⁹

Another UST document explicitly links nicotine with satisfaction, stating that “virtually all tobacco usage is based upon nicotine, ‘the kick’, *satisfaction*.”¹¹⁰⁰

Based on these statements and other statements in the record, the evidence in the record supports the Agency characterization of strength and satisfaction.

4. UST argues that there is nothing in the record to support FDA’s assertion that its advertisements encourage established users to graduate to higher nicotine delivery products.

The Agency disagrees with this comment. UST’s advertisements specifically promote graduation to higher-nicotine products. Low-nicotine products are marketed for new users, sometimes referred to as “You Guys Just Starting Out.” In contrast, advertisements for high-nicotine products use slogans like “Sooner or Later It’s Copenhagen” that promote graduation to the higher nicotine product. *See* section II.D.2.c., above.

Moreover, as discussed in section II.D.2.c, above, a UST chart depicts the graduation process as a bullseye and shows how UST’s marketing strategies encourage graduation.

¹⁰⁹⁹ *Health Effects of Smokeless Tobacco: Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, U.S. House of Representatives*, 103d Cong. 2d Sess. 61 (Nov. 29, 1994) (emphasis added). *See* AR (Vol. 710 Ref. 4).

¹¹⁰⁰ Deposition of Erik Lindqvist, *Marsee v. U.S. Tobacco*, transcript of jury trial proceedings, at 1662 (emphasis added). *See* AR (Vol. 29 Ref. 489-2).

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c. Other Comments

1. One comment argues that FDA intends to assert jurisdiction over the entire moist snuff industry by relying exclusively on information about one company, UST, without any information in the record about other companies.

FDA disagrees with this comment. In section II.A., above, FDA has concluded that the pharmacological effects and uses of smokeless tobacco would be foreseeable to any reasonable manufacturer of smokeless tobacco. On the basis of these foreseeable consequences, FDA has found that smokeless tobacco manufacturers intend to affect the structure and function of the body. This basis for establishing jurisdiction applies equally to all the smokeless tobacco manufacturers.

In section II.B., above, FDA has established that the intended use of smokeless tobacco is to affect the structure and function of the body based on the actual consumer use of smokeless tobacco. This finding applies equally to all the smokeless tobacco manufacturers.

In this section, FDA has found that the smokeless tobacco manufacturers intend to affect the structure and function of the body based on the statements, research, and actions of the manufacturers. Contrary to the comment, the record contains substantial evidence of the statements, research, and actions of smokeless tobacco manufacturers other than UST.

First, the evidence shows that the major smokeless tobacco manufacturers have knowledge of the pharmacological effects of nicotine, one of the major constituents of smokeless tobacco. Some of the smokeless tobacco manufacturers, like UST and Brown & Williamson, have conducted their own extensive research into nicotine pharmacology. All the major smokeless tobacco companies have acquired knowledge of nicotine pharmacology

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through their participation in the research of the Smokeless Tobacco Research Council. *See* section II.D.1., above.

Second, the evidence also shows that smokeless tobacco manufacturers manipulate the delivery of nicotine to consumers. In addition to testing the nicotine deliveries of UST products, FDA also tested the nicotine deliveries of smokeless tobacco manufactured by Conwood Co. and Swisher International. This testing showed that like UST, these companies also graduate their nicotine deliveries in a manner that promotes tolerance and addiction. Another company, Pinkerton Tobacco Co., also controls nicotine deliveries through the use of pouches for its starter products. *See* section II.D.2.a., above.

This evidence of (1) knowledge of nicotine's pharmacological effects and uses and (2) manipulation of nicotine deliveries in a manner that encourages tolerance and addiction thus applies to the major smokeless tobacco manufacturers. The evidence is sufficient to establish that these manufacturers intend their products to affect the structure and function of the body.¹¹⁰¹

2. One comment states that FDA fails to distinguish between different smokeless tobacco products, namely moist snuff and chewing tobacco. The comment states that FDA is required to establish independently that each product is intended to affect the structure and function of the body. The comment also claims that FDA does not have any information about categories of smokeless tobacco other than moist snuff.

FDA believes that there is no basis in the record for treating chewing tobacco differently than moist snuff. Studies demonstrate that both snuff and chewing tobacco

¹¹⁰¹ FDA's authority to assert jurisdiction over a class of similar products, such as smokeless tobacco, rather than assert jurisdiction company by company is further discussed in section II.F., below.

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products rapidly deliver equal or even greater amounts of nicotine to the bloodstream than the amounts delivered by cigarettes.¹¹⁰² These studies also show that both snuff and chewing tobacco produce similar peak blood levels of nicotine. Moreover, as described in sections II.A. and II.B., above, the evidence shows that all smokeless tobacco—including both moist snuff and chewing tobacco—is addictive and is used by consumers for pharmacological effects. Because the pharmacological effects of moist snuff and chewing tobacco are essentially the same, the two products should be treated the same.

In addition, moist snuff and chewing tobacco are generally manufactured by the same companies. The manufacturers do not argue that a “Chinese wall” exists at these companies that separates their moist snuff operations from their chewing tobacco operations. Therefore, having established that these manufacturers intend that their moist snuff products affect the structure and function of the body, FDA may properly presume that these manufacturers have the same intent when manufacturing another product (in this case, chewing tobacco) that causes the same pharmacological effects.

¹¹⁰² Department of Health and Human Services, Office on Smoking and Health, *Report of the Advisory Committee to the Surgeon General, The Health Consequences of Using Smokeless Tobacco* (Washington DC: DHHS, 1986), at 143-167. See AR (Vol. 128 Ref. 1591).

Benowitz N, Porchet H, Sheiner L, et al. Nicotine absorption and cardiovascular effects with smokeless tobacco use: comparison with cigarettes and nicotine gum, *Clinical Pharmacology and Therapeutics* 1988;44:23-28. See AR (Vol. 12 Ref. 134).

There is also evidence that tobacco manufacturers deliberately use high-nicotine tobaccos in chewing tobacco. A document submitted to the record by the tobacco industry states that chewing tobaccos utilize dark, air-cured tobacco types that are “cultivated in a manner conducive to heavy body and high nicotine content.” Tobacco, in *Encyclopedia of Chemical Technology*, eds., Kirk RE, Othmer DF (New York: The Interscience Encyclopedia Inc.), 14:244. See AR (Vol. 535 Ref. 96, vol. IV.B).

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E. THE “INTENDED USE” OF A PRODUCT IS NOT DETERMINED ONLY ON THE BASIS OF PROMOTIONAL CLAIMS

Sections II.A.-D., above, described the evidence before the Agency establishing that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, and briefly discussed FDA’s legal authority to consider evidence of foreseeable pharmacological effects and uses, actual consumer use, and the statements, research, and actions of manufacturers. In this section, FDA responds to comments on the legal basis for considering these groups of evidence.

Several comments agreed with the analysis of the intended use of cigarettes and smokeless tobacco set forth in the Jurisdictional Analysis. The tobacco industry, however, submitted several comments in opposition to the Agency’s analysis of the intended use of cigarettes and smokeless tobacco, including the joint comments submitted by the cigarette manufacturers and the joint comment submitted by the smokeless tobacco manufacturers. The Agency received additional comments that made arguments similar to those of the tobacco industry.

The principal contention of the tobacco industry is that whether a product is “intended” to affect the structure or any function of the body may be determined “only” on the basis of the claims made by the manufacturer to the consumer in connection with the sale and distribution of the product. According to the tobacco industry, because they do not overtly promote the pharmacological use of cigarettes and smokeless tobacco, their products are not “intended” to affect the structure or function of the body under the Act and FDA is therefore powerless to regulate them.

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The tobacco industry's argument cannot be correct. Their contention is contrary to the plain language of the Act, FDA's regulations, judicial precedent, and the Agency's long-standing interpretation of the Act. If adopted, this interpretation would allow any drug manufacturer or importer to avoid FDA jurisdiction simply by not making certain types of claims—even for products with powerful pharmacological effects.

As discussed more fully below, the Agency finds that the arguments made by the tobacco industry are unpersuasive and that the determination of whether a product is “intended” to affect the structure or function of the body may be based not only on the promotional claims of the manufacturer, but also on other objective evidence of intended use. This other objective evidence of intent may include evidence of the foreseeable pharmacological effects and uses of the product, evidence of how consumers actually use the product, and evidence of the manufacturers' statements, research, and actions that reveal the product's intended uses.

Moreover, the Agency disagrees with the premise of the manufacturers' argument—namely, that consideration of promotional claims shows that cigarettes and smokeless tobacco are not drugs or devices under the Act. As discussed in section II.E.2., below, the Agency agrees with the comments that argue that the manufacturers' advertisements do in fact support the Agency's conclusion that cigarettes and smokeless tobacco have intended pharmacological uses.

1. The “Intended Use” of a Product May Be Established on the Basis of All Relevant Objective Evidence of Intent

As noted in section II.A.1., above, in determining whether an article is “intended” to affect the structure or function of the body, “the FDA is not bound by the

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manufacturer's subjective claims of intent," but rather can find actual intent "on the basis of objective evidence." *National Nutritional Foods Ass'n (NNFA) v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). That is, the Agency determines a product's intended use objectively by evaluating all of the relevant evidence in the record from the perspective of a reasonable fact finder. See 21 CFR 201.128, 801.4. In determining intended use, the Agency may "examine a wide range of evidence." *United States v. Two Plastic Drums . . . Black Currant Oil*, 761 F. Supp. 70, 72 (C.D. Ill. 1991), *aff'd*, 984 F.2d 814 (7th Cir. 1993).

Although promotional claims are relevant objective evidence of intent, the statute, the Agency's regulations, and judicial and administrative precedent do not restrict FDA to consideration of only the manufacturer's promotional claims.¹¹⁰³ The Act has not been—and should not be—interpreted in a manner that would permit manufacturers of products that contain known drug ingredients and have known pharmacological uses to circumvent FDA regulation by deliberately avoiding overt drug claims. When a product contains a known drug ingredient like nicotine, the Agency may properly look beyond the manufacturer's promotional claims to other objective evidence of the intended uses of the product. This ability to look beyond and behind promotional claims that deliberately deny,

¹¹⁰³ The Agency agrees that the claims made by the manufacturer in advertising and promotional materials can be relevant evidence of the manufacturer's intent. Indeed, in many cases, no further evidence of intended use is needed. In the case of a typical approved drug, the manufacturer will forthrightly promote the pharmacological uses to which the drug should be put, the drug will in fact produce the promoted pharmacological effects, and consumers will use the drug for its promoted purposes. Promotional claims may be implied as well as express. For example, the Act provides that, in determining whether labeling or advertising is misleading, the Agency must consider the representations "suggested" as well as "made" in the labeling or advertising. Section 201(n), 21 U.S.C. 321(n). Similarly, courts have found an intent to affect the structure or function of the body based on commercial names that "suggest" drug uses. See, e.g., *United States v. Storage Spaces Designated Nos. "8" and "49,"* 777 F.2d 1363, 1366 (9th Cir. 1985), *cert. denied*, 479 U.S. 1086 (1987).

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or are silent about, the actual intended uses of a product is critical to FDA's capacity to protect the public health under the Act.

a. The Plain Meaning of the Statute Authorizes FDA To Consider All Evidence of Intent

"When interpreting a statute, [the courts] look first and foremost to its text."

United States v. Alvarez-Sanchez, 114 S. Ct. 1599, 1603 (1994). The pertinent provision from the statutory definition of "drug," section 201(g)(1)(C) of the Act, 21 U.S.C. 321 (g)(1)(C), states: "The term 'drug' means . . . articles (other than food) *intended* to affect the structure or any function of the body of man or other animals" (emphasis added). The corresponding device definition, section 201(h)(3), states:

The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including any component, part, or accessory, which is . . . *intended* to affect the structure or any function of the body of man or other animals.

21 U.S.C. 321(h)(3) (emphasis added).

These definitions do not dictate that the "intended" effects or uses of an article be established in any particular manner or by any specific type of evidence. Similarly, they do not preclude the use of any type of evidence to make the pertinent showing. The statutory language is plain on its face and permits FDA to consider any relevant evidence in determining what uses are "intended."

The broad statutory language cannot be reconciled with the narrow view that "only" claims made to the consumer in connection with the sale of a product are relevant in determining the "intended" uses of a product. If Congress had meant to so limit the evidence that could be used to determine intended uses, it would have used a phrase such

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as “promoted to,” “labeled to,” “advertised to,” or “represented to” in lieu of “intended to” in the definitional sections. Indeed, Congress explicitly refers to representations, labeling, and advertising in other sections of the Act. See section 201(n) of the Act, 21 U.S.C. 321(n) (whether a drug or device is misbranded depends, among other factors, on the manufacturer’s “representations” made in “labeling or advertising”); section 502(a), 21 U.S.C. 352(a) (a drug or device is misbranded if, among other bases, its “labeling” is false or misleading); section 502(n), 21 U.S.C. 352(n) (a drug is misbranded, among other bases, unless its “advertisements and other descriptive printed matter” contain certain true statements). That Congress did not expressly restrict the Agency to promotional claims means that evidence of intended use need not be limited to promotional claims. As the Supreme Court recently observed, “it is generally presumed that Congress acts intentionally and purposely when it includes particular language in one section of a statute but omits it in another.” *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993).¹¹⁰⁴

The tobacco industry’s position also conflicts with the canon of statutory construction that words used by Congress, unless otherwise defined, will be interpreted as taking their ordinary meaning. See, e.g., *Smith v. United States*, 113 S. Ct. 2050, 2054 (1993); *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 860 (1984). Contrary to the manufacturers’ view, the ordinary and widely accepted meanings of “intend” are significantly broader than those of “promote.”

¹¹⁰⁴ Similarly, the legislative history of the Act cited by the tobacco industry fails to support the tobacco industry’s position. Nowhere in that history are any authoritative statements that intended use may be established only by promotional claims. See S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935) reprinted in 3 Legislative History 660; S. Rep. No. 493, 73d Cong., 2d Sess. (1934) reprinted in 2 Legislative History 720; H. Rep. No. 853, 94th Cong., 2d Sess. (1976) reprinted in *An Analytical Legislative History of the Medical Device Amendments of 1976*, appendix III. Section II.E.3.a. provides additional discussion of the legislative history.

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As discussed in section II.C.1., above, one ordinary meaning of “intend” is to have in mind or design for a particular purpose. Consistent with this meaning, the Agency interprets “intended uses” to include those uses that are “in the mind” of or planned by the manufacturer or for which the manufacturer designs the product. The evidence that is relevant to establish the uses that the manufacturer “has in mind” or for which the manufacturer has designed the product is plainly substantially broader than evidence of only promotional claims. It may include, for instance, evidence of the internal statements, research, and actions of the manufacturer’s senior scientists and officials.

As discussed in section II.A.1., above, “intend” in its ordinary legal usage also encompasses readily foreseeable consequences. As the Supreme Court recognized nearly a century ago, “[t]he law presumes that every man intends the legitimate consequences of his own acts.” *Agnew v. United States*, 165 U.S. 36, 53 (1897). Consistent with this meaning, “intended uses” include the foreseeable pharmacological effects and uses of the product. The evidence that is relevant to establish these effects and uses is substantially broader than evidence of promotional claims. It may include, for instance, evidence of a product’s widely known pharmacological effects and uses.¹¹⁰⁵

¹¹⁰⁵ Additional demonstration that the intended use of a product may be determined based on evidence other than the express claims of the manufacturer is provided by the Dietary Supplement Health and Education Act (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325. Before the passage of the DSHEA, dietary ingredients and dietary supplements that did not have taste, aroma, or nutritive value (and thus were not foods, see *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 337 (7th Cir. 1983)) could be classified as “drugs” if, among other things, the manufacturer made claims that the product would affect the structure or any function of the body. In the DSHEA, Congress created an exception to section 201(g)(1)(C). Under this exception, a dietary supplement or dietary ingredient “for which a truthful and not misleading statement is made . . . is not a drug under clause (C) *solely* because the label or the labeling contains such a statement.” 21 U.S.C. 321(g)(1)(C) (emphasis added). The fact that Congress expressly provided that an intent to affect the structure and function of the body cannot be established “solely” on the basis of promotional claims plainly implies that other evidence beyond promotional claims can be relevant evidence of intent.

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The tobacco industry's view that the "intended use" of a product may be determined "only" by examining promotional claims thus cannot be squared with the plain language of the statute. Congress did not provide that FDA may regulate only products "promoted" to affect the structure or function of the body. Rather, Congress provided that FDA may regulate products "intended" to affect the structure or function of the body. A wide range of evidence can be probative of a manufacturer's intent.

b. FDA's Regulations Authorize FDA To Consider All Evidence of Intent

Consistent with the plain language of the statute, FDA's regulations defining "intended use" for drugs and devices, 21 CFR 201.128 (drugs) and 21 CFR 801.4 (devices), clearly contemplate that FDA may consider a range of evidence that extends well beyond the claims made by manufacturers in connection with the sale and distribution of their products. Even if the statute were not plain on its face, the Agency has broad discretion to interpret the Act in a reasonable manner consistent with its public health purposes. *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

These regulations, which have been in effect for four decades, define the "intended uses" of drugs and devices that must be included in the product's labeling. Although they do not specifically define the statutory terms "drug" or "device," the Agency routinely uses the regulations to interpret the statutory intent requirement. *See* section II.A.1.,

Indeed, in *United States v. Ten Cartons, More or Less, of an Article . . . Ener-B Vitamin B-12*, 72 F.3d 285, 287 (2d Cir. 1995), the Second Circuit Court of Appeals stated that this language clearly implies that a dietary supplement can be a drug under this section for reasons other than the claims made for it, such as its method of intake. Thus, the court found that Ener-B, which was a vitamin B-12 supplement designed to be applied to the inside of the nose and absorbed into the bloodstream through the nasal mucous membranes, was a drug. *Id.*

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above. Indeed, the comments of the tobacco industry assert that these regulations have

“authoritatively . . . defined” intended use under the Act.¹¹⁰⁶

The regulation that describes the intended use of drugs provides:

The words “intended use” or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

21 CFR 201.128 (emphasis added). Section 801.4, which defines “intended use” for devices, is essentially the same except for the use of the word “device” in lieu of “drug” and the reference to regulations governing devices.

The italicized language shows that the “intended uses” of a product may be determined not only by “labeling claims” and “advertising matter,” but also by other “expressions” and “oral or written statements” made by persons legally responsible for the

¹¹⁰⁶ Joint Comment of the Cigarette Manufacturers, Comment (Jan. 2, 1996), vol. II, at 6; *see* AR (Vol. 535 Ref. 96); *accord* Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996) at 102 (“[t]he regulation describing FDA’s understanding of ‘intended use’ is consistent with the congressional purpose behind the drug definition”). *See* AR (Vol. 526 Ref. 95).

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labeling of drugs (without limitation on the persons to whom the statements are made); “the circumstances surrounding the distribution of the article”; “the circumstances that the article is with the knowledge of such persons . . . offered and used for a purpose for which it is neither labeled nor advertised”; and evidence that “a manufacturer knows or has knowledge of facts that would give him notice” that a drug “is to be used” for purposes other than those for which the manufacturer offered the product.

Thus, the plain language of the regulations provides that the intended use of a product can be determined on the basis of evidence other than the promotional claims made by the manufacturer. If the Agency had meant to restrict its consideration to promotional claims exclusively, as the tobacco industry suggests, it would have written a narrow regulation expressly so providing—not the broadly written regulation it actually wrote and administers.

In effect, the tobacco industry unreasonably urges the Agency to ignore the express language of the regulation and refuse to consider any evidence of intended use other than promotional claims. The Agency disagrees with this interpretation. FDA interprets the regulation to allow the Agency to consider any relevant evidence of intent, including, as discussed in sections II.A., II.B., II.C., and II.D., above, the foreseeable and actual effects and uses of the product and the internal statements, research, and actions of the manufacturer. The Agency has for years consistently interpreted the regulation in this manner. The Agency’s interpretation of its own regulations is reasonable and is entitled to “controlling weight unless it is plainly erroneous or inconsistent with the regulation.”

Thomas Jefferson Univ. v. Shalala, 114 S. Ct. 2381, 2386 (1994).

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c. Judicial Decisions Authorize FDA To Consider All Evidence of Intent

The tobacco industry contends that the courts have repeatedly held that the “intended use” of a product must be based on promotional claims and that the Act does not permit FDA to exercise jurisdiction over a product as a drug or a device unless the manufacturer or vendor makes overt claims for the product in connection with its sale.

Clearly, courts have found that the vendor’s claims are a relevant source of evidence establishing the intended use of a product, and FDA fully agrees with these holdings. The Agency does not, however, agree with the tobacco industry’s view that the cited precedents can reasonably be read to *limit* the Agency to consider only such overt claims when determining the intended use of a product. In most of the cases cited by the tobacco industry, the relevance of other types of evidence was not at issue because the manufacturers’ promotional claims were found to be sufficient to establish the intended use of the products. Thus, FDA did not need to rely on other evidence to prove the intended use of the article, and the courts were not called upon to decide the relevance of other evidence. *See, e.g., Bradley v. United States*, 264 F. 79 (5th Cir. 1920); *United States v. Nutrition Service, Inc.*, 227 F. Supp. 375, 381, 383, 386 (W.D. Pa. 1964), *aff’d*, 347 F.2d 233 (3d Cir. 1965); *United States v. An Article . . . “Sudden Change,”* 409 F.2d 734, 737 (2d Cir. 1969); *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 2-3 (D.D.C. 1989).

Generically, the cases relied upon by the tobacco industry represent instances in which manufacturers made drug claims for products without known drug ingredients and without known pharmacological uses—not cases where manufacturers attempted to market a product with a known drug ingredient or use without complying with the Act. *Bradley*, for instance, involved pharmaceutical claims that were made for mineral water.

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In this situation, claims do have an essentially dispositive role. Pharmaceutical claims will bring the product within FDA's jurisdiction, whereas relabeling the product to eliminate these claims may, in some circumstances, remove the product from FDA's jurisdiction.

The situation is fundamentally different, however, where the product contains a known drug ingredient like nicotine and has known pharmacological uses such as addiction maintenance, sedation, and stimulation. In these cases, "[s]elf serving labels cannot be used to mask true intent." *Storage Spaces Designated Nos. "8" and "49,"* 777 F.2d. at 1366 n.5. As the Second Circuit has observed, "a fact finder should be free to pierce . . . a manufacturer's . . . misleading 'nutritional' labels to find actual therapeutic intent on the basis of objective evidence." *NNFA v. FDA*, 504 F.2d 761, 789 (2d Cir. 1974), *cert denied*, 420 U.S. 946 (1975); *accord NNFA v. Mathews*, 557 F.2d at 334 ("FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence.").

Contrary to the tobacco industry's assertions, numerous courts have unequivocally stated that FDA could consider evidence from "any relevant source" to establish the "intended" use of a product. The courts have enunciated a principle that defines broadly the scope of the evidence that is to be used to establish intended use. That is, the intended use is based on "labeling, promotional material, advertising *and any other relevant source.*" *United States v. An Article . . . "Sudden Change,"* 409 F.2d at 739 (emphasis added); *accord NNFA v. Mathews*, 557 F.2d at 334; *Action on Smoking and Health v. Harris (ASH)*, 655 F.2d 236, 239 (D.C. Cir. 1980); *Storage Spaces Designated Nos. "8" and "49,"* 777 F.2d at 1366; *Hanson v. United States*, 417 F. Supp. 30, 35 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976); *see also United States v. 250 Jars of U.S. Fancy Pure*

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Honey, 218 F. Supp. 208, 211 (E.D. Mich. 1963) (in determining intended use, a “court is not limited to the labels on such article or to the labeling which accompanies it, but may look at all relevant sources”), *aff’d*, 344 F.2d 288 (6th Cir. 1965).¹¹⁰⁷

The scope of “any relevant source” is extremely broad. As one court recently held, to determine intent under this standard, the Agency may “examine a wide range of evidence, including the vendor’s stated intent, actual use of the product, consumer use of the product, and product marketing.” *Two Plastic Drums*, 761 F. Supp. at 72. Without any implication that these are the exclusive types of evidence, courts have construed the Act to find the types of evidence discussed below, in addition to express claims, to be “other relevant sources” of a product’s intended use.

i. Pharmacological or Physical Effects.

In *United States v. Undetermined Quantities . . . “Pets Smellfree,”* 22 F.3d 235 (10th Cir. 1994), the court relied heavily on expert testimony about the physiological effects of a pharmacologically active ingredient, chlortetracycline (CTC), to establish that an animal food additive, “*Smellfree*,” was in fact a drug. Specifically, the court cited “affidavits demonstrating that the use of CTC will reduce the normal levels of bacteria in the animal’s intestine and that this can affect the way the animal’s body functions” to “establish[] that Smell Free is intended to affect a bodily function of animals.” *Id.* at 240.

¹¹⁰⁷ Courts have adopted a parallel approach in determining intent under similar provisions of the Act. For example, in the context of determining whether a product is “intended for export” for purposes of section 801(e)(1), 21 U.S.C. 801(e)(1), “a court must examine the manufacturer’s subjective intent as well as any other evidence relating to that issue.” *United States v. Various Articles of Drug, Bulk Antibiotics, etc.*, Civ. No. M-95-912, slip op. at 9 (D. Md. Jun. 6, 1996).

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ii. Consumer Use.

In *ASH*, a case involving a previous FDA decision not to regulate cigarettes as drugs, the court explicitly recognized that consumer use could establish the “intended use” of a product, stating that “[w]hether evidence of consumer intent is a ‘relevant source’ . . . depends upon whether such evidence is strong enough to justify an inference as to the vendor’s intent.” 655 F.2d at 239-240; *see also NNFA v. Weinberger*, 512 F.2d 688, 703 (2d Cir. 1975) (evidence before the Agency that vitamins “were used almost exclusively for therapeutic purposes” could be a proper basis to measure intent on an objective basis); *NNFA v. Mathews*, 557 F.2d 325 (2d Cir. 1977);¹¹⁰⁸ *United States v. 789 Cases . . . Latex Surgeons’ Gloves*, 799 F. Supp. 1275, 1294-1295 (D.P.R. 1992) (intended use determined by all the facts, including “actual use”); *Two Plastic Drums*, 761 F. Supp. at 72 (“a court should examine a wide range of evidence, including . . . actual use of the product . . .”); *United States v. Kasz Enterprises, Inc.*, 855 F. Supp. at 539 (“Objective intent can be demonstrated by, among other things . . . evidence that the vendor is aware that his product is being offered *or used* by others for a purpose for which it is neither labeled nor advertised”) (emphasis added).

Several other courts have concluded that relevant “consumer use” can be defined in terms of the uses that doctors and other medical practitioners make of medical devices. *See United States v. An Article of Device . . . Toftness Radiation Detector*, 731 F.2d

¹¹⁰⁸ The manufacturers attempt to diminish the force of the *NNFA* cases by characterizing the courts’ acceptance of evidence of actual consumer use as “dictum.” This argument trivializes the reality that two different panels (consisting of six different jurists) over the course of three years reviewed and—without expressing any reservations regarding its legal soundness—accepted the proposition that consumer use was relevant to determine the intended use of a product. The courts’ only reservation related to the lack of record *evidentiary* support regarding the extent of consumer use. *NNFA v. Weinberger*, 512 F.2d at 703; *NNFA v. Mathews*, 557 F.2d at 335.

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1253, 1257 (7th Cir. 1984) (chiropractic instrument was a device under the Act, relying in part on testimony of manufacturers' witnesses showing how they used the article to treat patients); *United States v. 22 . . . "The Ster-o-lizer MD-200,"* 714 F.Supp. at 1165 (actual use of a sterilizer by surgeons was evidence of intended use); *United States v. An Article of Device . . . Labeled in Part: "Cameron Spitler Amblo-Sytonizer,"* 261 F. Supp. 243, 245 (D. Neb. 1966) (physician use of a product for treatment of eye ailments caused the product to be a device even in the absence of express claims by the physician or by the manufacturer in the labeling).

iii. Other Evidence.

Contrary to the contention that the phrase "intended to affect" must be read narrowly to refer only to promotional representations used in connection with the sale of the product, courts have considered a wide variety of other relevant evidence. In *American Health Products Co. v. Hayes*, for example, in addition to considering product effect and other evidence, the court found that a "starch blocking" product (known as "Starchblocker") was a drug, based in part on evidence of how the product was formulated. 574 F. Supp. 1498, 1508 (S.D. N.Y. 1983) (citing evidence that the products were "manufacture[d] . . . by a process which concentrates the antinutrient to the exclusion of components which contribute food value"). In *Toftness Radiation Detector*, in addition to considering medical use and other evidence, the court cited as evidence of intended use the financial arrangements (such as tuition and leases) through which chiropractors were trained in use of the product. 731 F.2d at 1257 n.2. In *NNFA v. Mathews*, the court noted that both the toxicity of the product, 557 F.2d at 335, and FDA experience, *id.* at 335 n.8, may be considered in determining the intended use of a product.

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With regard to the latter evidence, the court stated that FDA's "general awareness of the 'numerous and widespread' therapeutic usages" can be relied upon if part of the record. *Id.* at 335 n.8; *see also Latex Surgeons' Gloves*, 799 F. Supp. at 1295 (circumstances surrounding storage and handling of products, as well as identity of customers, are relevant to intended use).

The tobacco industry contends that the court in *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497 (8th Cir. 1995), held that documentary materials must be promotional in nature before they can be considered as evidence of intended use. The comments, however, seriously mischaracterize the facts and holding of that case. The case involved products made from colostrum (a component of breast milk) that FDA argued were subject to regulation as drugs by virtue of the pharmacological claims made by the manufacturer, not because of the product's ingredients or actual pharmacological effects. This is simply another case in which promotional claims alone were sufficient to bring under FDA's drug jurisdiction a product without established pharmacological effects or uses. This case has no relevance in determining what kind of evidence can be used to establish the intended use of a product containing a known drug ingredient with widely known pharmacological effects and uses.

Similarly, the tobacco industry mischaracterizes *United States v. . . . "Instant Albery Food"*, 83 F. Supp. 882 (D.D.C. 1949), and *United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219 (D. Minn. 1991), *aff'd*, 968 F. 2d 681 (8th Cir. 1992). These cases involved "nutritional" products that lacked any established pharmacological effects and were promoted for treating disease or affecting the structure or function of the body. Because the *sole* basis for establishing intended use was promotional claims made to consumers, the courts held that the

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promotional material must ordinarily have been distributed and relied on by consumers purchasing the products. These cases are not relevant where the government is relying on evidence establishing the intended uses of products with known pharmacological effects and uses, including evidence of the actual knowledge of manufacturers who are marketing the products for those effects and uses.¹¹⁰⁹

Thus, as a review of the judicial precedent reveals, promotional claims are a sufficient basis for an intended use finding, but not a necessary or exclusive basis. Not only has no court ever held that a promotional claim must always be present, but numerous courts have held that a product's intended use may be determined based on evidence from "any relevant source."

d. The Agency's Administrative Precedent Supports the Agency's Consideration of More Than Promotional Claims

In administrative actions, the Agency has determined intended use on the basis of evidence other than promotional claims by the manufacturer. This administrative precedent is entitled to deference. *See Wichita and Affiliated Tribes v. Hodel*, 788 F.2d 765, 778 (D.C. Cir. 1986) ("a high level of deference [is] afforded an agency on review when the issue turns on the interpretation of the agency's own prior proclamations").

¹¹⁰⁹ Indeed, the court in *Alberty Food* recognized that, even if the manufacturer had long since stopped distributing the literature, the government could still establish intent if it could show that the manufacturer *actually intended* the products to be used for the treatment of disease:

it is only to the extent that the abandonment of such dissemination creates an inference that the shipper did not intend, when it shipped the drugs in interstate commerce, that they be used for the treatment of the diseases named on the booklets, that the abandonment can be said to be an effective defense. *The government might introduce evidence to show that, notwithstanding such abandonment, it was still the intention of the shipper that the drugs be used for the treatment of the diseases mentioned in the booklets.*

83 F. Supp. at 887 (emphasis added).

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Several of these precedents were described in the Jurisdictional Analysis. *See* 60 FR 41527–41531. Beginning in the 1980's, for instance, FDA took enforcement actions against “caine” products that were used as imitation cocaine. These imitation cocaine products contained bulk anesthetic powders, such as lidocaine or ephedrine, and were often sold as “incense.” To determine the products’ intended drug use, the Agency relied upon laboratory analyses of the products, the outlets in which the products were sold (e.g., “head shops”), and “street” information that the products provide a “cheap high.”¹¹¹⁰ *See* Jurisdictional Analysis, 60 FR 41528. Similarly, in the early 1980's, FDA started to regulate as unapproved drugs U.S. imports of *Catha edulis*, or “khat,” even though the Agency did not have any information about or claims by vendors.¹¹¹¹ Khat is a shrub whose leaves act as a stimulant narcotic that affects the central nervous system when chewed or used as tea. The Agency relied on evidence of khat’s actual effects and widely known uses to determine that it was intended for use as a drug.

The Agency has also taken the position that including a known drug ingredient in a product and listing this ingredient on the label of the product can be sufficient to make the product a drug. Thus, the Agency has formally taken the position that any skin cream that contains a pharmacologically active level of hormones and lists the presence of hormones

¹¹¹⁰ *See* memorandum from chief, prescription drug compliance branch (Aug. 4, 1982), reprinted in *Rx Drug Study Bulletin* #258; OH. FDC 64350, Case No.C-3-84-686 (S.D. Ohio 1984); FDA Administrative File for Mid-America Drug Co., regulatory letter 84-DT-12 and response; FDA Administrative File for Sam’s Imports, Dearborn, MI, regulatory letter 85-DT-3 and response; FDA Administrative File for NALPAC, Ltd., Oakpark, MI, regulatory letter 85-DT-5 and response; FDA Administrative File for Tower Enterprises, Ida, MI, regulatory letter 85-DT-2 and response. In 1994, the government prosecuted Edwin and Thomas Dews in Michigan for selling a product called “Milky Trails,” labeled as a room deodorizer but in fact containing lidocaine. Case No. 94 CR 20040-BC (E.D. Mich.). *See* AR (Vol. 4 Ref. 30-2).

¹¹¹¹ FDA Import Alert 66-23 (Mar. 26, 1982, revised Apr. 2, 1986, and Feb. 9, 1993). *See* AR (Vol. 4 Ref. 30-1).

