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Friday
August 11, 1995

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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.

WASHINGTON, DC

WHEN: September 12 at 9:00 am

WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street NW., Washington, DC (3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

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WHERE: Centers for Disease Control and Prevention
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Auditorium A
Atlanta, GA

RESERVATIONS: 404–639–3528 (Atlanta area)
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Contents

Federal Register

Vol. 60, No. 155

Friday, August 11, 1995

Agriculture Department
See Animal and Plant Health Inspection Service
See Food Safety and Inspection Service
See Forest Service

Animal and Plant Health Inspection Service
RULES
Plant-related quarantine, domestic:
Oriental fruit fly, 40993

Blind or Severely Disabled, Committee for Purchase From People Who Are
See Committee for Purchase From People Who Are Blind or Severely Disabled

Children and Families Administration
NOTICES
Agency information collection activities under OMB review:
Proposed agency information collection activities; comment request, 41074
Grants and cooperative agreements; availability, etc.:
Developmental disabilities—
Projects of national significance, 41074
Medicaid:
Welfare reform and combined welfare reform/Medicaid demonstration project proposals—
July, 41074–41079

Coast Guard
RULES
Dangerous cargoes:
Bulk hazardous materials
Correction, 41157
Ports and waterways safety:
Lower Mississippi River; safety zone, 41017–41018

Commerce Department
See Foreign-Trade Zones Board
See International Trade Administration
See Patent and Trademark Office

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement list; additions and deletions, 41059–41061

Customs Service
RULES
Drawback:
Crude petroleum and petroleum derivatives; accounting procedures, 40995–40997

Defense Department
RULES
Acquisition regulations:
Rights in technical data
Correction, 41157
Small business subcontracting goals for subcontracts with qualified nonprofit agencies for blind and severely disabled
Correction, 41157

Education Department
RULES
State-administered programs and Federal, State, and local partnership for educational improvement; State plan filing deadlines and pre-award costs, 41286–41296

Employment and Training Administration
NOTICES
Adjustment assistance:
Blairsville Machine et al., 41116
Footware Management Co., 41116–41117
Val Mode Lingerie, Inc., 41117
Grants and cooperative agreements; availability, etc.:
Job Training Partnership Act—
Specialized/targeted dislocated worker services demonstration program, 41117
NAFTA transitional adjustment assistance:
Footwear Management Co. et al., 41117
General Mills Inc., 41118
Val Mode Lingerie, Inc., 41117–41118

Employment Standards Administration
NOTICES
Minimum wages for Federal and federally-assisted construction; general wage determination decisions, 41114–41116

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
PROPOSED RULES
Superfund program:
National oil and hazardous substances contingency plan—
National priorities list update, 41051–41053
NOTICES
Air pollution control; new motor vehicles and engines:
California State motor vehicles pollution control standards; public hearing, 41066–41068
Clean Air Act:
Acid rain provisions—
Nitrogen oxides compliance plans and written exemptions, 41068–41071
Environmental statements; availability, etc.:
Agency statements—
Comment availability, 41071–41072
Weekly receipts, 41072–41073
Toxic and hazardous substances control:
Premanufacture notices receipts, 41298–41312

Executive Office of the President
See Presidential Documents

Federal Aviation Administration
RULES
Airworthiness directives:
de Havilland, 40993–40994
Restricted areas, 40994
PROPOSED RULES
Airmen certification:
Pilot,flight instructor, ground instructor, and pilot school certification rules, 41160–41284

Airworthiness directives:
de Havilland, 41030–41033
NOTICES
Airport noise compatibility program:
Noise exposure map—
Westover Metropolitan Airport/Air Reserve Base, MA, 41145–41146
Passenger facility charges; applications, etc.:
Chicago Aviation Department, IL, et al., 41146–41148

Federal Communications Commission
RULES
Radio stations; table of assignments:
Texas, 41027

Federal Deposit Insurance Corporation
NOTICES
Meetings; Sunshine Act, 41156

Federal Energy Regulatory Commission
NOTICES
Natural gas certificate filings:
East Tennessee Natural Gas Co. et al., 41062–41064
Northwest Pipeline Corp. et al., 41064–41066
Applications, hearings, determinations, etc.:
Niagara Mohawk Power Corp., 41061
Ross, Allen, 41061–41062
Sonat Power Marketing, Inc., 41061

Federal Reserve System
NOTICES
Meetings; Sunshine Act, 41156
Applications, hearings, determinations, etc.:
First Commerce Corp.; correction, 41073
Poulsen, Jackie Lynn, et al., 41073
Security State Bank Holding Co. et al., 41073–41074

Fish and Wildlife Service
NOTICES
Endangered and threatened species:
Recovery plans—
Florida scrub and high pineland plants, 41099
Endangered and threatened species permit applications, 41099–41100
Wildland fire management policy and program review, 41054

Food and Drug Administration
PROPOSED RULES
Medical devices:
Cigarettes and smokeless tobacco products; restriction of sale and distribution to protect children and adolescents, 41314–41451
NOTICES
Animal drugs, feeds, and related products:
Export applications—
Percorten-V (desoxycorticosterone privalate) sterile suspension, 41079
Human drugs:
Carter, Jr., Oscar E., Dr., Memorial Rehabilitation Center, Inc.; narcotic addiction treatment program; application approval revocation proposal, 41079–41082
Nicotine-containing cigarettes and smokeless tobacco products; analysis regarding FDA's jurisdiction, 41453–41787

Food Safety and Inspection Service
PROPOSED RULES
Meat and poultry inspection:
Pathogen reduction; hazard analysis and critical control point (HACCP) systems; technical conference, 41029

Foreign Assets Control Office
NOTICES
Middle East peace process; specially designated terrorists who threaten to disrupt; list, 41152–41153

Foreign-Trade Zones Board
NOTICES
Applications, hearings, determinations, etc.:
Louisiana
CITGO Petroleum Corp.; crude oil refinery complexes, 41054
Texas
CITGO Refining & Chemicals, Inc.; crude oil refinery complexes, 41054–41055

Forest Service
NOTICES
Wildland fire management policy and program review, 41054

Health and Human Services Department
See Children and Families Administration
See Food and Drug Administration
See Public Health Service

Housing and Urban Development Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Facilities to assist homeless—
Excess and surplus Federal property, 41083–41096

Indian Affairs Bureau
NOTICES
Wildland fire management policy and program review, 41054

Interior Department
See Fish and Wildlife Service
See Indian Affairs Bureau
See Land Management Bureau
See Minerals Management Service
See National Biological Service
See National Park Service
See Reclamation Bureau

Internal Revenue Service
RULES
Income taxes:
Conduit arrangements regulations, 40997–41016

International Trade Administration
NOTICES
Antidumping:
Oil country tubular goods from—
Argentina, 41055–41056
Italy, 41057
Japan, 41058–41059
Korea, 41057–41058
Mexico, 41056–41057

International Trade Commission
NOTICES
Antidumping:
Honey from—
China, 41113–41114

Interstate Commerce Commission
NOTICES
Railroad operation, acquisition, construction, etc.:
Kansas City Southern Railway Co., 41114

Labor Department
See Employment and Training Administration
See Employment Standards Administration
See Pension and Welfare Benefits Administration
RULES
Federal claims collection:
Federal income tax refund offset, 41016–41017
NOTICES
Committees; establishment, renewal, termination, etc.:
North American Agreement on Labor Cooperation National Advisory Committee, 41118

Land Management Bureau
NOTICES
Alaska Native claims selection:
Doyon, Ltd., 41096–41097
Management framework plans, etc.:
California, 41097
Oil and gas leases:
New Mexico, 41097–41099
Wildland fire management policy and program review, 41054

Minerals Management Service
PROPOSED RULES
Outer Continental Shelf; oil, gas, and sulphur operations, etc.:
Pipeline right-of-way applications and assignment fees; requirements for filing of transfer, 41034–41035
NOTICES
Environmental statements; availability, etc.:
Outer Continental Shelf oil and gas leasing program (1997–2002), 41100–41104
Outer Continental Shelf operations:
Western Gulf of Mexico—
Lease sales, 41105–41111
Leasing systems, 41105

National Biological Service
NOTICES
Wildland fire management policy and program review, 41054

National Highway Traffic Safety Administration
RULES
Motor vehicle safety standards:
Theft prevention; automatic transmission lock Correction, 41028
NOTICES
Motor vehicle safety standards; exemption petitions, etc.:
Century Products Co., 41148–41150
Cosco, Inc., 41150–41151
Fisher-Price, Inc., 41151–41152

National Park Service
NOTICES
Native American human remains and associated funerary objects:
Knife River Indian Villages National Historic Site, ND—
Inventory, 41111
Pipe fragments, 41111–41112
Wildland fire management policy and program review, 41054

Patent and Trademark Office
RULES
Patent and trademark cases:
Fee revisions, 41018–41027
PROPOSED RULES
Patent cases:
Reexamination proceedings, 41035–41051

Pension and Welfare Benefits Administration
NOTICES
Employee benefit plans; prohibited transaction exemptions:
Morgan Stanley & Co. Inc. et al., 41118–41136

Pension Benefit Guaranty Corporation
PROPOSED RULES
Single-employer plans:
Reportable Events Negotiated Rulemaking Advisory Committee—
Establishment, 41033–41034

Presidential Documents
ADMINISTRATIVE ORDERS
Toxic chemical release reporting; expedition of initiatives (Memorandum of August 8, 1995), 41791–41792

Public Health Service
See Food and Drug Administration
NOTICES
Agency information collection activities under OMB review, 41082
Organization, functions, and authority delegations:
National Institutes of Health, 41082–41083

Reclamation Bureau
NOTICES
Central Valley Project Improvement Act:
Water conservation plans; evaluation criteria; decision, 41112–41113
Realty actions; sales, leases, etc.:
Nevada, 41113

Securities and Exchange Commission
RULES
Securities:
Employee benefit plan exemptive rules; phase-in period extension, 40994–40995
NOTICES
Meetings; Sunshine Act, 41156
Self-regulatory organizations; proposed rule changes:
Depository Trust Co., 41139–41140
Philidelphia Stock Exchange, Inc., 41140–41142
Applications, hearings, determinations, etc.:
Public utility holding company filings, 41136–41139
Trademark Funds, 41139

Social Security Administration
NOTICES
Meetings:
Social Security Advisory Council, 41142–41143

Transportation Department
See Coast Guard
See Federal Aviation Administration
See National Highway Traffic Safety Administration
NOTICES
Agency information collection activities under OMB review, 41143–41145

Treasury Department
See Customs Service
See Foreign Assets Control Office
See Internal Revenue Service
NOTICES
Agency information collection activities under OMB review:
Proposed agency information collection activities; comment request, 41153–41155

Separate Parts In This Issue

Part II
Department of Transportation, Federal Aviation Administration, 41160–41284

Part III
Department of Education, 41286–41296

Part IV
Environmental Protection Agency, 41298–41312

Part V
Department of Health and Human Services, Food and Drug Administration, 41314–41787

Part VI
The President, 41791–41792

Reader Aids

Additional information, including a list of public laws, telephone numbers, and finding aids, appears in the Reader Aids section at the end of this issue.

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.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR

Administrative Orders:

Memorandums:

August 8, 1995 41791

7 CFR

301.....40993

9 CFR

Proposed Rules:

308.....41029
310.....41029
318.....41029
320.....41029
325.....41029
326.....41029
327.....41029
381.....41029

14 CFR

39.....40993
73.....40994

Proposed Rules:

1.....41160
39.....41030
61.....41160
141.....41160
143.....41160

17 CFR

240.....40994

19 CFR

191.....40995

21 CFR

Proposed Rules:

801.....41314
803.....41314
804.....41314
897.....41314

26 CFR

1.....40997
602.....40997

29 CFR

20.....41016

Proposed Rules:

2615.....41033

30 CFR

Proposed Rules:

250.....41034
256.....41034

33 CFR

165 (2 documents) 41017, 41018

34 CFR

76.....41286
667.....41286

37 CFR

1.....41018
2.....41018
7.....41018

Proposed Rules:

1.....41035

40 CFR

Proposed Rules:

300.....41051

46 CFR

30.....41157
150.....41157

47 CFR

73.....41027

48 CFR

219.....41157
227.....41157

49 CFR

571.....41028

Rules and Regulations

Federal Register
Vol. 60, No. 155
Friday, August 11, 1995

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

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 94–117–3]

Oriental Fruit Fly; Removal of Quarantined Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the Oriental fruit fly regulations by removing the quarantine on a portion of Los Angeles County, CA, and by removing the restrictions on the interstate movement of regulated articles from that area. The interim rule was necessary to relieve restrictions that are no longer needed to prevent the artificial spread of the Oriental fruit fly into noninfested areas of the United States. We have determined that the Oriental fruit fly has been eradicated from this portion of Los Angeles County and that the quarantine and restrictions are no longer necessary.

EFFECTIVE DATE: September 11, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Michael B. Stefan, Operations Officer, Domestic and Emergency Operations, PPQ, APHIS, Suite 4C03, 4700 River Road Unit 134, Riverdale, MD 20737–1236, (301) 734–8247.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule effective on April 7, 1995, and published in the **Federal Register** on April 13, 1995 (60 FR 18727–18728, Docket No. 94–117–2), we amended the Oriental fruit fly regulations in 7 CFR 301.93–3 by removing the quarantine on a portion of Los Angeles County, CA, and by removing the restrictions on interstate movement of regulated articles from that area.

Comments on the interim rule were required to be received on or before June 12, 1995. We did not receive any comments. The facts presented in the interim rule still provide a basis for the rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12778, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived the review process required by Executive Order 12866.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR 301.93–3(c) and that was published at 60 FR 18727–18728 on April 13, 1995.

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.17, 2.51, and 371.2(c).

Done in Washington, DC, this 3rd day of August 1995.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–19856 Filed 8–10–95; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–NM–104–AD; Amendment 39–9262; AD 95–12–12]

Airworthiness Directives; de Havilland Model DHC–8–102, –103, and –106, Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects a typographical error that appeared in airworthiness directive (AD) 95–12–12 that was published in the **Federal Register** on June 13, 1995 (60 FR 31063). The typographical error resulted in a reference to a part number that does not exist. This AD is applicable to certain de Havilland Models DHC–8–102, –103, and –106 series airplanes and requires repetitive operational testing of the stall warning computers.

DATES: Effective June 28, 1995.

The incorporation by reference of certain publications listed in the regulations was previously approved by the Director of the Federal Register as of June 28, 1995 (60 FR 31063, June 13, 1995).

FOR FURTHER INFORMATION CONTACT: Peter Cuneo, Aerospace Engineer, Systems and Equipment Branch, ANE–172, FAA, New York Aircraft Certification Office, Engine and Propeller Directorate, 10 Fifth Street, Third Floor, Valley Stream, New York 11581, telephone (516) 256–7506; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION: Airworthiness Directive (AD) 95–12–12, amendment 39–9262, applicable to certain de Havilland Model DHC–8–102, –103, and –106 series airplanes, was published in the **Federal Register** on June 13, 1995 (60 FR 31063). That AD requires repetitive operational testing of the stall warning computers and replacement of non-operational stall warning computers with new or serviceable units. That AD also provides an optional terminating action for the repetitive operational tests.

As published, that AD contained a typographical error in paragraph (b), which describes the optional terminating action. That paragraph stated that replacement of stall warning computers having part number (P/N) ''3605–5, –6, or –7'' with new stall warning computers having P/N 3605–8 would constitute terminating action. However, ''P/N 3605–7'' was inadvertently indicated in that paragraph instead of the correct part number of ''P/N 3605–4.'' (In fact, P/N 3605–7 does not exist.) In all other parts of the published AD and its preamble, these part numbers were correctly cited as ''P/N 3605–4, –5, and –6.''

Since no other part of the regulatory information has been changed, the final rule is not being republished.

The effective date of the AD remains June 28, 1995.

§ 39.13 [Corrected]

On page 31065, in the first column, paragraph (b) of AD 95–12–12 is corrected to read as follows:

* * * * *

(b) Replacement of stall warning computers having part number (P/N) 3605–4, –5, or –6 with new stall warning computers having P/N 3605–8, in accordance with Bombardier Service Bulletin S.B. 8–27–76, dated October 31, 1994, constitutes terminating action for the repetitive operational test requirements of this AD.

* * * * *

Issued in Renton, Washington, on August 3, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–19655 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 73

[Airspace Docket No. 95–ACE–8]

Change Time of Designation for Restricted Areas R–3601A and R–3601B, Brookville, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action reduces the time of designation for Restricted Areas R–3601A and R–3601B, Brookville, KS. The Department of the Air Force has reviewed current requirements for these areas and determined that the current designated times may be reduced. This action increases the availability of restricted airspace for public use.

EFFECTIVE DATE: 0901 UTC, November 9, 1995.

FOR FURTHER INFORMATION CONTACT: Jim Robinson, Military Operations Program Office (ATM–420), Office of Air Traffic System Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 493–4050.

SUPPLEMENTARY INFORMATION:

The Rule

This amendment to part 73 of the Federal Aviation Regulations amends the time of designation for Restricted Areas R–3601A and R–3601B. The time of designation for R–3601A and R–3601B are reduced from ''Monday, Wednesday, Friday and Saturday, 0800 to 1800 local time; Tuesday and Thursday, 0800 to 2230 local time; other times by NOTAM 24 hours in advance.'' to ''Monday through Friday, 0900 to 1700 local time; other times by NOTAM 6 hours in advance.'' I find that notice and public procedure under 5 U.S.C. 553(b) are unnecessary because this action is a minor technical amendment in which the public would not be particularly interested. Section 73.36 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8B dated March 9, 1994.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The action reduces the restricted areas time of designation. In accordance with FAA Order 1050.1D, ''Policies and Procedures for Considering Environmental Impacts,'' this action is not subject to environmental assessments and procedures and the National Environmental Policy Act.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—[AMENDED]

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

73.36 [Amended]

2. Section 73.36 is amended as follows:

R–3601A Brookville, KS [Amended]

By removing the existing ''Time of designation. Monday, Wednesday, Friday and Saturday, 0800 to 1800 local time; Tuesday and Thursday, 0800 to 2230 local time; other times by NOTAM 24 hours in advance.'' and substituting the following: ''Time of designation. Monday through Friday, 0900 to 1700 local time; other times by NOTAM 6 hours in advance.''

R–3601B Brookville, KS [Amended]

By removing the existing ''Time of designation. Monday, Wednesday, Friday and Saturday, 0800 to 1800 local time; Tuesday and Thursday, 0800 to 2230 local time; other times by NOTAM 24 hours in advance.'' and substituting the following: ''Time of designation. Monday through Friday, 0900 to 1700 local time; other times by NOTAM 6 hours in advance.''

Issued in Washington, DC, on August 2, 1995.

Nancy B. Kalinowski,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 95–19904 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release Nos. 34–36063; 35–26352; IC–21270]

RIN 3235–AB14

Employee Benefit Plan Exemptive Rules Under Section 16 of the Securities Exchange Act of 1934

AGENCY: Securities and Exchange Commission.

ACTION: Extension of Phase-In Period for § 240.16b–3.

SUMMARY: The Commission today is extending the phase-in period for compliance with the substantive conditions of new Rule 16b–3 regarding employee benefit plan transactions under the Securities Exchange Act of 1934 pending further notice and rulemaking under the provision.

DATES: Effective on August 11, 1995. The phase-in period for compliance with new § 240.16b–3, which previously has been extended to September 1, 1995, is extended until September 1, 1996, or such different date as set in further rulemaking under Section 16.

FOR FURTHER INFORMATION CONTACT: Anne M. Krauskopf, Office of the Chief Counsel, Division of Corporation Finance, at (202) 942–2900.

SUPPLEMENTARY INFORMATION: On February 8, 1991, the Commission adopted comprehensive revisions to the rules under Section 16 [1] of the Securities Exchange Act of 1934 (''Exchange Act'').[2] The new regulatory

[1] 15 U.S.C. 78p (1988).

[2] 15 U.S.C. 78a *et seq.* (1988).

scheme generally became effective on May 1, 1991, but a 16 month phase-in period was provided with respect to specified rules affecting employee benefit plans, in order to give registrants ample time to review the rule changes and amend their plans accordingly.[3] The Adopting Release provided that registrants could continue to rely on the exemptions from Section 16(b) of the Exchange Act[4] afforded by former Rules 16a–8(b),[5] 16a–8(g)(3),[6] and 16b–3[7] after May 1, 1991, but would be required to adopt the substantive conditions of new Rule 16b–3[8] by September 1, 1992.[9]

The Rule 16b–3 phase-in period was extended until September 1, 1995, in contemplation of further rulemaking under Section 16 with regard to employee benefit plans.[10] Because the Commission currently is engaged in such rulemaking,[11] the Commission is extending the phase-in period for new Rule 16b–3 until September 1, 1996, or such different date as is set by the Commission.

By the Commission.

Dated: August 7, 1995.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–19932 Filed 8–10–95; 8:45 am]

BILLING CODE 8010–01–M

[3] Exchange Act Release No. 28869 (February 8, 1991) [56 FR 7242] (''Adopting Release''). See Section VII of the Adopting Release for transition provisions generally and Section VII.C for transition provisions relating to employee benefit plans.

[4] 15 U.S.C. 78p(b).

[5] 17 CFR 16a–8(b).

[6] 17 CFR 16a–8(g)(3).

[7] 17 CFR 16b–3 (1990).

[8] 17 CFR 240.16b–3 (1991).

[9] The phase-in period applies only to the exemption from Section 16(b), not to the revised reporting requirements under Section 16(a) that became effective on May 1, 1991.

[10] See Exchange Act Release No. 34513 (August 10, 1994) [59 FR 42448].

[11] See Exchange Act Releases Nos. 34514 (August 10, 1994) [59 FR 42449] and 34–34681 (September 16, 1994) [59 FR 48579].

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 191

[T.D. 95–61]

Accounting Procedures for Drawback

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final interpretive rule.

SUMMARY: This document gives notice that Customs is amending the general drawback rate (or contract) for crude petroleum and petroleum derivatives (Treasury Decision (T.D.) 84–49) to permit first-in-first-out (FIFO) accounting for exports and drawback deliveries of petroleum products with different drawback factors which are commingled in inventory. Customs is also revoking a published ruling (Customs Service Decision (C.S.D.) 84–82) under which identification of merchandise and articles for drawback purposes is permitted on a ''higher-to-lower'' basis. However, drawback claimants operating under properly approved specific drawback rates may continue to claim drawback using higher-to-lower accounting procedures, as provided for in C.S.D. 84–82, if the drawback rates under which they are operating expressly provide for the use of such procedures, until such rates are modified, with notice to the rate holders.

EFFECTIVE DATE: The amendment of T.D. 84–49 and the revocation of C.S.D. 84–82 will be effective as to drawback entries or claims properly filed with Customs on or after November 9, 1995, unless there is a prior approved properly-executed contract.

FOR FURTHER INFORMATION CONTACT: Paul Hegland, Entry Rulings Branch, Office of Regulations and Rulings, 202–482–7040.

Background

Section 313, Tariff Act of 1930, as amended (19 U.S.C. 1313), authorizes ''drawback''. Drawback is a refund or remission, in whole or in part, of a Customs duty, internal revenue tax, or fee. There are a number of different kinds of drawback authorized under law, including manufacturing and unused merchandise drawback. Under section 1313(a), drawback is authorized when imported merchandise is used in the manufacture of articles which are exported or destroyed. Under section 1313(j)(1), drawback is authorized when imported merchandise is exported or destroyed without having been used in the U.S. Sections 1313(b) and (j)(2) respectively provide for the substitution of other merchandise (whether imported or domestic) for the imported merchandise in manufacturing and unused merchandise drawback. Section 1313(l) provides that the allowance of drawback shall be subject to compliance with such rules and regulations as the Secretary of the Treasury shall prescribe.

The regulations pertaining to drawback are found in part 191 of the Customs Regulations (19 CFR part 191). Under the Customs Regulations (19 CFR part 191, subparts B and D), manufacturers or producers of articles intended for exportation with drawback under section 1313(a) or (b) must apply for and obtain approval of a drawback rate (sometimes called a drawback contract) describing the manufacturing or production operations covered and setting forth the conditions which are to be met to obtain drawback.

Subpart D of part 191 of the Customs Regulations (19 CFR part 191, subpart D) authorizes general drawback rates for certain common manufacturing operations. A general drawback rate for substitution manufacturing drawback under section 1313(b) for crude petroleum and petroleum derivatives is provided for in T.D. 84–49, 18 Cust. Bull. 149. This general drawback rate was initially promulgated by T.D. 56487, which added the rate to the Customs Regulations then pertaining to drawback (see 19 CFR 22.6(g–1) (1983)). The general rate for crude petroleum and petroleum derivatives now in T.D. 84–49 is substantively the same as the rate formerly contained in the Customs Regulations.

The features and procedures of, as well as the background to, T.D. 84–49 and its predecessor (see 19 CFR 22.6(g–1)(1983), as promulgated by T.D. 56487) were extensively described in the June 28, 1994, **Federal Register** (59 FR 33322) notice inviting public comment on the subject of this document. Under T.D. 84–49, distribution of drawback among the products produced during a period of production is based on the relative values of all products manufactured or produced during the production period, as of the time of separation of the products. The time of separation of the products is considered to be the monthly period of production. Relative values are stated in terms of drawback factors, which attach to each of the products manufactured or produced during the production period. An example of the calculation of these drawback factors was given in the June 28, 1994, **Federal Register** notice.

Because the relative value of the petroleum products which may be produced under T.D. 84–49 may vary from month to month, the drawback factors for a particular product produced under the procedures in T.D. 84–49 may also vary from month to month. The T.D. contains explicit procedures to account for such variances. When the inventory of a particular product contains product with different drawback factors (*e.g.*, if the inventory of a product was from more than one month's production, each month's quantity could have a different drawback factor), withdrawals from the inventory for exports are required to be

from lowest factor on hand, withdrawals for drawback deliveries (i.e., for further manufacture resulting in a product on which drawback could be claimed) are required to be from lowest on hand after exports are deducted, and withdrawals for domestic (nondrawback) shipments are required to be from earliest on hand after withdrawals for export and drawback deliveries are deducted.

The above accounting procedures were based on the accounting requirements for drawback applicable at the time that the general drawback rate was initially promulgated, as fully described in the June 28, 1994, **Federal Register** notice. The general requirements in the Customs Regulations for records, storage, and identification pertaining to drawback are now found in 19 CFR 191.22. Section 191.22(c) authorizes the identification for drawback purposes of commingled lots of fungible merchandise or articles by applying FIFO accounting principles or any other accounting procedure approved by Customs. Customs has issued a number of rulings on the accounting procedures which may be used to identify merchandise or articles for drawback purposes. Those rulings and the background to them were extensively described in the June 28, 1994, **Federal Register** notice. In one of those rulings, Customs Service Decision (C.S.D.) 84–82, 18 Cust. Bull. 1036, Customs held that when fungible drawback and nondrawback input was placed in commingled storage, withdrawals for drawback purposes could be identified on a higher-to-lower basis against the drawback input commingled therein.

In the June 28, 1994, **Federal Register** notice, Customs furnished notice that it had been requested to amend T.D. 84–49 to permit the accounting for withdrawals for export and for drawback deliveries from the inventory of a particular product containing product with different drawback factors on the basis of FIFO or higher-to-lower. In the June 28, 1994, **Federal Register** notice, Customs stated that it believed that the proposal to amend T.D. 84–49 to permit the accounting on a FIFO basis in the described situation had merit. In the interest of administrative simplicity, Customs stated that it believed that the order of such withdrawals should continue to be the same (*i.e.*, first exports, then drawback deliveries, then domestic shipments). In regard to the proposal to amend T.D. 84–49 to permit the described accounting on a higher-to-lower basis, however, Customs stated that T.D. 84–49 should not be amended to permit such accounting. Customs also stated that C.S.D. 84–82, the only published Customs ruling permitting higher-to-lower accounting for drawback purposes, as well as any unpublished Customs rulings to the same effect, should be revoked. The reasons for these conclusions were fully described in the June 28, 1994, **Federal Register** notice.

In the June 28, 1994, **Federal Register** notice, Customs invited comments on the proposed changes. Four commenters responded to the notice. After review of these comments, Customs has decided to proceed as proposed (*i.e.*, to amend T.D. 84–49 to permit the described accounting on a FIFO basis and to revoke C.S.D. 84–82). In regard to the latter, it is Customs position that unless substitution is specifically provided for in the law, accounting methods used to identify merchandise or articles for drawback purposes must be revenue neutral or favorable to the Government. Other criteria for evaluating such accounting methods include consistency with commercial accounting procedures, consistency with the accounting procedures generally used by the drawback claimant, and ease of administration. The comments received are discussed below.

Discussion of Comments

Comment: The use of FIFO accounting for T.D. 84–49, as proposed in the June 28, 1994, **Federal Register** notice, is not opposed. However, in the interest of maximum flexibility in accounting for drawback, higher-to-lower accounting should also be permitted for the described accounting in T.D. 84–49.