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on the label is a drug. *See* 58 FR 47611, 47612 (Sep. 9, 1993); Drug Study Bulletin No. 67 (Mar. 28, 1994); *see also* 54 FR 40618, 40619 (Oct. 2, 1989). Similarly, FDA considers dentifrice products containing fluoride to be drugs, irrespective of whether any claims are made, because fluoride is widely accepted as an anticavity agent by the dental products industry and consumers and because fluoride affects the structure of the tooth. *See* 59 FR 6084, 6088 (Feb. 9, 1994); *see also* 50 FR 39854 (Sep. 30, 1985).

As these examples and the additional examples described in the Jurisdictional Analysis indicate, the Agency regularly looks beyond a manufacturer's express promotional claims to the likely pharmacological use and effect of a product in determining whether a product is intended to affect the structure or function of the body.

e. Policy Considerations Also Weigh Strongly in Favor of the Agency's Interpretation

Finally, policy considerations also conflict with the tobacco industry's position and weigh strongly in favor of the Agency's interpretation. The purpose of the Federal Food, Drug, and Cosmetic Act is to "safeguard the public health" and protect "consumer welfare." H. Rep. No. 2139, 75th Cong., 3d Sess. 1-2 (1938), *reprinted in* 6 Legislative History 360. The Supreme Court has recognized that "the Food, Drug and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969). As the Court stated:

The purposes of [the Act] thus touch . . . the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of [the Act] if it is to be treated as a working instrument of government and not merely as a collection of English words.

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United States v. Dotterweich, 320 U.S. 277, 280 (1943).

The tobacco industry's theory would frustrate these public health purposes. If promotional claims alone determined the "intended use" of a product, a manufacturer could market a potent tranquilizer solely for its "pleasurable" effect or an amphetamine for its "energizing" effect and avoid the Act's reach. The same manufacturer could coat the tranquilizer or amphetamine with sugar, advertise it for its "taste and flavor," and again escape FDA regulation. It is not hard to imagine a manufacturer of a generic version of Prozac, an antidepressant drug currently approved by FDA and available only by prescription, who would seek to avoid FDA regulation by advertising its product as intended solely for the "pleasure" of its consumers. If these products could so easily escape FDA regulation, the public health would be endangered.

These examples are not purely hypothetical. As discussed above, manufacturers of imitation cocaine or "caine" products, which contain anesthetic drugs such as lidocaine, have attempted to avoid FDA regulation by selling their products as "incense." Although FDA has successfully asserted jurisdiction over these products in the past, the Agency could be precluded from doing so under the manufacturers' legal theory.

New evidence received during the comment period provides another example of the possible results if the Agency accepted the manufacturers' legal theory. In 1992, the British American Tobacco Company (BATCO), the parent company of Brown & Williamson Tobacco Corporation, considered purchasing a manufacturer of nicotine patches, Stowic Resources Ltd., because "[t]here is currently a void in the market for a product that provides tobacco satisfaction in a form that is acceptable and available to

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many segments of the market.”¹¹¹² The purchase was ultimately rejected after BATCO and Brown & Williamson researchers found that nicotine patches did not provide the consumer with “[t]he rapid, peaking intake of nicotine which the smoker clearly wants.”¹¹¹³ Under the manufacturers’ theory, however, it would nonetheless be legally permissible for BATCO and Brown & Williamson to sell high-potency nicotine patches or any other product whose sole purpose was to deliver pharmacologically active doses of nicotine without FDA regulation so long as the manufacturers claimed to market the products exclusively for “tobacco satisfaction.”

For sound policy reasons, the Agency must be able to look beyond a manufacturer’s promotional claims when determining whether to regulate a product that contains a known drug or that has known pharmacological uses. Where manufacturers avoid promoting the pharmaceutical uses of products that contain drug ingredients or where manufacturers deliberately make ambiguous claims or otherwise seek to obscure the true nature of their products, FDA must be free to consider other objective evidence to establish the true intended use of the product. As discussed in sections II.A.1., II.B.1., and II.C.1., above, this other objective evidence may include the product’s foreseeable pharmacological effects and uses, actual consumer use, and the statements, research, and actions of manufacturers.

¹¹¹² Brown & Williamson, *Transdermal Nicotine Patches* (1992), at 3. See AR (Vol. 531 Ref. 124).

¹¹¹³ Kausch, Research and Development/Quality, *Transdermal Nicotine* (1992). See AR (Vol. 531 Ref. 124).

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2. Consideration of Tobacco Manufacturers' Promotional Claims Supports the Agency's Position

The Agency also disagrees with the premise of the tobacco industry's position—namely, that consideration of their promotional claims will demonstrate that cigarettes and smokeless tobacco products are not intended to affect the structure or function of the body. In fact, consideration of the claims made in tobacco advertising lends support to the Agency's determination that cigarettes and smokeless tobacco are “intended” to affect the structure and function of the body.

Several comments on the Jurisdictional Analysis urge FDA to consider the promotional claims of the tobacco manufacturers in determining whether the manufacturers intend to affect the structure or function of the body. The comments of the American Society of Addiction Medicine, for example, assert that consideration of promotional claims provides further support for the finding that tobacco manufacturers intend to affect the structure and function of the body. Conversely, the tobacco industry comments maintain that consideration of these claims will show that the manufacturers do not intend to affect the structure or function of the body.

The Agency agrees that promotional claims can be relevant evidence of intended use. *See* section II.E.1., above. As the tobacco industry comments recognize, these claims can be of two types, implied or express.¹¹¹⁴ Express claims for a product overtly promote the product's effects on the structure or function of the body. Implied claims

¹¹¹⁴ Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. II, at 91. *See* AR (Vol. 535 Ref. 96) (“the determining factor is claims—implied or expressed—made in marketing the product”) (emphasis added). *See also* section 201(n) of the Act (21 U.S.C. 321(n)) (in determining whether labeling or advertising is misleading the Agency must consider both the representations “made” and the representations “suggested” by the manufacturer).

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suggest, but do not explicitly recommend, pharmacological use. The courts have recognized that implied drug claims can make a product a drug even in the presence of express disclaimers warning against drug use. For instance, in a case involving an imitation cocaine product sold as incense and advertised as not for drug use, the Ninth Circuit held:

The fact that the items were called “incense” and advertised as “Not for drug use” cannot be controlling on the issue of whether they are drugs. Where, as here, the items are otherwise promoted and advertised in ways that *suggest* they are cocaine substitutes, [the vendor’s] intent in distributing the products is clear. Self-serving labels cannot be allowed to mask the vendor’s true intent as indicated by the overall circumstances.

United States v. Storage Spaces Designated Nos. “8” and “49,” 777 F.2d 1363, 1366 n.5 (9th Cir. 1985) (emphasis added), *cert. denied*, 479 U.S. 1086 (1987).

As suggested in the comments, the Agency has examined the promotional claims of the tobacco manufacturers. Although recent tobacco product advertisements do not make express drug claims, the implied pharmacological claims in some tobacco advertisements provide additional support for the Agency’s finding of intended pharmacological use. In particular, as described below, advertisements that promise that tobacco products will provide “satisfaction” suggest to the consumer that use of tobacco products will provide desired pharmacological benefits, including satisfying addiction.

The use of “satisfaction” claims in tobacco product advertising is common. Since the 1970’s, most major tobacco manufacturers have used advertising campaigns that promote “satisfaction.” For instance, the R.J. Reynolds Tobacco Company (RJR) has used a promise of “satisfaction” to advertise many cigarette brands, including Camel

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Lights, Salem, Real, More, and Now.¹¹¹⁵ A 1990 advertisement for Now brand cigarettes, for example, asks “Can a cigarette have just 2 mgs of tar and still be satisfying to smoke? . . . NOW can.”¹¹¹⁶ Likewise, “satisfaction” claims have been used by Brown & Williamson, Lorillard, and Liggett & Myers.¹¹¹⁷ In one typical, recent advertisement, Lorillard promoted its True brand with the slogan “The Lowest with True *Satisfaction* . . . True *Delivers*.”¹¹¹⁸ Some of these advertisements distinguish “satisfaction” from taste. For example, a Brown & Williamson advertisement for Barclay states:

If your ultra light is ultra boring, why do you still smoke it?
Because you probably think that’s the sacrifice you have to make.
Well, not any longer. We’ve just made ultra lights you don’t have
to make any sacrifices for. At least not on taste. *And not on
satisfaction.*¹¹¹⁹

Smokeless tobacco manufacturers also rely on “satisfaction” claims in advertising. The nation’s largest smokeless tobacco manufacturer, United States Tobacco Company (UST), has used satisfaction promises to advertise several brands, including Copenhagen,

¹¹¹⁵ See Tobacco Advertisements, in American Society of Addiction Medicine, Comment (Dec. 29, 1995), appendix 6, at 89-90, 92, 94-96, 98. See AR (Vol. 528 Ref. 97).

¹¹¹⁶ *Id.* at 98.

¹¹¹⁷ *Id.* at 82-86, 88, 91, 97, 99.

¹¹¹⁸ *Id.* at 99 (emphasis added).

¹¹¹⁹ *Id.* at 97 (emphasis added).

In addition to differentiating between taste and satisfaction in the quoted passage, this advertisement also uses the term “satisfying” in a subsequent passage to describe the flavor of Barclay, stating that “[w]e gave Barclay a new blend of tobaccos for a smoother, more satisfying flavor.” *Id.* This dual usage of satisfaction occurs in other advertisements. For instance, in an advertisement for Camel Lights, RJR uses satisfaction both as an independent attribute of its product (promising “All the flavor *and satisfaction* that’s been missing in your low tar cigarette”) and as an adjective to describe the product’s taste (promising “a rich, rewarding, truly satisfying taste”). *Id.*, at 95 (emphasis added).

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Skoal, and Happy Days.¹¹²⁰ In fact, the slogan “It Satisfies” is the signature of UST’s Copenhagen brand and appears on the lid of each package.¹¹²¹

The tobacco industry argues that “satisfaction” is not an implied drug claim. In its view, “satisfaction” is not a euphemism for the consumer’s pharmacological response to nicotine. Rather, as one cigarette manufacturer commented, “[s]atisfaction’ . . . reflects the consumer’s total reaction to the total smoking experience delivered by the cigarettes.”¹¹²²

The Agency agrees that the term “satisfaction” reflects the consumer’s reaction to the experience of smoking a cigarette or using smokeless tobacco. Indeed, it is precisely for this reason that the Agency finds that the use of the term to promote cigarette and smokeless tobacco is an implied drug claim.

The meaning of a promise of “satisfaction” depends upon the needs or expectations of the consumer. A “satisfying” meal means something quite different from a “satisfying” movie, which in turn means something different from a “satisfying” driving experience. A product that is satisfying to consumers is one that fulfills the needs or expectations of the consumer. Thus, a “satisfying” meal must meet the consumer’s desires for taste and nutrition, while a “satisfying” driving experience must meet the consumer’s desires for power, maneuverability, and comfort.

¹¹²⁰ *Id.* at 93, 100-101.

¹¹²¹ *Id.* at 100.

¹¹²² Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 8. *See* AR (Vol. 529 Ref. 104).

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In the case of cigarettes and smokeless tobacco, a “satisfying” product must meet the consumer’s motivations for using the product. As discussed in sections II.A. and II.B., above, these motivations are primarily pharmacological. Most users of tobacco products are addicted to nicotine. They use cigarettes and smokeless tobacco to satisfy their addiction and to obtain other pharmacological effects, such as anxiety reduction or stimulation. To these users, a manufacturer’s promise of “satisfaction” implies that the product will fulfill their craving for the pharmacological effects of nicotine—satisfying their addiction and providing the sought-after mood-altering effects of nicotine.

The tobacco industry’s internal documents themselves show that consumer “satisfaction” is intimately connected to nicotine’s pharmacological effects and that the tobacco manufacturers know this. The internal company documents that have recently become publicly available show that for the past three decades, tobacco industry officials have consistently expressed the view that nicotine’s pharmacological effects are essential to consumer satisfaction.

Officials at Brown & Williamson and its parent company, the British American Tobacco Company (BATCO), for instance, have consistently linked nicotine delivery to consumer satisfaction. Thus, BATCO scientists have stated:

- “Nicotine has well documented pharmacological action. . . . *It is believed to be responsible for the ‘satisfaction’ of smoking*, using this term in the physiological rather than the psychological sense.”¹¹²³
- “*The basic assumption is that nicotine . . . is almost certainly the key smoke component for satisfaction*”¹¹²⁴

¹¹²³ Wood DJ, BATCO Group Research and Development, *Aspects of the R&DE Function*, notes for a talk given at Chelwood, Sep. 1969 (Jul. 20, 1970), at 7 (emphasis added). See AR (Vol. 22 Ref. 287).

¹¹²⁴ BATCO Group R&D Research Conference, Rio de Janeiro, Brazil (Aug. 22-26, 1983), at 10 (emphasis added). See AR (Vol. 179 Ref. 2087).

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- “[N]icotine . . . probably provides the basis of smoking satisfaction.”¹¹²⁵
- “[I]n its simplest sense puffing behavior is the means of providing nicotine dose in a metered fashion.”¹¹²⁶
- “Intuitively it is felt that ‘satisfaction’ must be related to nicotine. Many people believe it [is] a ‘whole body response’ and involves the action of nicotine in the brain.”¹¹²⁷

Other industry officials have expressed the same view. For example:

- Senior RJR scientists have written that “the confirmed user of tobacco products is primarily seeking the physiological ‘satisfaction’ derived from nicotine”¹¹²⁸ and that “the ultimate satisfaction comes from the nicotine which is extracted . . . in the lungs.”¹¹²⁹

¹¹²⁵ BATCO, Proceedings of the Smoking Behaviour Marketing Conference, Session I slides (Jul. 9-12, 1984) (emphasis added). See AR (Vol. 21 Ref. 238).

¹¹²⁶ *Id.*

¹¹²⁷ BATCO, *Nicotine Conference Outline* (Jun. 6-8, 1984) at BW-W2-01977 (emphasis added). See AR (Vol. 22 Ref. 290).

The record contains numerous other similar BATCO and Brown & Williamson statements. For example, as part of their evaluation of whether BATCO should purchase a manufacturer of nicotine patches, Brown & Williamson researchers in 1992 stated that “[t]he fact that people use snuff and chewing tobacco indicates that administration routes [of nicotine] other than inhalation can deliver tobacco satisfaction.” *Transdermal Nicotine Patches*, at 3 (emphasis added). See AR (Vol. 531 Ref. 124).

Similarly, as part of Project Wheat, BATCO researchers reported that “there is evidence of a conflict between concern for health and the desire for a satisfying cigarette, from which it follows that low tar brands would be much more widely accepted if their nicotine deliveries could be brought within the range required by groups of consumer[s].” Wood DJ (BATCO), *Project Wheat -- Part 2: U.K. Male Smokers: Their Reactions to Cigarettes of Different Nicotine Deliveries as Influenced by Inner Need* (Jan. 30, 1976), at 48 (emphasis added). See AR (Vol. 20 Ref. 204-2).

¹¹²⁸ Teague CE, R.J. Reynolds, *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 1 (emphasis added). See AR (Vol. 531 Ref. 125).

Teague also wrote that “what we are really selling [is] nicotine satisfaction.” *Id.* at 5 (emphasis added).

¹¹²⁹ Senkus M (R.J. Reynolds Tobacco Co.), *Some effects of smoking (1976/1977)*, at 9 (emphasis added). See AR (Vol. 700 Ref. 593).

Senkus also wrote that “a zero nicotine cigarette . . . really has no potential to provide smoking satisfaction. It produces no taste in the mouth, but even more seriously it fails to provide the ultimate satisfaction in the lungs.” *Id.* at 9 (emphasis added).

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- William Farone, the former Philip Morris director of applied research, has written that “[t]he objective of industry scientists and product developers, simply stated, was *to provide the consumer with the . . . pharmacological satisfaction derived from nicotine. . .*.”¹¹³⁰
- The senior vice president for marketing at UST has written that “[v]irtually all tobacco usage is based upon nicotine, ‘the kick’, satisfaction.”¹¹³¹

Indeed, tobacco manufacturers have even conducted opinion surveys that show that tobacco users understand that their “satisfaction” is based on nicotine. For instance, an affiliate of Brown & Williamson reported that “[m]ost respondents, with a bias toward men, realised that *nicotine* was the attribute in cigarettes causing addiction. It was also usually seen as *the component providing satisfaction*.”¹¹³²

These statements show that, when consumers use cigarettes and smokeless tobacco, their degree of “satisfaction” is closely related to the pharmacological effects of nicotine delivered by the product. The statements also show that tobacco manufacturers have long been aware of the central role of nicotine in consumer satisfaction. In effect, the

¹¹³⁰ Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 7 (emphasis added). See AR (Vol. 638 Ref. 2).

¹¹³¹ Testimony of Erik Lindqvist, *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. Jun. 5, 1986) transcript of jury trial proceedings, at 1662 (emphasis added). See AR (Vol. 22 Ref. 292). In another document describing Skoal Bandits, UST states:

The nicotine contents are more or less equivalent to that of a good quality cigarette. The nicotine is absorbed, *giv[ing] satisfaction to the smoker*.

Potential Questions and Answers, submitted in *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986) (emphasis added). See AR (Vol. 30 Ref. 509).

¹¹³² *Attitudes Towards Smoking and Health*, attached to letter from Johnston AH (market research manager, Carreras Rothmans Ltd.) to Bentley HE (Imperial Tobacco Ltd.) (Jul. 26, 1979), at 12 (emphasis added). See AR (Vol. 21 Ref. 218).

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statements establish that the manufacturers use “satisfaction” as a code-word for the pharmacological effects of nicotine.

The Agency has reviewed the manufacturers’ promotional claims and finds that they are consistent with—and in fact provide further support for—the Agency’s conclusion that cigarettes and smokeless tobacco are “intended” to affect the structure and function of the body. When manufacturers of an addictive and psychoactive product use words like “satisfaction” in their advertisements, the word takes on special connotations to the consumer. The advertisements make an implicit pharmacological appeal and hence become further evidence that the products are intended to affect the structure and function of the body.

3. Response to Additional Comments on Legal Theory

The discussion in sections II.A.-E.2., above, has responded to many of the major comments regarding the Agency’s legal analysis of intended use. In this section, the Agency responds to additional comments of the manufacturers and others on this issue.

a. General Comments

1. The tobacco industry contends that the legislative history of the Federal Food, Drug, and Cosmetic Act conflicts with the Agency’s interpretation of the Act and shows that Congress determined that only promotional claims can be considered in determining whether a product is “intended to affect the structure or any function of the body.”

The Agency has carefully reviewed the legislative history of the Act and concludes that it fails to support the tobacco industry’s position. Indeed, what little legislative

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history there is confirms the Agency's interpretation that evidence of intent should not be restricted to promotional claims.

Congress most directly addressed the issue during consideration of the 1976 Medical Device Amendments. In the House Report, the Committee on Energy and Commerce specifically considered whether a manufacturer could avoid having its product regulated as a medical device intended for human use by labeling and promoting the device as intended for animal use only. Contrary to the tobacco industry's position, the House Report concluded that FDA would not be bound by the manufacturer's promotional claims:

This is not to say, however, that a manufacturer of a device that is banned by the Secretary [for human use] can escape the ban by labeling the device for veterinary use. *The Secretary may consider the ultimate destination of a product in determining whether or not it is for human use, just as he may consider actual use of a product in determining whether or not it is a device.*

Medical Device Amendments of 1976, H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 14 (emphasis added), *reprinted in* An Analytical Legislative History of the Medical Device Amendments of 1976, appendix III. Congress' reasoning confirms the plain meaning of the statutory definitions of "drug" and "device." It shows that Congress plainly intended FDA to be able to look behind a manufacturer's promotional claims and to determine intent based on the actions of the manufacturer and the actual uses of the product.

The tobacco industry relies primarily on a passage from the 1935 Senate Report, which states that "the manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put." S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935), *reprinted in* 3 Legislative History 60, 663.

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However, the first sentence of the paragraph from which the tobacco industry quotes states that “[t]he use to which the product is to be put will determine the category into which it will fall.” *Id.* This quotation is consistent with the Agency’s interpretation that consumer use can establish “intended use” independent of the manufacturer’s claims.

Furthermore, the passage quoted by the tobacco industry is taken out of context, however. Congress was not addressing the issue of how to determine whether a product is intended to affect the structure or function of the body under the Act’s drug definition, section 201(g)(1)(C). Rather, the issue being discussed was the circumstances under which the Agency must regulate a product both as a food and as a drug intended for use in the diagnosis or treatment of disease under section 201(g)(1)(B) of the Act. (By definition, a “food” cannot be regulated as a drug under section 201(g)(1)(C) of the Act.) In this context, the Senate Committee stated that a manufacturer could “escape” regulation of a product as a food by “representing the article fairly and unequivocally as a drug product.” *Id.*

The Senate Committee did not say that promoting the article exclusively as a food could remove the article from the drug definition of section 201(g)(1)(B), however. To the contrary, the Committee stated that “[i]f it is to be *used* only as a food it will come within the definition of food and none other.” *Id.* (emphasis added). Thus, this legislative history shows that a manufacturer’s representations cannot force the Agency to regulate a product containing a drug as a food; rather, regulation as a food is compelled only if the sole *use* of the product is as a food. Accordingly, the legislative history on which the comments rely supports only the limited argument that a manufacturer’s representations can ensure that a product *is* regulated as a drug. The passage does not support—and

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indeed contradicts—the position that a manufacturer's representations can prevent regulation of a product as a drug.

The cigarette industry also cites the following language from the same Senate Committee report to support the view that a manufacturer's claims are the only relevant consideration in determining the intended use of a product:

While soaps sold only for ordinary toilet or household use are specifically exempted from the definition of cosmetic and will not be subject to the definition of drug, soaps for which claims concerning disease are made or which are sold as pharmacopoeial articles will come within the definition of drug and will thus be subject to regulation.

Id. at 3-4, *reprinted in* 3 Legislative History 662-663. This language, however, merely states the unarguable and long-settled principle that a drug claim can bring any article (regardless of the article's composition or effects) within the Agency's jurisdiction. *See, e.g., United States v. An Article . . . "Sudden Change,"* 409 F.2d 734, 739 (2d Cir. 1969). This is not the issue before the Agency in this case.

The passages of the legislative history quoted by the tobacco industry, "when read fairly and in light of their true context, . . . cannot be said to demonstrate a [true] Congressional desire." *Jewell Ridge Coal Corp. v. United Mine Workers*, 325 U.S. 161, 168-169 (1945). The most that can reasonably be said in support of the tobacco industry's view is that the legislative history is sparse and ambiguous—a circumstance that calls for deference to the Agency's interpretation of the plain language of the statute. As the Supreme Court recently held, "[w]hen we find . . . that the legislative history is ambiguous and unenlightening on the matters with respect to which the regulations deal,

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we customarily defer to the expertise of the agency.” *Rust v. Sullivan*, 500 U.S. 173, 186 (1991).

2. The cigarette manufacturers contend that reading a foreseeability standard into “intended use” is unworkable because it would convert “every foreseeable off-label use” of a drug or a device into an “intended use” attributable to the manufacturer. In support of this contention, the cigarette industry points to what has become known as FDA’s “practice of medicine” policy, under which the Agency recognizes that physicians may, if their medical judgment so dictates, prescribe (but not promote) an approved drug for an unapproved use without violating the Act. *See* 37 FR 16503 (Aug. 15, 1972).

The Agency disagrees with this comment. Fundamental differences distinguish off-label uses of approved drugs from cigarettes and smokeless tobacco. First, before a drug can have an off-label use, the drug must first have been regulated by FDA for an approved use. Unlike off-label uses of approved drugs, cigarettes and smokeless tobacco have not previously been regulated by FDA for approved uses.

Second, FDA’s practice-of-medicine policy is based on FDA’s long-standing policy of not interfering with the practice of medicine. Most off-label uses of prescription drugs are prescribed by a physician. FDA has made a policy judgment that, because of the involvement of a doctor, FDA will not generally interfere with these off-label uses. The policy considerations that underlie the practice-of-medicine policy are entirely missing in the case of cigarettes and smokeless tobacco.

In any event, under the practice-of-medicine policy, “[w]here the unapproved use of an approved new drug *becomes widespread or endangers the public health*, ‘FDA will investigate and’ *take whatever action is warranted to protect the public.*” *See* 37 FR

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16504 (Aug. 15, 1972) (emphasis added). Thus, this policy recognizes that the Agency may assert jurisdiction over unapproved uses of drugs when they become “widespread” or endanger the public health—even in the absence of promotional claims by the manufacturer. This closely parallels the Agency’s interpretation that it may assert jurisdiction over products when it becomes foreseeable that they will have drug effects upon, and be used for drug purposes by, a significant proportion of consumers.

3. The smokeless tobacco industry asserts that FDA’s reliance on consumer use to confer drug or device status on an article is, in effect, an attempt to define drugs and devices in the same way that the Act defines foods. Under the Act, the term “food” means “articles used for food or drink for man or other animals.” Section 201(f), 21 U.S.C. 321(f). The smokeless tobacco industry argues that if “drug” or “device” status can be inferred whenever a product is used in a certain way, then the statutory intent requirement becomes mere surplusage.

The Agency disagrees. To determine that a product is a drug or device, FDA is required to show that the “intended use” by a manufacturer for a product is as a drug or device. This statutory intent requirement can be satisfied based on “use” alone only where the use is sufficiently widespread. Evidence of “use” can also provide a relevant source of information in combination with other types of evidence. *See ASH*, 655 F.2d at 239-240.

4. The tobacco industry characterizes evidence from the statements, research, and actions of manufacturers as “classic examples of subjective intent, i.e., motives that are not publicly expressed,” and states that the regulations allow the Agency to prove the “intended use” of a product based only on evidence of “objective intent.” Thus, the tobacco industry argues that the Agency must disregard the extensive evidence in the

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administrative record indicating that the manufacturers actually intend that cigarettes and smokeless tobacco have, and will be used for, pharmacological effects.

FDA concludes that evidence of the statements, research, and actions of tobacco manufacturers is relevant to determine the “intended use” of a product. The tobacco industry’s position that evidence bearing on their actual intentions is not relevant conflicts with the plain language of the Act. The tobacco industry’s position also conflicts with the regulations defining “intended uses.”¹¹³³

Moreover, acceptance of the tobacco industry’s argument that FDA must disregard evidence of the manufacturers’ statements, research, and actions would frustrate the public health purposes of the Act. FDA does not test products before they are marketed, nor does the Agency have the right to examine the manufacturer’s testing data before a new product is marketed unless the manufacturer submits an application for approval of the drug or device prior to marketing. Consequently, neither FDA nor the consumer is ordinarily in a position to know whether a new product that the manufacturer claims is *not* a drug or device in fact has pharmacological effects on consumers. In contrast, the manufacturer, through its research and product development activities, knows the effects of the product on consumers and knows how the manufacturer’s formulation and design choices are likely to influence the uses to which the product will be put. To interpret “intended use” to exclude evidence of what the manufacturer has

¹¹³³ The phrase “subjective intent” is ambiguous. To the extent that “subjective intent” is understood to refer to the actual intent of the manufacturer, the Agency may consider objective evidence of this “subjective” or actual intent in determining the manufacturers’ intent. Alternatively, to the extent that “subjective intent” is understood to refer to the intent the manufacturer claims to have, *see, e.g., NNFA v. Mathews*, 557 F.2d at 334; *see also Latex Surgeons’ Gloves*, 799 F. Supp. at 1295, “the FDA is not bound by the manufacturer’s subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence.” *Mathews*, 557 F.2d at 334.

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designed its product to do, and anticipates its product will be used for, would thus permit, and even encourage, unscrupulous manufacturers to conceal their knowledge of the products' significant pharmacological effects so as to avoid application of the Act. This would directly undercut the public health purposes of the Act.

Accordingly, FDA concludes that objective evidence of tobacco manufacturers' actual intent from their statements, research, and actions is relevant to establishing the intended use of cigarettes and smokeless tobacco.¹¹³⁴

b. Comments on Administrative Precedents

The tobacco industry and an individual commented on the administrative precedents. The comments make two main arguments. First, the comments argue that FDA did not rely solely on known pharmacological effects or consumer use to establish the intended use of the products discussed in the examples. Second, the comments argue that the examples cited did not represent authoritative interpretations of the law. The comments address each of the examples in some detail.

FDA's response is set forth below. In brief, the cited examples are valid precedents in which FDA found intended drug or device use based on factors other than express claims (i.e., known effects or consumer use). Moreover, contrary to the tobacco

¹¹³⁴ Even if the Agency accepted the tobacco industry's argument that manufacturers' statements, research, and actions cannot be considered to prove the manufacturers' intent, it does not follow that such evidence is not *also* relevant for other purposes. For example, much of this evidence corroborates the scientific evidence showing that tobacco products have significant pharmacological effects and are used by consumers to obtain these effects. The Agency may properly use the evidence of the statements, research, and actions to establish these facts. Furthermore, the Agency may properly use the evidence from the statements, research, and actions of the manufacturers to rebut assertions by the manufacturers that they do not intend to make products that have and are used for pharmacological effects.

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industry's assertions, the examples support the position that nicotine in tobacco products is a drug.

1. The tobacco industry asserts that FDA's administrative precedents are not analogous to tobacco products because the precedents in fact relied on implied promotional claims in establishing intended use. For instance, the comments assert that the mere listing of the word "hormone" on a skin cream was viewed by FDA as an implied drug claim and argue that "the Agency asserted that any statement in the labeling of these products that hormones are present is an implied drug claim . . . Thus, the determining factor is *claims*—implied or express—made *in marketing* the product."¹¹³⁵

These comments on the basis for FDA's finding of intended use are incorrect. First, in most of the administrative precedents, no implied claims were involved. For instance, there were no express or implied claims involved in the Agency's assertion of jurisdiction over "khat." Similarly, in most of the imitation cocaine precedents, the manufacturers were deliberately trying to avoid FDA jurisdiction by advertising their products for nondrug uses.¹¹³⁶ The novelty condom precedents discussed in the Jurisdictional Analysis, in which the condoms were labeled as novelty and not functional condoms, also did not involve any promotional claims. *See* 60 FR 41530 (Aug. 11, 1995).

¹¹³⁵ Joint Comment of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. II, at 91 (emphasis in original). *See* AR (Vol. 535 Ref. 96).

¹¹³⁶ The Agency recognizes that in one imitation cocaine case, *United States v. Storage Spaces Designated Nos. "8": and "49,"* 777 F.2d 1363 (9th Cir. 1985), the reviewing court did find some evidence of promotional claims. Even in that case, however, "the items were called 'incense' and advertised as 'Not for drug use,'" and the court stated that "[s]elf-serving labels cannot be allowed to mask the vendor's true intent as indicated by the overall circumstances." *Id.* at 1366 n.5. In most of FDA's actions against imitation cocaine, the manufacturers' promotional materials were generally designed to disguise the actual intended use.

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It is true that the listing of hormones on the label of skin creams can be considered an implied drug claim. However, this implied claim argument does not distinguish cigarettes and smokeless tobacco from the administrative precedents. If the mere listing of the drug ingredient "hormone" on a skin cream constitutes an implied drug claim, then similar implied drug claims are regularly made for tobacco products. Many cigarette advertisements list nicotine deliveries.¹¹³⁷ Nicotine is a widely recognized drug with significant pharmacological effects. It is the active ingredient in several products regulated as drugs by FDA. Therefore, if the listing of hormones in skin creams can be considered an implied drug claim, the listing of nicotine in cigarette advertisements can also be considered an implied drug claim.

Moreover, in the case of hormone-containing skin creams, FDA independently relied upon the foreseeable drug effects of the creams as a basis for establishing intent. FDA took the position that the inclusion of pharmacologically active levels of hormones in the skin creams was a sufficient basis for regulating the products as drugs. *See* 58 FR 47611, 47613 (Sep. 9, 1993).

2. The tobacco industry also alleges that, in some of the examples, intended drug use had previously been established because the product contained an active drug ingredient. For instance, the tobacco industry argues that the imitation cocaine cases involved bulk prescription drug ingredients (e.g., lidocaine and ephedrine) that were diverted for use in the imitation cocaine products. The comments' point seems to be that once intended drug use is established for one use of a drug, FDA can establish the same

¹¹³⁷ American Society of Addiction Medicine, Comment (Dec. 29, 1995), appendix 6. *See* AR (Vol. 528 Ref. 97).

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drug intent with respect to manufacturers of other products containing the drug as an ingredient.

The Agency agrees that the presence of a known drug ingredient can be substantial evidence of an intent to affect the structure and function of the body. However, the Agency disagrees that this point distinguishes any of the administrative precedents from tobacco products. To the contrary, cigarettes and smokeless tobacco contain a known drug, nicotine, that has addictive and other significant pharmacological effects. It is the active drug ingredient in several products regulated as drugs by FDA, including nicotine patches, nicotine gum, and nicotine nasal sprays. The comments' position leads to the conclusion that products containing nicotine, including cigarettes and smokeless tobacco, are also drugs.

3. The tobacco industry argues that the administrative precedents are not authoritative interpretations of the law. Instead, the comments assert, the examples consist of unchallenged assertions, preliminary pronouncements in certain rulemaking proceedings, and judicial default and consent decrees, rather than specific actions and litigated cases. One comment minimizes some of the examples by stating that preliminary views and opinions are not binding on FDA itself. Another comment asserts that the "Agency position" in the case of one example, vaginal products, was really that of an independent advisory committee, and, in any case, the Agency itself later rejected the position. Still another comment contends that the Agency cited a relatively small number of examples, implicitly suggesting that this limited the precedential value of the collection of examples.

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The Agency disagrees with the premise that only examples supported by binding regulation or judicial precedent would be valid evidence of Agency interpretation. FDA cited the examples to illustrate that the Agency has over the years consistently taken the position that express drug or device claims are not required for a finding of intended pharmacological use or effect. These examples constitute highly relevant evidence of the Agency's past interpretations of its governing statute.

Further, FDA's statements in *Federal Register* preambles and proposed regulations—although not binding—are official statements of Agency position. See 21 CFR 10.85(d)(1) and (e) (texts of proposed and final regulations, and related preambles, are valid FDA interpretations). Although the Agency did not concur fully with its advisory committee in the vaginal products example, the position expressed in the example was that of the Agency. See 59 FR 5226, 5227 (Feb. 3, 1994). These and other official Agency interpretive statements deserve strong consideration. Notifications to manufacturers also represent official Agency positions. See 21 CFR 10.85(d)(1); see also *Kickapoo Oil Co. v. Murphy Oil Corp.*, 779 F.2d 61, 66 (Temp. Em. Ct. App. 1985) (“Notice of Probable Violation” constitutes agency interpretation).