Response: In regard to the comment on FIFO accounting for T.D. 84–49, this document is proceeding as proposed and amending T.D. 84–49 to permit such accounting. In regard to permitting higher-to-lower accounting for the described purposes in T.D. 84–49, such accounting would not be revenue neutral or favorable to the Government (*i.e.*, withdrawals for drawback purposes (exports or drawback deliveries) would always be from the highest drawback factor first, thus always resulting in the greatest amount of drawback). Furthermore, higher-to-lower accounting methods are not consistent with commercial accounting procedures nor, based on information submitted to Customs by a representative of the petroleum industry, are they consistent with the accounting methods generally used by that industry. Therefore, Customs is *not* permitting higher-to-lower accounting for the described purposes in T.D. 84–49.

Comment: Customs should make it clear that T.D. 56487 (the predecessor of T.D. 84–49) is not authoritative on the issue of producibility, particularly that of proportional deductions.

Response: The June 28, 1994, document did not, and was not intended to, comment on the authoritativeness of T.D. 56487 on the issue of producibility or the issue of proportional deductions (see 19 CFR 22.6(g–1)(5)(1983) and T.D. 84–49, paragraph (5)). No change was proposed in this regard.

Comment: C.S.D. 84–82 should not be revoked. Higher-to-lower accounting procedures are consistent with the purposes of the drawback law and adequately protect the revenue and should continue to be allowed to be used for drawback. Drawback claimants under section 1313(b) are able to substitute any eligible merchandise of the same kind and quality as eligible imported merchandise received and put into production. This should continue.

Response: This comment appears to be based on a misunderstanding of the proposal to revoke C.S.D. 84–82. The proposal would not (and could not) change the current statutory provision allowing a drawback claimant to substitute any eligible merchandise of the same kind and quality as the designated imported merchandise to use in manufacture or production of the exported articles. In this regard, Customs notes the amendment of section 1313(b) by the North American Free Trade Agreement (NAFTA) Implementation Act, Title VI, section 632 (Pub. L. 103–182; 107 Stat. 2057, 2192–2193), specifically providing for the substitution of any other merchandise (whether imported or domestic) for the imported duty-paid merchandise designated for drawback under section 1313(b). The same is true of substitution unused merchandise drawback under section 1313(j)(2) (*i.e.*, any merchandise (whether imported or domestic) may be substituted for the designated imported merchandise, provided that the lots of merchandise are commercially interchangeable and that the other requirements of the law are met).

The revocation of C.S.D. 84–82 would apply to the identification by accounting procedures of merchandise or articles in situations where the law does not authorize substitution. For example, except in the case of petroleum derivatives under certain circumstances, the drawback law does not authorize the substitution of articles on which drawback is claimed under the manufacturing drawback law (section 1313 (a) or (b)) for other

articles. That is, when manufactured articles qualifying for drawback are commingled with nonqualifying articles after the former are manufactured by a drawback claimant, substitution under the law is not authorized. In such situations, identification of merchandise or articles for drawback purposes by accounting procedures must be revenue neutral or favorable to the Government and the accounting procedures should be consistent with the criteria for such accounting procedures described above.

Comment: The drawback law does not require any method of identifying fungible duty-paid imported materials which may be commingled in storage with other foreign or domestic materials; rather, the law delegates authority to the Secretary of the Treasury to prescribe appropriate accounting methods by regulation.

Response: Section 1313(l) of the drawback law provides that the allowance of drawback shall be subject to compliance with such rules and regulations as the Secretary of the Treasury shall prescribe. Under this authority, the agency has already prescribed, *inter alia*, a regulation governing the use of accounting methods (see, 19 CFR 191.22(c)). As stated above, the final interpretative ruling articulates Customs position that in situations where the law does not specifically authorize substitution, identification of merchandise or articles for drawback purposes by appropriate accounting procedures should be consistent with the criteria for such accounting procedures described above.

Comment: The higher-to-lower accounting method promotes administrative efficiency because it allows Customs to verify drawback claims without inquiring as to the order of withdrawal from commingled inventory.

Response: The drawback statute contains specific time limits (see *e.g.*, sections 1313 (i), (b), (c), (j), (p)). Any verification by Customs of whether a drawback claimant has complied with the drawback law and the regulations issued thereunder must include verification that the statutory time-limits were met.

Comment: If Customs decides to revoke C.S.D. 84–82 and proscribe the use of higher-to-lower accounting for drawback, Customs should specify a ''cut-off'' date for use of the higher-to-lower method. Customs should delay the effective date for this change in position because the drawback public may have relied on this ruling in establishing its inventory methods for drawback. One commenter suggests an implementation period of 3 years.

Response: Customs is delaying the effective date of the amendment of T.D. 84–49 and the revocation of C.S.D. 84–82 for 90 days after the publication of this document, the maximum delay provided for in the Customs Regulations for a modification or revocation of a ruling (see 19 CFR 177.9). Customs notes that, in regard to manufacturing drawback, a drawback claimant which relied on C.S.D. 84–82 should be able to document such reliance in its drawback rate (*i.e.*, in order to be paid manufacturing drawback, a claimant must have an approved drawback rate (see 19 CFR 191.23 and the general drawback rate for section 1313(a) (T.D. 81–234), as well as the sample drawback proposal for section 1313(b) provided for in 19 CFR 191.21(c), the latter of which contains specific sections in which the claimant is instructed to describe its inventory procedures)). In such instances (*i.e.*, when a claimant is operating under a drawback rate which specifically provides for higher-to-lower accounting), drawback claimants may continue to use higher-to-lower accounting procedures, as provided for in their drawback rates, until their rates are modified, and notice of the modification is sent to the rate holders.

Conclusion

For the reasons given in the June 28, 1994, **Federal Register** notice, and following careful consideration of the comments received and further review of the matter, Customs is taking the actions described in the June 28, 1994, **Federal Register** notice. That is:

1. T.D. 84–49 is amended to permit the accounting for withdrawals from inventory of exports and drawback deliveries on a FIFO basis. The order of such withdrawals will continue to be: first exports, then drawback deliveries, after which domestic shipments will be accounted for on a FIFO basis.

2. C.S.D. 84–82 is revoked.

This amendment of T.D. 84–49 and the revocation of C.S.D. 84–82 will be effective to drawback entries or claims properly filed with Customs on or after 90 days from the date of publication in the **Federal Register**. Drawback claimants operating under properly approved drawback rates under 19 CFR 191.23 may continue to claim drawback using higher-to-lower accounting procedures, as provided for in C.S.D. 84–82, if the drawback rates under which they are operating specifically provide for the use of such procedures, until such rates are modified, and notice of such modification is sent to the rate holders.

Michael H. Lane,

Acting Commissioner of Customs.

Approved: July 6, 1995.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 95–19911 Filed 8–10–95; 8:45 am]

BILLING CODE 4820–02–P

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8611]

RIN 1545–AS40

Conduit Arrangements Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to conduit financing arrangements issued under the authority granted by section 7701(l). The final regulations apply to persons engaging in multiple-party financing arrangements. The final regulations are necessary to determine whether such arrangements should be recharacterized under section 7701(l).

EFFECTIVE DATE: The regulations are effective September 11, 1995.

FOR FURTHER INFORMATION CONTACT: Elissa J. Shendalman of the Office of the Associate Chief Counsel (International), (202) 622–3870 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget for review in accordance with the Paperwork Reduction Act (44 U.S.C. 3504(h)) under control number 1545–1440. The estimated annual burden per recordkeeper is 10 hours.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, PC:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Background

On August 10, 1993, Congress enacted section 7701(l) of the Internal Revenue Code (Code), which authorizes the

Secretary to ''prescribe regulations recharacterizing any multiple-party financing transaction as a transaction directly among any 2 or more parties where such recharacterization is necessary to prevent avoidance of any tax imposed by [title 26].'' The legislative history to section 7701(l) noted with approval a series of tax court and IRS pronouncements that used ''substance over form'' principles to recharacterize conduit financing arrangements, but stated that the Secretary was not bound by the principles of these pronouncements in developing regulations.

On October 14, 1994, the IRS published a notice of proposed rulemaking in the **Federal Register** (59 FR 52110) under section 7701(l) of the Code. These proposed regulations permit the district director to disregard the participation of one or more intermediate entities in a conduit financing arrangement for purposes of sections 871, 881, 1441, and 1442.

Written comments responding to the notice were received, and a public hearing was held on December 16, 1994. After considering the written comments received and the statements made at the hearing, the IRS and Treasury adopt the proposed regulation as revised by this Treasury decision.

Explanation of Provisions and Summary of Significant Comments

A. Overview of Provisions

The final regulations make few substantive changes to the proposed regulations. Most changes are in the nature of refinements to, and clarifications of, the principles in the proposed regulations. It should be noted that the IRS and Treasury will continue to monitor conduit financing arrangements in the context of sections 871, 881, 1441 and 1442 after the publication of these final regulations. If the rules announced herein do not sufficiently address the avoidance of these taxes, the IRS and Treasury will consider modifying or supplementing these rules as they find necessary.

Section 1.881–3(a)(2) of the final regulations provides definitions of certain terms used throughout the regulations. A *financing arrangement* is defined as a series of transactions by which one person (the financing entity) advances money or other property, or grants rights to use property, and another person (the financed entity) receives money or other property, or the right to use property, if the advance and receipt are effected through one or more other persons (intermediate entities) and there are financing transactions linking the financing entity, each of the intermediate entities, and the financed entity. The final regulations supplement this basic rule with an anti-abuse rule that allows the IRS to treat related persons as a single entity where a taxpayer interposes a related person in an arrangement that would otherwise qualify as a *financing arrangement* to circumvent the application of the conduit rules.

A *financing transaction* includes a debt instrument, lease or license. In addition, an equity instrument may qualify as a *financing transaction* if the equity has certain debt-like characteristics. The term *financing transaction* also includes any other advance of money or property pursuant to which the transferee is obligated to repay or return a substantial portion of the money or other property advanced or the equivalent in value.

Section 1.881–3(a)(3)(i) authorizes the district director to determine that an intermediate entity is a conduit entity under the rules set forth in § 1.881–3(a)(4). Section 1.881–3(a)(3)(ii) describes the effects of conduit treatment. Section 1.881–3(a)(3)(ii)(B) generally provides that the character of the payments made under the recharacterized transaction (i.e. interest, rents, etc.) is determined by reference to the character of the payments made to the financing entity. However, if the financing transaction to which the financing entity is a party gives rise to a type of payment that would not be deductible if paid by the financed entity (e.g., dividends, as determined under U.S. tax principles), the character of the payments is not affected by the recharacterization.

Section 1.881–3(a)(3)(ii)(E) provides that a financing entity that is unrelated to both the intermediate entity and the financed entity is not liable for the tax imposed by section 881 unless it knows or has reason to know of a conduit financing arrangement. Moreover, the final regulations create a presumption that an unrelated financing entity does not know or have reason to know of a conduit financing arrangement where the intermediate entity that is a party to the financing transaction with the financing entity is engaged in a substantial trade or business.

Section 1.881–3(a)(4) provides the standards for determining whether an intermediate entity is a conduit entity for purposes of section 881. If an intermediate entity is related to either the financing entity or the financed entity, the intermediate entity will be a conduit entity only if (i) the participation of the intermediate entity in the financing arrangement reduces the U.S. withholding tax that otherwise would have been imposed, and (ii) the participation of the intermediate entity in the financing arrangement is pursuant to a plan one of the principal purposes of which is the avoidance of the withholding tax.

If a financing arrangement involves multiple intermediate entities, § 1.881–3(a)(4)(ii)(A) provides that the district director will determine whether each of the intermediate entities is a conduit entity. The factors, presumptions, and other rules in the regulations generally state how they should be applied in the case of multiple intermediate entities. The regulations state that, if no such rule is provided, the district director should apply principles consistent with the standards described above. Section 1.881–3(a)(4)(ii)(B) provides a general anti-abuse rule that allows the district director to treat related intermediate entities as a single intermediate entity if he determines that one of the principal purposes for the involvement of multiple intermediate entities in the financing arrangement is to prevent the characterization of an intermediate entity as a conduit entity, to reduce the portion of a payment that is subject to withholding tax or otherwise to circumvent the provisions of this section. The district director's determination is to be based upon all of the facts and circumstances, including, but not limited to, the factors indicating whether the intermediate entity's participation in a financing arrangement is pursuant to a tax avoidance plan.

Section 1.881–3(b) provides that the district director will weigh all available evidence regarding the purposes for the intermediate entity's participation in the financing arrangement. Moreover, § 1.881–3(b)(3) provides a presumption that a tax avoidance plan does not exist where an intermediate entity that is related to either the financing entity or the financed entity performs significant financing activities with respect to the financing transactions making up the financing arrangement.

In the case of an intermediate entity that is not related to either the financing entity or the financed entity, the intermediate entity will not be a conduit entity unless the requirements applicable to related parties are met (that is, there is a reduction in the tax imposed by section 881 and a tax avoidance plan) and, in addition, the intermediate entity would not have participated in the financing arrangement on substantially the same terms but for the fact that the financing entity advanced money or property to (or entered into a lease or license with) the intermediate entity. See § 1.881–

3(a)(4)(i)(C). Under § 1.881–3(c)(2), the district director may presume that the intermediate entity would not have participated in the financing arrangement on substantially the same terms but for the financing transaction between the financing entity and the intermediate entity if another person has provided a guarantee of the financed entity's obligation to the intermediate entity. The term *guarantee* includes, but is not limited to, a right of offset between the two financing transactions to which the intermediate entity is a party.

Once the district director has disregarded the participation of a conduit entity in a conduit financing arrangement, § 1.881–3(d)(1)(i) provides that a portion of each payment made by the financed entity is recharacterized as a payment directly between the financed entity and the financing entity. If the aggregate principal amount of the financing transaction(s) to which the financed entity is a party is less than or equal to the aggregate principal amount of the financing transaction(s) linking any of the parties to the financing arrangement, the entire amount of the payment by the financed entity shall be recharacterized. If the aggregate principal amount of the financing transaction(s) to which the financed entity is a party is greater than the aggregate principal amount of the financing transaction(s) linking any of the parties to the financing arrangement, then the recharacterized portion shall be determined by multiplying the payment by a fraction the numerator of which is equal to the lowest aggregate principal amount of the financing transaction(s) linking any of the parties to the financing arrangement and the denominator of which is the aggregate principal amount of the financing transaction(s) to which the financed entity is a party.

Under § 1.881–3(d)(1)(ii)(A), the principal amount of a financing transaction generally equals the amount of money, or the fair market value of other property, advanced, or subject to a lease or license, valued at the time of the financing transaction. However, in the case of a financing arrangement where the same property is advanced, or rights granted from the financing entity through the intermediate entity (or entities) to the financed entity, the property is valued on the date of the last financing arrangement. This rule is intended to minimize the distortive effect of currency or other market fluctuations when there is a time lag between financing transactions. In addition, the principal amount of certain types of financing transactions is subject to adjustment. Sections 1.881–3(d)(1)(ii) (B) through (D) provide more detailed guidance regarding how these general rules are applied to different types of financing transactions.