The examples document the Agency's consistent historical position that intended use is not limited to express claims. See *Udall v. Tallman*, 380 U.S. 1, 17-18 (1965) (consistent past agency practice can be evidence of agency interpretation). The examples cover a number of years and represent a variety of circumstances. They cover both individual products and categories of products. They include drugs and devices. The intended users ranged from physicians and researchers to ordinary consumers to those seeking a cocaine substitute. They include intended use based on both product effect and

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consumer use. The Agency's application of the intended use concept is not a new regulatory construct. Rather, as these examples illustrate, the Agency has applied the concept in a variety of contexts, both formal and informal. Whether any of these examples represent "binding" interpretation is irrelevant given the limited purpose for which they are cited. As the court in *Kickapoo Oil* found, enforcement actions, notices of potential violations, statements in various briefs, and similar documents all constitute persuasive evidence of an agency's past interpretation of its governing statute.

4. One comment attempts to distinguish tobacco products from khat by arguing that FDA relied on product effect and consumer use to regulate khat only because there were no express claims, whereas tobacco products have express claims (e.g., for smoking taste and pleasure). The Agency disagrees. Even if the khat had been labeled as a decorative plant or a culinary herb, for example, such express claims would not have been binding and FDA would have taken the same action. (In fact, as the comment acknowledges, FDA suspected that the khat might have been falsely declared as a permitted Egyptian vegetable.)

The same comment also argues that FDA was merely aiding a sister agency, the Drug Enforcement Agency (DEA), in controlling a product that DEA considered to be a drug of abuse. The comment notes that it is not necessary to establish intended use for a DEA-controlled substance. In fact, for a decade after FDA first issued the khat Import Alert, DEA did not have jurisdiction over the product. Even after the active ingredient was listed as a controlled substance, FDA retained separate jurisdiction to detain the product. Obviously, any FDA detention action—before or after khat was scheduled as a controlled substance—had to be accomplished under FDA's authority.

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The comment further argues that the example is not relevant because the evidentiary standard for import detention is low (i.e., that the product only has to “appear” to be violative under section 801(a) of the Act, 21 U.S.C. 381). A differing evidentiary standard does not render the evidence relied upon by the Agency in determining khat’s intended use irrelevant to establishing intended use. In determining whether an imported product “appears” to be a drug or device, the Agency uses the same kinds of evidence as it does in determining whether a domestic product “is” a drug or device. While the Agency’s evidentiary burden under section 801(a) may be lower than it is when the Agency finally determines that a product is a drug or device under the Act, the types of evidence that are relevant do not differ.

Still another comment asserts that, because khat is intended to be used as a tea, it is a food and not a drug. The Agency agrees that the Federal Food, Drug, and Cosmetic Act excludes a food from the definition of “drug” under section 201(g)(1)(C). However, khat is not a food because it is not used primarily for taste, aroma, or nutritive value. *Nutrilab, Inc.*, 713 F.2d at 337. Instead, its foreseeable use was to obtain stimulant narcotic effects. Moreover, the Agency notes that khat is not used exclusively as tea, but is also chewed and smoked like tobacco.

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F. RESPONSE TO ADDITIONAL COMMENTS

In this section, the Agency responds to additional comments regarding the evidence that cigarettes and smokeless tobacco are “intended to affect the structure or any function of the body” and the Agency’s use of that evidence.

1. Some comments assert that FDA may not rely on evidence relating to particular manufacturers to find intended use for all manufacturers of a particular product, but must instead determine intended use on a product-by-product basis by producing evidence specific to each individual manufacturer and even to each individual brand of tobacco products. The Agency disagrees with these comments. In appropriate circumstances, FDA can determine that a type of product is subject to its jurisdiction without focusing on the individual manufacturer or brand.

As discussed in other parts of section II., the evidence of intended use applies to all cigarettes and smokeless tobacco products on the market. This evidence establishes that cigarettes and smokeless tobacco are highly addictive, cause other psychoactive effects (such as relaxation and stimulation), and affect weight regulation and that these effects are widely accepted in the scientific community. Based on this evidence, it is foreseeable to any reasonable manufacturer that cigarettes and smokeless tobacco will have and be used for these addictive, psychoactive, and other pharmacological effects. The evidence also shows that *actual* consumer use of these products for their pharmacological effects is predominant and, in fact, nearly exclusive. Given the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco and the actual consumer use of cigarettes and smokeless tobacco for pharmacological effects, the Agency concludes that all of these products are “intended to affect the structure or any function of the body.”

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In addition, the Agency has collected evidence of the tobacco industry's statements, actions, and research demonstrating the industry's widespread awareness of the addictive and other pharmacological effects of cigarettes and smokeless tobacco, the industry's widespread knowledge that consumers use its products for these effects, and the industry's widespread manipulation of nicotine levels in its products to ensure that adequate amounts of nicotine are delivered to consumers. This evidence is further objective evidence that these products are "intended to affect the structure or any function of the body."

In the case of cigarettes, the evidence shows that the major manufacturers engaged in extensive research into nicotine pharmacology either as individual companies or through the industry-funded Council for Tobacco Research. Moreover, the evidence shows that the major cigarette manufacturers manipulate the nicotine level in cigarettes through techniques such as blending, the use of ammonia technologies, and the design of cigarette filters and ventilation. In the case of smokeless tobacco, the evidence shows that the major manufacturers of smokeless tobacco have also sponsored research into nicotine pharmacology either as individual companies or through the industry-funded Smokeless Tobacco Research Council. In addition, the evidence shows widespread nicotine manipulation by major smokeless tobacco manufacturers through pH adjustments or the use of teabag-like pouches that reduce nicotine delivery in their starter products.

Although the Agency often chooses to take enforcement actions against particular manufacturers of a specific product rather than to assert regulatory authority over all manufacturers of the product as a group, the Agency may choose a different regulatory approach when circumstances warrant. The Agency has concluded that such a different

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approach is appropriate here. In concluding that these products are drug delivery devices within the meaning of the Act, the Agency is relying not on product labeling or express representations in promotional materials,¹¹³⁸ but on other relevant objective evidence of intended use—dispositive evidence concerning the foreseeable pharmacological effects and uses of these products, actual consumer use of these products, and evidence of industry-wide actions, practices, and knowledge. Further, the public health concerns that the Final Rule seeks to address—the appeal and availability of tobacco products to young people—can be addressed effectively and efficiently only through the regulation of all cigarettes and smokeless tobacco as a group.

There is ample precedent to support FDA regulation of essentially identical products as a group, rather than setting criteria or restrictions on a product-by-product or manufacturer-by-manufacturer basis. For example, in administering the Act's device provisions, the Agency traditionally classifies at one time all products that are sufficiently similar that they can be considered the same type of device for purposes of applying the Act's regulatory controls. *See* 21 CFR 860.3(i) (definition of "generic type of device"). In making these device classification decisions, the Agency relies on the cumulative evidence from several manufacturers. Further, reclassification of one product of a particular type results in the reclassification of the entire group. *See* Proposed Rule: Medical Devices Classification Procedures, 42 FR 46028 (Sep. 13, 1977); *see also* Final Rule: Medical Devices Classification Procedures, 43 FR 32988 (Jul. 28, 1978). Thus, FDA applies the same regulatory requirements to all devices within an identified device

¹¹³⁸ As discussed in section II.E.2., above, however, the implied claims in tobacco manufacturers' promotional materials provide further support for the Agency's conclusion.

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type. This approach is necessary to provide similar regulatory treatment for essentially identical products of different manufacturers and distributors. *See* 42 FR 46031; 43 FR 32989. Proceeding otherwise would require FDA to classify individually each manufacturer's device and to undertake the classification process whenever a new manufacturer marketed a product within an existing category of devices. Because cigarettes and smokeless tobacco affect the structure and function of the body and are devices under the Act, it is consistent with the Agency's approach to device classification to determine the intended use of all cigarettes and smokeless tobacco.

Similarly, the Agency limits the use of certain potentially dangerous ingredients in drug products by establishing uniform standards rather than manufacturer-specific restrictions. *See, e.g.*, 21 CFR 310.506 (1974 action restricting use of vinyl chloride); 21 CFR 310.507 (1977 action restricting use of trichloroethane in aerosol products); 21 CFR 310.508 (1975 action restricting use of halogenated salicylanilides); 21 CFR 310.513 (1976 action restricting use of chloroform in drug products).

Regulating the products of some cigarette and smokeless tobacco manufacturers while allowing others to be marketed without the restrictions that FDA has determined are necessary would frustrate important public health goals. For example, the goal of reducing tobacco use among young people would be severely compromised if one tobacco company could continue advertising in the manner limited by the regulations. Similarly, it would be anomalous to prohibit some manufacturers, but not others, from filling vending machines with cigarettes in facilities accessible to persons under the age of 18. Furthermore, if FDA proceeded against some but not all manufacturers, the result would be inequitable because some companies would be subject to FDA regulation while their

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competitors remain unregulated. The Supreme Court has recognized that proceeding against similar products one at a time can result in “great inequities . . . [because] competitors selling drugs in the same category would go scot-free until the tedious and laborious procedures of litigation reached them.” *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 626 (1973).

One comment cites a statement in *Action on Smoking and Health v. Harris (ASH)*, 655 F.2d 236, 242 n.10 (D.C. Cir. 1980), that “[t]he very structure of the Act . . . calls for case-by-case analysis,” and argues that the statement supports its argument that the Agency must make jurisdictional determinations on a product-by-product or brand-by-brand basis. This statement in *ASH*, however, was made in the context of a discussion of the Agency’s freedom to revise its interpretation of its jurisdiction without constraint by long-standing interpretations. In *ASH*, the court found that FDA’s decision to deny a citizen’s petition requesting that the Agency exercise jurisdiction over cigarettes was not arbitrary, capricious, or contrary to law. *Id.* at 241, 243. The court made clear, however, that the Agency decision reviewed in the *ASH* case would not prevent FDA from revising its interpretation if new evidence became known. *Id.* at 242 n.10. New evidence would present a new “case” to the Agency that would appropriately be analyzed on its own merits.¹¹³⁹ The statement in *ASH* therefore does not stand for the proposition that the Agency must make jurisdictional determinations on a manufacturer- or brand-specific basis.

¹¹³⁹ See section IV., below, for a detailed discussion of why new evidence justifies the Agency’s change in position on the application for the Act to tobacco products.

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Moreover, although it is true that the Agency often conducts product-by-product analyses of its jurisdiction under the Act, it is by no means clear that a “product” is equivalent to a “brand” or a “manufacturer” in this instance, given that different brands of cigarettes, snuff, and chewing tobacco are, respectively, virtually identical in content, size, shape, and packaging and are marketed in a closely similar manner.

Here, the Agency has elected to assert regulatory authority over cigarettes and smokeless tobacco by issuing regulations, rather than by undertaking enforcement actions against particular brands or manufacturers, and litigating, on a case-by-case basis, the status of each product. This approach is authorized by the Act. *See* section 701(a) of the Act, 21 U.S.C. 371(a) (providing “[a]uthority to promulgate regulations for the efficient enforcement of [the] Act”); *see also Hynson*, 412 U.S. at 624-625 (noting that, although regulatory agencies “usually proceed[] on a case-by-case basis, giving each [party] subject to regulation separate hearings. . . . [t]here is not always a constitutional reason why that must be done”). The Agency concludes that the approach it has adopted here has provided the manufacturers with ample opportunity to raise the numerous issues and concerns they share, as reflected in the voluminous consolidated comments submitted by both the cigarette and smokeless tobacco industries, as well as to raise evidentiary and other issues specific to individual manufacturers. The Agency further concludes that this approach is the one that most effectively serves the public health concerns the final rule seeks to address.

In support of the argument that the Agency is required to have evidence specific to each manufacturer, the comments cite cases that involved instances in which the evidence of intended use consisted *only* of labeling and promotional materials containing express

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claims. These cases support the principle that a connection must exist between a manufacturer's product and the representations in labeling and promotional materials for such evidence to support a finding that the product is "intended" to be a drug or a device, for example, evidence that consumers rely on these representations. *See, e.g., United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500-501 (8th Cir. 1995); *United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219, 1226-1229 (D. Minn. 1991); *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 2-3 (D.D.C. 1989). *Estee Lauder*, for instance, involved traditional skin cream ingredients that by themselves were "cosmetics" but not "drugs" within the meaning of the Act. 727 F. Supp. at 3. The *only* evidence that made the products "drugs" was the manufacturer's anti-aging claims in the labeling. *Id.* In such a case, there would not be a basis to attribute Estee Lauder's drug claims to another manufacturer's skin cream whose labeling contained no drug claims. Evidence regarding drug claims in the labeling of a specific product is generally appropriately limited to the manufacturer that created or adopted the labeling and the product that accompanies the labeling.

These cases do not, however, support the argument that the Agency is required to have manufacturer-specific evidence when evidence other than labeling and promotional materials is used to determine intended use.¹¹⁴⁰ As a result, the cases are not controlling here because the evidence of the intended use of tobacco products is not based on express

¹¹⁴⁰ One comment also cites *Hanson v. United States*, 417 F. Supp. 30 (D. Minn. 1976), *aff'd per curiam*, 540 F.2d 947 (8th Cir. 1976). In *Hanson*, the court explained that "the 'intended use' of a product . . . is determined from its label, accompanying labeling, promotional claims, advertising, *and any other relevant source.*" *Id.* at 35 (emphasis added). The comment omitted the italicized language. Not only does the case not support the proposition for which it is cited, but the question of whether "intended use" determinations must be made on a product-by-product basis was not before the court.

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claims in labeling and promotional materials but on evidence that applies to all manufacturers of cigarettes and smokeless tobacco.

In the case of tobacco products, the evidence of intended use is far broader than labeling for specific products. The evidence regarding the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco and the actual consumer use of cigarettes and smokeless tobacco for pharmacological effects described in sections II.A. and II.B., above, applies equally to all of the manufacturers and is sufficient to establish that each individual product is “intended to affect the structure or any function of the body,” regardless of the identity of the manufacturer. The evidence concerning the statements, actions, research, and knowledge of the manufacturers also supports such a determination. As discussed in sections II.C. and II.D., above, this evidence shows that tobacco manufacturers conducted similar research into nicotine pharmacology; engaged in similar product research and development; use similar methods to manipulate and control nicotine deliveries in commercial products; and jointly belong to associations that have conducted further research into nicotine pharmacology. The evidence thus shows both a widespread understanding within the industry of the pharmacological effects and uses of cigarettes and smokeless tobacco and widespread design of these products to provide pharmacologically active doses of nicotine.

For all of these reasons, it is reasonable and consistent with the public health protection goals of the Act generally and of the tobacco regulations specifically to attribute evidence from all relevant sources—the foreseeability of the pharmacological effects of nicotine for which consumers use cigarettes and smokeless tobacco, the actual consumer use of these products for these effects, the industry’s widespread knowledge of

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nicotine's pharmacological effects and uses, and the industry's widespread manipulation and control of nicotine—to *all* manufacturers of cigarettes and smokeless tobacco.¹¹⁴¹

2. Tobacco industry comments argue that some of the statements, research, and actions attributed to particular manufacturers are not relevant to intended use because they are not contemporaneous with the sale of currently marketed products. The Agency disagrees with these comments. One industry comment cites cases involving products

¹¹⁴¹ The Agency has also determined that processed loose cigarette tobacco, which is used by smokers who roll their own cigarettes, is subject to FDA jurisdiction. One comment contends that the use of "roll-your-own" cigarette tobacco is "fundamentally different from other tobacco products." Consolidated comment of the "Roll-Your-Own" cigarette tobacco manufacturers (Brown & Williamson Tobacco Corp., Robert Burton Associates, Consolidated Cigar Corporation, Douwe Egberts Van Nelle Inc., House of Windsor, Inc., Lane Limited, and Republic Tobacco, L.P.) (Jan. 2, 1996), at 11. *See* AR (Vol. 702 Ref. 1578). The Agency disagrees. Processed loose cigarette tobacco is a cigarette that has not yet been assembled. Roll-your-own cigarettes contain tobacco and are smoked. Like the tobacco used in manufactured cigarettes, loose tobacco contains pharmacologically active doses of nicotine. And, like the tobacco incorporated into commercially manufactured cigarettes, loose tobacco is not simply raw leaves as they are picked from plants in the field. Rather, this tobacco has been cured and treated with many chemicals, and had its moisture content controlled. Consumers obtain separately the components of a cigarette (e.g., processed loose tobacco and special cigarette papers) and then use those components to assemble their own cigarettes. While these homemade products are more crudely manufactured than those produced by cigarette companies, they have the same effect—the smoke from these products is inhaled, and the products deliver nicotine, a drug, for inhalation by the lungs and absorption into the brain. Loose tobacco thus has foreseeable and actual pharmacological effects and uses parallel to manufactured cigarettes, and therefore is "intended to affect the structure or any function of the body" within the meaning of the Act. Further, one of the manufacturers of "roll your own" cigarette tobacco, Brown & Williamson, is also a manufacturer of cigarettes (as well as a manufacturer of smokeless tobacco). Evidence concerning Brown & Williamson's statements, research, and actions, particularly its knowledge that consumers use tobacco products for pharmacological purposes, is discussed in section II.C., above. Because a "roll your own" cigarette is fundamentally the same product as a commercially manufactured cigarette, the evidence discussed in section II.C., above, is also relevant to the manufacturers' intent in producing and selling "roll your own" cigarette tobacco, and is further evidence that processed loose tobacco is subject to FDA jurisdiction.

In addition to the factual and legal arguments supporting the Agency's assertion of jurisdiction over processed loose cigarette tobacco, public health concerns also support including processed loose cigarette tobacco in this proceeding. A "roll-your-own" cigarette poses the same risks as a commercially manufactured cigarette. The Agency's regulations include restrictions on the access of persons younger than 18 years of age to these products. As discussed in section III.E. of the Final Rule, the public health goals of the Agency's regulations would be thwarted if the regulations were limited to manufactured cigarettes and smokeless tobacco. To exclude processed loose tobacco would provide a simple and obvious way to avoid the restrictions in the regulation. If such an exception existed, cigarettes could be packaged and sold in such a way as to be considered "roll-your-own" products, and young persons would have access to addictive tobacco products, thereby undermining the purpose of the Final Rule.

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whose labeling expressly promoted the products as having therapeutic value in treating certain diseases or as affecting the structure or function of the body. *See United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219 (D. Minn. 1991), *aff'd*, 968 F.2d 681 (8th Cir. 1992); *United States v. Neptone*, No. C-83-0864 EFL, CCH ¶ 38,240 (N.D. Cal. Oct. 25, 1983); *United States v. Various Quantities . . . "Instant Alberty Food,"* 83 F. Supp. 882 (D.D.C. 1949). In these cases, however, promotional claims made to consumers were the *sole* basis for establishing intended use. As a result, the courts found that labeling and other promotional material must ordinarily accompany the product and be relied on by consumers purchasing the products. These cases are not controlling, however, where the product has widely recognized pharmacological effects and uses and the government is relying on evidence from other sources—such as evidence of the known and foreseeable pharmacological effects and uses and actual consumer use of the product, and the statements, research, and actions of the manufacturers that demonstrate their intention to facilitate the product's pharmacological effects.

Unlike labeling, which is usually evidence of a manufacturer's current express claims for a product,¹¹⁴² the internal documents remain relevant because they evidence an actual intent to affect the structure or function of the body that has not been refuted by more current actions. Indeed, the court in *Alberty Food*, a case cited by the comments, recognized that the mere fact that a manufacturer or shipper stops producing and

¹¹⁴² In certain circumstances, such as where consumers continue to rely on previous claims or where discontinued labeling shows a "continuity of purpose" to sell a product as a drug, old labeling can establish intended use. *See, e.g., United States v. Nutrition Service, Inc.*, 227 F. Supp. 375, 386-387 (W.D. Pa. 1964); *United States v. 789 Cases . . . Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285 (D.P.R. 1992), *aff'd*, 347 F.2d 233 (3d Cir. 1965).

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distributing literature that renders a drug misbranded is not an unconditional defense to a charge that the manufacturer or shipper intended to misbrand drugs subject to an enforcement action:

[i]t is only to the extent that the abandonment of such dissemination creates an inference that the shipper did not intend, when it shipped the drugs in interstate commerce, that they be used for the treatment of the diseases named on the booklets, that the abandonment can be said to be an effective defense. *The government might introduce evidence to show that, notwithstanding such abandonment, it was still the intention of the shipper that the drugs be used for the treatment of the diseases . . .*

83 F. Supp. at 887 (emphasis added).

The court's analysis is pertinent here. The record establishes that the manufacturers have not "abandoned" the design, manufacturing, and marketing practices discussed in the internal documents. To the contrary, the products continue to be marketed and sold in virtually the same manner and form as they were when those documents were produced. *See* section II.C.2.e., above. Thus, the record here supports the Agency's conclusion that the internal documents remain a relevant source of evidence of intended use.

II.G.

**G. CONSIDERED CUMULATIVELY, THE EVIDENCE
OVERWHELMINGLY DEMONSTRATES THAT CIGARETTES
AND SMOKELESS TOBACCO ARE INTENDED TO AFFECT
THE STRUCTURE AND FUNCTION OF THE BODY**

As discussed in sections II.A.-F., the evidence in the record provides several independent bases for the Agency's determination that cigarettes and smokeless tobacco are intended to affect the structure and function of the body. Independently, the evidence in each of these distinct categories of evidence is a sufficient basis for the Agency's conclusion that the manufacturers of cigarettes and smokeless tobacco "intend" their products to affect the structure and function of the body.

In reaching a final determination of the intended use of cigarettes and smokeless tobacco, it is also appropriate for the Agency to consider the objective evidence of intended use as a whole. Considered together, the evidence in each of the different categories of evidence before the Agency—the evidence of the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco; the evidence of the actual consumer use of cigarettes and smokeless tobacco for pharmacological purposes; and the evidence of the manufacturers' intent as revealed through the manufacturers' statements, research, and actions are highly consistent and support the same conclusion: cigarettes and smokeless tobacco are intended to affect the structure and function of the body. When viewed from the perspective of what a reasonable manufacturer would foresee, how consumers actually use the products, or what is revealed in internal company documents, the evidence in the record demonstrates that cigarettes and smokeless tobacco have intended pharmacological effects and uses. This convergence of independent categories of evidence is highly probative. Taken as a whole, therefore, the evidence in

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the record convincingly establishes that cigarettes and smokeless tobacco are “intended”
to affect the structure and function of the body within the meaning of the Act.

III.

III. CIGARETTES AND SMOKELESS TOBACCO ARE COMBINATION PRODUCTS CONSISTING OF “DRUG” AND “DEVICE” COMPONENTS

As discussed in sections I. and II., above, the Agency has determined that (1) cigarettes and smokeless tobacco “affect the structure or any function of the body,” and (2) these effects on the structure and function of the body are “intended” by the manufacturers. These two determinations establish that cigarettes and smokeless tobacco are subject to FDA jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act). This section explains the basis for the Agency’s conclusion that cigarettes and smokeless tobacco are “combination products” consisting of a “drug,” nicotine, and “device” components that deliver nicotine to the body.

Under the Act, a product that is intended to affect the structure or function of the body can be a “drug” under section 201(g)(1)(C) or a “device” under section 201(h)(3). The principal difference between a “drug” and a “device” is that a device is “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” that “does not achieve its primary intended purposes through chemical action within or on the body . . . and . . . is not dependent upon being metabolized for the achievement of its primary intended purposes.” Section 201(h)(3). Since the enactment of the Safe Medical Devices Act of 1990, certain products that are intended to affect the structure or function of the body can also be regulated as a “combination product,” consisting of a drug and a device. Section 503(g)(1), 21 U.S.C. 353(g)(1). A combination product is a product composed of two regulated components, such as a drug and a device, that “are physically, chemically, or otherwise combined or mixed and produced as a single entity.” 21 CFR 3.2(e)(1). Examples of combination

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products include drug delivery systems such as nebulizers, transdermal patches, and prefilled syringes,¹¹⁴³ as well as prefilled intravenous infusion pumps.

In the Jurisdictional Analysis, the Agency set forth its current view that cigarettes and smokeless tobacco products are combination products under the Act. The Agency explained that “FDA considers device-like products, such as instruments, implements, machines, contrivances, implants, or other similar or related articles . . . , whose primary purpose is delivery of a drug, and that are distributed with a drug product, to be drug delivery systems.” 60 FR 41521. The Agency concluded, based on the evidence then available to it, that:

Cigarettes and smokeless tobacco function in a similar manner in that they contain a drug, nicotine; are used to deliver that drug to the site at which the drug will be absorbed into the body, the mouth or lungs; and after the drug has been delivered, the delivery system, the cigarette butt or smokeless tobacco material, depleted of nicotine, remains and must be disposed of. Only the nicotine delivered by these products achieves its primary intended purpose by chemical action in or on the body.

60 FR 41521–41522. With respect to cigarettes, the Agency further explained that:

The primary purpose of parts of the cigarette . . . is to effectuate the delivery of a carefully controlled amount of nicotine to a site in the human body where it can be absorbed. The drug, nicotine, is generally contained within the treated rolled tobacco. The delivery system, the nicotine-containing cigarette, must be lit to have its intended effect on the structure or function of the body, and, once lit and used, is discarded. When lit, the cigarette produces nicotine-containing smoke, which is inhaled by the consumer and when absorbed into the lungs, yields on average approximately 1.0 mg of nicotine.

60 FR 41522. With respect to smokeless tobacco, the Agency further explained that:

Smokeless tobacco products function like infusion devices or transdermal patches that deliver continuous amounts of nicotine to the cheek tissue for

¹¹⁴³ Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (Oct. 31, 1991), at 6. See AR (Vol. 30 Ref. 289).

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absorption into the bloodstream. The device element of smokeless products is the tobacco, which contains the nicotine but is not intended to be consumed. Instead, in normal use, most of the tobacco in the product is not absorbed by the user and is removed from the mouth after absorption of the nicotine through the cheek tissue.

The primary purpose of the tobacco is to provide a palpable vehicle that allows nicotine to be extracted from the tobacco by the user's saliva so that it may be absorbed into the body.

60 FR 41522-41523.

After carefully considering the evidence in the administrative record and the comments received, the Agency reaffirms these findings and concludes that cigarettes and smokeless tobacco are combination products that contain a "drug" and a "device."

A. NICOTINE IN CIGARETTES AND SMOKELESS TOBACCO IS A DRUG

For the reasons set forth in sections I. and II., above, the Agency concludes that the nicotine in cigarettes and smokeless tobacco is a "drug" under section 201(g)(1)(C). The nicotine in these products "affect[s] the structure or any function of the body" by sustaining addiction, by producing other important pharmacological effects on the central nervous system, including tranquilizing and stimulant effects, and by controlling weight. *See* section I., above. These effects of the nicotine in cigarettes and smokeless tobacco are "intended" by the manufacturers. *See* section II., above. Therefore, the nicotine in cigarettes and smokeless tobacco meets the statutory definition of a "drug" under section 201(g)(1)(C).

III.B.

B. CIGARETTES AND SMOKELESS TOBACCO CONTAIN DELIVERY DEVICES AND ARE COMBINATION PRODUCTS UNDER THE ACT

Cigarettes and smokeless tobacco are not simply packaged nicotine. As discussed below, the rest of the cigarette or smokeless tobacco product includes a delivery device that delivers a controlled amount of nicotine to the body. This combination of the drug nicotine and a delivery device makes these products “combination products.”

Under the Act, a device is:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body of man . . . and which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Section 201(h)(3). This definition was intended to bring within the reach of the statute articles that are intended to affect the structure or function of the body, but are physically distinguishable from drugs, which in general are substances in liquid, powder, or other drug dosage form that are ingested, injected, rubbed, or otherwise absorbed into the body. The definition establishes a four-part test for a device. First, the article must be “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article.” Second, the article must be “intended to affect the structure or any function of the body.” Third, the article must not “achieve its primary intended purposes through chemical action within or on the body of man.” And fourth, the article must not be “dependent upon being metabolized for the achievement of its primary intended purposes.” Both cigarettes and smokeless tobacco contain a delivery device that meets these four criteria.

III.B.1.

1. Cigarettes Are Combination Products

By weight, the drug nicotine is only a small part of a cigarette.¹¹⁴⁴ First, the cigarette also has components that together constitute an “instrument, implement, . . . contrivance or similar or related article” under the Act. As a cigarette manufacturer has acknowledged, cigarettes are “a highly engineered product.”¹¹⁴⁵ They have components that have been carefully designed to deliver controlled, pharmacologically active doses of nicotine to the smoker, including the tobacco blend, the filter, and the ventilation system. *See* section II.C.4., above. Collectively, the drug delivery components of cigarettes are an instrument, implement, contrivance, or similar article that is designed to release a nicotine-containing aerosol, i.e., the tobacco smoke, that, upon combustion outside the body, is inhaled by the smoker and serves as the vehicle for nicotine delivery.

Second, consistent with section 201(h)(3) of the Act, the device components of cigarettes are “intended to affect the structure or any function of the body.” Cigarettes are “intended” to deliver nicotine to the body. *See* Section II, above. The nicotine delivered by the device components of cigarettes “affect[s] the structure or any function of the body.” *See* Section I, above. The device components of cigarettes are thus designed to achieve the specific purpose of affecting the structure and function of the body by delivering a controlled amount of nicotine to the body.

¹¹⁴⁴ *Regulation of Tobacco Products (Part 3): Hearings before the Subcommittee on Health and the Environment, House Energy and Commerce Committee, U.S. House of Representatives, 103d Cong., 2d Sess. 173 (Jun. 23, 1994). See AR (Vol. 709 Ref. 3).*

¹¹⁴⁵ *Response of R.J. Reynolds Tobacco Company, Appendix D, FDA Docket No. 94P-0069 (Nov. 2, 1994), at 78. See AR (Vol. 447 Ref. 7640).*

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Third, as required by the statutory definition, the device components do not achieve their delivery purpose through “chemical action within or on the body.” Although the *nicotine* delivered by cigarettes achieves its primary intended purpose through a series of chemical actions inside the body, the device components do not rely on chemical actions within or on the body to achieve their drug delivery purpose. Rather, the device components of cigarettes achieve their primary purpose by delivering nicotine to the body in an aerosol form. This nicotine-containing aerosol is produced by combustion outside the body—not by chemical actions within or on the body.

Fourth, as required by the statutory definition, the device components in cigarettes are not “dependent upon being metabolized” to achieve their primary intended purpose. Metabolism is “the conversion of one chemical species to another.”¹¹⁴⁶ To be metabolized, most substances must first be ingested or absorbed into the body, where metabolism occurs after the substance reaches the gastrointestinal tract (the liver) or the systemic circulation.¹¹⁴⁷ In the case of cigarettes, the nicotine delivered by a cigarette is inhaled and delivered to the bloodstream where it can achieve its intended purpose, before any metabolism takes place. Thus, the device components achieve their primary intended purpose without being metabolized.

Cigarettes are similar to other articles that are routinely regarded as combination products containing both a drug and a drug delivery instrument, apparatus, machine, contrivance, or similar or related article under the Act. In 1991, the Agency’s Center for

¹¹⁴⁶ Rowland M, Thomas TN, *Clinical Pharmacokinetics: Concepts and Applications* (Baltimore: Williams & Wilkins, 1995, 3d ed.), at 15. See AR (Vol. 711 Ref. 49).

¹¹⁴⁷ See *Id.* at 14.

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Drug Evaluation and Research and the Agency's Center for Devices and Radiological Health reached an intercenter agreement delineating the types of products that would be considered to have drug and device components. Under this agreement, an article "with [the] primary purpose of delivering or aiding in the delivery of a drug and distributed containing a drug (i.e., 'pre-filled delivery system')" is regarded as a combination product with drug and device components.¹¹⁴⁸ The intercenter agreement specifically lists nebulizers, transdermal patches, and pre-filled syringes as examples of "pre-filled delivery systems."¹¹⁴⁹ Prefilled intravenous infusion pumps, which are used to deliver drugs to patients intravenously, are another example. Cigarettes are comparable to these articles. Nebulizers and metered dose inhalers are products filled with a drug used by persons with asthma to relieve constricted airways. Like nebulizers and metered dose inhalers, cigarettes contain an instrument, implement, contrivance, or similar or related article for converting a drug into an aerosolized form for inhalation. Cigarettes are also similar to prefilled intravenous infusion pumps, in that drug delivery components of both deliver the drug to the body for absorption, after which the device components are discarded or destroyed.

The internal tobacco company documents themselves recognize that cigarettes should be regarded as nicotine delivery devices. For example, as early as 1972, a senior Philip Morris researcher characterized the cigarette as "*a dispenser for a dose unit of nicotine*" and stated that "[s]moke is beyond question the most optimized vehicle of

¹¹⁴⁸ *Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health* (Oct. 31, 1991), at 6. See AR (Vol. 30 Ref. 289).

¹¹⁴⁹ *Id.*

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nicotine and the cigarette the most optimized dispenser of smoke.”¹¹⁵⁰ Twenty years later, a Philip Morris official continued to describe cigarettes as “*nicotine delivery devices*,” placing “conventional cigarettes” in the same category as nicotine “chewing gums, patches, aerosol sprays and inhalers.”¹¹⁵¹

Researchers at other cigarette manufacturers have expressed similar views. In 1962, a senior BATCO scientist described the advantages of nicotine delivery through cigarettes, stating that “the techniques of administration by smoking ha[ve] considerable psychological advantages and a built-in control against excessive absorption.”¹¹⁵² Decades later, BATCO researchers continued to characterize cigarettes in device-like terms, describing cigarettes as “the means of providing nicotine doses in a metered fashion”¹¹⁵³ and as a delivery mechanism that allows “the smoker to have very flexible control over titrating his desired dose of nicotine.”¹¹⁵⁴ Similarly, in the words of one senior RJR scientist, “a tobacco product is, in essence, *a vehicle for delivery of nicotine*, designed to deliver the nicotine in a generally acceptable and attractive form.”¹¹⁵⁵

¹¹⁵⁰ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 5-6 (emphasis added). See AR (Vol. 12 Ref. 133).

¹¹⁵¹ Philip Morris Inc., Draft Report Regarding a Proposal for a “Safer” Cigarette, Code-named *Table*, at 2 (emphasis added). See AR (Vol. 531 Ref. 122).

¹¹⁵² Ellis C (BATCO), The smoking and health problem, in *Smoking and Health—Policy on Research*, Research Conference, Southampton, England (1962), at 4. See AR (Vol. 21 Ref. 220).

¹¹⁵³ Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference, Session I, slides (Jul. 9-12, 1984), at BW-W2-03242 (emphasis added). See AR (Vol. 24 Ref. 315).

¹¹⁵⁴ *Transdermal Nicotine Patches*, at 3. See (AR Vol. 531 Ref. 124).

¹¹⁵⁵ Teague CE (R.J. Reynolds Tobacco Co.), *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (Apr. 14, 1972), at 2 (emphasis added). See AR (Vol. 531 Ref. 125).

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The history of the manufacturers' product research and development further demonstrates that cigarettes are designed to deliver nicotine to the smoker. As described in section II.C.3., above, the manufacturers have engaged in extensive product research and development for over three decades to optimize the delivery of nicotine from cigarettes. This product research and development has even included the development of novel tobacco products, such as Premier by RJR, that are designed to deliver nicotine to the smoker "by heating, rather than burning, tobacco."¹¹⁵⁶ See section II.C.3., above.

For these reasons, the Agency has determined that cigarettes are most appropriately considered a prefilled delivery system under the intercenter agreement. They are a combination product under the Act consisting of the drug nicotine and a device for delivering nicotine to the smoker.¹¹⁵⁷

2. Smokeless Tobacco Is a Combination Product

The Agency has also determined that smokeless tobacco is a combination product. First, as required by the statutory definition, smokeless tobacco is an "instrument, . . . implement, contrivance, . . . or similar or related article" for delivering nicotine to the consumer. The principal device component in these products is the processed tobacco, the purpose of which is to deliver the nicotine to the cheek and gum tissue for absorption

¹¹⁵⁶ *Chemical and Biological Studies on New Cigarette Prototypes that Heat Instead of Burn Tobacco* (Winston-Salem NC: R.J. Reynolds Tobacco Co., 1988), at 3. See AR (Vol. 107 Ref. 980).

¹¹⁵⁷ As discussed in Section II.F., above, the Agency has also determined that processed loose cigarette tobacco, which is used by smokers who roll their own cigarettes, is subject to FDA jurisdiction. Processed loose tobacco has a drug and a device component. As noted in Section II.F., consumers obtain separately the components of a cigarette (e.g., processed loose tobacco and special cigarette papers) and then use those components to assemble their own cigarettes. While these homemade products are more crudely manufactured than those produced by cigarette companies, they perform the same device function of delivering a nicotine-containing aerosol to the body for inhalation by the lungs.

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into the body. The processed tobacco provides the nicotine to the consumer's body in a form that is palatable and absorbable, thereby allowing the nicotine to diffuse from the tobacco to the buccal mucosa. Some products also have a device component consisting of a porous pouch that holds the processed tobacco in position in the mouth, controlling the absorption of nicotine into the buccal mucosa.

Smokeless tobacco is placed in the mouth, where it forms a matrix from which nicotine is solubilized and then diffused across the buccal mucous membranes into the bloodstream. Thus, the tobacco matrix is the vehicle for rapidly and efficiently delivering nicotine to the smokeless tobacco user through buccal absorption. Smokeless tobacco is thus similar to other combination products that contain instruments, apparatuses, contrivances, or similar or related articles intended to deliver drugs. For example, smokeless tobacco resembles transdermal nicotine patches. Transdermal nicotine patches are considered combination products under an intercenter agreement.¹¹⁵⁸ Similar to transdermal nicotine patches, smokeless tobacco contains an instrument, implement, or similar or related article that brings the nicotine into close contact with body tissue, where it can diffuse through the body's membranes into the bloodstream. Smokeless tobacco is also comparable to prefilled intravenous infusion pumps, in that the drug delivery components of both products deliver a drug to the body and are discarded after drug delivery is complete. This feature distinguishes the delivery device components of smokeless tobacco from drugs. A drug is typically ingested or absorbed in the body; in the case of smokeless tobacco, most of the tobacco in the product is not ingested or absorbed

¹¹⁵⁸ *Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health* (Oct. 31, 1991), at 6. See AR (Vol. 30 Ref. 289).

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by the user and is removed from the mouth. Several aspects of the smokeless tobacco may be engineered by the manufacturer to control the rate and extent of absorption of nicotine, the drug to be delivered. For example, the cut of the tobacco may be altered to affect the rate of diffusion of the nicotine through the buccal mucosa.

Second, consistent with section 201(h)(3) of the Act, the device components of smokeless tobacco are “intended to affect the structure or any function of the body.” Smokeless tobacco are “intended” to deliver nicotine to the body. *See* Section II., above. The nicotine delivered by the device components of smokeless tobacco “affect[s] the structure or any function of the body.” *See* Section I., above. The device components of smokeless tobacco are thus designed to achieve the specific purpose of affecting the structure and function of the body by delivering a controlled amount of nicotine to the body.

Third, as required by the statutory definition, the device components of smokeless tobacco do not “achieve [their] primary intended purposes through chemical action within or on the body.” The *nicotine* in smokeless tobacco achieves its primary purposes through chemical actions in the body. The device components, however, achieve their drug delivery function simply by bringing nicotine into contact with the buccal mucosa. To achieve the drug delivery purpose, the tobacco blend (and pouch, if any) must be placed in the mouth and the nicotine must diffuse away from the tobacco. These are

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physical processes, not chemical ones,¹¹⁵⁹ that are analogous to the physical processes through which transdermal nicotine patches deliver nicotine to the body.

Fourth, as required by the statutory definition, the device components in smokeless tobacco are not “dependent upon being metabolized.” After buccal absorption of nicotine is complete, the remaining tobacco material (and pouch, if any) is expectorated whole. The critical absorption of nicotine does not require the metabolism of any part of the tobacco matrix.

For these reasons, the Agency has determined that smokeless tobacco is a combination product under the Act consisting of the drug nicotine and device components for delivering nicotine to the user.

C. RESPONSE TO COMMENTS

1. Several tobacco industry comments assert that drug delivery systems containing drugs are simply drugs, not combination products. These comments maintain that the Agency’s position removes any distinction between the terms “drug” and “device” and could result in drugs in tablet or capsule forms being viewed as a combination product consisting of a drug and a drug delivery device.

Since passage of the Safe Medical Devices Act of 1990, however, the Agency could consider some capsules or tablets as combination products under section 503(g). For example, capsules utilizing osmotic pumps to deliver a drug could be regarded as a

¹¹⁵⁹ See *Webster’s Collegiate Dictionary* (Springfield, MA: G&C Merriam, 1977 ed.), at 318; *Remington’s Pharmaceutical Sciences* (Easton, PA: Mack Publishing, 1980, 16th ed.), at 1388. See AR (Vol. 711 Ref. 50).

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combination of a “drug” and a “device.” The capsules, emptied of the drug, are not absorbed into the body, but are excreted. The delivery mechanism of these capsules is similar to that of a prefilled syringe. Yet there are basic differences between drug delivery systems like cigarettes and smokeless tobacco, on the one hand, and most drugs in tablet or capsule form, on the other. As discussed in section III.B., above, cigarettes and smokeless tobacco have major physical components that deliver nicotine to the consumer but are not absorbed or metabolized within the body. This is not the case with most tablets and capsules, which are absorbed completely along with the drug they deliver and act “through chemical action within or on the body.” These basic differences mean that the Agency’s decision to consider cigarettes and smokeless tobacco as combination products is reasonable and will not require the Agency to change its treatment of most products that have been adequately regulated as drugs, and begin to regulate them as combination products. The Supreme Court has recognized that the Agency has the discretion to apply the Act’s statutory terms to products that reasonably meet those definitions. The fact that a strained extension of the Agency’s analysis could lead to an illogical result will not preclude its use when the use itself is reasonable. *United States v. Sullivan*, 332 U.S. 689, 694 (1948).

2. Tobacco industry comments also argue that cigarettes and smokeless tobacco cannot have device components, because if the Agency is right that nicotine is a drug, the primary intended purpose of a cigarette or a smokeless tobacco product taken as a whole is dependent upon the chemical action of nicotine within the body. According to the comments, if the primary mode of action of a cigarette or a smokeless tobacco product

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taken as a whole involves the chemical action of nicotine, the cigarette or smokeless tobacco product cannot meet the statutory definition of a device.

FDA disagrees with these comments. These comments confuse the definition of a device with the definition of a combination product. While it is true that under the statute, a device or device component cannot achieve its primary purpose by chemical action within or on the body, a combination product consisting of a drug and a device very well may. Indeed, Congress enacted section 503(g) of the Act specifically to recognize and address products, for example, that have a device component whose primary intended purpose is to deliver a drug by means other than chemical action or metabolizing action within or on the body, *and* a drug component that achieves its primary intended purpose through chemical action and/or by being metabolized. The statute recognizes that a single product can contain components with interdependent, yet distinct, purposes. Under the interpretation urged by the comments, there could never be a combination product composed of a drug and a device where the primary mode of action of the product is by chemical action. That interpretation is entirely at odds with the statutory language and purpose of section 503(g), as well as with FDA's long-standing practice of regulating as combination products many products containing a drug and a device.

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IV. FDA'S ASSERTION OF JURISDICTION OVER CIGARETTES AND SMOKELESS TOBACCO AT THIS TIME IS JUSTIFIED

The Food and Drug Administration (FDA) has always exercised jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act) over tobacco products when there was evidence that these products were "intended" to treat or prevent disease or to affect the structure or function of the body. As discussed in section II.E., above, the Agency may consider relevant evidence from any source in determining whether a product is intended as a drug or device. On previous occasions when the Agency has been asked to consider whether tobacco products were within its jurisdiction, however, there was insufficient evidence to conclude that tobacco products were intended to affect the structure or function of the body, except where the manufacturer expressly promoted a tobacco product for use in treating disease or affecting the structure or function of the body.

Since the last occasion on which FDA considered whether to assert jurisdiction over tobacco products without claims, the state of the evidence has changed dramatically. A wealth of new evidence has become available demonstrating that: (1) the ability of nicotine in cigarettes and smokeless tobacco to produce addiction and other significant pharmacological effects is widely known and therefore foreseeable to a reasonable tobacco manufacturer; (2) consumers use cigarettes and smokeless tobacco predominantly to obtain the pharmacological effects of nicotine; and (3) previously undisclosed statements, research, and actions of tobacco manufacturers demonstrate that they intend their products to be used as nicotine delivery devices. As described in section II., above, FDA has determined that this evidence establishes that cigarettes and smokeless tobacco are

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“intended to affect the structure or any function of the body” within the meaning of the Act’s “drug” and “device” definitions. FDA has therefore revised its position and concluded that all currently marketed cigarettes and smokeless tobacco are in fact “intended to affect the structure or any function of the body” and therefore are within its jurisdiction.

Information developed since 1980 also demonstrates that for most people tobacco use and nicotine addiction begin in childhood and adolescence. The data now suggest that if children and adolescents can be prevented from initiating tobacco use, they are unlikely to begin tobacco use later in life, thereby preventing the onset of tobacco-related disease and premature death. Before the importance of youth-centered interventions was identified, most of the regulatory approaches available under the Federal Food, Drug, and Cosmetic Act to address tobacco-related disease and death, such as removal of the products from the market, were not believed to be feasible. The new information that nicotine addiction is a pediatric disease provides an additional basis to conclude that restricting the sale, distribution, and use of cigarettes and smokeless tobacco to people under the age of eighteen is an effective tool to reduce the adverse health consequences of tobacco use. Thus, asserting jurisdiction over cigarettes and smokeless tobacco now presents an opportunity to use the Agency’s resources efficiently for substantial public health gains.

Several comments maintain that the Agency is not permitted to change its earlier interpretation of the Act. However, it is a well-established principle of administrative law that an Agency may revise its interpretation or application of a statute if it supplies a reasoned explanation for its changed interpretation or position. *See Action on Smoking*

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and Health v. Harris (ASH), 655 F.2d 236, 242, n.10 (D.C. Cir. 1980) (recognizing that FDA is permitted to modify its earlier position on tobacco products and that the new position would be accorded deference by the courts); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 862 (1984); *Rust v. Sullivan*, 500 U.S. 173, 186-187 (1991); *Smiley v. Citibank, N.A.*, 116 5. Ct. 1730 (1996). Indeed, an agency is expected to reevaluate the wisdom of its interpretations and make changes in those interpretations when warranted by current knowledge and circumstances. *Rust*, 500 U.S. at 186-187. In *Rust*, the Court explained as follows:

This Court has rejected the argument that an agency's interpretation is not entitled to deference because it represents a sharp break with prior interpretations of the statute in question. In *Chevron*, we held that a revised interpretation deserves deference because an initial agency interpretation is not instantly carved in stone and the agency, to engage in informed rule making, must consider varying interpretations and the wisdom of its policy on a continuing basis. An agency is not required to establish rules of conduct to last forever, but rather must be given ample latitude to adapt its rules and policies to the demands of changing circumstances.

Id. (citations and internal quotation marks omitted); *see also American Trucking Ass'n v. Atchison, Topeka, and Santa Fe Ry. Co.*, 387 U.S. 397 (1967) (an agency, "faced with new developments or in light of reconsideration of the relevant facts and its mandate, may alter its past interpretation and overturn past administrative rulings and practice"). The new evidence presented in the Jurisdictional Analysis and in section II., above, provides a reasoned basis for FDA's change in position on the applicability of the Act to cigarettes

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and smokeless tobacco without claims. In this section, FDA describes its earlier decisions on whether to regulate particular tobacco products and reviews the new evidence that now supports the Agency's assertion of jurisdiction over cigarettes and smokeless tobacco.

A. FDA HAS ALWAYS EXERCISED AUTHORITY TO REGULATE TOBACCO PRODUCTS WHEN THE EVIDENCE ESTABLISHED THAT THEY FELL WITHIN THE DRUG OR DEVICE DEFINITIONS

FDA's assertion of jurisdiction over tobacco products is not new. For more than 80 years FDA has taken the position that it has jurisdiction over tobacco products that fall within the Act's definitions of regulated products. As early as 1914, the Agency claimed jurisdiction to regulate tobacco products labeled *or used* for "medicinal purposes."¹¹⁶⁰ In the succeeding decades, FDA brought and won enforcement actions against cigarettes that were intended to treat or prevent disease or to affect the structure and function of the body. *See, e.g., United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes claimed to reduce weight were intended to affect the structure or function of the body); *United States v. 46 Cartons, More or Less, Containing Cigarettes*, 113 F. Supp. 336, 338-339 (D.N.J. 1953) (cigarettes claimed to

¹¹⁶⁰ The predecessor to FDA issued the following statement about its jurisdiction over tobacco: "Tobacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act, and, as such, are subject to the provisions thereof. . . . On the other hand, tobacco and its preparations which are not so labeled *and are used for smoking or chewing or as snuff and not for medicinal purposes* are not subject to the provisions of the act." *U.S. Department of Agriculture Service and Regulatory Announcements*, No. 13 (1914), cited in Joint Comment of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. I, at 5 (emphasis added). *See* administrative record (AR) (Vol. 535 Ref. 96). Thus, to escape regulation under this interpretation of the Agency's authority, a tobacco product must not be labeled as a drug *and* must not be used as a drug. At the time this statement was issued, a drug was defined only as an article intended for the cure, mitigation, or prevention of disease, hence the limitation to use for "medicinal purposes." The definition was expanded in 1938 to include "articles intended to affect the structure or any function of the body."

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prevent respiratory diseases were intended to treat or prevent disease). For many years, the existing evidence about the intended use of tobacco products was insufficient to conclude that tobacco manufacturers intended tobacco products as drugs or devices except when disease or structure-function claims were expressly made for the products. It is nevertheless indisputable that the Agency has consistently claimed jurisdiction over tobacco products when it has determined that they are intended to affect the structure or function of the body or to treat or prevent disease. What has changed is the nature of the evidence before the Agency on the question of whether cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body."

B. A CHANGE IN THE EVIDENCE BEFORE THE AGENCY NOW ESTABLISHES "INTENT" TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY

1. Previous Agency Position and the Evidence on Which It Was Based

The Agency last considered whether to regulate tobacco products without disease or structure-function claims in connection with citizen petitions submitted in the late 1970's by Action on Smoking and Health (ASH) and others. The petitions sought to have FDA regulate all cigarettes as drugs or devices.

At the time that FDA responded to ASH's citizen petitions, the only evidence before the Agency was that presented by the petitioners: studies showing that nicotine produces some pharmacological effects in animals and humans and some very early evidence concerning the addictive properties of nicotine. The proposition that nicotine in cigarettes was addictive was not yet widely accepted in the scientific community, and the petition provided insufficient evidence to demonstrate addiction. Indeed, at the time the

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petitions were submitted, no major public health organizations had concluded that nicotine is addictive. Because it was not yet recognized that nicotine is addictive, no data were available quantifying the proportion of smokers who were addicted and thus using cigarettes to satisfy their addiction.

The petitioners also presented no evidence that the tobacco companies knew of the pharmacological properties of nicotine, or that consumers used cigarettes for their pharmacological effects, or that the companies manipulated the levels of nicotine in cigarettes to satisfy smokers' need for nicotine. The petitions thus rested on evidence that nicotine has some pharmacological effects and the largely unsubstantiated assertion that many consumers used cigarettes for a drug purpose.

FDA concluded that although intended use could be established by evidence other than promotional claims, the evidence in the petitions was insufficient to find that the manufacturers of cigarettes "intended" these products to prevent, mitigate, or treat disease or to affect the structure or function of the body. For example, in response to the petition urging FDA to regulate filtered cigarettes as devices because they were intended to mitigate disease, the Agency said:

ASH asserts that objective evidence other than manufacturers' claims can be material to a determination of intended use under the statutory definition, and that *National Nutritional Foods Ass'n v. Food and Drug Administration*, 504 F.2d 761 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975), is authority for this interpretation (Petition No. 2, p. 21). We agree. However, the court there held that the vendor's intent is the crucial element in the statutory definition and that objective evidence sufficient to pierce the manufacturer's subjective claims must be presented (504 F.2d at 789).

. . . [*National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688 (2d Cir. 1975) and *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325 (2d Cir. 1977)] support FDA's position that it is the intent of the manufacturers or vendors that objective evidence must establish and that

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evidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act. ASH has not established that consumers use attached cigarette filters for the prevention, mitigation, or treatment of disease to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.¹¹⁶¹

ASH appealed the Agency's decision not to regulate cigarettes as drugs. In *ASH*, the Court of Appeals deferred to FDA's determination and concluded that the evidence on "intended use" was not sufficient to overrule the Agency's interpretation. *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). The *ASH* court recognized both that FDA was permitted to modify its interpretation and that the Agency's new position would be accorded deference by the courts. *Id.* at 237, 242, n.10. The court expressly left open the possibility that at some point in the future FDA might appropriately determine that cigarettes did fall within the Agency's jurisdiction: "Nothing in this opinion should suggest that the Administration is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations." *Id.* at 242, n.10.

The *ASH* decision, moreover, by no means supports the proposition that the industry comments urge, namely, that evidence of intended use must be limited to manufacturers' drug claims. The *ASH* court held that a finding that tobacco products were intended to affect the structure or function of the body could be based on substantial consumer use evidence alone or in combination with other evidence of vendor intent. *Id.* at 239-240. Nor was it the Agency's position at the time of the *ASH* case that the

¹¹⁶¹ Letter from Goyan JE to Banzhaf, III JF and Georgiades PN (Nov. 25, 1980), at 8-9. See AR (Vol. 28 Ref. 238).

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intended use of cigarettes could be established only through a manufacturer's overt drug claims. As noted above, FDA's 1980 response to ASH on its petition urging FDA to regulate filtered cigarettes as devices expressly stated that objective evidence other than claims is relevant to establishing intended use. In addition, the brief filed by the Agency before the Court of Appeals repeatedly stated the Agency's formal legal position that the intended use of cigarettes could be established through manufacturer's representations *or* other objective evidence of intent.¹¹⁶² As stated in that brief, the petition denial was based on "two findings":

(1) that there was no evidence in the record that manufacturers or vendors of cigarettes *represent* that cigarettes are intended to affect the structure or any function of the body; and (2) that there was no evidence in the record of any other sort that manufacturers or vendors of cigarettes *intend* that cigarettes affect the structure or any function of the body (Denial Letter at 4).¹¹⁶³

Thus, even at the time of the Agency's last decision on its jurisdiction over cigarettes, the Agency recognized that intended use could be established on the basis of objective evidence of intent other than manufacturers' claims. FDA concluded at that time that such other evidence had not been presented to the Agency.

2. New Evidence Supporting the Agency's Change in Position

In the years since FDA's decision on the ASH petitions, dramatic new evidence has become available on the issue of the intended use of cigarettes and smokeless tobacco. FDA has therefore reevaluated the issue of its jurisdiction over tobacco products and finds

¹¹⁶² Brief for Appellees at 9 n.7, 27-28, 30, *Action on Smoking and Health v. Harris*, No. 79-1397, reported at 655 F.2d 236 (D.C. Cir. 1980). See AR (Vol. 504 Ref. 8918).

¹¹⁶³ *Id.* at 30 (emphasis in original).

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that the evidence now supports a determination that cigarettes and smokeless tobacco are intended to affect the structure and function of the body, regardless of whether drug claims are made for the products. FDA bases this determination on three important categories of evidence that have emerged since FDA last declined to exercise jurisdiction over tobacco products without claims: (1) the development of a scientific consensus, on the basis of overwhelming scientific evidence, that nicotine in cigarettes and smokeless tobacco is highly addictive and produces significant effects on the structure and function of the body, making it foreseeable to a reasonable tobacco manufacturer that its products will have pharmacological effects and be used for those effects by a substantial proportion of consumers; (2) scientific data establishing that the vast majority of consumers who use cigarettes and smokeless tobacco are addicted to them and use these products nearly exclusively to obtain the pharmacological effects of nicotine; and (3) newly disclosed evidence showing that tobacco companies have in mind that their products will be used by consumers for pharmacological purposes and have designed their products to affect the structure and function of the body. As described in section II., above, FDA believes that each category of evidence provides an independent basis on which to conclude that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

In the Jurisdictional Analysis and in section II., above, FDA describes at length the body of evidence now before it. The vast majority of that evidence—including evidence that predates FDA's denial of the *ASH* petitions but was not made public by the tobacco industry—was not available to FDA in 1980. Since 1980, the quality, quantity, and scope of the evidence regarding the intended use of cigarettes and smokeless tobacco have

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increased and sharpened dramatically. As described below, the evidence on the addictive nature of nicotine and on manufacturers' research on, manipulation of, and control over nicotine levels has grown exponentially.

a. Since 1980, a Scientific Consensus Has Emerged That Nicotine Is Addictive and Has Other Significant Pharmacological Effects and Uses

As described in section II.A., above, evidence that the pharmacological effects and uses of cigarettes and smokeless tobacco are foreseeable in a significant proportion of consumers is a sufficient basis on which to find that cigarettes and smokeless tobacco are intended to affect the structure and function of the body. Since 1980, the last time that FDA considered whether cigarettes were intended to affect the structure or function of the body, evidence of nicotine's addictiveness and other significant pharmacological effects and uses has become widely known and thus foreseeable by the manufacturers.

Before 1980, no major public health organization had determined that nicotine was an addictive drug. Between 1980 and 1994, however, every leading scientific deliberative panel and organization with expertise in addiction concluded that nicotine is addictive or dependence-producing. These organizations include the American Psychiatric Association, in its *Diagnostic and Statistical Manual of Mental Disorders*, Third Edition (DSM-III); the World Health Organization; the American Medical Association; the American Psychological Association; the American Society of Addiction Medicine; the Royal Society of Canada; and the Medical Research Council in the United Kingdom. In 1986, the U.S. Surgeon General issued a report concluding for the first time that smokeless tobacco is addictive. And in 1988, the Surgeon General issued a landmark report concluding that nicotine in cigarettes is addictive.

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These organizations relied on data from animal and human studies demonstrating nicotine's ability to produce addiction. Definitive studies had not been conducted before 1980. During the 1980's and 1990's, however, there was an explosion of new studies on nicotine designed to determine whether nicotine is addictive. Thus, new studies, not available when the ASH petitions were decided, now conclusively demonstrate that nicotine has the characteristics of an addictive drug.¹¹⁶⁴ The new data support the following findings, among others:

- Nicotine is self-administered by animals, demonstrating that it is a "positive reinforcer" (i.e., it causes repeated, compulsive use of the drug), one of the hallmark characteristics of addictive drugs;¹¹⁶⁵

¹¹⁶⁴ See section II.A.3., above, for a complete description of these studies and their significance in assessing nicotine's addictiveness.

¹¹⁶⁵ Goldberg SR, Spealman RD, Goldberg DM, Persistent behavior at high rates maintained by intravenous self-administration of nicotine, *Science* 1981;214:573-575. See AR (Vol. 5 Ref. 35-2).

Goldberg SR, Spealman RD, Maintenance and suppression of behavior by intravenous nicotine injections in squirrel monkeys, *Federation Proceedings* 1982;41(2):216-220. See AR (Vol. 39 Ref. 52).

Spealman RD, Goldberg SR, Maintenance of scheduled-controlled behavior by intravenous injections of nicotine in squirrel monkeys, *Journal of Pharmacology and Experimental Therapeutics* 1982;223(2):402-408. See AR (Vol. 42 Ref. 146).

Risner ME, Goldberg SR, A comparison of nicotine and cocaine self-administration in the dog: fixed-ratio and progressive-ratio schedules of intravenous drug infusion, *Journal of Pharmacology and Experimental Therapeutics* 1983;224(2):319-326. See AR (Vol. 42 Ref. 119).

Cox BM, Goldstein A, Nelson WT, Nicotine self-administration in rats, *British Journal of Pharmacology* 1984;83:49-55. See AR (Vol. 8 Ref. 93-1).

Slifer BL, Balster RL, Intravenous self-administration of nicotine: with and without schedule-induction, *Pharmacology, Biochemistry and Behavior* 1985;22:61-69. See AR (Vol. 8 Ref. 93-3).

Corrigall WA, Coen KM, Nicotine maintains robust self-administration in rats on a limited-access schedule, *Psychopharmacology* 1989;99:473-478. See AR (Vol. 347 Ref. 5495).

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- Consistent with the animal self-administration data, nicotine serves as a positive reinforcer in humans;¹¹⁶⁶
- Nicotine is psychoactive, serving as a discriminative stimulus in animals¹¹⁶⁷ and producing subjective effects in humans;¹¹⁶⁸

¹¹⁶⁶ Henningfield JE, Miyasato K, Jasinski DR, Cigarette smokers self-administer intravenous nicotine, *Pharmacology, Biochemistry and Behavior* 1983;19:887-890. See AR (Vol. 39 Ref. 71).

Surgeon General's Report, 1988, at 192. See AR (Vol. 129 Ref. 1592).

¹¹⁶⁷ Stolerman IP, Discriminative stimulus effects of nicotine in rats trained under different schedules of reinforcement, *Psychopharmacology* 1989;97:131-138. See AR (Vol. 8 Ref. 90-6).

Craft RM, Howard JL, Cue properties of oral and transdermal nicotine in the rat, *Psychopharmacology* 1988;96:281-284. See AR (Vol. 74 Ref. 115).

Stolerman IP, Garcha HS, Pratt JA, *et al.*, Role of training dose in discrimination of nicotine and related compounds by rats, *Psychopharmacology* 1984;84:413-419. See AR (Vol. 8 Ref. 90-5).

Garcha HS, Goldberg SR, Reavill C, *et al.*, Behavioural effects of the optical isomers of nicotine and normicotine, and cotinine, in rats, *British Journal of Pharmacology* 1986;88:298. See AR (Vol. 38 Ref. 44).

Takada K, Swedberg MDB, Goldberg SR, *et al.*, Discriminative stimulus effects of intravenous l-nicotine and nicotine analogs or metabolites in squirrel monkeys, *Psychopharmacology* 1989;99:208-212. See AR (Vol. 43 Ref. 153).

¹¹⁶⁸ Henningfield JE, Miyasato K, Jasinski DR, Abuse liability and pharmacodynamic characteristics of intravenous and inhaled nicotine, *Journal of Pharmacology and Experimental Therapeutics* 1985;234:1-12. See AR (Vol. 39 Ref. 69).

Pomerleau CS, Pomerleau OF, Euphoriant effects of nicotine in smokers, *Psychopharmacology* 1992;108:460-465. See AR (Vol. 87 Ref. 426).

Perkins KA, Grobe JE, Epstein LH, *et al.*, Effects of nicotine on subjective arousal may be dependent on baseline subjective state, *Journal of Substance Abuse* 1992;4:131-141. See AR (Vol. 348 Ref. 5516).

Perkins KA, Grobe JE, Epstein LH, *et al.*, Chronic and acute tolerance to subjective effects of nicotine, *Pharmacology, Biochemistry and Behavior* 1993;45:375-381. See AR (Vol. 271 Ref. 3728).

Sutherland G, Russell MA, Stapleton J, *et al.*, Nasal nicotine spray: a rapid nicotine delivery system, *Psychopharmacology* 1992;108:512-518. See AR (Vol. 91 Ref. 526).

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- Nicotine reliably produces a withdrawal syndrome;¹¹⁶⁹
- Nicotine, like other addictive drugs (e.g., cocaine, amphetamine, and morphine), produces its addictive effects by actions increasing dopamine concentrations within the mesolimbic system of the brain.¹¹⁷⁰

In addition to the core studies demonstrating nicotine's addictiveness, other widely publicized information relevant to the finding that nicotine in cigarettes and smokeless tobacco has significant pharmacological effects has become available since 1980. This new information includes, for example:

- Studies showing that nicotine produces EEG effects on the brain that are reproducible and are known to be associated with changes in mood and alertness;¹¹⁷¹

¹¹⁶⁹ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (Washington DC: American Psychiatric Association, 1994), at 244-245. See AR (Vol. 37 Ref. 8).

West RJ, Jarvis MJ, Russell MAH, *et al.*, Effect of nicotine replacement on the cigarette withdrawal syndrome, *British Journal of Addiction* 1984;79(2):215-219. See AR (Vol. 8 Ref. 102-1).

Hughes JR, Hatsukami D, Signs and symptoms of tobacco withdrawal, *Archives of General Psychiatry* 1986;43:289-294. See AR (Vol. 8 Ref. 102-2).

Hughes JR, Higgins ST, Hatsukami D, Effects of abstinence from tobacco: a critical review, *Research Advances in Alcohol and Drug Problems* 1990;10:317-398, at 381-382. See AR (Vol. 535 Ref. 96, III.G).

¹¹⁷⁰ Clarke PBS, Mesolimbic dopamine activation—the key to nicotine reinforcement? *CIBA Foundation Symposium* 1990;152:153-168. See AR (Vol. 3 Ref. 19-2).

Di Chiara G, Imperato A, Drugs abused by humans preferentially increase synaptic dopamine concentrations in the mesolimbic system of freely moving rats, *Proceedings of the National Academy of Sciences of the United States of America* 1988;85:5274-5278. See AR (Vol. 75 Ref. 128).

Corrigall WA, Franklin KBJ, Coen KM, *et al.*, The mesolimbic dopaminergic system is implicated in the reinforcing effects of nicotine, *Psychopharmacology* 1992;107:285-289. See AR (Vol. 8 Ref. 93-4).

¹¹⁷¹ Norton R, Brown K, Howard R, Smoking, nicotine dose and the lateralisation of electrocortical activity, *Psychopharmacology* 1992;108:473-479. See AR (Vol. 3 Ref. 22).

Pritchard WS, Gilbert DG, Duke DW, Flexible effects of quantified cigarette-smoke delivery on EEG dimensional complexity, *Psychopharmacology* 1993;113:95-102. See AR (Vol. 3 Ref. 23-1).

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- Data that have led expert bodies to conclude that marketed cigarettes and smokeless tobacco deliver pharmacologically active (addicting) doses of nicotine;¹¹⁷²
- Studies showing that nicotine exposure causes an increase in the number of nicotinic receptors in the central nervous system, a phenomenon associated with development of tolerance to the effects of nicotine;¹¹⁷³ and
- Studies done in the 1980's and 1990's showing that nicotine replacement therapies are effective in assisting smoking cessation, which provide additional evidence that nicotine is the ingredient in cigarettes that causes addiction.¹¹⁷⁴

Pritchard WS, Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490. See AR (Vol. 3 Ref. 23-2).

Golding JF, Effects of cigarette smoking on resting EEG, visual evoked potentials and photic driving, *Pharmacology, Biochemistry and Behavior* 1988;29:23-32. See AR (Vol. 3 Ref. 23-3).

¹¹⁷² Department of Health and Human Services, Public Health Service, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General*, 1986, NIH Publication No. 86-2874 (Bethesda MD: DHHS, PHS, 1986). See AR (Vol. 128 Ref. 1591).

Surgeon General's Report, 1988, at 13-17. See AR (Vol. 129 Ref. 1592).

Transcript to the FDA Drug Abuse Advisory Committee, Meeting 27, "Issues Concerning Nicotine-Containing Cigarettes and Other Tobacco Products," Aug. 2, 1994, at 336-342. See AR (Vol. 255 Ref. 3445).

¹¹⁷³ Marks MJ, Burch JB, Collins AC, Effects of chronic nicotine infusion on tolerance development and nicotine receptors, *Journal of Pharmacology and Experimental Therapeutics* 1983;226:817-825. See AR (Vol. 41 Ref. 103).

Surgeon General's Report, 1988, at 53-54. See AR (Vol. 129 Ref. 1592).

Department of Health and Human Services, Centers for Disease Control and Prevention, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (Atlanta: USDHHS, 1994), at 32-33. See AR (Vol. 133 Ref. 1596).

Benwell MEM, Balfour DJK, Anderson JM, Evidence that tobacco smoking increases the density of (-)-[³H]nicotine binding sites in human brain, *Journal of Neurochemistry* 1988;50:1243-1247. See AR (Vol. 136 Ref. 1570).

¹¹⁷⁴ See, e.g., Fiore MC, Smith SS, Jorenby DE, *et al.*, The effectiveness of the nicotine patch for smoking cessation: a meta analysis, *Journal of the American Medical Association* 1994;271:1940-1947. See AR (Vol. 6 Ref. 64-1).