Section 1.881–4 uses the general recordkeeping requirements under section 6001 to require a financed entity or any other person to keep records relevant to determining whether such person is a party to a financing arrangement and whether that financing arrangement may be recharacterized under § 1.881–3. Corporations that otherwise would report certain information on total annual payments to related parties pursuant to sections 6038(a) and 6038A(a) must also maintain such records where the corporation knows or has reason to know that such transactions are part of a financing arrangement. Specifically, the final regulations require the entity to retain all records relating to the circumstances surrounding its participation in the financing transactions and financing arrangements, including minutes of board of directors meetings and board resolutions and materials from investment advisors regarding the structuring of the transaction.

Under § 1.1441–7(d), any person that is a withholding agent for purposes of section 1441 with respect to the transaction (whether the financed entity or an intermediate entity that is treated as an agent of the financing entity) must withhold in accordance with the recharacterization if it knows or has reason to know that the financing arrangement is a conduit financing arrangement. The final regulations provide examples of how the ''knows or has reason to know'' standard, which generally applies to all withholding agents, is to be applied in this context.

B. Discussion of Significant Comments

Significant comments that relate to the application of the proposed regulation and the responses to them, including an explanation of the revisions made to the final regulation, are summarized below. Technical or drafting comments that have been reflected in the final regulations generally are not discussed.

1. General Approach

As described above, the final regulations adopt the general ''tax avoidance'' standard of the proposed regulations. Several commentators criticized the proposed regulations for setting forth new standards for the recharacterization of conduit transactions. They argued that the rulings that preceded these regulations required matching cash flows from the financed entity to the conduit entity and from the conduit entity to the financing entity. Some commentators argued that, because in their view the regulations adopt new standards, the regulations should only be effective for transactions entered into after the enactment of section 7701(l), while others argued that the regulations should only apply to transactions entered into after the publication of the final regulations. Finally, some commentators suggested that the regulations constituted an override of our treaty obligations and might therefore be invalid.

The IRS and Treasury believe that pre-section 7701(l) conduit rulings rested on a taxpayer having a tax avoidance purpose for structuring its transactions. The fact that an intermediate entity received and paid matching, or nearly matching, cash flows was evidence that the participation of the intermediate entity in the transaction did not serve a business purpose. Nevertheless, the fact that cash flows were not matched did not mean that the transaction had a business purpose.

The final regulations generally apply to payments made by financed entities after the date which is 30 days after the date of publication of the regulations because the IRS and Treasury believe that the regulations reflect existing conduit principles. Moreover, even if the regulations had adopted a new standard, it would be inappropriate to grandfather transactions that admittedly had a tax avoidance purpose. The final regulations do not apply to interest payments covered by section 127(g)(3) of the Tax Reform Act of 1984, and to interest payments with respect to other debt obligations issued prior to October 15, 1984 (whether or not such debt was issued by a Netherlands Antilles corporation). Prior law continues to apply with respect to payments on any such debt instruments.

As noted in the preamble to the proposed regulations, the IRS and Treasury believe that these regulations supplement, but do not conflict with, the limitation on benefits articles in tax treaties. They do so by determining which person is the beneficial owner of income with respect to a particular financing arrangement. Because the financing entity is the beneficial owner of the income, it is entitled to claim the benefits of any income tax treaty to which it is entitled to reduce the amount of tax imposed by section 881 on that income. The conduit entity, as an agent of the financing entity, cannot claim the benefits of a treaty to reduce the amount of tax due under section 881

with respect to payments made pursuant to the financing arrangement.

2. Discretion given to District Director

a. *Determination of whether conduit entity's participation will be disregarded.* Because the proposed regulations utilize a tax avoidance test that depends on the facts and circumstances, discretion is given to the district director to determine whether the participation of an intermediate entity had as one of its principal purposes the avoidance of U.S. withholding tax. Among other things, the district director may determine the composition of the financing arrangement and the number of parties to the financing arrangement.

Some commentators criticized this grant of discretion because they claimed that the regulations provide insufficient guidance regarding what factors the district director should take into account. Several commentators proposed adding presumptions, making certain existing presumptions irrebuttable or otherwise providing bright-line tests. One commentator suggested that the district director's discretion to determine the parties to a financing arrangement should be limited to the extent necessary to ensure that a taxpayer could prove that a different party that was entitled to treaty benefits was the real financing entity. Finally, another commentator suggested that the determination whether an intermediate entity's participation will be disregarded should be subject to review by a central control board in the National Office of the IRS.

Because the final regulations retain the facts and circumstances test used in the proposed regulations, the final regulations do not significantly reduce the district director's discretion. As discussed below, it was not considered necessary to add additional factors because the objective list of factors is not exclusive. The final regulations do, however, provide more guidance regarding the tax avoidance purpose test by adding several more examples. In addition, the final regulations modify the factor relating to whether there has been a significant reduction in tax to allow the taxpayer to produce evidence that there was not a reduction in tax because the entity that was the ultimate source of funds also was entitled to treaty benefits. See § 1.881–3(b)(2)(i).

The final regulations do not adopt the suggestion that the district director's discretion be subject to review at the National Office level. The final regulations, like the proposed regulations, provide that the determination of whether a tax avoidance plan exists is based on all of the facts and circumstances surrounding the intermediate entity's participation in the financing arrangement. The IRS and Treasury believe that such a determination would best be made at the local level.

b. *Judicial standard of review.* Because the district director is granted discretion by the regulations, his determinations generally will be reviewed by the court under an abuse of discretion standard. Commentators suggested that the district director's determination that an intermediate entity's participation should be disregarded should be reviewed by the court under this standard. One commentator instead suggested that courts review a district director's determination using a de novo standard of review. Another suggested that the IRS should be afforded only its normal presumption of correctness. The final regulations do not adopt these suggestions because they are fundamentally inconsistent with the grant of discretion to the district director.

3. Definitions

a. *Financing transaction, in general.* Commentators pointed out that thedefinition of *financing transaction* in the proposed regulations encompassed transactions that clearly were not meant to be covered by the proposed regulations. For example, under the proposed regulations, a foreign parent that contributed an existing note from its domestic subsidiary to a foreign subsidiary in exchange for common stock of the subsidiary that did not have any debt-like features nevertheless would be treated as a financing entity because the foreign parent had made an advance of property (the note) pursuant to which the foreign subsidiary had ''become a party to an existing financing transaction''.

The definitions of *financing transaction* and *financing arrangement* have been redrafted to address these concerns. See § 1.881–3(a)(2) (i) and (ii). The effect of the new definitions is to take a ''snapshot'' after all the transactions are in place to determine whether there is a *financing arrangement.*

b. Equity. Commentators noted that the proposed regulations were inconsistent in their treatment of how a controlling interest in a corporation, either before or after a default, affected whether an equity arrangement was a financing transaction. In addition, commentators requested that the final regulations explicitly exempt ''common stock'' and ''ordinary preferred stock'' from treatment as financing transactions.

In response to the first of these comments and in a general attempt to clarify the types of equity instruments that are financing transactions, the final regulations revise the definition of *financing transaction* with respect to equity. See § 1.881–3(a)(2)(ii) (A)(*2*) and (B). The new definition provides that the right to elect the majority of the board of directors will not, in and of itself, cause an equity instrument to be a financing arrangement. See § 1.881–3(a)(2)(ii)(B)(*2*)(*i*).

As to the second suggestion, the final regulations do not create a separate exception from the definition of financing transaction for ''common stock'' or ''ordinary perpetual preferred stock.'' Whether a transaction constitutes a financing transaction depends upon the terms of the transaction, not simply on the label attached to the transaction. Moreover, because these terms are not themselves well-defined in either the Code or common law, the IRS and Treasury believe that excluding these categories of instruments would lead to disputes as to whether a particular instrument is ''common stock'' or, if not, whether it is ''ordinary'' perpetual preferred stock.

c. Guarantees. Commentators asked that final regulations explicitly provide that guarantees are exempted from treatment as financing transactions. The IRS and Treasury believe that the new definition of financing transaction, which does not treat becoming a party to a financing transaction as itself a financing transaction, clarifies that a guarantee is not a financing transaction. Moreover, the final regulations add an example to eliminate any doubt in this regard. See § 1.881–3(e) *Example 1.*

d. Leases and licenses. The proposed regulations provide that leases and licenses are financing transactions. Some commentators suggested that the regulations not include leases and licenses in the definition of financing transaction or that the IRS reserve on the subject of leases until it had more time to study the matter.

Other commentators proposed that certain types of leases, for instance short-term leases and leveraged leases, be excluded from the definition of financing transaction. The commentators pointed out that certain leveraged leases would be subject to recharacterization under the proposed regulations even though, in substance, the financing arrangement is the equivalent of a loan from a financing entity entitled to a zero rate of withholding on interest. Under § 1.881–3(d)(2) of the proposed regulations,

which provides that the nature of the recharacterized payments is determined by reference to the transaction to which the financed entity is a party, the participation of the intermediate entity in a leveraged lease would substantially reduce the tax imposed under section 881 if the treaty between the United States and the country in which the lender was organized allowed withholding on rental payments. Because all of the negative factors of § 1.881–3(c)(2) and the ''but-for'' test of § 1.881–3(b) of the proposed regulations are met in a standard leveraged lease, this reduction in tax would allow the district director to recharacterize the financing arrangement as a conduit financing arrangement.

The IRS and Treasury believe that all leases and licenses, of whatever duration, can be used by taxpayers to structure a conduit financing arrangement. Accordingly, the final regulations continue to include leases and licenses in the definition of financing transaction. See § 1.881–3(a)(2)(ii)(A)(*3*). However, the final regulations change the character rule in the case of deductible payments. In those cases, the character of the payments under the recharacterized transaction is determined by reference to the financing transaction to which the financing entity is a party. As a result, under the final regulations, a leveraged lease generally will not be recharacterized as a conduit arrangement if the ultimate lender would be entitled to an exemption from withholding tax on interest received from the financed entity, even if rental payments made by the financed entity to the financing entity would have been subject to withholding tax.

e. Related. As noted above, it is more difficult for an intermediate entity to be a conduit entity if it is not related to either the financing entity or the financed entity. The definition of persons who are *related* to another person generally follows the definition used in section 6038A. One commentator suggested that the final regulations eliminate the constructive ownership rule of section 267(c)(3) from the definition of related. The same commentator further suggested that a person under common control within the meaning of section 482 should not be a related person for purposes of this regulation.

The IRS and Treasury believe that the term *related* should be broadly defined to ensure that the additional protection from recharacterization provided by the so-called ''but for'' test flows only to those entities that are not under the effective control of either the financing or the financed entity. Accordingly, the final regulations retain the definition of related provided in the proposed regulations. See § 1.881–3(a)(2)(v).

4. Factors Indicating the Presence or Absence of a Tax Avoidance Plan

a. In general. The proposed regulations provide that whether the participation of the intermediary in the financing arrangement is pursuant to a tax avoidance plan is determined based on all the relevant facts and circumstances. In addition, the proposed regulations provide a list of some of the factors that will be taken into account: the extent of the reduction in tax; the liquidity of the intermediate entity; the timing of the transactions; and, in the case of related entities, the nature of the business(es) of such entities.

Commentators asked that the final regulations adopt a number of additional factors. For example, commentators asked that the dissimilarity of cash flows or of financing transactions making up the financing arrangement constitute a positive factor (i.e., a factor that evidences the absence of a tax avoidance plan). Commentators also suggested that the positive factors include the fact that income was subject to net tax in the United States or in a foreign jurisdiction or, alternatively, that the transaction reduced other U.S. or foreign taxes more than it reduced the U.S. withholding tax (indicating that the purpose of the transaction was to avoid taxes other than the tax imposed by section 881).

The factors proposed by commentators generally relate to the issue of whether there were purposes, other than the avoidance of the tax imposed by section 881, for the participation of the intermediate entity in the financing arrangement. The final regulations do not add factors relating to purposes for the participation of an intermediate entity in a financing arrangement. However, § 1.881–3(b)(1) of the final regulations addresses the issue by clarifying that the district director will consider all available evidence regarding the purposes for the participation of the intermediate entity.

b. Factor relating to a complementary or integrated business. One of the factors listed in the proposed regulations is whether, if the intermediate entity is related to the financed entity, the two parties enter into a financing transaction to finance a trade or business actively engaged in by the financed entity that forms a part of, or is complementary to, a substantial trade or business actively engaged in by the intermediate entity. One commentator expressed uncertainty as to the policy behind this factor.

The intent of this factor was to take into account the fact that related corporations engaged in integrated businesses may enter into many financing transactions in the course of conducting those businesses, the vast majority of which have no tax avoidance purpose. Accordingly, § 1.881–3(b)(2)(iv) of the final regulations clarifies that the district director will take into account whether a transaction is entered into in the ordinary course of integrated or complementary trades or businesses in determining whether there is a tax avoidance plan. In addition, the factor is broadened so as to apply not only to transactions between the intermediate entity and the financed entity but to transactions between any two parties to the financing arrangement that are related to each other.

5. Presumption Regarding Significant Financing Activities

The proposed regulations provide that, in the case of an intermediate entity that is related to either the financing entity or the financed entity, a presumption of no tax avoidance arises where the intermediate entity performs significant financing activities for such entities. Among other things, the provision required employees of the intermediate entity (other than an intermediate entity that earned ''active rents'' or ''active royalties'') to manage ''business risks'' arising from the transaction on an ongoing basis. The proposed regulations provide an example showing that, if there are no such business risks because the intermediate entity has hedged itself fully at the time it entered into the financing transactions, the entity is not described in the provision.

One commentator criticized the articulation of the significant financing activities presumption in the proposed regulations on the grounds that the test should be solely whether the participation of the intermediate entity produces (or could be expected to produce) efficiency savings through a reduction in overhead costs and the ability to hedge the group's positions on a net basis. Another commentator proposed extending the presumption for significant financing activities to intermediate entities that are unrelated to both the financed entity and the financing entity.

As to the first comment, the IRS and Treasury agree that there is not a sufficient business purpose for the centralization of financing activities of a group of related corporations in a single

corporation unless the taxpayer anticipates efficiency savings. Although the prospect of such savings in general may establish a business purpose for the establishment of the subsidiary, it does not prevent the subsidiary from acting as a conduit with respect to any particular financing arrangement. This is demonstrated by the hedging example described above, the rationale for which is that either the financed entity or the financing entity could have entered into the long-term hedge so there is no economic justification for the participation of the intermediate entity in the particular financing arrangement. The IRS and Treasury believe that an affiliate that is not taking a continuing active role in coordinating and managing a financing transaction should not be entitled to the presumption that its participation is not pursuant to a tax avoidance plan.