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On the basis of the voluminous new data on nicotine that have become available since 1980 and the virtually universal consensus that has emerged from these data that nicotine is highly addictive and produces other significant pharmacological effects, FDA has concluded that nicotine's addictive and other pharmacological effects and uses are so widely recognized that they must be considered foreseeable to a reasonable tobacco manufacturer. The conclusion that nicotine's effects are so widely known and foreseeable would have been impossible when FDA last considered whether to regulate cigarettes because neither the definitive data nor the scientific consensus existed.

b. Since 1980, Evidence Has Become Available That Consumers Use Tobacco Predominantly for Its Pharmacological Effects

As described in section II.B., above, evidence that consumers use a product predominantly or nearly exclusively for its pharmacological effects permits the Agency to conclude that the product is intended to affect the structure or function of the body. The Agency recognizes that for many years there was general awareness of the difficulty smokers experienced in trying to stop smoking. Since 1980, however, scientific evidence has shown that the vast majority of smokers and users of smokeless tobacco use cigarettes and smokeless tobacco to satisfy addiction or for other pharmacological effects. The evidence that has emerged since the last time that FDA considered whether to regulate cigarettes includes, for example:

- Evidence that 77% to 92% of smokers and as many as 75% of young regular smokeless tobacco users are addicted;¹¹⁷⁵

See appendix 1 to Jurisdictional Analysis, at 62-83. See AR (Vol. 1 Appendix 1).

¹¹⁷⁵ Hughes JR, Gust SW, Pechacek TF, Prevalence of tobacco dependence and withdrawal, *American Journal of Psychiatry* 1987;144(2):205-208. See AR (Vol. 66 Ref. 4).

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- Evidence that a higher percentage of people who use cigarettes become addicted than people who use other addictive drugs, including cocaine and heroin;¹¹⁷⁶
- Evidence that, of young people aged 10 to 22 years, 72.8% of daily smokers and 53.8% of daily users of smokeless tobacco use tobacco to “relax” themselves;¹¹⁷⁷ and
- Data demonstrating that many smokers believe that smoking helps them control their weight and that continued smoking is related to concerns about weight gain.¹¹⁷⁸

This new evidence, together with some existing evidence that smokers use cigarettes to control their moods, is sufficient to demonstrate that cigarette smokers and smokeless tobacco users consume tobacco predominantly to satisfy addiction, alter moods, and control weight. FDA would have been unable to reach this conclusion in 1980. At that time there was no evidence on the proportion of smokers and smokeless tobacco users who were addicted to tobacco (indeed, there was no agreement that nicotine was

Woody GE, Cottler LB, Cacciola J, Severity of dependence: data from the DSM-IV field trials, *Addiction* 1993;88:1573-1579. See AR (Vol. 13 Ref. 150).

Cottler L, Comparing DSM-III-R and ICD-10 substance use disorders, *Addiction*, 1993;88:689-696. See AR (Vol. 13 Ref. 149).

Hale KL, Hughes JR, Oliveto AH, *et al.*, Nicotine dependence in a population-based sample, in *Problems of Drug Dependence, 1992*, NIDA Research Monograph 132 (Washington DC: Government Printing Office, 1993). See AR (Vol. 39 Ref. 60).

Department of Health and Human Services, Office on Smoking and Health, *Spit Tobacco and Youth* (Washington DC: Government Printing Office, 1992), at 8. See AR (Vol. 7 Ref. 76).

¹¹⁷⁶ Anthony JC, Warner LA, Kessler RC, Comparative epidemiology of dependence on tobacco, alcohol, controlled substances and inhalants: basic findings from the National Comorbidity Survey, *Experimental and Clinical Psychopharmacology* 1994;2:244-268. See AR (Vol. 535 Ref. 96, vol. III.A).

¹¹⁷⁷ Centers for Disease Control and Prevention, Reasons for tobacco use and symptoms of nicotine withdrawal among adolescent and young adult tobacco users—United States, 1993, *Morbidity and Mortality Weekly Report* 1994;43(41):745-750, at 747. See AR (Vol. 43 Ref. 162).

¹¹⁷⁸ Surgeon General's Report, 1988, at 438-441. See AR (Vol. 129 Ref. 1592).

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addictive), and evidence on the use of tobacco for other pharmacological effects was insufficient to conclude that cigarettes and smokeless tobacco are consumed predominantly for their pharmacological effects.

c. Since 1980, Evidence Has Become Available Demonstrating That Tobacco Manufacturers Actually Intend Their Products To Affect the Structure and Function of the Body

As described in section II.C., above, FDA may also find that cigarettes and smokeless tobacco are “intended to affect the structure or any function of the body” on the basis of objective evidence that the manufacturers of these products actually intend them to affect the structure or function of the body. Such objective evidence includes company-funded research and internal statements showing that the manufacturers know or have knowledge of facts that would give them notice that consumers are using cigarettes and smokeless tobacco to obtain nicotine’s pharmacological effects. Relevant objective evidence of intent also includes evidence that manufacturers have taken actions to ensure that consumers obtain pharmacologically active doses of nicotine from marketed tobacco products.

As discussed in section II., above, FDA, congressional, and other investigations into tobacco products over the last two years have uncovered a wealth of documents from a wide range of tobacco companies, the vast majority of which had not been made public by the tobacco industry. Although in some cases these documents date back to the early 1960’s, they have not been available to the public or to FDA until recently. As described in greater detail in section II., above, the newly discovered documents reveal the following facts, among others, none of which were known when FDA last considered its jurisdiction over cigarettes:

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- Statements from tobacco company researchers and executives show that the tobacco industry knows that nicotine is a drug, that consumers use tobacco primarily for the pharmacological effects of nicotine, and that nicotine is addictive;
- The tobacco industry has conducted extensive and sophisticated research to understand precisely how nicotine affects the structure and function of the body;
- The tobacco industry has conducted product development research on how to manipulate nicotine delivery from cigarettes to ensure that cigarettes deliver pharmacologically active doses of nicotine;
- The tobacco industry has manipulated the delivery of nicotine from marketed cigarettes to maintain and enhance the delivery of nicotine from low-yield cigarettes through the use of higher nicotine tobaccos, chemicals added to tobacco, and selective filtration and ventilation;
- The smokeless tobacco industry has manipulated the delivery of nicotine from smokeless tobacco to create product lines with graduating nicotine deliveries, and at least one company has used a “graduation strategy” designed to encourage new users to begin with the lowest nicotine products and then graduate to the higher nicotine products.

These facts, among others, demonstrate that the tobacco industry knows that consumers use their products to obtain nicotine’s pharmacological effects and that they have taken specific actions to facilitate that use. FDA has concluded on the basis of this new evidence that tobacco manufacturers actually intend cigarettes and smokeless tobacco to affect the structure or function of the body.

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Almost none of the evidence of tobacco industry knowledge and actions was available to the Agency when it last declined to exercise jurisdiction over cigarettes without claims. One comment argues that FDA's earlier decision not to regulate tobacco products without claims is directly attributable to the tobacco industry's withholding of material documents. Indeed, Joseph Califano, who was Secretary of the Department of Health, Education, and Welfare at the time that FDA last declined to regulate cigarettes, has testified under oath before Congress that he would have "moved to regulate" had he known what FDA now knows about the internal tobacco company documents.¹¹⁷⁹ He further testified that he had consulted with both President Jimmy Carter and then Surgeon General Julius Richmond and both agreed that, had this evidence been available, they too would have moved to regulate.¹¹⁸⁰ FDA agrees with several comments that argue that not allowing FDA to change its position on the basis of this new evidence would reward the tobacco industry for its long-successful efforts to conceal its knowledge and actions related to nicotine.

FDA's decision to change its previous position that cigarettes and smokeless tobacco are not intended to affect the structure or function of the body is thus based on an overwhelming body of new evidence that has become available since FDA last considered this issue. The new evidence persuades the Agency to conclude that its previous position is no longer consistent with the relevant facts and should be changed. FDA's lengthy description of the new evidence in the Jurisdictional Analysis and in this document

¹¹⁷⁹ *Regulation of Tobacco Products (Part 2): Hearings Before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, 103d Cong., 2d Sess. 166 (May 17, 1994). See AR (Vol. 708 Ref. 2).*

¹¹⁸⁰ *Id.*

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provides a reasoned explanation for its change in position. The Agency's new position is therefore entitled to deference. *American Trucking*, 387 U.S. at 416.

C. NEW EVIDENCE THAT NICOTINE ADDICTION IS A PEDIATRIC DISEASE PERMITS EFFECTIVE REGULATORY INTERVENTION

In addition to the new evidence establishing that cigarettes and smokeless tobacco are "intended to affect the structure or any function of the body," new information developed since 1980 on young people's use of tobacco products shows that FDA's regulatory resources can be used effectively to reduce tobacco-related disease and death. Recent data establish that most of the people who suffer the adverse health consequences of using cigarettes and smokeless tobacco begin tobacco use in childhood and adolescence. Moreover, new data suggest that anyone who does not begin tobacco use in childhood or adolescence is unlikely ever to begin. This information provides a unique public health opportunity to substantially reduce the more than 400,000 deaths from tobacco use each year in the United States. If children and adolescents can be successfully prevented from initiating tobacco use and becoming addicted to cigarettes and smokeless tobacco, they are unlikely to begin tobacco use later in life, thereby preventing the onset of tobacco-related disease and premature death.

Major recent reports have emphasized the effectiveness of legislative and regulatory interventions that focus on restricting children's access to tobacco products and on reducing the appeal of tobacco products to youth.¹¹⁸¹ Before the importance of youth-centered interventions was identified, the regulatory approaches available under the Act to

¹¹⁸¹ Department of Health and Human Services, Office on Smoking and Health, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (Washington, DC: Government Printing Office, 1994) (hereinafter cited as Surgeon General's Report, 1994). See AR (Vol. 133 Ref. 1596).

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address tobacco-related disease and death, such as removal of the products from the market, were not believed to be feasible. It is now apparent, however, that FDA's authority to restrict the sale, distribution, and use of cigarettes and smokeless tobacco to people under the age of eighteen is an effective tool to reduce the adverse health consequences of tobacco use. Thus, asserting jurisdiction over cigarettes and smokeless tobacco now presents an opportunity to use the Agency's resources effectively for substantial public health gains.

1. New Information Shows that Cigarette and Smokeless Tobacco Use Begins Almost Exclusively in Childhood and Adolescence

Although it has long been known that some people begin tobacco use before adulthood, definitive analyses of data published in the 1990's have revealed that the vast majority of tobacco users begin their use while children or adolescents. Moreover, new evidence shows that children and adolescents are beginning to smoke at younger ages than ever before. The new analyses show that the average age when people first try smoking a cigarette is 14.5 years of age,¹¹⁸² 82% of adults who have ever smoked had their first cigarette before age 18, and more than half of them had already become regular smokers by that age.¹¹⁸³ Recent analyses also show that the mean average age when people become daily smokers is 17.7 years of age.¹¹⁸⁴ These data have critical implications for public health interventions. As stated by the Surgeon General in 1994, "[n]early all first

¹¹⁸² *Id.* at 67.

¹¹⁸³ *Id.* at 65.

¹¹⁸⁴ *Id.* at 67.

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use of tobacco occurs before high school graduation; this finding suggests that if adolescents can be kept tobacco-free, most will never start using tobacco.”¹¹⁸⁵

Not only does tobacco use begin predominantly among children and adolescents, but recent evidence shows that more and more children and adolescents are using tobacco. Approximately three million American youths currently smoke and an additional one million adolescent males use smokeless tobacco.¹¹⁸⁶ Despite a decline in smoking rates in most segments of the American adult population, the rates among children and adolescents have recently begun to rise.¹¹⁸⁷ Tobacco use has been increasing among eighth and tenth graders in each of the last four years. In December 1995, 19% of eighth graders and 29% of tenth graders reported having smoked in the last 30 days, an increase of one-third since 1991.¹¹⁸⁸ Tobacco use has also been increasing among high school seniors in each of the last three years. In December 1995, 33.5% of high school seniors reported having smoked in the last 30 days, an increase of one-fifth since 1992.¹¹⁸⁹

¹¹⁸⁵ *Id.* at 5.

¹¹⁸⁶ *Id.*

¹¹⁸⁷ Centers for Disease Control and Prevention, *Cigarette smoking among adults—United States, 1991, Mortality and Morbidity Weekly Report*, 1993;42(12):230-233. See AR (Vol. 2 Ref. 17-1).

Johnston LD, O'Malley PM, Bachman JG, *National Survey Results on Drug Use from the Monitoring the Future Study 1975-1993, Vol. I: Secondary School Students*, NIH Pub. No. 94-3809 (Rockville, MD: National Institute on Drug Abuse, 1994), at 9, 19. See AR (Vol. 2 Ref. 17-1).

University of Michigan, News and Information Service, *Smoking rates climb among American teenagers, who find smoking increasingly acceptable and seriously underestimate the risks* (Jul. 20, 1995), at table 1. See AR (Vol. 3 Ref. 10-2).

¹¹⁸⁸ Price J, *Teen smoking, marijuana use increase sharply, study shows*, *Washington Times* (Dec. 16, 1995), at A2. See AR (Vol. 711 Ref. 5).

¹¹⁸⁹ *Id.*

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There has been a similar increase in smokeless tobacco use by young people. Over the past 25 years, the market for smokeless tobacco has shifted dramatically from adults to young people. *See* Jurisdictional Analysis, 60 FR 41748. For example, use of moist snuff among males aged 18-19 increased from 0.5% in 1970 to 7.5% in 1991.¹¹⁹⁰ Current use of smokeless tobacco by children and adolescents is high and begins early. School-based surveys in 1991 estimated that 19.2% of ninth- to twelfth-grade boys use smokeless tobacco.¹¹⁹¹ Among high school seniors who had ever tried smokeless tobacco, 73% did so by the ninth grade.¹¹⁹²

This increase in tobacco use by young people has severe public health consequences. Although they believe that they will not become addicted to tobacco, recent data establish that children and adolescents become addicted to nicotine in the same manner as adults. Among smokers aged 12-17, 70% already regret their decision to smoke and 66% say they want to quit.¹¹⁹³ Those who are able to quit experience withdrawal symptoms and relapse rates similar to those reported in adults.¹¹⁹⁴ As stated in a study of youthful smoking sponsored by the Canadian affiliate of Brown & Williamson:

¹¹⁹⁰ Centers for Disease Control and Prevention, Office of Smoking and Health, unpublished data.

Informal communication between Office of Smoking and Health and Ann Witt, FDA.

¹¹⁹¹ Kann L, Warren W, Collins JL, Results from the national school-based 1991 youth risk behavior survey and progress toward achieving related youth objectives for the nation, *Public Health Reports*, 1993;108(Supp.1):47-54. *See* AR (Vol. 4 Ref. 24).

¹¹⁹² Surgeon General's Report, 1994, at 101. *See* AR (Vol. 133 Ref. 1596).

¹¹⁹³ The George H. Gallup International Institute, *Teenage Attitudes and Behavior Concerning Tobacco-Report of the Findings* (Sep. 1992), at 54. *See* AR (Vol. 36 Ref. 381).

¹¹⁹⁴ Centers for Disease Control and Prevention, Reasons for tobacco use and symptoms of nicotine withdrawal among adolescent and young adult tobacco users-United States, 1993, *Morbidity and Mortality Weekly*, 1994;43(41):745-750. *See* AR (Vol. 2 Ref. 14-1). *See* AR (Vol. 2 Ref. 14-1).

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The desire to quit seems to come earlier now than before, even prior to the end of high school. In fact, it often seems to take hold as soon as the recent starter admits to himself that he is hooked on smoking. However, the desire to quit, and actually carrying it out, are two quite different things, as the would-be quitter soon learns.¹¹⁹⁵

A child or adolescent whose cigarette use continues into adulthood increases his or her risk of dying from cancer, cardiovascular disease, or lung disease.¹¹⁹⁶ Indeed, approximately one out of every three young people who become regular smokers will die prematurely as a result.¹¹⁹⁷ Moreover, the younger one begins to smoke, the more likely one is to become a heavy smoker and suffer from smoking-related diseases.¹¹⁹⁸

Smokeless tobacco use can cause oral cancer and the risk increases with increased exposure to smokeless tobacco use.¹¹⁹⁹ One study of 117 high school students who were

Surgeon General's Report, 1994, at 78. See AR (Vol. 133 Ref. 1596).

¹¹⁹⁵ Kwechansky Marketing Research for Imperial Tobacco, Ltd., Project Plus/Minus (May 7, 1982), in Study Highlights. See AR (Vol. 21 Ref. 214).

¹¹⁹⁶ McGinnis JM, Foege WH, Actual causes of death in the United States, *Journal of the American Medical Association*, 1993;270(18):2207-2212. See AR (Vol. 277 Ref. 3906).

¹¹⁹⁷ Memorandum from Eriksen MP (CDC) to Lorraine C (FDA) (Aug. 7, 1995); CDC Fact Sheet based on Pierce JP, Fiore, MC, Novotny, TE, *et al.*, Trends in cigarette smoking in the United States: projections to the year 2000, *Journal of the American Medical Association* 1989;261:61-65 and Peto R, Lopez AD, Boreham J, *et al.*, *Mortality from Smoking in Developed Countries, 1950-2000: Indirect Estimates from National Vital Statistics* (Oxford: Oxford University Press, 1994); Centers for Disease Control and Prevention, Office on Smoking and Health, unpublished data from the 1986 National Mortality Followback Survey. See AR (Vol. 711 Ref. 20).

¹¹⁹⁸ Taioli E, Wyder EL, Effect of the age at which smoking begins on frequency of smoking in adulthood, *New England Journal of Medicine*, 1991;325(13):968-969. See AR (Vol. 101 Ref. 876).

Escobedo LG, Marcus SE, Holtzman D, Sports participation, age of smoking initiation, and the risk of smoking among U.S. high school students, *Journal of the American Medical Association*, 1993;269(11):1391-1395. See AR (Vol. 75 Ref. 149).

¹¹⁹⁹ Department of Health and Human Services, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General* (1986) (Washington DC: DHHS), at 44. See AR (Vol. 128 Ref. 1591).

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smokeless tobacco users revealed that nearly 50% had oral leukoplakia, a precancerous lesion that cannot be scraped off.¹²⁰⁰ Five percent of oral leukoplakias become malignant in 5 years.¹²⁰¹ Tobacco use, which overwhelmingly begins in childhood, is ultimately responsible for over 400,000 deaths each year in the United States.¹²⁰²

2. New Information Shows that Effective Restrictions on Access and Advertising to Children and Adolescents Can Decrease Tobacco Use by Children

Despite laws in every State making it illegal for minors to purchase tobacco, America's children have easy access to tobacco products and are subjected to pervasive advertising images that portray tobacco use in terms that are highly attractive to them. As described in the Proposed Rule, 60 FR 41321–41338 (Aug. 11, 1995) and in sections IV and VI.D.6 of the final rule, recent studies have shown that regulatory programs that are effective in restricting access to tobacco products by those under 18, and that restrict advertising of these products can substantially reduce illegal tobacco use by children and adolescents.

State laws prohibiting the purchase of tobacco by minors are rarely enforced¹²⁰³ and a significant percentage of underage smokers are able to obtain cigarettes through

¹²⁰⁰ Greer RO, Poulson TC, Oral tissue alterations associated with the use of smokeless tobacco by teenagers, *Oral Surgery, Oral Medicine, Oral Pathology*, 1983;56(3):275-284. See AR (Vol. 5 Ref. 95).

Surgeon General's Report, 1994, at 39. See AR (Vol. 133 Ref. 1596).

¹²⁰¹ Surgeon General's Report, 1994, at 39. See AR (Vol. 133 Ref. 1596).

¹²⁰² Centers for Disease Control and Prevention, Cigarette smoking-attributable mortality and years of potential life lost--United States, 1990, *Morbidity and Mortality Weekly Report*, 1993;42(33):645-649. See AR (Vol. 4 Ref 43).

¹²⁰³ Department of Health and Human Services, Office of the Inspector General, *Youth Access to Tobacco* (Washington DC: DHHS, Publication No. OEI-02-91-00880, Dec. 1992), at 5-8. See AR (Vol. 14 Ref. 19-1).

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vending machines and over-the-counter sales.¹²⁰⁴ Studies show that most children and adolescents who use tobacco products purchase their own cigarettes and smokeless tobacco. The 1994 Surgeon General's Report, *Preventing Tobacco Use Among Young People*, examined 13 studies of over-the-counter sales and determined that approximately 67 percent of minors are able to purchase tobacco illegally. Moreover, successful cigarette purchases by children and adolescents from vending machines averaged 88%.¹²⁰⁵ In addition to over-the-counter and vending machine purchases, many children and adolescents receive cigarettes and smokeless tobacco through free samples distributed by tobacco manufacturers at shopping malls, zoos, baseball games, rock concerts, and through the mail.¹²⁰⁶ Even elementary school children receive free samples.¹²⁰⁷ Distributing free samples of "starter" brands to young people has been a cornerstone of the successful campaign to boost moist snuff sales by the largest smokeless tobacco

Kusserow RP, Department of Health and Human Services, Office of the Inspector General, *Youth Access to Tobacco* (Washington DC: DHHS, Publication No. OEI-02-90-02310, May 1990), at 3-5. See AR (Vol. 4 Ref. 19-2).

¹²⁰⁴ Battelle for Centers for Disease Control and Prevention, Office of Smoking and Health, *Design of Inspection Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors* (Apr. 1994), at 14, 18. See AR (Vol. 49 Ref. 529).

¹²⁰⁵ Surgeon General's Report, 1994, at 249. See AR (Vol. 133 Ref. 1596).

¹²⁰⁶ Davis RM, Jason LA, The distribution of free cigarette samples to minors, *American Journal of Preventive Medicine*, 1988;4(1):21-26. See AR (Vol. 7 Ref. 70-1).

Department of Health and Human Services, *Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General* (Washington DC: DHHS, 1989), at 597. See AR (Vol. 130 Ref. 1593).

¹²⁰⁷ Davis RM, Jason LA, The distribution of free cigarette samples to minors, *American Journal of Preventive Medicine*, 1988;4(1):21-26. See AR (Vol. 7 Ref. 70-1).

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manufacturer.¹²⁰⁸ See also section II.D., above. The distribution of free samples to minors occurs despite the industry's voluntary code against distributing tobacco products to minors.

Recent studies have shown that effective youth access restrictions can reduce tobacco use by young people. In one community, for example, a comprehensive and intense community intervention involving retailer licensing, regular compliance checks, and penalties for merchant violations significantly reduced illegal sales from 70% to less than 5% two years later. Further, rates of experimentation and regular smoking dropped by more than 50% among seventh- and eighth-graders.¹²⁰⁹ Both the Surgeon General of the United States and the Institute of Medicine have recently concluded that effective, enforced restrictions on minor's access to tobacco products are important tools to reduce use of tobacco by children and adolescents.¹²¹⁰

Pervasive advertising of tobacco products using imagery that is attractive to young people also influences children and adolescents to use tobacco products. Many studies have shown that young people are aware of, respond favorably to, and are influenced by cigarette advertising.¹²¹¹ Even very young children are aware of cigarette advertisements.

¹²⁰⁸ National Cancer Institute, *Strategies to Control Tobacco Use in the United States: A Blueprint for Public Health Action in 1990's* (Washington DC: NIH Publication No. 92-3316, Oct. 1991), at 236. See AR (Vol. 7 Ref. 72).

¹²⁰⁹ Jason LA, Ji PY, Aries MD, Active enforcement of cigarette control laws in the prevention of cigarette sales to minors, *Journal of the American Medical Association*, 1991;266(22):3159-3161. See AR (Vol. 6, Ref. 8).

¹²¹⁰ Surgeon General's Report, 1994, at 254, 275. See AR (Vol. 133 Ref. 1596).

Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* (Washington DC: National Academy Press, 1994), at 199. See AR (Vol. 6 Ref. 11).

¹²¹¹ Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* (Washington DC: National Academy Press, 1994), at 123-124. See AR (Vol. 12 Ref. 149-1).

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One study found that 30% of 3-year-olds and 91% of 6-year-olds could identify Joe Camel as a symbol for smoking.¹²¹² Another study found that Joe Camel was more familiar to young children than Ronald McDonald, despite the fact that Ronald McDonald appears in television commercials, while cigarette commercials do not appear on the airwaves.¹²¹³

Moreover, recent studies show that campaigns that use imagery that is appealing to children and adolescents are successful in attracting young people to those brands. Before the Joe Camel cartoon character was introduced in 1986, Camel cigarettes had less than 3% of the youth market. By 1989, Camel's share of the youth market had risen to 8.1% and, by 1992, 13-16% of smokers under 18 were smoking Camel. During this same period, however, there was no significant increase in adult purchases of Camel cigarettes.¹²¹⁴ These and other studies discussed in the Proposed Rule, 60 FR 41329–

Surgeon General's Report, 1994, at 188-192.

Tye JB, Warner K, Glantz SA, Tobacco advertising and consumption: evidence of a causal relationship, *Journal of Public Health Policy*, 1987;8:492-508. See AR (Vol. 48 Ref. 520).

Pierce JP, Evans N, Farkas AJ, Tobacco Use in California, *An Evaluation of the Tobacco Control Program, 1989-1993, A Report to the California Department of Health Services* (San Diego: University of California, 1994), at 85. See AR (Vol. 7 Ref. 93).

¹²¹² Fischer PM, MP Schwartz, Richards JW, Brand logo recognition by children aged 3 to 6 years, Mickey Mouse and Old Joe the Camel, *Journal of the American Medical Association*, 1991;266(22):3145-3148. See AR (Vol. 2 Ref. 24-2).

¹²¹³ Mizerski R, *The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children*, presented at Marketing & Public Policy Conference (May 13-14, 1994). See AR (Vol. 13 Ref. 169).

¹²¹⁴ Surgeon General's Report, 1994, at 70. See AR (Vol. 133 Ref. 1596).

U.S. Public Health Service and U.S. Department of Education, Teenage Attitudes and Practices Survey (1989), cited in Centers for Disease Control and Prevention, Changes in the cigarette brand preferences of adolescent smokers—United States, 1989-1993, *Morbidity and Mortality Weekly Report*, 1994;43(32):577-581. See AR (Vol. 13 Ref. 172).

The George H. Gallup International Institute, *Teenage Attitudes and Behavior Concerning Tobacco—Report of the Findings* (Sep. 1992), at 64. See AR (Vol. 36 Ref. 381).

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41333, and in section VI.D. of the Final Rule provide compelling evidence that promotional campaigns can be extremely effective in attracting young people to tobacco products. Both the Surgeon General of the United States and the Institute of Medicine have concluded that unrestricted advertising of cigarettes and smokeless tobacco promotes consumption of tobacco by young people.¹²¹⁵ Recent studies also show that government restrictions on tobacco promotion can reduce both tobacco consumption in the population as a whole, and initiation of tobacco use by young people.¹²¹⁶

3. New Information Indicates that Regulatory Interventions Can Reduce Tobacco-Related Illness If They Focus on Preventing Children from Becoming Addicted

Tobacco products have historically been legal and widely available in this country. It was only after millions of people became legally addicted to the nicotine in cigarettes and smokeless tobacco that health experts became fully aware of the extraordinary health risks involved in the consumption of these products. Consequently, tobacco use has

Centers for Disease Control and Prevention, Changes in the cigarette brand preference of adolescent smokers, U.S. 1989-1993, *Morbidity and Mortality Weekly Report*, 1994;43(32):577-581. See AR (Vol. 2 Ref. 25-1).

¹²¹⁵ Surgeon General's Report, 1994, at 10, 159-195. See AR (Vol. 133 Ref. 1596).

Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* (Washington DC: National Academy Press, 1994), at 131. See AR (Vol. 7 Ref. 96).

¹²¹⁶ Toxic Substances Board, Wellington, New Zealand, *Health or Tobacco—an End to Tobacco Advertising and Promotion* (May 1989). See AR (Vol. 14 Ref. 178).

Smee C, *Effect of Tobacco Advertising on Tobacco Consumption-A Discussion Document Reviewing the Evidence*, 1-50 (London: Department of Health, Economics, and Operational Research Division, 1992) (draft). See AR (Vol. 14 Ref. 181).

Laugeson M, Meads C, Tobacco advertising restrictions, price, income and tobacco consumption in OECD countries, 1960-1986, *British Journal of Addiction* 1991;86:1343-1354. See AR (Vol. 15 Ref. 185).

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become not only one of the most serious public health problems facing the United States today but one of the most difficult to solve.

Because of the grave health consequences of the use of tobacco products, it has been argued that FDA should exercise its jurisdiction to remove them from the market. As described in the Proposed Rule, 60 FR 41348–41349, and in section I.B of the final rule, however, a ban is not a feasible approach to a product to which 35 to 45 million Americans are addicted. Abrupt removal of these products from the market could cause widespread adverse reactions and, in any event, is unlikely to keep cigarettes and smokeless tobacco out of the hands of addicted users. Black markets are likely to develop to supply addicted users with these products, and these black market products could be even more dangerous than those currently on the market. Thus, removal of cigarettes and smokeless tobacco from the market would not be an effective use of FDA's regulatory resources. Before it was understood that nicotine addiction is a pediatric disease, moreover, there was an insufficient basis to conclude that other regulatory approaches available to FDA would constitute effective uses of the Agency's resources.

To effectively address the death and disease caused by tobacco products, addiction to cigarettes and smokeless tobacco must be eliminated or substantially reduced. The new evidence that nicotine addiction begins almost exclusively in childhood and adolescence demonstrates that this can be achieved by preventing children and adolescents from starting to use tobacco. Because the new evidence suggests that anyone who does not begin tobacco use in childhood or adolescence is unlikely ever to begin,¹²¹⁷ effective

¹²¹⁷ Surgeon General's Report, 1994, at 5, 58, 65-67. See AR (Vol. 133 Ref. 1596).

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regulatory strategies to prevent children from initiating tobacco use and becoming addicted to nicotine, including restrictions on access and advertising, are likely to result in a significant reduction in tobacco-related illness and death. The information that has developed since 1980 that nicotine addiction is a pediatric disease thus provides a rationale for regulating tobacco in a manner that is likely to produce significant public health gains.

D. RESPONSE TO COMMENTS

Most of the comments that the Agency received generally recognized that an agency may change its position under appropriate circumstances. The comments differed widely, however, on whether such circumstances are present in this proceeding.

1. Some tobacco industry comments assert that relevant circumstances are unchanged since 1980—the date of the *ASH* decision and the last time the Agency evaluated this issue—and that therefore the Agency cannot offer a reasoned explanation for its change in position. Other comments differ sharply and contend that the available data have grown substantially. One comment stated that FDA has “obtained and considered substantial, new relevant data never previously considered, analyzed, or known by the FDA, never previously presented to or considered by Congress, and apparently, intentionally withheld by the tobacco industry from the FDA, Congress, and the American public.”¹²¹⁸ The Agency agrees that the evidence available to FDA today is far greater than the data available in 1980.

Of the comments contending that there has been no change in the legally relevant facts since 1980, one comment asserts that, because it has been widely reported for

¹²¹⁸ Coalition on Smoking or Health, Comment (Jan. 2, 1996), at 6. See AR (Vol. 533 Ref. 102).

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centuries that nicotine has “drug effects,” there cannot be any new information on nicotine’s drug effects that would warrant a change in the Agency’s jurisdiction. This contention is unpersuasive. Although the Agency recognizes that nicotine has long been known to have some “drug effects,” as set forth in this section and in section II. above, both the scientific understanding of nicotine’s effects and the nature of the effects that are known to occur have changed dramatically since the last time that FDA considered its jurisdiction over tobacco products. The fact that nicotine is now universally recognized as highly addictive, but was generally unrecognized as such before 1980, adequately demonstrates the change in evidence on the nature of nicotine’s drug effects. In addition, there has been a dramatic change in the evidence of consumers’ use of tobacco products primarily for their pharmacological effects and on the tobacco industry’s knowledge of nicotine’s pharmacological effects and deliberate manipulation of nicotine levels. The new evidence on these issues fully warrants a change in position.

Tobacco industry comments further assert that tobacco industry research or studies comparable to such research were available in published scientific literature before 1980. The Agency notes that none of the evidence of tobacco industry research on nicotine was presented to the Agency in support of the ASH petitions. The fact that a few pieces of this evidence existed in 1980 but were never collected in one place or brought to the Agency’s attention, moreover, is clearly not equivalent to the overwhelming accumulation of newer evidence before the Agency today, especially when coupled with the recent virtual consensus reached by the scientific community regarding the addictive nature of nicotine.

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Similarly, some comments assert that, because ASH alleged in 1977 that nicotine was addictive and that many consumers used cigarettes to satisfy addiction, there has been no change to justify a new policy. ASH's allegations, however, did not constitute evidence. FDA must make its decisions on the basis of well-founded scientific facts. Today there is a well-founded consensus that nicotine is addictive in a huge proportion of its consumers. Neither the consensus nor the data to support it existed when FDA responded to the ASH petitions.

2. Comments both in favor of and opposed to the Agency's changed position discuss the current applicability of *Federal Trade Commission v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D.N.Y. 1952), *aff'd mem.*, 203 F.2d 955 (2d Cir. 1953). One comment explained that the *Liggett & Myers* decision underscores the dramatic change in the quality and quantity of the evidence over the decades. The Agency agrees with that comment. The *Liggett & Myers* court, whose decision predated the 1964 Surgeon General's Report, found that the "soothing" properties of cigarettes were insufficient to establish that cigarettes were intended to affect the structure or function of the body. *Id.* at 576-577 ("[M]any things soothe the troubled mind of modern man and I do not feel that this is the type of effect which the statute contemplates."). No evidence was presented to the court to show that any "soothing" effects of cigarettes were due to nicotine or were even pharmacological in nature. FDA's current initiative is not based on unspecified "soothing" properties of cigarettes, but on the significant pharmacological effects of the drug nicotine, including its addictive effects, consumer use of tobacco for these effects, and on the tobacco industry's knowledge of nicotine's effects and its deliberate manipulation of nicotine delivery.

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3. One public interest group comment asserts that there need not be any change in the underlying evidence for FDA to revise its application of the Act; disagreement with the prior policy alone is sufficient. The Agency agrees that the case law supports this proposition. *See, e.g., Rust*, 500 U.S. at 187; *Chevron*, 467 U.S. at 865. The Agency's change in position is fully justified, however, by the overwhelming new evidence that has become available to FDA since 1980. The Agency also notes that a change in the case law can justify a change in position and that new case law on "intended use" since 1980 provide further support for the Agency's determination that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

4. One comment argues that public attention on the health consequences of tobacco has changed its focus over the decades from tar content to nicotine addiction. That is, until the mid-1980's, public perception of the dangers of cigarette smoking was on tar and the components of tar rather than on the addictiveness of nicotine. The Agency finds that this historical point further supports the Agency's changed position regarding its jurisdiction over tobacco products without claims.

5. One comment states that new disclosures since the issuance of the Jurisdictional Analysis provide further support for FDA's assertion of jurisdiction. The Agency agrees that the evidence demonstrating that manufacturers of tobacco products intend to affect the structure and function of the body has continued to accumulate.

In sum, after review of all of the comments, the Agency finds that a change in FDA's position on jurisdiction over cigarettes and smokeless tobacco is warranted by the new evidence.

V.A.

V. CONGRESS HAS NOT PRECLUDED OR PREEMPTED FDA FROM REGULATING CIGARETTES AND SMOKELESS TOBACCO

The comments of the tobacco industry and others assert that Congress has precluded or preempted the Agency from regulating cigarettes and smokeless tobacco. As described in this section, the Agency disagrees. Contrary to the position of the tobacco industry, Congress has neither expressly nor impliedly preempted or precluded FDA from regulating tobacco products. The language of the Federal Food, Drug, and Cosmetic Act (the Act) does not preclude FDA jurisdiction. Indeed, the history of FDA's regulation of tobacco shows that Congress understood that FDA could regulate tobacco products when an intent to affect the structure or function of the body is established. Moreover, FDA's assertion of jurisdiction is fully consistent with the narrowly crafted preemption provisions in the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act and with the existence of other statutes that address tobacco products.

A. THE PLAIN LANGUAGE OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DOES NOT PRECLUDE FDA JURISDICTION OVER TOBACCO PRODUCTS

"[T]he first place where we must look to see if Congress has spoken to the issue with which we are concerned and whether congressional intent in that regard is clear is the face of the statute." *Kofa v. INS*, 60 F.3d 1084, 1088 (4th Cir. 1995); *see also Time Warner Cable v. Doyle*, 66 F.3d 867, 875 (7th Cir. 1995), *cert. denied*, 116 S. Ct. 974 (1996). In the instant case, the express language of the Act does not exclude tobacco products from FDA's jurisdiction. The key language that defines drugs and devices as products "intended to affect the structure or any function of the body" nowhere excludes

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tobacco products. Because Congress has not excluded tobacco products from the drug and device definitions under the Act, it cannot be said to be clear that Congress intended to preclude FDA from regulating cigarettes and smokeless tobacco. *See Central Bank of Denver v. First Interstate Bank of Denver*, 114 S. Ct. 1439, 1448 (1994) (Congress knows how to enact legislation expressly).

Congress is able to exclude and has excluded specific products, including tobacco products, from a statute's reach when it wishes to do so. For example, Congress has expressly excluded other products from FDA's jurisdiction under the Act. *See, e.g.*, 21 U.S.C. 321(i) (excluding "soap" from definition of "cosmetic"); 21 U.S.C. 392 (excluding meat products to the extent that they are covered by the Meat Products Inspection Act); 21 U.S.C. 321(s) (excluding pesticides from the definition of food additive under certain circumstances). Moreover, Congress has expressly excluded tobacco products from the reach of other regulatory statutes. *See* 15 U.S.C. 2052(a)(1)(B) (excluding "tobacco and tobacco products" from the definition of "consumer products" in the Consumer Product Safety Act); 15 U.S.C. 1261(f)(2) (excluding "tobacco and tobacco products" from the definition of "hazardous substance" in the Federal Hazardous Substances Act); 15 U.S.C. 2602(2)(B)(iii) (excluding "tobacco or any tobacco product" from the definition of "chemical substance" in the Toxic Substances Control Act); 21 U.S.C. 802(6) (excluding "tobacco" from the definition of "controlled substance" in the Controlled Substances Act); 15 U.S.C. 1459(a)(1) (excluding "tobacco or tobacco product" from the definition of "consumer commodity" in the Fair Packaging and Labeling Act). Indeed, tobacco is excluded from the definition of "dietary supplement" under the Act, but no similar exclusion appears in the definition of "drug" or "device." *See* 21 U.S.C. 321(g), (h), (ff).

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Accordingly, the absence of an express exclusion from the Act for tobacco demonstrates that Congress has chosen not to exclude from FDA's jurisdiction tobacco products that fall within the Act's definitions of "drug" or "device." Because Congress chose not to exclude tobacco products from the reach of the Act, the Agency need not read an exemption into the Act administratively.

B. THE LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DEMONSTRATES THAT FDA'S JURISDICTION OVER TOBACCO PRODUCTS IS NOT PREEMPTED OR PRECLUDED

Several comments from the tobacco industry and others assert that FDA lacks jurisdiction over cigarettes and smokeless tobacco without therapeutic claims because FDA communicated its prior position to Congress and Congress "acquiesced" in that interpretation by failing to enact legislation expressly authorizing FDA to regulate tobacco without therapeutic claims. These comments cite to unenacted legislation that, if passed, would have explicitly granted jurisdiction over tobacco products to FDA, and they contend that Congress' failure to enact these bills demonstrates that Congress concluded that FDA should not have jurisdiction over cigarettes. These comments variously rely on *Flood v. Kuhn*, 407 U.S. 258 (1972), *Zemel v. Rusk*, 381 U.S. 1, 11 (1965), *United States v. Rutherford*, 442 U.S. 544 (1979), *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 274-275 (1974), *United States v. Leslie Salt Co.*, 350 U.S. 383, 396-397 (1956), and *Ruhe v. Bergland*, 683 F.2d 102, 104 (4th Cir. 1982).

FDA disagrees with these comments on three independent grounds. Congress' failure to enact legislation explicitly granting FDA authority over tobacco products does not preclude FDA's assertion of jurisdiction over tobacco products because: (1) Congress

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has long known that FDA asserts jurisdiction over tobacco products that are intended to affect the structure or function of the body and has taken no action to alter this interpretation of FDA's jurisdiction; (2) even if Congress has acquiesced in an interpretation that FDA lacks jurisdiction, the Supreme Court has made clear that congressional acquiescence in an Agency's interpretation cannot be used to prevent the Agency from changing that interpretation; and (3) the Supreme Court has rejected the argument that Congress' failure to adopt legislation or amendments to a statute can be used to interpret a law adopted by a prior Congress.

First, the Agency does not agree that Congress has ratified or otherwise acquiesced in an interpretation of the Act that precludes FDA regulation of cigarettes and smokeless tobacco that are intended to affect the structure or function of the body. As discussed in section IV., above, FDA has long exercised legal authority to regulate tobacco products when the evidence established that the products had intended uses that fell within the Act's definition of a "drug." *See, e.g., U.S. Department of Agriculture Service and Regulatory Announcements, No. 13 (1914);*¹²¹⁹ *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (cigarettes claimed to reduce weight were drugs because they were intended to affect the structure or function of the body); *United States v. 46 Cartons, More or Less, Containing Cigarettes*, 113 F. Supp. 336, 338-339 (D.N.J. 1953) (cigarettes claimed to prevent respiratory diseases were drugs because they were intended to treat or prevent disease). Indeed, as the comments point out, FDA has repeatedly told Congress that a tobacco

¹²¹⁹ The USDA citation appears in the Joint Comment of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. I. at 5. *See* AR (Vol. 535 Ref. 96).

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product that falls within the definition of a drug or device because it was promoted to treat disease or to affect the structure or function of the body would be within the Agency's jurisdiction. *See, e.g., Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong., 2d Sess. 239 (1972) (FDA Commissioner Charles C. Edwards testified that "cigarettes and other tobacco products would be drugs subject to the Federal Food, Drug, and Cosmetic Act if medical claims are made for the product . . . [or] if recommended for use in controlling appetite . . .").

Second, even if the Agency had consistently interpreted the Act to preclude FDA regulation of tobacco products even when they were intended to affect the structure or function of the body, the legislative history cited by the tobacco industry would not preclude FDA from changing its interpretation. Acquiescence in an agency interpretation can be used only to confirm that an agency is acting within its authority, not to prevent an agency from changing its interpretation. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 45 (1983) ("While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation . . . even an unequivocal congressional ratification . . . of [a prior regulatory standard] would not connote approval or disapproval of an agency's later decision to rescind the regulation") (internal citations omitted); *Massachusetts v. Secretary of Health and Human Services*, 899 F.2d 53, 61 (1st Cir. 1990) ("the ratification of one agency policy by Congress does not preclude a change in that policy"), *vacated on other grounds*, 500 U.S. 949 (1991).

Finally, it is well established that "subsequent legislative history" cannot be relied upon to interpret previous legislation. The principal evidence cited by the comments that

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Congress intended to preclude FDA jurisdiction over tobacco is unenacted legislation that, if passed, would have explicitly granted jurisdiction over tobacco products to FDA. The comments contend that Congress' failure to enact these bills demonstrates that Congress intended to exclude tobacco products from FDA's jurisdiction over drugs and devices.

FDA disagrees. Congress can implement policy in only one way: passage of a bill by the House and the Senate that is either signed by the President or approved by an overridden veto. *INS v. Chadha*, 462 U.S. 919, 954-955 (1983); *Central Bank*, 114 S. Ct. at 1453. Congress has not enacted any legislation, signed by the President or approved by an overridden veto, that excludes cigarettes and smokeless tobacco from the drug and device definitions. The comments' argument is inconsistent with *Chadha* because it would allow Congress to change the law (by inaction) without any role for the President.¹²²⁰

The gravamen of the comments' argument is that Congress' failure to modify the "drug" and "device" definitions after their original passage can be used to discern congressional intent as to the scope of those definitions. This argument has been rejected by the courts. Courts have repeatedly rejected claims that the failure of Congress to adopt legislation or amendments to a statute can be used to interpret a law adopted by a prior Congress. As the Supreme Court has explained:

We have stated . . . that failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute. Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the

¹²²⁰ In addition, under Supreme Court authority, Congress's explicit grant of jurisdiction to an agency does not necessarily indicate that the agency previously lacked jurisdiction. *United States v. New York Tel. Co.*, 434 U.S. 159, 177 n.25 (1977).

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inference that the existing legislation already incorporated the offered change.

Central Bank, 114 S. Ct. at 1453 (citations and internal quotation marks omitted); *see also Brecht v. Abrahamson*, 113 S. Ct. 1710, 1719 (1993) (“[a]s a general matter, we are reluctant to draw inferences from Congress’ failure to act”) (citations and internal quotation marks omitted); *United States v. Wise*, 370 U.S. 405, 411 (1962).

Moreover, as discussed in some comments, bills have been proposed, but not enacted, that would explicitly *exclude* tobacco products from the reach of the Act. *See, e.g.*, S. 1295, 104th Cong., 1st Sess. (1995); H.R. 2265, 104th Cong., 1st Sess. (1995); H.R. 2283, 104th Cong., 1st Sess. (1995). Under the comments’ theory, as discussed above, the fact that such legislation was proposed but not enacted would mean that Congress intends FDA to have jurisdiction over tobacco products. Therefore, because bills have been proposed but not enacted on both sides of the issue, Congress would have implicitly both granted jurisdiction to FDA and excluded jurisdiction from FDA. That result would, of course, be absurd.

Other legislative history relied on by the comments also fails to establish that FDA lacks jurisdiction over tobacco products that are intended to affect the structure or function of the body. In asserting that FDA does not have jurisdiction over tobacco products, some comments rely heavily on statements and actions in Congresses that followed the enactment of the 1938 Federal Food, Drug, and Cosmetic Act (e.g., statements by members that FDA lacks jurisdiction over tobacco products). Several comments also cite to remarks regarding FDA’s lack of jurisdiction made by individual

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members of Congress who were antismoking advocates. The comments assert that these statements are akin to admissions.

These statements are unpersuasive as evidence of Congress' intent in enacting the "drug" and "device" definitions in sections 201(g)(1)(C) and 201(h)(3) of the Act, 21 U.S.C. 321 (g)(1)(c) and 321(h)(3). The courts have made clear that informal statements by subsequent Congresses cannot negate the broad reach of the language from the 1938 Act granting FDA authority to regulate articles "intended to affect the structure or any function of the body." See *Waterman Steamship Corp. v. United States*, 381 U.S. 252, 269 (1965) ("the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one") (citations and internal quotation marks omitted); *Pennsylvania Med. Soc'y v. Snider*, 29 F.3d 886, 898 (3d Cir. 1994) ("Post-enactment legislative history is not a reliable source for guidance. Even when a subsequent House Committee has actually commented upon an earlier statute, the interpretation carries little weight with the courts") (citations and internal quotation marks omitted); *Central Bank*, 114 S. Ct. at 1452 ("the interpretation given by one Congress (or a committee or Member thereof) to an earlier statute is of little assistance in discerning the meaning of that statute") (citations and internal quotation marks omitted); *Heintz v. Jenkins*, 115 S. Ct. 1489, 1492 (1995) (where Congressman made statement after the statute became law, the statement "is not a statement upon which other legislators might have relied in voting for or against the Act, but it simply represents the views of one informed person on an issue about which others may (or may not) have thought differently").

Furthermore, as other comments argue, neither the Agency nor the congressional committees and members involved were aware, at the time when the statements and

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actions were made, of the new evidence, summarized in section II., above, showing that: (1) nicotine is highly addictive; (2) the vast majority of consumers use tobacco products to satisfy their addiction and for other pharmacological effects; and (3) the tobacco industry has long known that consumers use tobacco products for the pharmacological effects of nicotine and have facilitated these effects through manipulation of nicotine delivery. These comments contend that reliance on congressional statements or actions made before this evidence was known would reward the tobacco industry for concealing evidence about the nature of its products. Other comments assert that the legislative history cited by the tobacco industry is not dispositive in this instance because only now has FDA amassed sufficient evidence to demonstrate that nicotine in tobacco products is intended to act as a drug.

FDA agrees. Evidence that has come to light in the last few years demonstrates that cigarettes and smokeless tobacco are intended to affect the structure and function of the body. Earlier Congresses did not have access to this evidence of intended use. Thus, statements and actions by members of previous Congresses have no bearing on whether the current evidence shows that cigarettes and smokeless tobacco are within FDA's jurisdiction because they are "intended to affect the structure or any function of the body."

C. OTHER STATUTES DO NOT PRECLUDE OR PREEMPT FDA'S JURISDICTION OVER TOBACCO PRODUCTS

Several comments assert that the Federal Cigarette Labeling and Advertising Act (the Cigarette Act), 15 U.S.C. 1331-1341, and the Comprehensive Smokeless Tobacco Health Education Act (the Smokeless Act), 15 U.S.C. 4401-4408, which concern health warnings on packaging of cigarettes and packaging and advertising of smokeless tobacco

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respectively, explicitly preempt FDA action concerning the labeling or advertising of tobacco products. Other comments assert that the existence of several statutes relating to tobacco products—including the Cigarette Act and the Smokeless Act, as well as section 1926 of the Public Health Service Act—demonstrates Congress’ intent to establish a “comprehensive” tobacco regulation program that somehow implicitly precludes or preempts FDA’s regulation of cigarettes under the Act.

The Agency disagrees. None of the statutes cited either expressly or impliedly preempts FDA regulation of tobacco products generally, nor do the statutes cited conflict with the final rule. These comments have misread the Cigarette Act and the Smokeless Act. Both of these statutes contain specific provisions addressing the extent to which FDA and other Federal agencies are preempted from regulating cigarettes and smokeless tobacco. These provisions are narrowly written and do not preempt FDA from asserting jurisdiction when an intent to affect the structure or function of the body can be established. The Cigarette Act, for instance, contains two preemption provisions relating to cigarettes. The first provision is narrowly tailored in scope, applying only to “statement[s] relating to smoking and health . . . on any cigarette package.” 15 U.S.C. 1334(a). That provision is not triggered by the content of the final rule because the Agency is not requiring any statements regarding smoking and health on the cigarette package.

The Cigarette Act’s second preemption provision, which applies to the advertising and promotion of cigarettes, is expressly directed at State law: “No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in

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conformity with the provisions of this Act.” 15 U.S.C. 1334(b). If Congress had intended to preempt other Federal initiatives by this provision, it would have done so by, for example, adding the words “or Federal” between “State” and “law” in section 1334(b). In fact, Congress did just the opposite. The legislative history of the Cigarette Act establishes that Congress considered and rejected preemption of Federal regulation in the advertising preemption provision. Conf. Rep. 897, 91st Cong., 2d Sess. 2 (1970), *reprinted in* 1970 U.S.C.C.A.N. 2652, 2677. (“The House bill contained a blanket preemption (applicable to all Federal departments and agencies as well as State and local governments) with respect to requiring statements relating to smoking and health in advertisements of cigarettes The Senate preemption applied only to States and their political divisions. . . . With minor technical amendments the conference version is the same as the Senate amendment.”).

Because Congress specifically addressed the question of Federal preemption in the Cigarette Act, the Agency must follow Congress’ determination. General preemption jurisprudence (although applicable to preemption of State law, and not controlling in situations involving preemption of Federal law) also counsels against reading the express preemption provision in the Cigarette Act to extend beyond its terms. *See Cippollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (“the pre-emptive scope of the 1965 Act and the 1969 Act is governed entirely by the express language in § 5 of each Act”); *see also Medtronic, Inc. v. Lohr*, 64 U.S.L.W. 4625 (U.S. Jun. 26, 1996) (rejecting broad interpretation of preemption provision).¹²²¹ Accordingly, the Agency declines to read a

¹²²¹ See Preamble to the Final Rule, Section X., for a more detailed discussion of preemption principles.

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blanket preemption of FDA jurisdiction over cigarettes into the Cigarette Act when Congress expressly drafted a narrow preemption provision.

The preemptive reach of the Smokeless Act is also circumscribed to particular areas. *See* 15 U.S.C. 4406(a). The preemption provision in that act applies only to “statement[s] relating to use of smokeless tobacco and health” on packages and advertisements other than outdoor billboard advertisements. *Id.* This narrow provision cannot be read to preempt FDA jurisdiction, which authorizes regulation in a variety of areas unrelated to the specific statements covered by the preemption provision. As described in the preamble to the final rule, FDA is exercising its jurisdiction without imposing requirements that conflict with this provision.

Nor does the existence of other statutes that regulate tobacco impliedly preempt FDA’s regulation of tobacco under its authority to regulate drugs and devices. “It is, of course, a cardinal principle of statutory construction that repeals by implication are not favored.” *United States v. United Continental Tuna Corp.*, 425 U.S. 164, 168 (1976). Moreover, the doctrine of implied preemption has been applied only in the context of congressional preemption of *State* laws. *See, e.g., Time Warner Cable*, 66 F.3d at 874; *see also Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 396 (4th Cir. 1995) (“the doctrine of preemption is based on the Supremacy Clause of the United States Constitution,” which is used to invalidate State laws that conflict with Federal legislation), *petition for cert. filed*, 64 U.S.L.W. 3439 (US Dec. 22, 1995) (No. 95-1010). Because the matter here does not involve Federal preemption of State law, the doctrine has no applicability.

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In the absence of an express preemption provision, one Federal statute precludes giving effect to another Federal statute only where there is an irreconcilable conflict between the two laws. *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253 (1992) ("so long as there is no 'positive repugnancy' between two laws, a court must give effect to both") (citation omitted); *Morton v. Mancari*, 417 U.S. 535, 551 (1974) ("The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective"). As described in detail in the preamble to the final rule, FDA regulation of tobacco products under the authority of the Act does not conflict with other statutes in the current regulatory scheme for tobacco products, and is clearly capable of coexisting with those statutes.

The fact that FDA's jurisdiction over tobacco products may overlap with the jurisdiction of other Federal agencies is not sufficient to invalidate that jurisdiction. FDA has overlapping jurisdiction with other agencies for several products. For example, while FDA regulates pesticides with respect to their content in food, *see* 21 U.S.C. 342 (adulteration), 21 U.S.C. 343 (misbranding), 21 U.S.C. 1401 (pesticide residue monitoring), the Environmental Protection Agency (EPA) regulates the registration, use, and labeling of pesticides with respect to their effect on the environment under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., and the U.S. Department of Agriculture is charged with monitoring pesticide research and development to improve methods of pest control, 7 U.S.C. 5881. In addition, both FDA and the U.S. Department of Agriculture regulate meat and poultry products, including animal drug

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residues found within those products. Finally, FDA and the Federal Trade Commission share responsibilities for the regulation of the advertising of drugs and devices.

Other Federal agencies have overlapping and complementary jurisdiction that arises from their differing missions and expertise. *See, e.g., Rueth v. U.S. EPA*, 13 F.3d 227, 228 (7th Cir. 1993) (EPA and Army Corps of Engineers have concurrent jurisdiction under the Clean Water Act); *Public Utility Dist. No. 1 v. Bonneville Power Admin.*, 947 F.2d 386, 395 (9th Cir. 1991) (the Federal Energy Regulatory Commission has concurrent jurisdiction with other Federal agencies, as well as States, over hydroelectric projects), *cert. denied*, 503 U.S. 1004 (1992); *United Packinghouse, Food and Allied Workers Int'l Union, AFL-CIO v. NLRB*, 416 F.2d 1126, 1133-1134 n.11 (D.C. Cir.) (National Labor Relations Board and the Equal Employment Opportunity Commission have concurrent jurisdiction over racial discrimination claims), *cert. denied*, 396 U.S. 903 (1969). Accordingly, the mere fact that other agencies regulate tobacco for certain purposes does not mean that FDA lacks jurisdiction.

D. RESPONSE TO COMMENTS

Most of the comments received on this issue have been addressed in the preceding discussion. The remaining comments are addressed below.

1. Many of the comments regarding congressional intent rely primarily on attenuated inferences. For example, several comments assert that, because Congress exempted tobacco from the reach of other statutes, such an exemption should be found by implication in the Act. Similarly, another comment asserts that, because tobacco, drugs, and devices are each exempted under the Toxic Substances Control Act, Congress clearly believed that tobacco products were not drugs or devices. FDA disagrees. If the

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reasoning reflected in these comments were adopted, Congress would be legislating by inference. Moreover, as discussed previously in this section, earlier Congresses did not have access to the new evidence on the intended use of tobacco products. This change in the evidence makes it especially inappropriate to construe such specific and limited past congressional actions so expansively.

2. One comment argues that under *Flood v. Kuhn*, 407 U.S. 258 (1972), FDA is precluded from asserting jurisdiction over cigarettes and smokeless tobacco because the tobacco industry has relied on previous Agency statements that it lacked jurisdiction over tobacco products without claims.

FDA disagrees that the decision in *Flood* precludes FDA's assertion of jurisdiction over tobacco products that are intended to affect the structure or function of the body. *Flood* is inapplicable to tobacco products on at least two grounds. First, the *Flood* court, noting that baseball is "an exception and an anomaly," held that the antitrust laws could not be applied to baseball to invalidate baseball's "reserve system" for players without new legislation, based in part on baseball's "unique place in our American heritage." 407 U.S. at 266, 282. Cigarettes and smokeless tobacco occupy a very different place in American life. Tobacco products, unlike baseball, are responsible for the deaths of over 400,000 Americans each year. The Supreme Court has refused to extend the principle upheld in *Flood* beyond baseball even to other professional sports. See, e.g., *Haywood v. National Basketball Association*, 401 U.S. 1204 (1971); *Radovich v. National Football League*, 352 U.S. 445 (1957); *United States v. International Boxing Club*, 348 U.S. 236 (1955). It is inconceivable that the principle extends to bar the application of public health statutes to products previously unregulated by those statutes.

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Second, the court in *Flood* was concerned about the retroactive application of its decision to an industry that had relied on its exemption from the antitrust laws. There is no evidence that the tobacco industry has relied to its detriment on any belief that tobacco products without claims are not subject to FDA jurisdiction. In *Flood*, there was ample evidence of such reliance; the baseball industry had set up an elaborate contracting system, in place since 1887, that would plainly violate the antitrust laws, in reliance on Supreme Court holdings that baseball was exempt from those laws. The plaintiff in the case sought to have that system invalidated retroactively. The tobacco industry has pointed to no evidence of reliance in the form of actions it has taken that plainly violate the Federal Food, Drug, and Cosmetic Act and that the Agency is seeking to remedy retroactively. The industry is simply interested in maintaining its ability to sell its products free of FDA regulation. Moreover, even had the industry relied on the absence of comprehensive FDA regulation, such reliance would have been inappropriate given the tobacco industry's failure to disclose information relevant to the intended use of cigarettes and smokeless tobacco.

In fact, internal tobacco company documents show that the tobacco industry has not acted in reliance on the belief that tobacco products without claims are always outside FDA's jurisdiction. These documents disclose that members of the industry were aware that evidence other than claims could be used to declare jurisdiction over tobacco products and took steps to avoid the disclosure of such evidence. For example, a Brown & Williamson memorandum submitted to the record in this proceeding reveals that a company lawyer recommended to the president and chief executive officer of Brown & Williamson that the company not become involved in the sale of nicotine patches, stating:

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“If we did anything which suggested we were simply in the nicotine delivery business, we would run a serious risk of facing FDA jurisdiction.”¹²²² There was no suggestion in any of the submitted documents that any claims would be placed on cigarettes as a result of the company’s sale of nicotine patches. Nevertheless, the company recognized that FDA jurisdiction might follow solely based on evidence suggesting company knowledge that cigarettes are related to other nicotine delivery systems. The company ultimately chose not to become involved in the sale of nicotine patches. For these reasons, *Flood v. Kuhn* is inapplicable.

¹²²² McGraw M, *Nicotine Delivery Systems* (Apr. 24, 1992), at 1. See AR (Vol. 531 Ref. 124).

VI.

VI. FDA EMPLOYED PROCEDURES THAT PROVIDED AN OPPORTUNITY FOR FULL PUBLIC PARTICIPATION AND EXCEEDED ALL LEGAL REQUIREMENTS

The Agency went to great lengths to involve the public in the process by which the Agency made its final jurisdictional determination. On February 25, 1994, FDA Commissioner David Kessler wrote to Scott Ballin, chairman of the Coalition on Smoking OR Health, regarding the possibility of FDA regulation of cigarettes in response to certain petitions that had been filed with the Agency. The Commissioner explained:

[T]he agency has examined the current data and information on the effects of nicotine in cigarettes. . . . Evidence brought to our attention is accumulating that suggests that cigarette manufacturers may intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. . . . This evidence . . . suggests that cigarette vendors intend the obvious -- that many people buy cigarettes to satisfy their nicotine addiction. Should the agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis on which to regulate these products¹²²³

The letter was made publicly available and covered by the press.¹²²⁴

¹²²³ Letter from Kessler DA (FDA) to Ballin SD (Coalition on Smoking OR Health) (Feb. 25, 1994). See AR (Vol. 35 Ref. 365).

¹²²⁴ Neergaard L (Associated Press) FDA considers calling nicotine a drug, banning cigarettes (Feb. 26, 1994). See AR (Vol. 711 Ref. 30).

Associated Press, FDA considers classification of nicotine as drug, *Chicago Tribune* (Feb. 26, 1994). See AR (Vol. 711 Ref. 31).

Chen E, Government agency claims power to ban nearly all cigarettes; FDA fears nicotine used for addiction, *The Houston Chronicle* (Feb. 26, 1994). See AR (Vol. 711 Ref. 32).

Chen E, In shift, FDA says it could classify nicotine as a drug, *Los Angeles Times* (Feb. 26, 1994). See AR (Vol. 711 Ref. 33).

Hilts PJ, U.S. Agency suggests regulating cigarettes as an addictive drug, *New York Times* (Feb. 25, 1994). See AR (Vol. 711 Ref. 34).

Tribune News Services, *The Salt Lake Tribune* (Feb. 26, 1994). See AR (Vol. 711 Ref. 35).

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In the months that followed, Commissioner Kessler testified twice before Congress regarding the accumulating evidence relating to the intended use of cigarettes.¹²²⁵ That testimony was extensive and detailed.

In July and August of that year, FDA Associate Commissioner for Regulatory Affairs Ronald G. Chesemore wrote to all of the major cigarette and smokeless tobacco companies requesting all documents relating to “all research on nicotine . . . , including their pharmacological effects, and all documents relevant to nicotine” in their products.¹²²⁶ On August 1, 1994, FDA held a Drug Abuse Advisory Committee meeting that was fully open to the public on the subject of the abuse potential of nicotine.

On August 11, 1995, FDA provided the public with an extensive *Federal Register* document analyzing the Agency’s authority to assert jurisdiction over cigarettes and smokeless tobacco based on the evidence before the Agency at that time. *See* Jurisdictional Analysis, 60 FR 41453–41787. This document, which accompanied the Agency’s announcement of its proposal to regulate the sale and distribution of cigarettes and smokeless tobacco, *see* 60 FR 41314–41375, provided the public with a full view of

FDA claims authority to regulate nicotine; agency cites manipulation of cigarette ‘drug,’ *St. Louis Post Dispatch* (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 36).

Schwartz J, In policy shift, FDA is ready to consider regulating tobacco, *The Washington Post* (Feb. 26, 1994). *See* AR (Vol. 711 Ref. 37).

¹²²⁵ Statement by David Kessler, M.D., Commissioner of Food and Drugs, on Nicotine-Containing Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (Mar. 25, 1994). *See* AR (Vol. 1 Appendix 7).

Statement by David Kessler, M.D., Commissioner of Food and Drugs, on the Control and Manipulation of Nicotine in Cigarettes, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives (Jun. 21, 1994). *See* AR (Vol. 1 Appendix 8).

¹²²⁶ *See, e.g.,* Letter from Chesemore RG (FDA) to Bible GC (Philip Morris Inc.) (Jul. 11, 1994) *See* AR (Vol. 1 Appendix 3)

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the Agency's legal analysis. In addition, the Jurisdictional Analysis was supported by over 600 footnotes, each of which identified for the public the evidence on which the Agency relied to support its findings. The Agency also placed on the record 313 pages of appendices related to the Jurisdictional Analysis.

On August 16, 1995, the Agency put on public display some 20,000 pages of materials that it cited in the Jurisdictional Analysis and the proposed rule. With the exception of three documents, discussed below, the Agency made available to the public all of the materials on which it relied to support the Jurisdictional Analysis and the Proposed Rule. On September 29, 1995, the Agency supplemented the administrative record by putting on public display approximately 13,000 documents comprising some 190,000 pages of factual and analytical materials the Agency considered in the course of issuing the Jurisdictional Analysis and the Proposed Rule. Although it was under no legal obligation to do so, the Agency made these additional materials available because of the importance of the jurisdictional issue and the Proposed Rule.

The administrative record also includes the comments received from the public, as discussed in more detail below. The Agency received over 700,000 comments, some directed to the Jurisdictional Analysis, some directed to the Proposed Rule, and many with overlapping discussions. Though many comments consisted of form letters, the Agency received over 95,000 distinct or unique sets of comments. The cigarette manufacturers jointly submitted 2,000 pages of comments and 45,000 pages of exhibits. The smokeless tobacco manufacturers jointly submitted 474 pages of comments and 3,372 pages of exhibits. The initial comment period remained open for 144 days.

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The Agency also made one other significant addition to the public record relating to its jurisdictional determination. On March 20, 1996, the Agency published a notice in the *Federal Register* providing an additional 30 day comment period limited to specific documents the Agency added to the docket in support of its Jurisdictional Analysis. See 61 FR 11419. These materials consisted of declarations and a report from three former tobacco industry employees.

In addition, as discussed further below, the Agency has added to the final record of the jurisdictional determination a comparatively small number of documents that expand upon or confirm information made available in the Jurisdictional Analysis or the Proposed Rule, or that address alleged deficiencies in the Agency's initial record.

Despite the Agency's efforts to involve the public in this jurisdictional determination, FDA received several comments regarding the procedures the Agency followed in publishing the Jurisdictional Analysis. Some of these comments complained that the Agency designated certain documents in the administrative record supporting the Jurisdictional Analysis as "confidential," and that the shielding of these documents denied the public a meaningful opportunity to comment on the Agency's analysis. One of these comments also contended that FDA refused to disclose nonconfidential information on which the Agency relied in the Jurisdictional Analysis. Some comments claimed that FDA failed to set forth a balanced view of the issues raised in the Jurisdictional Analysis. Instead, they argued, FDA concealed certain issues in order to deny the public the opportunity to comment on the Agency's analysis. At least one interested person also maintained that the comment period was so short as to be arbitrary and capricious.

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Finally, one comment objected to the Agency's use of certain affidavits and reports from former tobacco industry scientists without first providing the public an opportunity to cross-examine these individuals. However, other than this one comment on a narrow category of evidence in the administrative record, the Agency received no comments concerning, and no objection to, the Agency's decision to use a notice-and-comment type format to reach a final jurisdictional determination.¹²²⁷

As the discussion that follows demonstrates, the procedures the Agency employed in reaching its final jurisdictional determination exceeded the requirements of the APA, the case law construing the APA, and the Agency's own procedural requirements either for a jurisdictional determination or for a conventional informal rulemaking.

A. ADEQUACY OF THE RECORD

Several tobacco industry comments complained about the adequacy of the record in support of the Jurisdictional Analysis. They contended that the Agency violated the APA, 5 U.S.C. 553(b) and (c), and the Due Process Clause of the Fifth Amendment to the Constitution,¹²²⁸ by failing to disclose all of the information the Agency "considered or

¹²²⁷ Because of the unique importance of the jurisdictional issue, the Agency published the Jurisdictional Analysis in the *Federal Register* and invited comments on it. The Agency, however, was not required by the Administrative Procedure Act (APA) to invite public comment on the issue of the Agency's jurisdiction. Likewise, the Act neither requires that the Agency commence a rulemaking proceeding, nor conduct a formal evidentiary hearing, before it makes a jurisdictional determination. Nevertheless, because of the great importance of this issue, FDA employed a notice-and-comment-type procedure to give the public an opportunity to participate in the Agency's analysis of its jurisdiction. None of the comments the Agency received identified a statutory requirement that would have compelled the Agency to follow any additional or different procedures. Thus, while the Agency endeavored in its publication of the Jurisdictional Analysis to provide notice, a supportive record, and a comment period sufficient to meet the procedural requirements of the APA for informal rulemaking, the Agency was not bound by the APA's informal rulemaking procedures with respect to the Jurisdictional Analysis.