As to the suggestion of extending the significant financing activities presumption to unrelated parties, the IRS and Treasury believe that this extension would be inconsistent with the purpose of the presumption. The significant financing presumption recognizes that there are legitimate business reasons for conducting financing activities through a centralized financing and hedging subsidiary. The decision to have an unrelated intermediate entity participate in a financing transaction is based on different considerations, including the regulatory effects of such transactions and the interests of the shareholders of the unrelated intermediary. These considerations are addressed by providing that such entities will not be conduit entities unless they satisfy the ''but for'' test. The final regulations do not extend the significant financing activities presumption to unrelated parties.

Accordingly, the requirements for the significant financing activities presumption in § 1.881–3(b)(3) of the final regulations are generally the same as those in the proposed regulations. However, the final regulations do add a requirement that the participation of the intermediate entity generate efficiency savings, and change the term *business risks* to *market risks* (to differentiate the risks of currency and interest rate movements from other, primarily credit, risks). In addition, one of the examples that illustrates the significant financing activities presumption has been revised to indicate that a finance subsidiary may be managing market risks even in the case of a fully-hedged transaction if the intermediate entity routinely terminates such long term arrangements when it finds cheaper hedging alternatives. See § 1.881–3(e) *Example 22.*

6. ''But for'' Test

a. In general. Under the proposed regulations, if the intermediate entity is not related to either the financing entity or the financed entity, the financing arrangement will not be recharacterized unless the intermediate entity would not have participated in the financing arrangement on substantially the same terms ''but for'' the fact that the financing entity advanced money or property to (or entered into a lease or license with) the intermediate entity.

Commentators asked for clarification regarding what it means for terms to be not substantially the same. One commentator proposed using the standards for material modifications under section 1001.

The IRS and Treasury believe that an attempt to set forth a comprehensive system of bright-line rules like those suggested by commentators would add unnecessary complexity to the regulation, given its anti-abuse purpose. Accordingly, the final regulations make no change to the proposed regulations in this regard.

b. Presumption where financing entity guarantees the liability of the financed entity. Under the proposed regulations, it is presumed that the intermediate entity would not have participated in the financing arrangement on substantially the same terms if, in addition to entering into a financing transaction with the intermediate entity, the financing entity guarantees the financed entity's liabilities under its financing transaction with the intermediate entity. A taxpayer may rebut this presumption by producing clear and convincing evidence that the intermediate entity would have participated in the financing arrangement on substantially the same terms even if the financing entity had not entered into a financing transaction with the intermediate entity.

Several commentators asked for clarification of this presumption. Some commentators suggested that the existence of a guarantee makes the existence of the financing transaction between the financing entity and the intermediate entity irrelevant to the determination of whether the intermediate entity would have participated in the financing arrangement on substantially the same terms. Another commentator proposed eliminating the ''clear and convincing evidence'' standard on the grounds that it is too difficult an evidentiary burden for the taxpayer to overcome.

The presumption regarding guarantees originated in Rev. Rul. 87–89 (1987–2 C.B. 195), which articulated the ''but for'' test in substantially the same terms as adopted in the final regulations. Rev. Rul. 87–89 provided that a statutory or contractual right of offset is presumptive evidence that the unrelated intermediary would not have participated in the financing arrangement on substantially the same terms without the financing transaction from the financing entity. The proposed regulations extend the presumption to all guarantees in order to prevent taxpayers from using forms of credit support other than the right of offset to avoid this presumption. The final regulations retain this rule. See § 1.881–3(c)(2).

The final regulations also retain the ''clear and convincing evidence'' standard. The taxpayer always must overcome the presumption of correctness in favor of the government by a preponderance of the evidence. Therefore, in order for this additional presumption to have any effect, it is necessary to raise the evidentiary standard. In addition, this standard of proof is not unreasonable, because an intermediate entity that is unrelated to the financing entity and the financed entity and that proves, by clear and convincing evidence, that it would have entered into the financing arrangement on substantially the same terms will avoid recharacterization as a conduit entity *even though* its participation in the financing arrangement is pursuant to a tax avoidance plan.

7. Multiple Intermediate Entities

a. In general. The proposed regulations provide guidance as to how some but not all of the operative provisions and presumptions apply to multiple intermediate entities. Several commentators asked that the final regulations clarify the manner in which the operative rules apply in the case of multiple intermediate entities. The final regulations provide additional guidance in the relevant operative rules and presumptions. In addition, the final regulations modify the example in the proposed regulations relating to multiple intermediate entities to clarify how some of these provisions and presumptions apply. See § 1.881–3(e) *Example 8.*

b. Special rule for related persons. Section 1.881–3(a)(4)(ii)(B) of the proposed regulations allows the district director to treat related persons as a single intermediate entity if he determines that one of the principal purposes for the structuring of a transaction was the avoidance of the

application of the conduit financing arrangement rules. Several commentators suggested that the final regulations eliminate this section. One commentator suggested that the rule be limited to situations where one related corporation made an equity investment in another. Another believed that the IRS and Treasury should ''wait and see'' whether such a rule was really necessary to prevent taxpayers from circumventing the conduit financing arrangement rules.

The IRS and Treasury believe that an anti-abuse rule is necessary to prevent the circumvention of these rules through manipulation of the definition of financing arrangement. Accordingly, § 1.881–3(a)(2)(i)(B) of the final regulations retains the related party anti-abuse rule. Moreover, the final regulations include another more general anti-abuse rule that allows the district director to treat related intermediate entities as a single intermediate entity if he determines that one of the principal purposes for the involvement of multiple intermediate entities in the financing arrangement is to prevent the characterization of an entity as a conduit, to reduce the portion of a payment that is subject to withholding tax or otherwise to circumvent any other provision of this section. See § 1.881–3(a)(4)(ii)(B). This rule prevents a taxpayer from structuring a financing transaction with a small principal amount to reduce the amount of the recharacterized payment, and thus replaces the second half of the rule set forth in proposed regulation § 1.881–3(a)(4)(ii)(B). This rule is illustrated in § 1.881–3(e) *Example 7*.

8. Principal Amount

The proposed regulations provide that the principal amount of a financing transaction shall be determined on the basis of all of the facts and circumstances. Under the proposed regulations, the principal amount generally equals the amount of money, or the fair market value of other property (determined as of the time that the financing transaction is entered into), advanced in the financing transaction. The principal amount of a financing transaction is subject to adjustments, as appropriate.

Some commentators asked for clarification regarding whether adjustments would be made to the principal amount of a financing transaction to take account of amortization or depreciation. Another commentator suggested that the final regulations provide that calculations be performed in the functional currency of the intermediate entity in order to isolate currency fluctuations.

The final regulations provide that adjustments for depreciation and amortization are made when calculating the principal amount of a leasing or licensing financing transaction. See § 1.881–3(d)(1)(ii)(A).

Although the IRS and Treasury agree that the effect of currency fluctuations should be minimized, they believe that determining the principal amount in the functional currency of the intermediate entity would not always yield the correct result. Accordingly, the final regulations eliminate currency and market fluctuations to the extent possible by providing that, when the same property has been advanced by the financing entity and received by the financed entity, the determination of the principal amount is made as of the date the last financing transaction is entered into. See § 1.881–3(d)(1)(ii)(A). An example has been added to demonstrate how this rule applies to transactions in currencies other than the U.S. dollar. See § 1.881–3(e) *Example 25*.

9. Correlative Adjustments

The proposed regulations do not provide for correlative adjustments in the case of the district director's recharacterization of a financing arrangement as a transaction directly between a financing entity and a financed entity.

Commentators have requested that taxpayers be allowed to make correlative adjustments if their transactions are recharacterized. Commentators generally would not, however, allow the IRS to make correlative adjustments where such adjustments would result in greater tax liability.

The final regulations, like the proposed regulations, do not provide for correlative adjustments. The IRS and Treasury agree with commentators that it is not appropriate to use regulations that are intended to prevent the avoidance of tax under section 881 to recharacterize transactions for purposes of other code sections. Accordingly, taxpayers should not be able to use these regulations to make correlative adjustments to their tax returns.

10. Recordkeeping and Reporting Requirements

The proposed regulations require corporations that would otherwise report certain information on total annual payments to related parties pursuant to sections 6038(a) and 6038A(a) to report such information on a transaction-by-transaction basis where the corporation knows or has reason to know that such transactions are part of a financing arrangement. In addition, the proposed regulations require a financed entity or any other person to keep records relevant to determining whether such person is a party to a financing arrangement that is subject to recharacterization as part of their general recordkeeping requirements under section 6001.

Commentators criticized the reporting requirements imposed by the proposed regulation as unduly burdensome in that they would require reporting of all financing arrangements and not simply those subject to recharacterization as conduit financing arrangements. Moreover, they pointed out that, because the regulations only would require reporting of those transactions to which the financed entity is a party, the information reported would not be of significant value. The reported information would not be sufficient to allow the IRS to connect the reported financing transaction to the other financing transactions making up a financing arrangement.

The final regulations eliminate the reporting requirements provided in the proposed regulations and provide more specific guidance as to the type of records affected entities must retain. The recordkeeping requirements of § 1.881–4 have been revised to incorporate all of the information that entities would have had to report under the proposed regulations. In addition, the final regulations require the entity to retain all records relating to the circumstances surrounding its participation in the financing transactions and financing arrangements, including minutes of board of directors meetings and board resolutions and materials from investment advisors regarding the structuring of the transaction. See § 1.881–4(c)(2).

11. Withholding Obligations

Under the proposed regulations, a person that is otherwise a withholding agent is required to withhold tax under section 1441 or section 1442 in accordance with the recharacterization of a financing arrangement if the person knows or has reason to know that the financing arrangement is subject to recharacterization under sections 871 or 881. Commentators asked for additional guidance regarding the application of the ''know or have reason to know'' standard in the context of conduit financing arrangements. The final regulations include several examples regarding the circumstances in which a financed entity does and does not have

reason to know of the existence of a conduit financing arrangement.

C. Status of Revenue Rulings

The proposed regulations did not address the status of the existing revenue rulings relating to conduit arrangements. Commentators have asked for guidance regarding their status.

Concurrent with the publication of these regulations, the IRS is issuing a revenue ruling modifying the existing rulings. The revenue ruling limits the application of the old revenue rulings in the context of withholding tax to payments made before the effective date of the final regulations and to other provisions not covered by the conduit regulations.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. This certification is based on the information that follows. These regulations affect entities engaged in cross-border multiple-party financing arrangements. It is assumed that a substantial number of small entities will not engage in such financing arrangements. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small businesses.

Drafting Information: The principal author of these regulations is Elissa J. Shendalman, Office of the Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by removing the entry for ''Sections 1.6038A–1 through 1.6038A–7'' and adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.871–1 also issued under 26 U.S.C. 7701(l). * * *

Section 1.881–3 also issued under 26 U.S.C. 7701(l).

Section 1.881–4 also issued under 26 U.S.C. 7701(l). * * *

Section 1.1441–3 also issued under 26 U.S.C. 7701(l). * * *

Section 1.1441–7 also issued under 26 U.S.C. 7701(l). * * *

Section 1.6038A–1 also issued under 26 U.S.C. 6038A.

Section 1.6038A–2 also issued under 26 U.S.C. 6038A.

Section 1.6038A–3 also issued under 26 U.S.C. 6038A and 7701(l).

Section 1.6038A–4 also issued under 26 U.S.C. 6038A.

Section 1.6038A–5 also issued under 26 U.S.C. 6038A.

Section 1.6038A–6 also issued under 26 U.S.C. 6038A.

Section 1.6038A–7 also issued under 26 U.S.C. 6038A. * * *

Section 1.7701(l)–1 also issued under 26 U.S.C. 7701(l). * * *

Par. 2. In § 1.871–1, paragraph (b)(7) is added to read as follows:

§ 1.871–1 Classification and manner of taxing alien individuals.

* * * * *

(b) * * *

(7) *Conduit financing arrangements.* For rules regarding conduit financing arrangements, see §§ 1.881–3 and 1.881–4.

* * * * *

Par. 3. Sections 1.881–0, 1.881–3 and 1.881–4 are added to read as follows:

§ 1.881–0 Table of contents.

This section lists the major headings for §§ 1.881–1 through 1.881–4.

§ 1.881–1 Manner of Taxing Foreign Corporations

(a) Classes of foreign corporations.
(b) Manner of taxing.
(1) Foreign corporations not engaged in U.S. business.
(2) Foreign corporations engaged in U.S. business.
(c) Meaning of terms.
(d) Rules applicable to foreign insurance companies.
(1) Corporations qualifying under subchapter L.
(2) Corporations not qualifying under subchapter L.
(e) Other provisions applicable to foreign corporations.
(1) Accumulated earnings tax.
(2) Personal holding company tax.
(3) Foreign personal holding companies.
(4) Controlled foreign corporations.
(i) Subpart F income and increase of earnings invested in U.S. property.
(ii) Certain accumulations of earnings and profits.
(5) Changes in tax rate.
(6) Consolidated returns.
(7) Adjustment of tax of certain foreign corporations.
(f) Effective date.

§ 1.881–2 Taxation of Foreign Corporations Not Engaged in U.S. Business

(a) Imposition of tax.
(b) Fixed or determinable annual or periodical income.
(c) Other income and gains.
(1) Items subject to tax.
(2) Determination of amount of gain.
(d) Credits against tax.
(e) Effective date.

§ 1.881–3 Conduit Financing Arrangements

(a) General rules and definitions.
(1) Purpose and scope.
(2) Definitions.
(i) Financing arrangement.
(A) In general.
(B) Special rule for related parties.
(ii) Financing transaction.
(A) In general.
(B) Limitation on inclusion of stock or similar interests.
(iii) Conduit entity.
(iv) Conduit financing arrangement.
(v) Related.
(3) Disregard of participation of conduit entity.
(i) Authority of district director.
(ii) Effect of disregarding conduit entity.
(A) In general.
(B) Character of payments made by the financed entity.
(C) Effect of income tax treaties.
(D) Effect on withholding tax.
(E) Special rule for a financing entity that is unrelated to both intermediate entity and financed entity.
(iii) Limitation on taxpayers's use of this section.
(4) Standard for treatment as a conduit entity.
(i) In general.
(ii) Multiple intermediate entities.
(A) In general.
(B) Special rule for related persons.
(b) Determination of whether participation of intermediate entity is pursuant to a tax avoidance plan.
(1) In general.
(2) Factors taken into account in determining the presence or absence of a tax avoidance purpose.
(i) Significant reduction in tax.
(ii) Ability to make the advance.
(iii) Time period between financing transactions.
(iv) Financing transactions in the ordinary course of business.
(3) Presumption if significant financing activities performed by a related intermediate entity.
(i) General rule.
(ii) Significant financing activities.
(A) Active rents or royalties.
(B) Active risk management.
(c) Determination of whether an unrelated intermediate entity would not have participated in financing arrangement on substantially same terms.
(1) In general.