¹²²⁸ Because the APA in this context provides the public at least as much protection as the Due Process Clause of the Constitution, the Agency will address these procedural objections solely under the APA. See *Forester v. Consumer Product Safety Commission*, 559 F.2d 774, 787 (D.C. Cir. 1977); *Ass'n of National Advertisers, Inc., v. Federal Trade Commission*, 627 F.2d 1151, 1166 (D.C. Cir. 1979), cert. denied, 447 U.S. 921 (1981).

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relied upon in the proceeding.”¹²²⁹ In particular, these comments complained that the public was deprived of the opportunity to comment meaningfully on the Jurisdictional Analysis because, according to these comments, the Agency had relied on confidential documents and on substantial amounts of undisclosed data. One comment went so far as to claim that “a substantial portion” of the material FDA relied upon, both in the Jurisdictional Analysis and in the Proposed Rule, was not made available for public scrutiny.

The record in support of the Jurisdictional Analysis provided the public not only with a “reasonable opportunity” for comment, but with an extraordinary opportunity to examine the Agency’s position. The claim that the Agency withheld “a substantial portion” of the materials on which it relied is simply unfounded.

1. The Administrative Record the Agency Assembled for This Proceeding Surpassed the Requirements of the APA

Even in an informal rulemaking proceeding—which the Jurisdictional Analysis was simply modeled on—the APA requires only that the “notice of proposed rule making” include a statement of the time, place, and nature of the proceeding, “reference to the legal authority under which the rule is proposed,” and “either the terms or substance of the proposed rule or a description of the subjects and issues involved.” *See* 5 U.S.C. 553(b). The APA, thus, does not expressly require disclosure of the information on which the Agency relies in proposing a rule.

¹²²⁹ Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 1. *See* AR (Vol. 535 Ref. 96)

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Nevertheless, courts have implied under the APA a requirement that an agency give notice of the information on which it actually relies to support a proposed rule, and make that information available to the extent it is not readily accessible to the public. *See generally* K. Davis, *Administrative Law Treatise*, § 7.3 at 305-309 (3d ed. 1994) (discussing one of the seminal cases on disclosure of data relied on to support a rulemaking proceeding, *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974)). No court, however, has required the degree of public disclosure at the notice stage of a rulemaking proceeding that FDA undertook here.

Indeed, the primary cases cited by the comments, namely, *Portland Cement Ass'n, United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), and *United States Lines, Inc. v. Federal Maritime Commission*, 584 F.2d 519 (D.C. Cir. 1978), address agency conduct that bears little resemblance to FDA's efforts in this proceeding. While FDA has provided a remarkable degree of factual support and procedural openness, these cases involve instances in which agencies provided the public with no information whatsoever or otherwise excluded a study that was critical to the agency's decision. In *Portland Cement Ass'n*, the Environmental Protection Agency failed altogether to provide the public an opportunity to comment on the test results and procedures on which the agency relied as the "critical" basis for the emission control level adopted by the agency. That is, the agency set very specific technical control limits, but failed to make public until after the close of the comment period the details of crucial tests relied upon to determine the limits. 486 F.2d at 392.

In *Nova Scotia Food Products*, "all the scientific research was collected by the agency, and *none of it was disclosed* to interested parties as the material upon which the

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proposed rule would be fashioned.” 568 F.2d at 251 (emphasis added). And in *United States Lines*, where a common carrier challenged an order of the Federal Maritime Commission amending a contract between two competitors, the court found that the Commission had made “critical findings” on the basis of data which was neither identified in its decision nor included in the administrative record. Rather, the Commission based its decision on “reliable data reposing in the Commission’s files.” 584 F.2d at 533. The reviewing court simply had no idea of the factors or data on which the Commission had relied. *Id.*

Thus, at most, the case law requires agencies to disclose studies and data actually relied upon by the agency. Even then, the cases that have struck down agency rulemaking are generally confined to instances in which the agency provided woefully inadequate information to the public or failed to disclose a critical piece of information. *See, e.g., Kennecott Corp. v. Environmental Protection Agency*, 684 F.2d 1007, 1018-1019 (D.C. Cir. 1982) (agency acted arbitrarily and capriciously when it failed to include in the public docket during the comment period any documents supporting a particular proposed regulation); *compare Personal Watercraft Industry Ass’n v. Department of Commerce*, 48 F.3d 540, 544-545 (D.C. Cir. 1995) (while agency must disclose information critical to its decision to regulate a particular activity, absent prejudice an agency may rely on studies developed after close of comment period that are not critical to the underlying proposal).

Finally, FDA’s own procedural regulations require that the Agency include with a notice of proposed rulemaking, among other things, “references to all *information on which the Commissioner relies for the proposal.*” 21 CFR 10.40(b)(vii) (emphasis added); *see* 21 CFR 10.3 (defining the term “administrative record” to mean the materials on

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which the Agency “relies to support the action”). Thus, even under the Agency’s own procedural regulations, FDA is required—when it initiates informal rulemaking—to supply the public only with the materials the Agency is relying upon to support the proposed action.

Here, the materials the Agency relied upon at the opening of this proceeding are the materials the Agency cited in the two August 11, 1995, *Federal Register* documents. Not only did the Agency provide these materials to the public, but it also provided the roughly 190,000 pages of factual and analytical materials the Agency considered but did not rely on and, hence, did not reference in either the Jurisdictional Analysis or the Proposed Rule. Moreover, the Agency provided over 1000 endnotes and footnotes directing readers to each document, including every study, government report, journal article, industry document, and Agency record on which FDA relied to support the Jurisdictional Analysis and the Proposed Rule.

Out of all of this material, the only nonpublic materials on which the Agency relied in its Jurisdictional Analysis were two confidential documents¹²³⁰ and two lines of text the Agency redacted from a document placed on the public Administrative Record.¹²³¹ None

¹²³⁰ The two confidential documents the Agency directly referenced, which are discussed in detail in the text, are the 1991 *Handbook on Leaf Blending and Product Development* (Confidential Document 75) and the unredacted summary of notes of FDA trip visits (Confidential Document 74). The summary was compiled from notes and handouts that are also designated as confidential (Confidential Documents 69, 70, 71, 72 and 73). The Agency views the summary as a stand-alone document to the extent it distills a large volume of disparate handwritten notes and handouts. Also, the Agency cited only to the summary itself. Nevertheless, even if the summary were counted as five documents rather than one, the Agency at most relied for support on six confidential documents.

¹²³¹ On page 255 of the Jurisdictional Analysis (60 FR 41716), the Agency redacted several lines of text along with a footnote that identified the sources for the redacted text. The footnote consisted of references to two sources, both of which appeared on the agency’s public docket: Kiefer JE, Tennessee Eastman Company, *Cigarette Filters for Altering the Nicotine Content of Smoke* (Report No. 71 5003 7), Aug. 18, 1971 at 1-2, *See AR* (Vol. 28 Ref. 463-1); and Curran Jr. JG, Miller EG, Factors influencing the elution of high boiling components of cigarette smoke from filters, *Beitr. Tabakforsch* 1969;5:67, *See AR* (Vol.

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of these documents is pivotal in that none provides the sole or principal basis for the Agency's conclusion that cigarettes and smokeless tobacco are intended to affect the structure and function of the body under the Act. Further, as discussed below, the decision to keep these materials confidential did not undermine the quality of the public participation in the Agency's jurisdictional determination. In sum, the procedures the Agency followed in assembling a public record in support of this jurisdictional determination are not analogous to the facts described in cases like *Portland Cement Ass'n*, *Nova Scotia Food Products*, and *United States Lines*.

2. The Agency's Use of Confidential Documents

a. Confidential Documents on Which the Agency Did *Not* Rely

The Agency placed in a confidential docket 75 documents from the approximately 210,000 pages of materials the Agency made available at the opening of the jurisdictional determination and the companion rulemaking proceeding. The Agency identified each of these 75 documents for the public in an index filed on September 29, 1995, on the public docket. See 60 FR 66981, 66982 (Dec. 27, 1995). Of these 75 documents, 73 were not even relied upon by the Agency to support either the Proposed Rule or the Jurisdictional Analysis.

Sixty-one of these 73 confidential documents consisted either of commercial information and trade secrets which the industry urged FDA to keep confidential (Confidential Documents 1-12, 16-21, 62-73), or unpublished manuscripts for which the Agency lacked the authors' permission, as of September 29, 1995, to publicly release

28 Ref. 463-2). The Kiefer document appeared on the public docket with certain trade secret and confidential information redacted from the document. The Curran document was made available to the public in full.

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(Confidential Documents 22-52). The remaining twelve documents were either proprietary reports and other copyrighted information—such as financial reports generated by Dun and Bradstreet—which the Agency lacked permission to reprint (Confidential Documents 13-15, 53-58), or confidential documents that support a pending new drug application (Confidential Documents 59-61).

Again, the Agency did not rely on any of these 73 documents as support for the Jurisdictional Analysis. Therefore, the Agency was not even required to include these documents in the administrative record. *See* 21 CFR 10.40(b)(vii). It likewise follows that because the Agency did not rely upon these documents, the decision to protect them cannot be said to have unfairly interfered with the public's ability to question the Agency's Jurisdictional Analysis. *See Mid-Tex Electric Cooperative, Inc. v. Federal Energy Regulatory Commission*, 773 F.2d 327, 344 (D.C. Cir. 1985) (agency's failure to disclose two studies was "manifestly harmless" because the agency did not rely on the studies to support any finding or conclusion); *Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 843 (D.D.C. 1992) (there is no violation of the APA's notice requirements where the agency has declined to disclose materials on which it did not rely in proposing the rule); *B. F. Goodrich Co. v. Dept. of Transportation*, 541 F.2d 1178, 1184 (6th Cir.) (only the basic data "upon which the agency relied in formulating the regulation" must be published for public comment), *cert. denied*, 430 U.S. 930 (1976); K. Davis, *Administrative Law Treatise*, § 7.3 at 307 (3d ed. 1994) ("If an agency does not attempt to support its final rule by reference to an undisclosed study, it seems apparent that the agency was not required to make the study available to potential commentators"). The fact that the Agency went well beyond existing requirements to

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make publicly available thousands of additional documents for public review—in recognition of the uniqueness and public importance of this proceeding—should not be used now as a basis for suggesting that the Agency was under a legal obligation to disclose publicly all information that it had at hand.

Finally, at the close of this jurisdictional determination and the companion rulemaking proceeding, the Agency will supplement the public docket with copies of those confidential items for which the Agency previously lacked permission to publish, but for which permission has now been granted. Most of the unpublished manuscripts in the confidential docket—none of which were relied upon by the Agency to support last year's Jurisdictional Analysis—will be available through this addition to the public record.

b. Confidential Information on Which the Agency Relied

In support of the Jurisdictional Analysis, FDA relied on only 2 of the 75 documents designated as confidential: a summary of notes taken by FDA investigators during site visits to manufacturing plants run by Brown & Williamson, Philip Morris, and R. J. Reynolds (Confidential Document 74); and a 1991 Brown & Williamson handbook on leaf blending and product development (Confidential Document 75).¹²³² The Agency described the two confidential documents cited in the Jurisdictional Analysis in an index made available to the public on September 29, 1995. In addition, the Agency relied on

¹²³² The Agency did not attribute ownership of the handbook in the Jurisdictional Analysis, or in the September 29, 1995, index to the administrative record. However, in a set of comments filed by Brown & Williamson, the company itself acknowledged publicly its ownership of the handbook. Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 37-38. See AR (Vol. 529 Ref. 104).

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two lines of text that it redacted from a document regarding cigarette filters that the Agency placed on the public docket.¹²³³

The Agency placed in the confidential docket the summary of notes at the request of Brown & Williamson, Philip Morris, and R. J. Reynolds, each of whom urged the Agency to keep confidential their commercial information and trade secrets. *See* 60 FR 66981 (Dec. 27, 1995). Brown & Williamson likewise vigorously urged the Agency not to put its leaf blending handbook on the public docket.¹²³⁴ These same companies have now commented that it was improper for the Agency to rely on this information because the information “cannot be subjected to comment by interested parties.”¹²³⁵

The Agency disagrees that its decision to place in the confidential docket these two documents (out of 20,000 pages of documents the Agency cited in support of its position), or rely on two lines of redacted text from a document the Agency made available to the public, in any way undermined the public’s ability to comment on the Agency’s Jurisdictional Analysis. Nor does the Agency agree that its reliance in this proceeding on confidential commercial information or confidential industry trade secrets violated the APA.

¹²³³ *See* Kiefer JE, Tennessee Eastman Company, *Cigarette Filters for Altering the Nicotine Content of Smoke* (Report No. 71 5003 7), Aug. 18, 1971, at 1-2. *See* AR (Vol. 28 Ref. 463-1). Although the Agency also redacted from the document the confidential measurements of the effects of filter additives on nicotine content in cigarettes smoke, the Agency did not directly rely on these measurements in the text of the Jurisdictional Analysis.

¹²³⁴ Letter from Krulwich AS (counsel to Brown & Williamson) to Porter MJ (FDA) (Jan. 11, 1996). *See* AR (Vol. 711 Ref. 38).

¹²³⁵ Joint Comments of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 14. *See* AR (Vol. 535 Ref. 96).

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First, none of the authorities cited in the comments supports the proposition that agencies, even in a rulemaking context, are precluded from considering or relying upon privileged documents. To the contrary, several courts have indicated that reliance on protected documents in an informal rulemaking proceeding is permissible. *See Home Box Office, Inc. v. Federal Communications Commission*, 567 F.2d 9, 58 n.130 (D.C. Cir.) (stating, in *dicta*, that “it is conceivable that trade secrets . . . if proffered as the basis for rulemaking, should be kept secret. *Cf.* 5 U.S.C. 552.”), *cert. denied*, 434 U.S. 829 (1977); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 251 (2d Cir. 1977) (“We can think of no sound reasons for secrecy or reluctance to expose to public view (*with an exception for trade secrets or national security*) the ingredients of the deliberative process” (emphasis added)).

Second, the Agency put the confidential materials on which it relied in sufficient context so that the public could comment on, and challenge, the Agency’s use of the material. With respect to the handbook, the Agency quoted from the document in several instances in the Jurisdictional Analysis. *See* 60 FR 41453, 41710–41711; 60 FR 41453, 41510–41511. The Jurisdictional Analysis also incorporated testimony before the House Subcommittee on Health and the Environment of the Committee on Energy and Commerce on June 21, 1994, in which the Commissioner discussed the content of the handbook and quoted from relevant portions. *See* 60 FR 41453, 41710–41711 and nn. 443-447. In both settings, the Agency made the language from the handbook on which the Agency relied available, and carefully explained how these portions of the handbook were relevant to the overall proceeding. Thus, while the Agency kept the bulk of the document confidential, it provided as much actual content and context as possible to allow

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for meaningful public comment on the quoted passages. In the end, the only comments the Agency received regarding the decision to keep the handbook confidential were from tobacco industry trade associations with whom Brown & Williamson jointly submitted comments. No other commenter objected to the Agency's reliance on the handbook or the way the Agency safeguarded information the industry regarded as confidential.

As for the summary of notes (Confidential Document 74), the Agency assembled this document from handwritten notes recorded by FDA employees during site visits in March, April, and May 1994 to Brown & Williamson, Philip Morris, and R. J. Reynolds, as well as handouts distributed by R. J. Reynolds and Philip Morris during those visits. During these visits, company representatives requested that FDA employees not disclose certain confidential commercial and trade secret information. The Agency, in an effort to accommodate this request, withheld from the public docket trade secret or confidential commercial information provided to the Agency.

As with the handbook, the Agency is not persuaded that the public has been prejudiced by the decision to withhold this comparatively small amount of information. Again, the Agency presented the notes in context to allow the public to see precisely what points they were being used to support. *See* 60 FR 411453, 41704–41719. The Agency also put on the public docket the original handwritten notes from these visits (less the redactions needed to protect information the companies regarded as confidential), so that the public could see as much of what transpired as possible and understand the full context of the protected information. As with the handbook, nonindustry commenters did not object to this procedure.

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Finally, with respect to the Tennessee Eastman document, the Agency placed the document on the public docket, but redacted the two lines of text that identified the name of a manufacturer who used polyethylene glycol in cigarette filters, resulting in a higher nicotine delivery than from other cigarettes. The text that identified the name of the manufacturer (both as it appeared in the Jurisdictional Analysis and in the Tennessee Eastman document), was redacted from public view to protect that firm's confidential commercial information and its trade secrets. The balance of the text of the Tennessee Eastman document, as well as the balance of the text of the Jurisdictional Analysis, gave the public ample opportunity to comment on the Agency's findings regarding "the use of filter additives to enhance nicotine delivery." 60 FR 41453, 41715.

In sum, the Agency carefully developed a mechanism to accommodate the industry's need to protect its confidential commercial information and its trade secrets, while at the same time providing ample notice to the public of the information on which it relied in this proceeding. Based on the quality and quantity of comments received, and based on the lack of objection from other commenters, the Agency is not persuaded that its decision to rely on confidential information prejudiced the public's ability to participate in the Agency's jurisdictional determination. Rather, the lack of comment from the public at large confirms that the Agency struck a reasonable balance between the need for public process, the need to protect trade secrets and confidential commercial information, and, of course, the need to protect the public health.

3. The Claim that FDA Relied on “Unknown” Undisclosed Data

A tobacco industry comment claimed that the Agency withheld certain data and calculations used to construct a series of charts showing that nicotine and tar levels in smoke have risen steadily from 1982 to 1991. *See* 60 FR 41728–41731.

As the comment acknowledges, the Agency relied on summaries of industry-supplied data gathered by the FTC to construct these charts. *See* 60 FR 41727–41731.

The comment claims, however, that the Agency relied on “unknown” data to construct the tar and nicotine yields for the years 1982 and 1984–86.¹²³⁶ According to the comment, the FTC did not generate data for these years. The industry comment also questions where the Agency obtained the sales figures used to calculate weighted averages, how the Agency calculated these averages, and why the Agency’s figures did not always track those of the FTC.

The industry raised precisely the same issues in a December 8, 1995, letter to the Agency. In a December 27, 1995, response, FDA identified the specific documents in the administrative record that address each concern.¹²³⁷

The only issue not fully resolved by that exchange of correspondence is the industry’s claim that FDA’s figures for 1990 and 1991 reflect fewer brands than FTC reported on for those years. As the Agency stated in its December 27 letter, it is not apparent from the face of the charts what, exactly, the industry association is referring to.

¹²³⁶ Joint Comments of the Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 3. *See* AR (Vol. 535 Ref. 96).

¹²³⁷ *See* Letter from Schultz WB (FDA) to Merrill R (Covington and Burling) (Dec. 27, 1995). *See* AR (Vol. 711 Ref. 7).

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Although the association acknowledges this exchange of correspondence in its January 2, 1996, comments, it failed to provide any greater specificity in its comments than it did in the December 8 letter.

FDA based its charts on sales-weighted averages calculated by the FTC based on industry-supplied data. In most years, the FTC publishes this data in two reports: one on sales volume and one on tar, nicotine, and carbon monoxide content. Some manufacturers, however, fail from time to time to report to the FTC for each brand on all three of the values of interest to FDA, namely, tar, nicotine, and sales volume. The FTC, therefore, excluded from the sales-weighted averages it supplied to FDA any brand for which the manufacturer failed to supply data on any of the three values of interest to FDA. That is why, in 1990 and 1991, the points FDA plotted on its graphs reflect fewer brands than the total number of brands that the FTC reported on in those years. *See* section II.C.6.c.ii., above.

The decision to exclude in 1990 and 1991 brands for which FTC lacked complete data was reasonable. The slight variation between FDA's figures and FTC's figures for 1990 and 1991 are not the result of FDA having relied on "unknown" or "undisclosed" data. Rather, FDA has made publicly available all of the information necessary to allow for meaningful comment on these charts.

4. The Claim That FDA Failed To Include in the Record NDA Data on Which It Relied

One comment claimed that the Agency relied on studies in seven new drug applications (NDA's) for the proposition that a high proportion of smokers are addicted to nicotine, but failed to make adequate disclosure of these NDA's. In particular, this

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comment stated that the Agency failed to include any information in the public docket for NDA 18-612 (Nicorette gum, 2 mg) and NDA 20-385 (Nicotine nasal spray), and included only summaries for five other NDA's the Agency cited. As discussed below, FDA did in fact include in the public docket sufficient information regarding the NDA's on which it relied. As for the particular NDA studies the Agency referenced, the relevant data in support of these studies was recounted in sufficient detail in Appendix 1 to the Jurisdictional Analysis to provide the public a meaningful opportunity to comment.

a. The Agency's Reference to Five NDA's

With respect to NDA 18-612 (Nicorette gum, 2 mg), the Agency did not rely on the NDA for this product in either the Proposed Rule or the Jurisdictional Analysis. *See* 60 FR 41549, n.62 (citing only to NDA 20-076 Habitrol, NDA 20-150 Nicotrol, NDA 19-983 ProStep, NDA 20-165 Nicoderm, NDA 20-066 Nicorette, 4 mg); *see also* 60 FR 41550, n.64 (citing only to the same five NDA's listed in footnote 62 of the Jurisdictional Analysis). Therefore, the Agency is under no obligation to include in the public record the NDA itself or a summary of the application.

With respect to NDA 20-385 (Nicotine nasal spray), the Agency similarly did not rely on the NDA for this product in either the Jurisdictional Analysis or the proposed rule. *See* 60 FR 41549, n.62 and 60 FR 41550, n.64. While the Agency did discuss an aqueous nicotine nasal spray in the Jurisdictional Analysis, the Agency did not rely on the NDA itself to support its point. Rather, the Agency relied on the discussion of the nasal spray at an August 1994 FDA Drug Abuse Advisory Committee meeting. The relevant portions of the transcript, cited in footnote 116 in the Jurisdictional Analysis, and the background materials provided to the advisory committee, cited in footnote 117, were included in the

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public record.¹²³⁸ See 60 FR 41565, n.116 and n.117. The only other reference to the nasal spray in the Jurisdictional Analysis is at 60 FR 41569, where again the Agency relied on a statement offered at the August 1994 advisory committee meeting, not on the NDA itself. 60 FR 41569 and n.126. Therefore, all the materials relating to the nasal spray on which the Agency relied in the to the Jurisdictional Analysis are in the public docket.

As for the five NDA's the Agency cited in footnotes 62 and 64 of the Jurisdictional Analysis, the Agency put into the administrative record an extensive summary, prepared at the time of approval, for each of these NDA's.¹²³⁹ Given the volume of materials that make up each of these NDA's, and the limited purpose for which the Agency was relying on them, see 60 FR 41549-41550, it was appropriate for the Agency to include only the summaries. See *National Ass'n of Pharmaceutical Mfrs. v. Department of Health and Human Services*, 586 F. Supp. 740, 755-756 (S.D.N.Y. 1984). A complete NDA can run into the tens of thousands of pages, particularly when one includes the records which must be kept for each patient enrolled in each clinical trial. Putting this volume of materials on the record in this instance would serve no useful purpose. Instead, the Agency included on the record the summaries it prepared in anticipation of approving each of these smoking cessation products as safe and effective. The summaries themselves are peer reviewed within the Agency to ensure that they thoroughly and accurately discuss each of

¹²³⁸ Kramer ED, Transcript of testimony before the Drug Abuse Advisory Committee (Aug. 1, 1994). See AR (Vol. 9 Ref. 116).

FDA Drug Abuse Advisory Committee Background Information, Joint Abuse Liability Review of Nicotine Nasal Spray (Aug. 1, 1994). See AR (Vol. 9 Ref. 117).

¹²³⁹ NDA 20-076 Habitrol (CIBA); NDA 20-150 Nicotrol (Kabi); NDA 19-983 ProStep (Elan); NDA 20-165 Nicoderm (Alza); NDA 20-066 Nicorette (Merrell Dow). See AR (Vol. 6 Refs. 62-63).

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the studies on which the approval is based. They generally provide more detail about a sponsor's underlying clinical data and methodology than one would expect to find in published peer-reviewed medical literature.

As discussed in greater detail, below, notice is sufficient under the APA when it provides the public a "reasonable opportunity" to participate in the proceeding. *Forester v. Consumer Product Safety Commission*, 559 F.2d 774, 787 (D.C. Cir. 1977). This is not an instance in which the Agency failed to explain the technical basis for its position, failed to disclose its reasoning, or otherwise failed to identify and make available the data on which it relied to reach a particular conclusion. See *Connecticut Light and Power Co. v. Nuclear Regulatory Commission*, 673 F.2d 525, 530-532 (D.C. Cir. 1982). Rather, the summaries the Agency placed on the public docket provided detailed access to the pivotal data on which the Agency relied in approving these NDA's. Even more, the summaries identified the very data on which FDA relied in this proceeding to support the position that nicotine replacement therapy helps reduce withdrawal symptoms in smokers trying to quit, and that participants enrolled in clinical studies of nicotine replacement therapy demonstrated addiction to nicotine. 60 FR 41453, 41459-41460. This is also the data on which the Agency relied to support the position that the efficacy of nicotine replacement therapy shows that most smokers are indeed addicted to nicotine. *Id.* at 41459. Thus, these summaries provided the public with ample access to the information needed to comment meaningfully on the Agency's position.

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b. The Agency's Reference to Nineteen Smoking Cessation Studies

FDA prepared Appendix 1 to the Jurisdictional Analysis to provide the public with background materials supporting the Agency's scientific judgments with respect to nicotine pharmacology. In that Appendix, the Agency discussed a number of smoking cessation studies, including 19 studies submitted in support of the NDA's for Habitrol, Nicotrol, ProStep, Nicoderm, Nicorette (4mg), Nicorette (2 mg), and nicotine nasal spray.¹²⁴⁰

The Agency referenced these studies as yet another way to demonstrate that nicotine obtained from tobacco products produces dependency. The efficacy of nicotine replacement therapy in reducing withdrawal symptoms strongly suggests this conclusion.

To further demonstrate the point, the Agency supplied the public with efficacy data for each of the 19 studies. The incorporation in Appendix 1 of the relevant data from these studies in itself allowed for a reasonable opportunity to comment on the Agency's use of the studies. Again, the fact that the Agency has approved these products as smoking cessation aids, because of their effectiveness in relieving withdrawal from nicotine, supports the Agency's point that nicotine from certain tobacco products causes dependency.

In addition to providing in the Appendix itself the data on which FDA relied, the Agency relied on studies that have been widely reported on in the medical and scientific literature. For example, each of the studies the Agency cited from the NDA's for Nicorette (2mg) and nicotine nasal spray have been reported on in "refereed" or peer-

¹²⁴⁰ See appendix 1 to Jurisdictional Analysis, at 62-85. See AR (Vol. 1 Appendix 1).

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reviewed journal articles.¹²⁴¹ See *National Ass'n of Pharmaceutical Mfrs.*, 586 F. Supp. at 756 n.45 ("The public availability of information not included in the administrative record is a factor to be considered in determining whether the record is inadequate for failing to include it") (citations omitted). Thus, to the extent Appendix 1 or the administrative record itself did not provide the public with enough information to comment on the Agency's analysis, the public had easy access to journal articles authored by the individuals who designed and conducted each of the studies.

Finally, with respect to all but the five studies referenced from the NDA's for Nicorette (2mg) and nicotine nasal spray, the public had access to the "backup" for the data on which the Agency relied through the NDA summaries the Agency included on the public docket. For the Agency to put on the record further documentation to support this "backup" would have been excessive, given the limited purpose for which the Agency relied on these studies.

¹²⁴¹ See Christen AG, McDonald JL, Olson BL, Drook CA, Stookey GK, "Efficacy of a nicotine chewing gum in facilitating smoking cessation," *Journal of the American Dental Ass'n* 1984; 108: 594-597. See AR (Vol. 711 Ref. 25).

Jarvis MJ, Martin RAW, Russel MAH, Feyerabend C, "Randomised controlled trial of nicotine chewing-gum," *British Medical Journal* 1982; 285:537-540. See AR (Vol. 711 Ref. 26).

Schneider NG, Olmstead R, Mody F, Doan K, Franzon M, Jarvik ME, Steinberg C, Efficacy of nicotine nasal spray in smoking cessation: a placebo-controlled, double-blind trial, *Addiction* 1995; 90:1671-1682. See AR (Vol. 711 Ref. 27).

Sutherland G, Stapleton JA, Russel MAH, Jarvis MJ, Hajek P, Belcher M, Feyerabend C, Randomised controlled trial of nasal nicotine spray in smoking cessation, *Lancet* 1992; 340:324-29; See AR (Vol. 348 Ref. 5511).

Hjalmarson A, Franzon M, Westin A, Wiklund O, Effect of nicotine nasal spray on smoking cessation, *Archives of Internal Medicine* 1994; 154:2567-2572. See AR (Vol. 711 Ref. 28).

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The Agency, then, referenced 19 studies to prove a single point. The public docket included detailed summaries, prepared for purposes of approving a drug product as safe and effective, of 14 of the 19 studies. For the tobacco industry to claim that it lacked adequate data with which to challenge the Agency's conclusion, which could have been supported by far fewer than 19 studies, is unreasonable.

In sum, the complaint that FDA did not put on the public docket the "actual studies" used to support these NDA's is misplaced. When FDA relied on a specific NDA, it put a detailed summary of the NDA in the public docket; and when FDA relied on particular NDA studies, it provided the public with the data from those studies in the appendix itself. The Agency also took care to rely on studies which have been widely reported on in the medical and scientific literature. The comment from the tobacco industry that the Agency in this instance withheld crucial information is tantamount to arguing that for each journal article on which the Agency relies, it must also include in the record all the raw data discussed or analyzed in the article. This is a level of disclosure that exceeds reason, not to mention the basic tenets of notice under the APA. The Agency, therefore, is not persuaded that the industry, or any other interested person, was deprived of a meaningful opportunity to comment on the Agency's reference to certain smoking cessation studies or certain NDA's.

5. The Agency's Reliance in the Final Jurisdictional Determination on New Materials

In an ordinary informal rulemaking proceeding, the final administrative record must contain the proposed rule, including all information that the Commissioner identifies or files with the proposal, all comments received on the proposal, including all information

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submitted as part of the comments, and the notice promulgating the final regulation, including all information that the Commissioner identifies or files with the final regulation.

21 CFR 10.40(g). An agency may rely on information and data that was not included at the proposal stage that expands on or confirms information in the proposal or addresses alleged deficiencies in the pre-existing data, provided that no prejudice is shown.¹²⁴²

Otherwise, “[r]ulemaking proceedings would never end if an Agency’s response to comments must always be made the subject of additional comments.” *Community Nutrition Inst.*, 749 F.2d at 58. Accordingly, the Agency has cited in the final jurisdictional determination a small amount of information that is needed to respond fully to comments or that otherwise supplements the information contained in or filed with the proposal. These documents include published scientific articles, reference texts, a Centers for Disease Control and Prevention memorandum and supporting data, letters to tobacco industry counsel, an abstract that the tobacco industry asked to include in the record, a small number of publicly released tobacco company documents, Congressional hearing transcripts, and newspaper articles. The Agency has placed this cited information in the administrative record for the jurisdictional determination.

¹²⁴² See, e.g., *Personal Watercraft v. Dep’t of Commerce*, 48 F.3d 540, 544 (D.C. Cir. 1995) (“Agencies may develop additional information in response to public comments and rely on that information without starting anew unless prejudice is shown.”); *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (“[C]onsistent with the APA, an agency may use ‘supplementary’ data, unavailable during the notice and comment period, that expands on and confirms information contained in the proposed rulemaking and addresses alleged deficiencies in the pre-existing data, so long as no prejudice is shown.”); *Community Nutrition Inst. v. Block*, 749 F.2d 50, 57-58 (D.C. Cir. 1984) (agency may rely on information that “expanded on and confirmed” information in the proposal and addressed alleged deficiencies in the record); see also K. Davis, *Administrative Law Treatise*, § 7.3 (3d ed. 1994).

VI.B.

B. ADEQUACY OF THE NOTICE

Two industry comments argued that the public's participation in the jurisdictional determination, as well as in the rulemaking process, has been frustrated because the Agency presented a "one-sided" view of the Jurisdictional Analysis and the Proposed Rule. Although neither comment disagreed with the Agency's use of notice and comment-type procedures to reach a jurisdictional determination, both comments claimed that FDA failed to satisfy the APA's notice requirement for informal rulemaking because the Agency neither disclosed nor discussed the supposedly "large body" of information "that is inconsistent with, or otherwise not supportive of, the Proposed Rule."¹²⁴³ Further, the Agency did not, in their view, provide a "reasoned explanation" for departing from past precedent on the issue of whether FDA should regulate all cigarettes and smokeless tobacco.¹²⁴⁴

These comments provided no legal authority to support the proposition that, assuming the Agency is bound here by APA precedent governing informal rulemaking, the Agency was required at the notice stage to anticipate all challenges to its reasoning, and should have attempted in its notice to answer those challenges. Rather, at the notice stage of a rulemaking proceeding, the Agency's obligation is to include sufficient detail to allow for meaningful and informed comment. *See American Medical Ass'n v. Reno*, 57 F.3d

¹²⁴³ Joint Comments of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 15. *See* AR (Vol. 535 Ref. 96). *See also* Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 33-38. *See* AR (Vol. 526 Ref. 95).

¹²⁴⁴ Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 38-39. *See* AR (Vol. 526 Ref. 95).

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1129, 1132 (D.C. Cir. 1995); *Home Box Office, Inc. v. Federal Communications Commission*, 567 F.2d 9, 35-36 (D.C. Cir.), *cert. denied*, 434 U. S. 829 (1977).

More specifically, in an informal rulemaking proceeding, the APA requires public notice of an Agency's intention to issue a regulation. 5 U.S.C. 553(b). The notice must include "reference to the legal authority under which the rule is proposed," and "either the terms or substance of the Proposed Rule or a description of the subjects and issues involved." 5 U.S.C. 553(b)(2) and (b)(3). FDA's own regulations require that a notice of proposed rulemaking include "a preamble that summarizes the proposal and the facts and policy underlying it, . . . all information on which the Commissioner relies for the proposal, . . . and cites the authority under which the regulation is proposed." 21 CFR 10.40(b)(vii).