(2) Effect of guarantee.
(i) In general.
(ii) Definition of guarantee.
(d) Determination of amount of tax liability.
(1) Amount of payment subject to recharacterization.
(i) In general.
(ii) Determination of principal amount.
(A) In general.
(B) Debt instruments and certain stock.
(C) Partnership and trust interests.
(D) Leases and licenses.
(2) Rate of tax.
(e) Examples.
(f) Effective date.

§ 1.881–4 Recordkeeping Requirements Concerning Conduit Financing Arrangements

(a) Scope.
(b) Recordkeeping requirements.
(1) In general.
(2) Application of sections 6038 and 6038A.
(c) Records to be maintained.
(1) In general.
(2) Additional documents.
(3) Effect of record maintenance requirement.
(d) Effective date.

§ 1.881–3 Conduit financing arrangements.

(a) *General rules and definitions*—(1) *Purpose and scope.* Pursuant to the authority of section 7701(l), this section provides rules that permit the district director to disregard, for purposes of section 881, the participation of one or more intermediate entities in a financing arrangement where such entities are acting as conduit entities. For purposes of this section, any reference to tax imposed under section 881 includes, except as otherwise provided and as the context may require, a reference to tax imposed under sections 871 or 884(f)(1)(A) or required to be withheld under section 1441 or 1442. See § 1.881–4 for recordkeeping requirements concerning financing arrangements. See §§ 1.1441–3(j) and 1.1441–7(d) for withholding rules applicable to conduit financing arrangements.

(2) *Definitions.* The following definitions apply for purposes of this section and §§ 1.881–4, 1.1441–3(j) and 1.1441–7(d).

(i) *Financing arrangement*—(A) *In general.* Financing arrangement means a series of transactions by which one person (the financing entity) advances money or other property, or grants rights to use property, and another person (the financed entity) receives money or other property, or rights to use property, if the advance and receipt are effected through one or more other persons (intermediate entities) and, except in cases to which paragraph (a)(2)(i)(B) of this section applies, there are financing transactions linking the financing entity, each of the intermediate entities, and the financed entity. A transfer of money or other property in satisfaction of a repayment obligation is not an advance of money or other property. A financing arrangement exists regardless of the order in which the transactions are entered into, but only for the period during which all of the financing transactions coexist. See *Examples 1, 2,* and *3* of paragraph (e) of this section for illustrations of the term financing arrangement.

(B) *Special rule for related parties.* If two (or more) financing transactions involving two (or more) related persons would form part of a financing arrangement but for the absence of a financing transaction between the related persons, the district director may treat the related persons as a single intermediate entity if he determines that one of the principal purposes for the structure of the financing transactions is to prevent the characterization of such arrangement as a financing arrangement. This determination shall be based upon all of the facts and circumstances, including, without limitation, the factors set forth in paragraph (b)(2) of this section. See *Examples 4* and *5* of paragraph (e) of this section for illustrations of this paragraph (a)(2)(i)(B).

(ii) *Financing transaction*—(A) *In general.* Financing transaction means—

(*1*) Debt;

(*2*) Stock in a corporation (or a similar interest in a partnership or trust) that meets the requirements of paragraph (a)(2)(ii)(B) of this section;

(*3*) Any lease or license; or

(*4*) Any other transaction (including an interest in a trust described in sections 671 through 679) pursuant to which a person makes an advance of money or other property or grants rights to use property to a transferee who is obligated to repay or return a substantial portion of the money or other property advanced, or the equivalent in value. This paragraph (a)(2)(ii)(A)(*4*) shall not apply to the posting of collateral unless the collateral consists of cash or the person holding the collateral is permitted to reduce the collateral to cash (through a transfer, grant of a security interest or similar transaction) prior to default on the financing transaction secured by the collateral.

(B) *Limitation on inclusion of stock or similar interests*—(*1*) *In general.* Stock in a corporation (or a similar interest in a partnership or trust) will constitute a financing transaction only if one of the following conditions is satisfied—

(*i*) The issuer is required to redeem the stock or similar interest at a specified time or the holder has the right to require the issuer to redeem the stock or similar interest or to make any other payment with respect to the stock or similar interest;

(*ii*) The issuer has the right to redeem the stock or similar interest, but only if, based on all of the facts and circumstances as of the issue date, redemption pursuant to that right is more likely than not to occur; or

(*iii*) The owner of the stock or similar interest has the right to require a person related to the issuer (or any other person who is acting pursuant to a plan or arrangement with the issuer) to acquire the stock or similar interest or make a payment with respect to the stock or similar interest.

(*2*) *Rules of special application*—(*i*) *Existence of a right.* For purposes of this paragraph (a)(2)(ii)(B), a person will be considered to have a right to cause a redemption or payment if the person has the right (other than rights arising, in the ordinary course, between the date that a payment is declared and the date that a payment is made) to enforce the payment through a legal proceeding or to cause the issuer to be liquidated if it fails to redeem the interest or to make a payment. A person will not be considered to have a right to force a redemption or a payment if the right is derived solely from ownership of a controlling interest in the issuer in cases where the control does not arise from a default or similar contingency under the instrument. The person is considered to have such a right if the person has the right as of the issue date or, as of the issue date, it is more likely than not that the person will receive such a right, whether through the occurrence of a contingency or otherwise.

(*ii*) *Restrictions on payment.* The fact that the issuer does not have the legally available funds to redeem the stock or similar interest, or that the payments are to be made in a blocked currency, will not affect the determinations made pursuant to this paragraph (a)(2)(ii)(B).

(*iii*) *Conduit entity* means an intermediate entity whose participation in the financing arrangement may be disregarded in whole or in part pursuant to this section, whether or not the district director has made a determination that the intermediate entity should be disregarded under paragraph (a)(3)(i) of this section.

(*iv*) *Conduit financing arrangement* means a financing arrangement that is effected through one or more conduit entities.

(*v*) *Related* means related within the meaning of sections 267(b) or 707(b)(1), or controlled within the meaning of section 482, and the regulations under those sections. For purposes of

determining whether a person is related to another person, the constructive ownership rules of section 318 shall apply, and the attribution rules of section 267(c) also shall apply to the extent they attribute ownership to persons to whom section 318 does not attribute ownership.

(*3*) *Disregard of participation of conduit entity*—(i) *Authority of district director.* The district director may determine that the participation of a conduit entity in a conduit financing arrangement should be disregarded for purposes of section 881. For this purpose, an intermediate entity will constitute a conduit entity if it meets the standards of paragraph (a)(4) of this section. The district director has discretion to determine the manner in which the standards of paragraph (a)(4) of this section apply, including the financing transactions and parties composing the financing arrangement.

(ii) *Effect of disregarding conduit entity*—(A) *In general.* If the district director determines that the participation of a conduit entity in a financing arrangement should be disregarded, the financing arrangement is recharacterized as a transaction directly between the remaining parties to the financing arrangement (in most cases, the financed entity and the financing entity) for purposes of section 881. To the extent that a disregarded conduit entity actually receives or makes payments pursuant to a conduit financing arrangement, it is treated as an agent of the financing entity. Except as otherwise provided, the recharacterization of the conduit financing arrangement also applies for purposes of sections 871, 884(f)(1)(A), 1441, and 1442 and other procedural provisions relating to those sections. This recharacterization will not otherwise affect a taxpayer's Federal income tax liability under any substantive provisions of the Internal Revenue Code. Thus, for example, the recharacterization generally applies for purposes of section 1461, in order to impose liability on a withholding agent who fails to withhold as required under § 1.1441–3(j), but not for purposes of § 1.882–5.

(B) *Character of payments made by the financed entity.* If the participation of a conduit financing arrangement is disregarded under this paragraph (a)(3), payments made by the financed entity generally shall be characterized by reference to the character (e.g., interest or rent) of the payments made to the financing entity. However, if the financing transaction to which the financing entity is a party is a transaction described in paragraph (a)(2)(ii)(A)(*2*) or (*4*) of this section that gives rise to payments that would not be deductible if paid by the financed entity, the character of the payments made by the financed entity will not be affected by the disregard of the participation of a conduit entity. The characterization provided by this paragraph (a)(3)(ii)(B) does not, however, extend to qualification of a payment for any exemption from withholding tax under the Internal Revenue Code or a provision of any applicable tax treaty if such qualification depends on the terms of, or other similar facts or circumstances relating to, the financing transaction to which the financing entity is a party that do not apply to the financing transaction to which the financed entity is a party. Thus, for example, payments made by a financed entity that is not a bank cannot qualify for the exemption provided by section 881(i) of the Code even if the loan between the financed entity and the conduit entity is a bank deposit.

(C) *Effect of income tax treaties.* Where the participation of a conduit entity in a conduit financing arrangement is disregarded pursuant to this section, it is disregarded for all purposes of section 881, including for purposes of applying any relevant income tax treaties. Accordingly, the conduit entity may not claim the benefits of a tax treaty between its country of residence and the United States to reduce the amount of tax due under section 881 with respect to payments made pursuant to the conduit financing arrangement. The financing entity may, however, claim the benefits of any income tax treaty under which it is entitled to benefits in order to reduce the rate of tax on payments made pursuant to the conduit financing arrangement that are recharacterized in accordance with paragraph (a)(3)(ii)(B) of this section.

(D) *Effect on withholding tax.* For the effect of recharacterization on withholding obligations, see §§ 1.1441–3(j) and 1.1441–7(d).

(E) *Special rule for a financing entity that is unrelated to both intermediate entity and financed entity—(1) Liability of financing entity.* Notwithstanding the fact that a financing arrangement is a conduit financing arrangement, a financing entity that is unrelated to the financed entity and the conduit entity (or entities) shall not itself be liable for tax under section 881 unless the financing entity knows or has reason to know that the financing arrangement is a conduit financing arrangement. But see § 1.1441–3(j) for the withholding agent's withholding obligations.

(*2*) *Financing entity's knowledge*—(*i*) *In general.* A financing entity knows or has reason to know that the financing arrangement is a conduit financing arrangement only if the financing entity knows or has reason to know of facts sufficient to establish that the financing arrangement is a conduit financing arrangement, including facts sufficient to establish that the participation of the intermediate entity in the financing arrangement is pursuant to a tax avoidance plan. A person that knows only of the financing transactions that comprise the financing arrangement will not be considered to know or have reason to know of facts sufficient to establish that the financing arrangement is a conduit financing arrangement.

(*ii*) *Presumption regarding financing entity's knowledge.* It shall be presumed that the financing entity does not know or have reason to know that the financing arrangement is a conduit financing arrangement if the financing entity is unrelated to all other parties to the financing arrangement and the financing entity establishes that the intermediate entity who is a party to the financing transaction with the financing entity is actively engaged in a substantial trade or business. An intermediate entity will not be considered to be engaged in a trade or business if its business is making or managing investments, unless the intermediate entity is actively engaged in a banking, insurance, financing or similar trade or business and such business consists predominantly of transactions with customers who are not related persons. An intermediate entity's trade or business is substantial if it is reasonable for the financing entity to expect that the intermediate entity will be able to make payments under the financing transaction out of the cash flow of that trade or business. This presumption may be rebutted if the district director establishes that the financing entity knew or had reason to know that the financing arrangement is a conduit financing arrangement. See *Example 6* of paragraph (e) of this section for an illustration of the rules of this paragraph (a)(3)(ii)(E).

(iii) *Limitation on taxpayer's use of this section.* A taxpayer may not apply this section to reduce the amount of its Federal income tax liability by disregarding the form of its financing transactions for Federal income tax purposes or by compelling the district director to do so. See, however, paragraph (b)(2)(i) of this section for rules regarding the taxpayer's ability to show that the participation of one or more intermediate entities results in no significant reduction in tax.

(4) *Standard for treatment as a conduit entity*—(i) *In general.* An intermediate entity is a conduit entity with respect to a financing arrangement if—

(A) The participation of the intermediate entity (or entities) in the financing arrangement reduces the tax imposed by section 881 (determined by comparing the aggregate tax imposed under section 881 on payments made on financing transactions making up the financing arrangement with the tax that would have been imposed under paragraph (d) of this section);

(B) The participation of the intermediate entity in the financing arrangement is pursuant to a tax avoidance plan; and

(C) Either—

(*1*) The intermediate entity is related to the financing entity or the financed entity; or

(*2*) The intermediate entity would not have participated in the financing arrangement on substantially the same terms but for the fact that the financing entity engaged in the financing transaction with the intermediate entity.

(ii) *Multiple intermediate entities*—(A) *In general.* If a financing arrangement involves multiple intermediate entities, the district director will determine whether each of the intermediate entities is a conduit entity. The district director will make the determination by applying the special rules for multiple intermediate entities provided in this section or, if no special rules are provided, applying principles consistent with those of paragraph (a)(4)(i) of this section to each of the intermediate entities in the financing arrangement.

(B) *Special rule for related persons.* The district director may treat related intermediate entities as a single intermediate entity if he determines that one of the principal purposes for the involvement of multiple intermediate entities in the financing arrangement is to prevent the characterization of an intermediate entity as a conduit entity, to reduce the portion of a payment that is subject to withholding tax or otherwise to circumvent the provisions of this section. This determination shall be based upon all of the facts and circumstances, including, but not limited to, the factors set forth in paragraph (b)(2) of this section. If a district director determines that related persons are to be treated as a single intermediate entity, financing transactions between such related parties that are part of the conduit financing arrangement shall be disregarded for purposes of applying this section. *See Examples 7* and *8* of paragraph (e) of this section for illustrations of the rules of this paragraph (a)(4)(ii).

(b) *Determination of whether participation of intermediate entity is pursuant to a tax avoidance plan*—(1) *In general.* A tax avoidance plan is a plan one of the principal purposes of which is the avoidance of tax imposed by section 881. Avoidance of the tax imposed by section 881 may be one of the principal purposes for such a plan even though it is outweighed by other purposes (taken together or separately). In this regard, the only relevant purposes are those pertaining to the participation of the intermediate entity in the financing arrangement and not those pertaining to the existence of a financing arrangement as a whole. The plan may be formal or informal, written or oral, and may involve any one or more of the parties to the financing arrangement. The plan must be in existence no later than the last date that any of the financing transactions comprising the financing arrangement is entered into. The district director may infer the existence of a tax avoidance plan from the facts and circumstances. In determining whether there is a tax avoidance plan, the district director will weigh all relevant evidence regarding the purposes for the intermediate entity's participation in the financing arrangement. See *Examples 11* and *12* of paragraph (e) of this section for illustrations of the rule of this paragraph (b)(1).

(2) *Factors taken into account in determining the presence or absence of a tax avoidance purpose.* The factors described in paragraphs (b)(2)(i) through (iv) of this section are among the facts and circumstances taken into account in determining whether the participation of an intermediate entity in a financing arrangement has as one of its principal purposes the avoidance of tax imposed by section 881.

(i) *Significant reduction in tax.* The district director will consider whether the participation of the intermediate entity (or entities) in the financing arrangement significantly reduces the tax that otherwise would have been imposed under section 881. The fact that an intermediate entity is a resident of a country that has an income tax treaty with the United States that significantly reduces the tax that otherwise would have been imposed under section 881 is not sufficient, by itself, to establish the existence of a tax avoidance plan. The determination of whether the participation of an intermediate entity significantly reduces the tax generally is made by comparing the aggregate tax imposed under section 881 on payments made on financing transactions making up the financing arrangement with the tax that would be imposed under paragraph (d) of this section. However, the taxpayer is not barred from presenting evidence that the financing entity, as determined by the district director, was itself an intermediate entity and another entity should be treated as the financing entity for purposes of applying this test. A reduction in the absolute amount of tax may be significant even if the reduction in rate is not. A reduction in the amount of tax may be significant if the reduction is large in absolute terms or in relative terms. See *Examples 13, 14* and *15* of paragraph (e) of this section for illustrations of this factor.

(ii) *Ability to make the advance.* The district director will consider whether the intermediate entity had sufficient available money or other property of its own to have made the advance to the financed entity without the advance of money or other property to it by the financing entity (or in the case of multiple intermediate entities, whether each of the intermediate entities had sufficient available money or other property of its own to have made the advance to either the financed entity or another intermediate entity without the advance of money or other property to it by either the financing entity or another intermediate entity).

(iii) *Time period between financing transactions.* The district director will consider the length of the period of time that separates the advances of money or other property, or the grants of rights to use property, by the financing entity to the intermediate entity (in the case of multiple intermediate entities, from one intermediate entity to another), and ultimately by the intermediate entity to the financed entity. A short period of time is evidence of the existence of a tax avoidance plan while a long period of time is evidence that there is not a tax avoidance plan. See *Example 16* of paragraph (e) of this section for an illustration of this factor.

(iv) *Financing transactions in the ordinary course of business.* If the parties to the financing transaction are related, the district director will consider whether the financing transaction occurs in the ordinary course of the active conduct of complementary or integrated trades or businesses engaged in by these entities. The fact that a financing transaction is described in this paragraph (b)(2)(iv) is evidence that the participation of the parties to that transaction in the financing arrangement is not pursuant to a tax avoidance plan. A loan will not be considered to occur in the ordinary

course of the active conduct of complementary or integrated trades or businesses unless the loan is a trade receivable or the parties to the transaction are actively engaged in a banking, insurance, financing or similar trade or business and such business consists predominantly of transactions with customers who are not related persons. See *Example 17* of paragraph (e) of this section for an illustration of this factor.

(3) *Presumption if significant financing activities performed by a related intermediate entity*—(i) *General rule*. It shall be presumed that the participation of an intermediate entity (or entities) in a financing arrangement is not pursuant to a tax avoidance plan if the intermediate entity is related to either or both the financing entity or the financed entity and the intermediate entity performs significant financing activities with respect to the financing transactions forming part of the financing arrangement to which it is a party. This presumption may be rebutted if the district director establishes that the participation of the intermediate entity in the financing arrangement is pursuant to a tax avoidance plan. See *Examples 21, 22* and *23* of paragraph (e) of this section for illustrations of this presumption.

(ii) *Significant financing activities*. For purposes of this paragraph (b)(3), an intermediate entity performs significant financing activities with respect to such financing transactions only if the financing transactions satisfy the requirements of either paragraph (b)(3)(ii)(A) or (B) of this section.

(A) *Active rents or royalties*. An intermediate entity performs significant financing activities with respect to leases or licenses if rents or royalties earned with respect to such leases or licenses are derived in the active conduct of a trade or business within the meaning of section 954(c)(2)(A), to be applied by substituting the term *intermediate* entity for the term *controlled foreign corporation*.

(B) *Active risk management*—(*1*) *In general*. An intermediate entity is considered to perform significant financing activities with respect to financing transactions only if officers and employees of the intermediate entity participate actively and materially in arranging the intermediate entity's participation in such financing transactions (other than financing transactions described in paragraph (b)(3)(ii)(*B*)(*3*) of this section) and perform the business activity and risk management activities described in paragraph (b)(3)(ii)(*B*)(*2*) of this section with respect to such financing transactions, and the participation of the intermediate entity in the financing transactions produces (or reasonably can be expected to produce) efficiency savings by reducing transaction costs and overhead and other fixed costs.

(*2*) *Business activity and risk management requirements*. An intermediate entity will be considered to perform significant financing activities only if, within the country in which the intermediate entity is organized (or, if different, within the country with respect to which the intermediate entity is claiming the benefits of a tax treaty), its officers and employees—

(*i*) Exercise management over, and actively conduct, the day-to-day operations of the intermediate entity. Such operations must consist of a substantial trade or business or the supervision, administration and financing for a substantial group of related persons; and

(*ii*) Actively manage, on an ongoing basis, material market risks arising from such financing transactions as an integral part of the management of the intermediate entity's financial and capital requirements (including management of risks of currency and interest rate fluctuations) and management of the intermediate entity's short-term investments of working capital by entering into transactions with unrelated persons.

(*3*) *Special rule for trade receivables and payables entered into in the ordinary course of business*. If the activities of the intermediate entity consist in whole or in part of cash management for a controlled group of which the intermediate entity is a member, then employees of the intermediate entity need not have participated in arranging any such financing transactions that arise in the ordinary course of a substantial trade or business of either the financed entity or the financing entity. Officers or employees of the financing entity or financed entity, however, must have participated actively and materially in arranging the transaction that gave rise to the trade receivable or trade payable. Cash management includes the operation of a sweep account whereby the intermediate entity nets intercompany trade payables and receivables arising from transactions among the other members of the controlled group and between members of the controlled group and unrelated persons.

(*4*) *Activities of officers and employees of related persons*. Except as provided in paragraph (b)(3)(ii)(B)(*3*) of this section, in applying this paragraph (b)(3)(ii)(B), the activities of an officer or employee of an intermediate entity will not constitute significant financing activities if any officer or employee of a related person participated materially in any of the activities described in this paragraph, other than to approve any guarantee of a financing transaction or to exercise general supervision and control over the policies of the intermediate entity.

(c) *Determination of whether an unrelated intermediate entity would not have participated in financing arrangement on substantially the same terms*—(1) *In general*. The determination of whether an intermediate entity would not have participated in a financing arrangement on substantially the same terms but for the financing transaction between the financing entity and the intermediate entity shall be based upon all of the facts and circumstances.

(2) *Effect of guarantee*—(i) *In general*. The district director may presume that the intermediate entity would not have participated in the financing arrangement on substantially the same terms if there is a guarantee of the financed entity's liability to the intermediate entity (or in the case of multiple intermediate entities, a guarantee of the intermediate entity's liability to the intermediate entity that advanced money or property, or granted rights to use other property). However, a guarantee that was neither in existence nor contemplated on the last date that any of the financing transactions comprising the financing arrangement is entered into does not give rise to this presumption. A taxpayer may rebut this presumption by producing clear and convincing evidence that the intermediate entity would have participated in the financing transaction with the financed entity on substantially the same terms even if the financing entity had not entered into a financing transaction with the intermediate entity.

(ii) *Definition of guarantee*. For the purposes of this paragraph (c)(2), a guarantee is any arrangement under which a person, directly or indirectly, assures, on a conditional or unconditional basis, the payment of another person's obligation with respect to a financing transaction. The term shall be interpreted in accordance with the definition of the term in section 163(j)(6)(D)(iii).

(d) *Determination of amount of tax liability*—(1) *Amount of payment subject to recharacterization*—(i) *In general*. If a financing arrangement is a conduit financing arrangement, a portion of each payment made by the financed entity with respect to the

financing transactions that comprise the conduit financing arrangement shall be recharacterized as a transaction directly between the financed entity and the financing entity. If the aggregate principal amount of the financing transaction(s) to which the financed entity is a party is less than or equal to the aggregate principal amount of the financing transaction(s) linking any of the parties to the financing arrangement, the entire amount of the payment shall be so recharacterized. If the aggregate principal amount of the financing transaction(s) to which the financed entity is a party is greater than the aggregate principal amount of the financing transaction(s) linking any of the parties to the financing arrangement, then the recharacterized portion shall be determined by multiplying the payment by a fraction the numerator of which is equal to the lowest aggregate principal amount of the financing transaction(s) linking any of the parties to the financing arrangement (other than financing transactions that are disregarded pursuant to paragraphs (a)(2)(i)(B) and (a)(4)(ii)(B) of this section) and the denominator of which is the aggregate principal amount of the financing transaction(s) to which the financed entity is a party. In the case of financing transactions the principal amount of which is subject to adjustment, the fraction shall be determined using the average outstanding principal amounts for the period to which the payment relates. The average principal amount may be computed using any method applied consistently that reflects with reasonable accuracy the amount outstanding for the period. See *Example 24* of paragraph (e) of this section for an illustration of the calculation of the amount of tax liability.

(ii) *Determination of principal amount*—(A) *In general*. Unless otherwise provided in this paragraph (d)(1)(ii), the principal amount equals the amount of money advanced, or the fair market value of other property advanced or subject to a lease or license, in the financing transaction. In general, fair market value is calculated in U.S. dollars as of the close of business on the day on which the financing transaction is entered into. However, if the property advanced, or the right to use property granted, by the financing entity is the same as the property or rights received by the financed entity, the fair market value of the property or right shall be determined as of the close of business on the last date that any of the financing transactions comprising the financing arrangement is entered into. In the case of fungible property, property of the same type shall be considered to be the same property. See *Example 25* of paragraph (e) for an illustration of the calculation of the principal amount in the case of financing transactions involving fungible property. The principal amount of a financing transaction shall be subject to adjustments, as set forth in this paragraph (d)(1)(ii).

(B) *Debt instruments and certain stock*. In the case of a debt instrument or of stock that is subject to the current inclusion rules of sections 305(c)(3) or (e), the principal amount generally will be equal to the issue price. However, if the fair market value on the issue date differs materially from the issue price, the fair market value of the debt instrument shall be used in lieu of the instrument's issue price. Appropriate adjustments will be made for accruals of original issue discount and repayments of principal (including accrued original issue discount).

(C) *Partnership and trust interests*. In the case of a partnership interest or an interest in a trust, the principal amount is equal to the fair market value of the money or property contributed to the partnership or trust in return for that partnership or trust interest.

(D) *Leases or licenses*. In the case of a lease or license, the principal amount is equal to the fair market value of the property subject to the lease or license on the date on which the lease or license is entered into. The principal amount shall be adjusted for depreciation or amortization, calculated on a basis that accurately reflects the anticipated decline in the value of the property over its life.

(2) *Rate of tax*. The rate at which tax is imposed under section 881 on the portion of the payment that is recharacterized pursuant to paragraph (d)(1) of this section is determined by reference to the nature of the recharacterized transaction, as determined under paragraphs (a)(3)(ii)(B) and (C) of this section.

(e) *Examples*. The following examples illustrate this section. For purposes of these examples, unless otherwise indicated, it is assumed that FP, a corporation organized in country N, owns all of the stock of FS, a corporation organized in country T, and DS, a corporation organized in the United States. Country T, but not country N, has an income tax treaty with the United States. The treaty exempts interest, rents and royalties paid by a resident of one state (the source state) to a resident of the other state from tax in the source state.

Example 1. Financing arrangement. (i) On January 1, 1996, BK, a bank organized in country T, lends $1,000,000 to DS in exchange for a note issued by DS. FP guarantees to BK that DS will satisfy its repayment obligation on the loan. There are no other transactions between FP and BK.

(ii) BK's loan to DS is a financing transaction within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section. FP's guarantee of DS's repayment obligation is not a financing transaction as described in paragraphs (a)(2)(ii)(A)(*1*) through (*4*) of this section. Therefore, these transactions do not constitute a financing arrangement as defined in paragraph (a)(2)(i) of this section.

Example 2. Financing arrangement. (i) On January 1, 1996, FP lends $1,000,000 to DS in exchange for a note issued by DS. On January 1, 1997, FP assigns the DS note to FS in exchange for a note issued by FS. After receiving notice of the assignment, DS remits payments due under its note to FS.

(ii) The DS note held by FS and the FS note held by FP are financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section, and together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section.

Example 3. Financing arrangement. (i) On December 1, 1994 FP creates a special purposes subsidiary, FS. On that date FP capitalizes FS with $1,000,000 in cash and $10,000,000 in debt from BK, a Country N bank. On January 1, 1995, C, a U.S. person, purchases an automobile from DS in return for an installment note. On August 1, 1995, DS sells a number of installment notes, including C's, to FS in exchange for $10,000,000. DS continues to service the installment notes for FS.

(ii) The C installment note now held by FS (as well as all of the other installment notes now held by FS) and the FS note held by BK are financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section, and together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section.

Example 4. Related persons treated as a single intermediate entity. (i) On January 1, 1996, FP deposits $1,000,000 with BK, a bank that is organized in country N and is unrelated to FP and its subsidiaries. M, a corporation also organized in country N, is wholly-owned by the sole shareholder of BK but is not a bank within the meaning of section 881(c)(3)(A). On July 1, 1996, M lends $1,000,000 to DS in exchange for a note maturing on July 1, 2006. The note is in registered form within the meaning of section 881(c)(2)(B)(i) and DS has received from M the statement required by section 881(c)(2)(B)(ii). One of the principal purposes for the absence of a financing transaction between BK and M is the avoidance of the application of this section.

(ii) The transactions described above would form a financing arrangement but for the absence of a financing transaction between BK and M. However, because one of the principal purposes for the structuring of these financing transactions is to prevent characterization of such arrangement as a financing arrangement, the district director may treat the financing transactions between

FP and BK, and between M and DS as a financing arrangement under paragraphs (a)(2)(i)(B) of this section. In such a case, BK and M would be considered a single intermediate entity for purposes of this section. See also paragraph (a)(4)(ii)(B) of this section for the authority to treat BK and M as a single intermediate entity.

Example 5. Related persons treated as a single intermediate entity. (i) On January 1, 1995, FP lends $10,000,000 to FS in exchange for a 10-year note that pays interest annually at a rate of 8 percent per annum. On January 2, 1995, FS contributes $10,000,000 to FS2, a wholly-owned subsidiary of FS organized in country T, in exchange for common stock of FS2. On January 1, 1996, FS2 lends $10,000,000 to DS in exchange for an 8-year note that pays interest annually at a rate of 10 percent per annum. FS is a holding company whose most significant asset is the stock of FS2. Throughout the period that the FP–FS loan is outstanding, FS causes FS2 to make distributions to FS, most of which are used to make interest and principal payments on the FP–FS loan. Without the distributions from FS2, FS would not have had the funds with which to make payments on the FP–FS loan. One of the principal purposes for the absence of a financing transaction between FS and FS2 is the avoidance of the application of this section.