Under case law construing section 553 of the APA, notice of informal rulemaking must be "sufficiently descriptive of the 'subjects and issues involved' so that interested parties may offer informed criticism and comments." *Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 48 (D.C. Cir.) (*en banc*), *cert. denied* 426 U.S. 941 (1976). Notice is sufficient under the APA "if it affords interested parties a reasonable opportunity to participate in the rulemaking process." *Forester*, 559 F.2d at 787; *accord State of South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 885 (4th Cir. 1983), *cert. denied*, 465 U. S. 1080 (1984). And, insofar as the proposal to regulate relies on a technical study or specific data essential to an understanding of the rule, the notice should disclose this information to the extent needed to allow for "meaningful comment." *Connecticut Light and Power Co. v. Nuclear Regulatory Commission*, 673 F.2d 525, 530-531 (D.C. Cir.), *cert. denied*, 459 U. S. 835 (1982).

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In this instance, the Agency's Jurisdictional Analysis met both the APA's notice requirements (as interpreted by prevailing case law), as well as FDA's own procedural requirements. The Agency by any standard "fulfilled its obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible." *Air Transport Ass'n of America v. Civil Aeronautics Board*, 732 F.2d 219, 225 (D.C. Cir. 1984) (quoting *Home Box Office, Inc.*, 567 F.2d at 36).

1. The Agency Provided Adequate Notice of the Key Legal and Factual Issues

Although the APA's notice requirements could have been met by a far briefer presentation, the Agency chose to supply the public with a discussion of its Jurisdictional Analysis that explored in full the wide range of factual and legal issues presented. In doing so, the Agency discussed a number of the issues that the industry commenters claimed were missing from the Jurisdictional Analysis.

The comments contended that the Agency failed to discuss past instances in which it declined to exercise jurisdiction over cigarettes and smokeless tobacco products, including FDA's response to a 1977 citizen petition. One comment in particular insisted that such a discussion would have alerted the public to the idea that Congress enacted preemptive legislation in reliance on FDA's past pronouncements, legislation which the comments argue bars FDA from regulating these products.

The Agency acknowledged in its Jurisdictional Analysis that it has in the past refrained from exercising jurisdiction generally over all cigarettes and smokeless tobacco products (provided claims were not made for the product). 60 FR 41482 n.5. Among other things, the Agency referred readers to the published decision in *Action on Smoking*

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and Health (ASH) v. Harris, 655 F.2d 236 (D.C. Cir. 1980). That decision reviewed the Agency's rejection of the 1977 citizen petition, which one comment claimed the Agency "conscientiously avoid[ed]" in the Jurisdictional Analysis in order to "mislead[]" the public.¹²⁴⁵ Not only does the *ASH* opinion discuss the petition and the Agency's position at that time with respect to exercising jurisdictional generally over cigarettes, it also recounts for the reader the Agency's historical position on the issue. 655 F.2d at 237-241. Moreover, the Agency placed in the administrative record copies of documents in which FDA declined to exercise jurisdiction, including FDA's response to ASH's 1977 citizen petition.¹²⁴⁶

In addition, the Agency attached as part of an appendix to its Jurisdictional Analysis, copies of the Commissioner's testimony before the House Subcommittee on Health and the Environment of the Committee on Energy and Commerce on March 25, 1994.¹²⁴⁷ At the outset, Commissioner Kessler stated:

Although FDA has long recognized that the nicotine in tobacco products produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. One of the obstacles has been a legal one. A product is subject to regulation as a drug based primarily on its intended use. . . . With certain exceptions, we have not had sufficient

¹²⁴⁵ Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 35. See AR (Vol. 526 Ref. 95).

¹²⁴⁶ See Letter from Kennedy D (FDA) to Banzhaf J (ASH) (Dec. 5, 1977). See AR (Vol. 503 Ref. 8882) (denial of 1977 petition).

Letter from Goyan JE (FDA) to Banzhaf J (ASH) (Nov. 25, 1980). See AR (Vol. 503 Ref. 8881).

Public Health Cigarette Amendments of 1971, *Hearings before the Consumer Subcommittee of the Committee on Commerce, U.S. Senate*, 92d Cong., 2d Sess. at 239-246. See AR (Vol. 503 Ref. 8894).

¹²⁴⁷ See appendix 7 to the Jurisdictional Analysis. See AR (Vol. 1, Appendix 7).

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evidence of such intent with regard to nicotine in tobacco products. . . .

Mr. Chairman, we now have cause to reconsider this historical view . . . This question arises today because of an accumulation of information in recent months and years. In my testimony today, I will describe some of the information.

Appendix 7 at 1-2 (footnote omitted). This testimony, like the reference to the *ASH* decision, adequately put the public on notice of FDA's past position.¹²⁴⁸

Nor does FDA agree with the comment's argument that Congress, in reliance on past FDA pronouncements, enacted legislation precluding FDA from regulating tobacco products under the Act. As discussed in detail in sections IV. and V., above, the Agency has never categorically disclaimed jurisdiction over tobacco products and Congress has never expressly forbidden FDA from asserting jurisdiction over these products. The Agency had no affirmative obligation to posit in the Jurisdictional Analysis arguments it believes are legally infirm. *Cf. Florida Power and Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988), *cert. denied*, 490 U.S. 1045 (1989).

Two tobacco industry comments also claimed that the Agency unfairly underplayed the complexity of issues such as "intended use," product categorization,

¹²⁴⁸ The Agency's decision not to include a prolonged discussion of past Agency decisions is also based on the fact that the Agency is operating under a different set of facts. *See* section IV., above. The Agency did not commit a procedural error by failing to chronicle exhaustively decisions it made in a factually distinguishable context.

One of the comments also faults the Agency for failing to give notice of the "several" citizen petitions filed since 1977 that request that the Agency regulate cigarettes. In fact, the Agency incorporated by reference into the docket for this jurisdictional determination all significant dockets opened since the conclusion of the *ASH* litigation that relate to the Agency's jurisdiction over cigarettes and other nicotine delivery systems. The index the Agency provided to the public on September 29, 1995, in conjunction with the public display of the administrative record (as of that date), included a description of 9 dockets the Agency incorporated by reference into the record supporting the Jurisdictional Analysis. *See* AR (Vol. 504 Ref. 8934).

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regulatory authority over combination products, and the applicability of the medical device provisions of the Act to cigarettes and smokeless tobacco. Instead, one of these comments asserted that all the Agency had done was publish “a tendentious anti-tobacco, pro-FDA-regulation manifesto” and, as such, the Agency’s notice was “fraudulent.”¹²⁴⁹ The Agency disagrees with this characterization, whether it was directed at the Proposed Rule or at the Jurisdictional Analysis. More to the point, the Agency disagrees with the argument that the Agency somehow deprived the public of fair notice of its Jurisdictional Analysis.

Again, to satisfy the APA’s notice requirement for informal rulemaking, the Agency must specify with particularity the legal authority on which its proposal is based. K. Davis, *Administrative Law Treatise* (3d ed. 1994), at 299. Notice must be “informative” and must “fairly apprise” interested persons. *Id.* at 299-300. The Agency notes, however, that it need not unravel for the public each and every theoretical step in the analysis. *See Chemical Waste Management, Inc. v. Environmental Protection Agency*, 869 F.2d 1526, 1535 (D.C. Cir. 1989) (even where Agency statement in notice of rulemaking assumes rather than invites comments on an issue, notice is sufficient if it provides interested parties “with a clear indication of the agency’s intended course of action. . . .”); *Center for Auto Safety v. Peck*, 751 F.2d 1336, 1361 (D.C. Cir. 1985) (“It is simply not the case, however, that all of the essential postulates for an agency rule must be contained in the record”).

¹²⁴⁹ Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 33. *See* AR (Vol. 526 Ref. 95).

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Nevertheless, the Agency provided the public a detailed explanation of why it regards cigarettes and smokeless tobacco as drug/device combinations products, and why it believes the device provisions of the Act may, and should, be used to regulate these products. The Agency set forth its rationale for regulating these products as devices in both the Jurisdictional Analysis itself, *see* 60 FR 41521–41525, and in the Proposed Rule, *see* 60 FR 41348–41350. Further, the Agency identified for the public in the Proposed Rule the precise statutory provisions under which it proposed to regulate these products. 60 FR 41346–41352, 41372.

The Agency also put the public on notice, by referencing the Intercenter Agreement, *see* 60 FR 41521, that preloaded drug delivery systems are often regulated using the drug authorities under the Act. The Agency adequately explained—for notice purposes—why in this instance it proposed a different approach. 60 FR 41348–41350.

With respect to the application of the concept of “intended use,” the lengthy discussion in Part II of the Jurisdictional Analysis provided the public with full disclosure of the Agency’s rationale for regulating cigarettes and smokeless tobacco based on the “intended use” of these products. The core facts and precedents on which the Agency relied were displayed in a manner the Agency believes invited maximum public scrutiny. The Agency even provided the public with 11 different examples (9 from the 1980’s and 1990’s) of the application of the intended use concept to the determination of whether a product, absent express claims, may be regulated as a drug or a device. 60 FR 41527–41531. This level of explanation more than satisfied the requirements of the APA as interpreted by the relevant case law.

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Finally, the quantity and quality of comments the Agency received on the Jurisdictional Analysis and the proposed rule suggest that, in fact, the public was adequately notified of the relevant issues. The Agency received more comments on these two documents than it has ever received on any other subject, with over 700,000 comments (including form letters) and over 95,000 distinct or unique sets of comments. More important, the Agency received hundreds of pages of comments on the very issues the Agency is said to have hidden from the public. Indeed, the two industry commenters who complained most vigorously about the supposed deficiencies in the Jurisdictional Analysis and the Proposed Rule themselves literally filed volumes of comments on the issues they claim the Agency concealed.¹²⁵⁰ Even the comments of interested nonindustry persons evidenced fair notice of the Agency's historical position and fair notice of the Agency's reasoning for applying the device provisions of the act to cigarettes and smokeless tobacco.¹²⁵¹

In *Chemical Waste Management*, 869 F.2d at 1535, the plaintiff complained that the Environmental Protection Agency's notice of proposed rulemaking treated a certain controversial issue "as an accomplished fact." Like two of the comments here, the plaintiff in *Chemical Waste Management* argued that the APA required the agency to

¹²⁵⁰ See, e.g., Joint Comments of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996), at 43-73 (discussing the Agency's historical position on Agency jurisdiction over tobacco products), 99-258 (discussing the Agency's application of the concept of intended use to tobacco products), and 259-307 (analyzing the Agency's position that cigarettes and smokeless tobacco are combination products that may be regulated as restricted devices). See AR (Vol. 526 Ref. 95). Accord Joint Comments of Cigarette Manufacturers at, among other places, Vol. I (discussing FDA's historical position on jurisdiction), Vol. II (discussing the concept of intended use), and Vol. V (discussing the regulation of cigarettes as medical devices). See AR (Vol. 535 Ref. 96).

¹²⁵¹ See, e.g., Public Citizen Litigation Group, Comment (Jan. 2, 1996), at 29-43. See AR (Vol. 700 Ref. 591); American Heart Association, Comment (Dec. 26, 1995). See AR (Vol. 700 Ref. 592).

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highlight the fact that its position was subject to debate and to solicit comments on the issue. The United States Court of Appeals for the District of Columbia rejected this argument because EPA had provided notice of its intended course *and* because the agency in fact received numerous comments on the issue. *Id.*; *see also Shell Oil Co. v. EPA*, 950 F.2d 741, 757 (D.C. Cir. 1991) (recognition of a certain issue by commenters may be used to infer that adequate notice of the issue was given); *Haralson v. Federal Home Loan Bank Board*, 678 F. Supp. 925, 926 (D.D.C. 1987) (same).

As in cases such as *Chemical Waste Management*, the comments FDA received demonstrate that there is no serious claim to be made that the Agency has concealed issues from the public. Interested persons representing both sides in this controversial proceeding commented on the very issues the Agency supposedly underplayed in its notice of proposed rulemaking.

At bottom, the comments that challenge the adequacy of the Agency's proposal confuse the merits of the issue with procedure. The supposed deficiencies in FDA's legal reasoning, and the supposed failure to discuss contrary authorities, raise substantive issues to be resolved during the comment and response-to-comment phase of the proceeding. The possibility that some of the Agency's legal conclusions may be subject to debate does not render the notice inadequate. *See Chemical Waste Management*, 869 F.2d at 1535; *Natural Resources Defense Council, Inc. v. Hodel*, 618 F. Supp. 848, 864-865 (E.D. Cal. 1985).

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2. The Agency Provided a “Reasoned Explanation” for Its Current Position

Several tobacco industry comments also claimed that the Agency violated the APA’s notice provisions by failing to include a “reasoned explanation” for departing from past precedent on the issue of whether to regulate all cigarettes and smokeless tobacco. In their view, the Jurisdictional Analysis and Proposed Rule are procedurally infirm because the Agency did not adequately explain its basis for past decisions not to regulate these products, and did not distinguish those decisions from its present position. One of these comments likewise asserted that the Agency was required to include in the administrative record each and every document “that formed the basis for, or was an expression or reflection of, FDA’s consistent position over more than 80 years that it does *not* have jurisdiction to regulate cigarettes.” The absence of this material, according to the comment, demonstrates that the Agency failed to consider “obviously relevant” contrary information in asserting jurisdiction and in proposing to regulate these products.¹²⁵²

The authorities cited in the comments require that, by the *close* of an administrative proceeding, the Agency must provide a “reasoned explanation” to the extent the Agency has departed from a prior formal position. *See, e.g., International Union, United Auto Workers v. NLRB*, 459 F.2d 1329 (D.C. Cir. 1972) (challenge to final decision of labor board); *Greyhound Corp. v. ICC*, 551 F.2d 414 (D.C. Cir. 1977) (challenge to final order of the ICC); *Baltimore and Annapolis Railroad Co. v. Washington Metro. Area*, 642 F.2d 1365 (D.C. Cir. 1980) (challenge to final order of

¹²⁵² Joint Comments of Cigarette Manufacturers, Comment (Jan. 2, 1996), Vol. XII, at 16. *See* AR (Vol. 535 Ref. 96).

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transit commission); *RKO Gen., Inc. v. FCC*, 670 F.2d 215 (D.C. Cir. 1981), *cert. denied*, 456 U.S. 927 (1982) (challenge to final order of Federal Communications Commission denying renewal of television license); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983) (challenge to final rule rescinding passive restraint seatbelt requirement contained in a Department of Transportation standard).

None of these cases, which involve challenges to final Agency orders and final rules, holds that at the notice stage of a proceeding, when an Agency is proposing to depart from a prior position, the Agency must provide a comprehensive "reasoned explanation."

The Agency nevertheless agrees that the rulemaking proceeding, taken as a whole, should clearly and rationally justify changes in existing policies. Thus, FDA included in its Jurisdictional Analysis ample reference to its prior policy and a more than ample discussion of the Agency's rationale for changing its policy. Indeed, the very intent of the Jurisdictional Analysis, the 622 footnotes supporting the analysis, its appendices, and the more than 13,000 documents put on the administrative record was to provide the public with a full view of the new evidence that supports the need for the Agency to take a different approach to the regulation of these products.

As FDA made clear at the outset of its Jurisdictional Analysis, its decision to propose to regulate these products, when in the past it did so only when claims were made, is based on the fact that "[t]he quality, quantity, and scope of the evidence available to FDA today is greater than any other time when FDA has considered regulation of cigarettes and smokeless products." 60 FR 41464, n.1. Footnote 5 of the Jurisdictional Analysis, in particular, made clear that: (1) The Agency in the past had declined to exercise jurisdiction generally over these products; and (2) the reason for taking a different

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position today is that the evidence before the Agency regarding the intended use of these products “has changed dramatically.” 60 FR 41482, n.5. In addition, the Agency repeatedly stated that its analysis was based on “evidence now available to the Agency,” 60 FR 41464, “current evidence,” 60 FR 41466, evidence accumulated since 1980, 60 FR 41482, n.5, and evidence that has emerged since 1980 or was not widely known until recently, 60 FR 41483–41484, 41539.

Neither the APA nor the case law cited in the comments requires an agency to provide a thorough “reasoned explanation” for departing from precedent at the notice stage of a proceeding. Rather, the APA at most requires that the Agency give notice of its proposal to take a different position or view, and give enough information to allow the public a reasonable opportunity to comment. Not until the close of the proceeding, after public comment has been received, must the Agency ensure that it has provided a full “reasoned explanation.” The Agency believes in this instance that its discussion at the notice stage met the standard that courts ordinarily do not impose until the close of an administrative proceeding. Nonetheless, the Agency has provided further, detailed discussion of the legal and factual bases for taking its current position in this document. *See* section IV., above.

Finally, the Agency does not agree that it was required to include in the record, at the notice stage, each and every prior Agency “decision, statement, and finding.” Rather, the Agency appropriately included in the record of proposed rulemaking enough documentation to give the public notice of the Agency’s prior position, and notice of the Agency’s prior reasoning for declining to exercise jurisdiction generally over these products (absent express claims). For example, the Agency incorporated by reference into

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the administrative record for this jurisdictional determination all significant dockets opened since the conclusion of the 1977 *ASH* litigation that relate to the Agency's jurisdiction over these products. In addition, the Agency included in the record its response and supplemental response to the original *ASH* citizen petition. Those documents outline in detail the "contrary" view the Agency has allegedly concealed, including full discussions of the Agency's enforcement history with respect to tobacco products and the Agency's significant past pronouncements on the subject. In any case, the tobacco industry itself, through its comments, has introduced many of the Agency's earlier statements into the administrative record for this proceeding. Thus, unlike the facts presented in cases such as *Public Citizen v. Heckler*, 653 F. Supp. 1229 (D.D.C. 1986) and *Walter O. Boswell Memorial Hospital v. Heckler*, 749 F.2d 788 (D.C. Cir. 1984), as referenced in the comment, the administrative record for this proceeding already contains the "adverse" information claimed to be lacking, by virtue of the Agency's inclusion of documents in the record and the comments received by the Agency.

C. ADEQUACY OF THE COMMENT PERIOD

FDA received at least one comment urging that the comment period for both the Jurisdictional Analysis and the Proposed Rule was unreasonably short in light of the complexity of the Proposed Rule, the number of materials the Agency put on public display, and the possible impact of the rule on the tobacco industry. This comment argued that the Agency acted arbitrarily and capriciously in deciding to "limit" the comment period to 144 days from the publication of the August 11, 1995, Proposed Rule and Jurisdictional Analysis and 95 days from the public release of the documents FDA considered but did not rely upon.

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Far from having "limited" the comment period, FDA provided more than twice as much time for comment as the Agency's regulations require. *See* 60 FR 53560 (Oct. 16, 1995) (extending comment period for Proposed Rule); 60 FR 53620 (Oct. 16, 1995) (extending comment period on Jurisdictional Analysis).

The APA requires only that an agency "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments. . . ." 5 U.S.C. 553(c). This is all the APA requires; there is no statutory requirement concerning how many days an Agency must allow, nor is there a requirement that an Agency must extend the period at the request of an interested person. *See Phillips Petroleum Co. v. Environmental Protection Agency*, 803 F.2d 545, 559 (10th Cir. 1986).

FDA's own regulations generally afford the public 60 days to comment on a Proposed Rule, unless the Commissioner shortens or lengthens the period for good cause. 21 CFR 10.40(b)(2). Executive Order 12889 implementing the North American Free Trade Agreement prescribes a minimum comment period of 75 days on certain proposed rules, except when good cause is shown for a shorter comment period. *See* 58 FR 69681 (Dec. 27, 1993).

Here, the Agency provided the public with 144 days from the publication of the Jurisdictional Analysis, 139 days from the release of the documents the Agency cited in support of the Jurisdictional Analysis (on August 16, 1995), and 95 days from the release of the materials the Agency considered but did not directly rely upon (on September 29, 1995). Thus, even when counting from the date the Agency released additional documents on which it did not rely, the Agency provided much more time for comment than its regulations, or the Executive Order, require.

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Further, on March 20, 1996, the *Federal Register* published notice of an additional 30 day comment period limited to specific documents the Agency added to the docket in support of the Agency's analysis of its jurisdiction. *See* 61 FR 11419 (Mar. 20, 1996). Although the Agency expressly limited the scope of the matters on which interested persons could comment, the March 20, 1996, action did provide the public with yet another 30 days on which to comment on issues related to such core subjects as the manipulation of the nicotine content of cigarettes and smokeless tobacco.

The Agency is not persuaded that any interested person has been unfairly prejudiced. First, FDA considers requests to extend the comment period on a case-by-case basis. Here, on the one hand, the commenter (the Tobacco Institute together with five major tobacco companies) presented in its request for additional time no compelling reasons to extend the period (such as a new, material study). On the other hand, FDA is faced with a matter raising serious public health concerns. For those reasons, the Agency denied the request to extend the period for as much time as the commenter had requested. *See* 60 FR 53560.

Second, each of the five tobacco companies that submitted this joint comment also filed suit against FDA immediately after FDA's Jurisdictional Analysis and notice of proposed rulemaking went on public display. The timing appears to indicate that these firms had been preparing to respond to an FDA proposal to regulate cigarettes and smokeless tobacco for some time. In any case, the cigarette manufacturers were able, jointly, to submit 2,000 pages of comments and 45,000 pages of exhibits and the smokeless tobacco manufacturers were able to jointly submit 474 pages of comments and 3,372 pages of exhibits within the time allotted for commenting on the Jurisdictional

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Analysis and Proposed Rule. Their submissions far outweigh any others. The Agency, therefore, is not persuaded that these commenters suffered prejudice as a result of FDA's allowing twice as much time as the Agency's regulations require. *See Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 843 (D.D.C. 1992) (in light of the comments received, court declined to find that 30 day comment period was insufficient to allow opportunity for meaningful public participation); *Phillips Petroleum Co.*, 803 F.2d at 559 (citing cases in which courts have upheld notice periods of 45 days or less).

In sum, the Agency believes it provided ample additional time for comments—nearly 90 days more than is provided for in the Agency's own procedural regulation. Given that it received over 700,000 comments, including 95,000 distinct sets of comments, the Agency is not persuaded that the length of the comment period unfairly hampered the quality of the public debate on this matter.

D. THE NEED FOR "ADDITIONAL PROCEDURES"

Finally, one comment claimed that the Agency's use of William A. Farone's statement¹²⁵³ "and other similar documents" raises "serious issues of procedural fairness."¹²⁵⁴ The comment asserted that "FDA appears to treat" Farone as if he has current first-hand knowledge of internal company deliberations, and that FDA is using Farone's statement as "testimonial evidence." Based on this characterization of the

¹²⁵³ William A. Farone was the director of applied research in the research and development department of Philip Morris U.S.A. *See* Farone WA, *The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective* (Mar. 8, 1996), at 17. *See* AR (Vol. 638 Ref. 2).

¹²⁵⁴ Joint Comments of the Cigarette Manufacturers, Supplemental Comment on the Statement of William A. Farone (Apr. 19, 1996), at 15. *See* AR (Vol. 700 Ref. 223).

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Farone report, the commenter argued that it should be allowed the opportunity to confront and cross-examine Farone on the record, examine any notes taken by FDA in interviews with Farone, and obtain an extension of the comment period in order to take Farone's deposition in a pending civil proceeding (to which FDA is not a party).¹²⁵⁵

The Agency added the Farone statement and two affidavits from former tobacco industry employees as possible additional support (but by no means crucial) for the Agency's determination that it has jurisdiction over cigarettes and smokeless tobacco (because these products are intended for use as drug delivery devices). The comment failed to cite any legal authority to advance the proposition that, in making such a jurisdictional determination, the Agency must allow for cross-examination of witnesses and discovery of investigatory notes.

A brief review of the procedures the Agency employed in reaching its final jurisdictional determination is in order. At the same time that the Agency published notice of its proposal to regulate nicotine-containing cigarettes and smokeless tobacco, *see* 60 FR 41314, the Agency also published the results of its lengthy investigation into, and comprehensive analysis of, the Agency's jurisdiction over these products. *See* 60 FR 41453. Because of the unique importance of the jurisdictional issue, the Agency made its analysis available to the public, put the administrative record in support of its analysis on public display, and invited comments from the public on its analysis. When the Agency later supplemented the record in support of its Jurisdictional Analysis with the Farone

¹²⁵⁵ In a letter to Grossi PT, Jr., counsel for Philip Morris Inc., from Schultz WB, FDA deputy commissioner for policy, dated Apr. 12, 1996, the Agency responded to these very arguments. In addition to the Agency's discussion in that letter, the Agency offers the response in the text of this document. *See* AR (Vol. 711 Ref. 44).

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report and two affidavits from former tobacco industry employees, the Agency invited public comment on these documents. *See* 61 FR 11419. Interested persons thus were provided the opportunity to present written statements consisting of facts, data, expert affidavits, studies, argument, and other relevant information with which to challenge, if they chose, the Agency's Jurisdictional Analysis and documents such as the Farone report that support it. Finally, in this document, the Agency is responding to all pertinent comments to the Agency's Jurisdictional Analysis.

FDA has primary jurisdiction to determine its jurisdiction. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). At best, FDA must ensure that it meets "the rudiments of fair play" in determining its jurisdiction. *Id.* However, neither the Act nor the APA directs the Agency to commence a rulemaking proceeding, or conduct a formal evidentiary hearing, before making a jurisdictional determination. Nevertheless, FDA chose to employ the process outlined above—a notice and comment-type procedure—as a means by which to give the public an opportunity to participate the Agency's analysis of its jurisdiction and, thereby, met the conditions of "fair play."

There is nothing about the Farone report or the affidavits from former industry employees that would now require that the Agency employ even more procedures. In an ordinary informal rulemaking proceeding, such as that by which the Agency is promulgating its regulations governing cigarettes and smokeless tobacco, *see* 21 U.S.C. 371(a), an interested person generally has no right to cross-examine witnesses. *Compare* 21 U.S.C. 371(e) (enumerating those instances in which rulemaking under the Act may be subject to additional procedures, including the opportunity for a formal evidentiary hearing under sections 556 and 557 of the APA); *see Vermont Yankee Nuclear Power Corp. v.*

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Natural Resources Defense Council, Inc., 435 U.S. 519, 524 (1978). Exceptions to this rule can be made where Congress has expressly provided for additional procedures, *see* 5 U.S.C. 553(c), or where the rulemaking proceeding is in fact a “quasi-judicial determination” in which “a very small number of persons are ‘exceptionally affected, in each case upon individual grounds’” *Vermont Yankee Nuclear Power Corp.*, 435 U.S. at 542 (quoting *United States v. Florida East Coast Ry. Co.*, 410 U.S. 224, 242-245 (1973), and holding that the APA established “the maximum procedural requirements” that courts can impose upon agencies in conducting rulemaking procedures and that the circumstances in which courts may require additional procedures, “if they exist, are extremely rare”); *Lead Indus. Ass’n, Inc. v. EPA*, 647 F.2d 1130, 1169-1170 (D.C. Cir.) (interested persons face an extremely heavy burden when they demand that an Agency provide procedures not required by statute, such as cross-examination), *cert. denied*, 449 U.S. 1042 (1980).

The comment FDA received did not seriously attempt to show that the Agency is in fact engaged in the type of individualized determination described in *Vermont Yankee*, nor did it reference any statutory provisions that would require additional procedures in this instance. Instead, the comment rested its argument on the “testimonial” and “first-hand” nature of the Farone report. The mere labeling of evidence in this way does not change the nature of a proceeding. Indeed, the tobacco industry with their comments submitted statements of individuals as exhibits. Nor is the company-specific nature of the evidence determinative.

The issue, instead, depends upon the purpose for which the Agency intends to use the evidence. *See United Air Lines, Inc.*, 766 F.2d at 1119; *Ass’n of National*

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Advertisers, Inc. v. FTC, 627 F.2d 1151, 1164-1165 (D.C. Cir. 1979), *cert. denied*, 447 U.S. 921 (1980). Where, as FDA has done here, the Agency is relying on evidence to reach essentially legislative judgments, for prospective application, and for the purpose of regulating an entire industry, there is overwhelming authority that an evidentiary hearing with cross-examination of witnesses is not required. *See, e.g., Vermont Yankee Nuclear Power Corp.*, 435 U.S. at 524; *Lead Indus. Ass'n, Inc.*, 647 F.2d at 1169-1170; *United Air Lines, Inc. v. Civil Aeronautics Board*, 766 F.2d 1107, 1116-1121 (7th Cir. 1985); *Cleveland Elec. Illuminating Co. v. EPA*, 572 F.2d 1150, 1160 (6th Cir.), *cert. denied*, 439 U.S. 910 (1978); *Miami Nation of Indians of Indiana, Inc. v. Babbitt*, 887 F. Supp. 1158, 1173 (N.D. Ind. 1995).

The Agency is relying on documents such as the Farone report to support its jurisdiction over two broad categories of products (cigarettes and smokeless tobacco), and over all persons who manufacture, distribute, and sell these products. The Agency's inquiry into the operations of the leading tobacco firms was intended not to restrict or punish particular firms based on individualized grounds, but rather was intended to support regulatory controls that extend to the entire industry. Thus, the Agency's Final Rule governing youth access to cigarettes and smokeless tobacco products is properly characterized as rulemaking proceeding "in its purest form." *Vermont Yankee*, 435 U.S. at 542 n.16; *accord Lead Indus. Ass'n*, 647 F.2d at 1171 n.119. The fact, then, that Farone at one time worked for a leading tobacco firm does not change the purpose of this jurisdictional determination or in any way trigger the need for additional procedures. *See Commodity Exchange, Inc. v. Commodity Futures Trading Comm.*, 543 F. Supp. 1340, 1351 (S.D.N.Y. 1982) (summarizing case law holding that "informal rulemaking could

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include an examination of past practice in order to prescribe future rules,” and that “even when only one entity is the immediate subject of an Agency’s action, this alone does not change its rulemaking nature . . .”), *aff’d*, 703 F.2d 682 (2d Cir. 1983).

The comment also complained that FDA’s decision not to make available its interview notes with witnesses who have come forward with public statements (*i.e.*, Farone, Rivers, and Uydess) raised issues of “procedural fairness.”¹²⁵⁶ This concern, however, is offset by the confidential nature of such material and by the limited extent to which the Agency relied on the public statements of Uydess and Farone. The public is entitled to notice of, and the opportunity to comment on, all materials upon which the Agency has relied. For that reason, the Agency published notice of the three witnesses’ statements, placed the statements on the public docket, and afforded the public an opportunity to comment on them. The former employers of these witnesses, in particular, had the opportunity to challenge the witnesses’ statements by affidavit or rebuttal documentation. The Agency has decided to cite to the publicly-released Uydess affidavit and the Farone report in this jurisdictional determination only to the extent it has on hand information from other sources that corroborates or confirms the information that Uydess and Farone have given.¹²⁵⁷ Therefore, the Agency has proceeded fairly in its use of these witnesses’ statements.

The comment’s suggestion that there should be public access to the notes and transcripts of the confidential interviews with these witnesses raises a fundamental issue

¹²⁵⁶ Joint Comment of Cigarette Manufacturers, Comment (Apr. 19, 1996), at 16. *See* AR (Vol. 700 Ref. 223).

¹²⁵⁷ The Agency has decided not to rely on the Rivers affidavit in this document.

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with implications that go beyond this jurisdictional determination. The Agency has broad authority to conduct investigations for the purposes of the Food, Drug, and Cosmetic Act. 21 U.S.C. 372 and 374. In conducting these investigations, it may be necessary for the Agency to pledge confidentiality to individuals who provide certain information and who fear retaliation if their identities are disclosed. Such disclosure may occur, directly, by naming them, or indirectly, by disclosing information only they could have provided. It is essential to the overall mission of the Agency that it sustain a reputation for maintaining the confidentiality of information given to it in confidence. Otherwise, the Agency risks losing invaluable sources of information which the Agency must have to carry out its statutory responsibilities. Moreover, disclosure of underlying investigatory materials may, in some instances, reveal the Agency's investigatory techniques, procedures, and methods, that it is entitled to shield from the public. *See* 5 U.S.C. 552(b)(7). In other instances, underlying investigatory materials may include trade secrets or other confidential commercial information, which the Agency is obligated to keep confidential. *See* 5 U.S.C. 552(b)(4). *See* generally 60 FR 66981, 66982 (Dec. 27, 1995) (the Agency's Statement of Procedures for Handling Confidential Information in Rulemaking); *see also* 5 U.S.C. 552(b)(6) and (b)(7). Thus, an express, unequivocal waiver of confidentiality on the part of a declarant would not necessarily obviate the Agency's obligation to protect such investigatory materials.

Information conveyed to the Agency during its interviews of these three witnesses, as reflected in the notes and transcripts of the interviews, includes the identification of other possible sources of information and other possible leads for the Agency to pursue, as well as trade secrets and other confidential commercial information. This information was

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conveyed to the Agency with the understanding that it would be kept confidential. The Agency is duty-bound to honor its pledge of confidentiality, without which its investigation in this matter would have been severely hampered, and maintain its reputation as a reliable protector of confidential sources and information. The public interest is enhanced, and not harmed, by the Agency's commitment to honor this pledge, particularly where, as here, the Agency has afforded the public notice and an opportunity to comment on the only information given by these witnesses that the Agency is citing in its jurisdictional determination. *Cf. Lame v. Department of Justice*, 654 F.2d 917, 925 (3d Cir. 1981) ("[O]nce there has been an expressed or implied assurance of confidentiality, a subsequent release or publication by the government of a portion of the information does not negate the exemption for any of the information originally given.").

In light of the notice and opportunity for public comment afforded by the Agency with respect to the public statements of these three witnesses, the limited extent of the Agency's use of the Uydess affidavit and the Farone report, and the confidentiality concerns outlined above, the Agency properly declined to make its underlying interview notes and transcripts publicly available in the course of this proceeding.

Finally, the Agency does not agree that it was in any way required to delay this important public health proceeding in order for Farone's deposition to be taken. The Agency is not a participant in the civil litigation in which Farone may be called to testify and has no ability to influence the procedures to be followed in that proceeding, let alone the schedule. In any case, the Agency has no statutory obligation to delay a jurisdictional determination in order to allow for the submission of cross-examination testimony from a wholly separate proceeding.

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E. CONCLUSION

Because of the importance of the issues involved, the Agency took the unusual step of inviting public participation in the process of developing the final jurisdictional determination set forth in this Annex. The result is the most extensive administrative record in the history of the Agency. FDA employed procedures that exceeded all legal requirements and gave the public the opportunity for full participation.

Dated: Aug 1st 9, 1996



David A. Kessler, M.D.
Commissioner of Food and Drugs

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