(ii) The conditions of paragraph (a)(4)(i)(A) of this section would be satisfied with respect to the financing transactions between FP, FS, FS2 and DS but for the absence of a financing transaction between FS and FS2. However, because one of the principal purposes for the structuring of these financing transactions is to prevent characterization of an entity as a conduit, the district director may treat the financing transactions between FP and FS, and between FS2 and DS as a financing arrangement. See paragraph (a)(4)(ii)(B) of this section. In such a case, FS and FS2 would be considered a single intermediate entity for purposes of this section. See also paragraph (a)(2)(i)(B) of this section for the authority to treat FS and FS2 as a single intermediate entity.

Example 6. Presumption with respect to unrelated financing entity. (i) FP is a corporation organized in country T that is actively engaged in a substantial manufacturing business. FP has a revolving credit facility with a syndicate of banks, none of which is related to FP and FP's subsidiaries, which provides that FP may borrow up to a maximum of $100,000,000 at a time. The revolving credit facility provides that DS and certain other subsidiaries of FP may borrow directly from the syndicate at the same interest rates as FP, but each subsidiary is required to indemnify the syndicate banks for any withholding taxes imposed on interest payments by the country in which the subsidiary is organized. BK, a bank that is organized in country N, is the agent for the syndicate. Some of the syndicate banks are organized in country N, but others are residents of country O, a country that has an income tax treaty with the United States which allows the United States to impose a tax on interest at a maximum rate of 10 percent. It is reasonable for BK and the syndicate banks to have determined that FP will be able to meet its payment obligations on a maximum principal amount of $100,000,000 out of the cash flow of its manufacturing business. At various times throughout 1995, FP borrows under the revolving credit facility until the outstanding principal amount reaches the maximum amount of $100,000,000. On December 31, 1995, FP receives $100,000,000 from a public offering of its equity. On January 1, 1996, FP pays BK $90,000,000 to reduce the outstanding principal amount under the revolving credit facility and lends $10,000,000 to DS. FP would have repaid the entire principal amount, and DS would have borrowed directly from the syndicate, but for the fact that DS did not want to incur the U.S. withholding tax that would have applied to payments made directly by DS to the syndicate banks.

(ii) Pursuant to paragraph (a)(3)(ii)(E)(*1*) of this section, even though the financing arrangement is a conduit financing arrangement (because the financing arrangement meets the standards for recharacterization in paragraph (a)(4)(i)), BK and the other syndicate banks have no section 881 liability unless they know or have reason to know that the financing arrangement is a conduit financing arrangement. Moreover, pursuant to paragraph (a)(3)(ii)(E)(*2*)(*ii*) of this section, BK and the syndicate banks are presumed not to know that the financing arrangement is a conduit financing arrangement. The syndicate banks are unrelated to both FP and DS, and FP is actively engaged in a substantial trade or business—that is, the cash flow from FP's manufacturing business is sufficient for the banks to expect that FP will be able to make the payments required under the financing transaction. See § 1.1441–3(j) for the withholding obligations of the withholding agents.

Example 7. Multiple intermediate entities—special rule for related persons. (i) On January 1, 1995, FP lends $10,000,000 to FS in exchange for a 10-year note that pays interest annually at a rate of 8 percent per annum. On January 2, 1995, FS contributes $9,900,000 to FS2, a wholly-owned subsidiary of FS organized in country T, in exchange for common stock and lends $100,000 to FS2. On January 1, 1996, FS2 lends $10,000,000 to DS in exchange for an 8-year note that pays interest annually at a rate of 10 percent per annum. FS is a holding company that has no significant assets other than the stock of FS2. Throughout the period that the FP–FS loan is outstanding, FS causes FS2 to make distributions to FS, most of which are used to make interest and principal payments on the FP–FS loan. Without the distributions from FS2, FS would not have had the funds with which to make payments on the FP–FS loan. One of the principal purposes for structuring the transactions between FS and FS2 as primarily a contribution of capital is to reduce the amount of the payment that would be recharacterized under paragraph (d) of this section.

(ii) Pursuant to paragraph (a)(4)(ii)(B) of this section, the district director may treat FS and FS2 as a single intermediate entity for purposes of this section since one of the principal purposes for the participation of multiple intermediate entities is to reduce the amount of the tax liability on any recharacterized payment by inserting a financing transaction with a low principal amount.

Example 8. Multiple intermediate entities. (i) On January 1, 1995, FP deposits $1,000,000 with BK, a bank that is organized in country T and is unrelated to FP and its subsidiaries, FS and DS. On January 1, 1996, at a time when the FP–BK deposit is still outstanding, BK lends $500,000 to BK2, a bank that is wholly-owned by BK and is organized in country T. On the same date, BK2 lends $500,000 to FS. On July 1, 1996, FS lends $500,000 to DS. FP pledges its deposit with BK to BK2 in support of FS' obligation to repay the BK2 loan. FS', BK's and BK2's participation in the financing arrangement is pursuant to a tax avoidance plan.

(ii) The conditions of paragraphs (a)(4)(i)(A) and (B) of this section are satisfied because the participation of BK, BK2 and FS in the financing arrangement reduces the tax imposed by section 881, and FS', BK's and BK2's participation in the financing arrangement is pursuant to a tax avoidance plan. However, since BK and BK2 are unrelated to FP and DS, under paragraph (a)(4)(i)(C)(*2*) of this section, BK and BK2 will be treated as conduit entities only if BK and BK2 would not have participated in the financing arrangement on substantially the same terms but for the financing transaction between FP and BK.

(iii) It is presumed that BK2 would not have participated in the financing arrangement on substantially the same terms but for the BK–BK2 financing transaction because FP's pledge of an asset in support of FS' obligation to repay the BK2 loan is a guarantee within the meaning of paragraph (c)(2)(ii) of this section. If the taxpayer does not rebut this presumption by clear and convincing evidence, then BK2 will be a conduit entity.

(iv) Because BK and BK2 are related intermediate entities, the district director must determine whether one of the principal purposes for the involvement of multiple intermediate entities was to prevent characterization of an entity as a conduit entity. In making this determination, the district director may consider the fact that the involvement of two related intermediate entities prevents the presumption regarding guarantees from applying to BK. In the absence of evidence showing a business purpose for the involvement of both BK and BK2, the district director may treat BK and BK2 as a single intermediate entity for purposes of determining whether they would have participated in the financing arrangement on substantially the same terms but for the financing transaction between FP and BK. The presumption that applies to BK2 therefore will apply to BK. If the taxpayer does not rebut this presumption by clear and convincing evidence, then BK will be a conduit entity.

Example 9. Reduction of tax. (i) On February 1, 1995, FP issues debt to the public

that would satisfy the requirements of section 871(h)(2)(A) (relating to obligations that are not in registered form) if issued by a U.S. person. FP lends the proceeds of the debt offering to DS in exchange for a note.

(ii) The debt issued by FP and the DS note are financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section and together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section. The holders of the FP debt are the financing entities, FP is the intermediate entity and DS is the financed entity. Because interest payments on the debt issued by FP would not have been subject to withholding tax if the debt had been issued by DS, there is no reduction in tax under paragraph (a)(4)(i)(A) of this section. Accordingly, FP is not a conduit entity.

Example 10. Reduction of tax. (i) On January 1, 1995, FP licenses to FS the rights to use a patent in the United States to manufacture product A. FS agrees to pay FP a fixed amount in royalties each year under the license. On January 1, 1996, FS sublicenses to DS the rights to use the patent in the United States. Under the sublicense, DS agrees to pay FS royalties based upon the units of product A manufactured by DS each year. Although the formula for computing the amount of royalties paid by DS to FS differs from the formula for computing the amount of royalties paid by FS to FP, each represents an arm's length rate.

(ii) Although the royalties paid by DS to FS are exempt from U.S. withholding tax, the royalty payments between FS and FP are income from U.S. sources under section 861(a)(4) subject to the 30 percent gross tax imposed by § 1.881–2(b) and subject to withholding under § 1.1441–2(a). Because the rate of tax imposed on royalties paid by FS to FP is the same as the rate that would have been imposed on royalties paid by DS to FP, the participation of FS in the FP–FS–DS financing arrangement does not reduce the tax imposed by section 881 within the meaning of paragraph (a)(4)(i)(A) of this section. Accordingly, FP is not a conduit entity.

Example 11. A principal purpose. (i) On January 1, 1995, FS lends $10,000,000 to DS in exchange for a 10-year note that pays interest annually at a rate of 8 percent per annum. As was intended at the time of the loan from FS to DS, on July 1, 1995, FP makes an interest-free demand loan of $10,000,000 to FS. A principal purpose for FS' participation in the FP–FS–DS financing arrangement is that FS generally coordinates the financing for all of FP's subsidiaries (although FS does not engage in significant financing activities with respect to such financing transactions). However, another principal purpose for FS' participation is to allow the parties to benefit from the lower withholding tax rate provided under the income tax treaty between country T and the United States.

(ii) The financing arrangement satisfies the tax avoidance purpose requirement of paragraph (a)(4)(i)(B) of this section because FS participated in the financing arrangement pursuant to a plan one of the principal purposes of which is to allow the parties to benefit from the country T-U.S. treaty.

Example 12. A principal purpose. (i) DX is a U.S. corporation that intends to purchase property to use in its manufacturing business. FX is a partnership organized in country N that is owned in equal parts by LC1 and LC2, leasing companies that are unrelated to DX. BK, a bank organized in country N and unrelated to DX, LC1 and LC2, lends $100,000,000 to FX to enable FX to purchase the property. On the same day, FX purchases the property and engages in a transaction with DX which is treated as a lease of the property for country N tax purposes but a loan for U.S. tax purposes. Accordingly, DX is treated as the owner of the property for U.S. tax purposes. The parties comply with the requirements of section 881(c) with respect to the debt obligation of DX to FX. FX and DX structured these transactions in this manner so that LC1 and LC2 would be entitled to accelerated depreciation deductions with respect to the property in country N and DX would be entitled to accelerated depreciation deductions in the United States. None of the parties would have participated in the transaction if the payments made by DX were subject to U.S. withholding tax.

(ii) The loan from BK to FX and from FX to DX are financing transactions and, together constitute a financing arrangement. The participation of FX in the financing arrangement reduces the tax imposed by section 881 because payments made to FX, but not BK, qualify for the portfolio interest exemption of section 881(c) because BK is a bank making an extension of credit in the ordinary course of its trade or business within the meaning of section 881(c)(3)(A). Moreover, because DX borrowed the money from FX instead of borrowing the money directly from BK to avoid the tax imposed by section 881, one of the principal purposes of the participation of FX was to avoid that tax (even though another principal purpose of the participation of FX was to allow LC1 and LC2 to take advantage of accelerated depreciation deductions in country N). Assuming that FX would not have participated in the financing arrangement on substantially the same terms but for the fact that BK loaned it $100,000,000, FX is a conduit entity and the financing arrangement is a conduit financing arrangement.

Example 13. Significant reduction of tax. (i) FS owns all of the stock of FS1, which also is a resident of country T. FS1 owns all of the stock of DS. On January 1, 1995, FP contributes $10,000,000 to the capital of FS in return for perpetual preferred stock. On July 1, 1995, FS lends $10,000,000 to FS1. On January 1, 1996, FS1 lends $10,000,000 to DS. Under the terms of the country T-U.S. income tax treaty, a country T resident is not entitled to the reduced withholding rate on interest income provided by the treaty if the resident is entitled to specified tax benefits under country T law. Although FS1 may deduct interest paid on the loan from FS, these deductions are not pursuant to any special tax benefits provided by country T law. However, FS qualifies for one of the enumerated tax benefits pursuant to which it may deduct dividends paid with respect to the stock held by FP. Therefore, if FS had made a loan directly to DS, FS would not have been entitled to the benefits of the country T-U.S. tax treaty with respect to payments it received from DS, and such payments would have been subject to tax under section 881 at a 30 percent rate.

(ii) The FS–FS1 loan and the FS1–DS loan are financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section and together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section. Pursuant to paragraph (b)(2)(i) of this section, the significant reduction in tax resulting from the participation of FS1 in the financing arrangement is evidence that the participation of FS1 in the financing arrangement is pursuant to a tax avoidance plan. However, other facts relevant to the presence of such a plan must also be taken into account.

Example 14. Significant reduction of tax. (i) FP owns 90 percent of the voting stock of FX, an unlimited liability company organized in country T. The other 10 percent of the common stock of FX is owned by FP1, a subsidiary of FP that is organized in country N. Although FX is a partnership for U.S. tax purposes, FX is entitled to the benefits of the U.S.-country T income tax treaty because FX is subject to tax in country T as a resident corporation. On January 1, 1996, FP contributes $10,000,000 to FX in exchange for an instrument denominated as preferred stock that pays a dividend of 7 percent and that must be redeemed by FX in seven years. For U.S. tax purposes, the preferred stock is a partnership interest. On July 1, 1996, FX makes a loan of $10,000,000 to DS in exchange for a 7-year note paying interest at 6 percent.

(ii) Because FX is required to redeem the partnership interest at a specified time, the partnership interest constitutes a financing transaction within the meaning of paragraph (a)(2)(ii)(A)(*2*) of this section. Moreover, because the FX-DS note is a financing transaction within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section, together the transactions constitute a financing arrangement within the meaning of (a)(2)(i) of this section. Payments of interest made directly by DS to FP and FP1 would not be eligible for the portfolio interest exemption and would not be entitled to a reduction in withholding tax pursuant to a tax treaty. Therefore, there is a significant reduction in tax resulting from the participation of FX in the financing arrangement, which is evidence that the participation of FX in the financing arrangement is pursuant to a tax avoidance plan. However, other facts relevant to the existence of such a plan must also be taken into account.

Example 15. Significant reduction of tax. (i) FP owns a 10 percent interest in the profits and capital of FX, a partnership organized in country N. The other 90 percent interest in FX is owned by G, an unrelated corporation that is organized in country T. FX is not engaged in business in the United States. On January 1, 1996, FP contributes $10,000,000 to FX in exchange for an instrument documented as perpetual subordinated debt that provides for quarterly interest payments at 9 percent per annum. Under the terms of the instrument, payments

on the perpetual subordinated debt do not otherwise affect the allocation of income between the partners. FP has the right to require the liquidation of FX if FX fails to make an interest payment. For U.S. tax purposes, the perpetual subordinated debt is treated as a partnership interest in FX and the payments on the perpetual subordinated debt constitute guaranteed payments within the meaning of section 707(c). On July 1, 1996, FX makes a loan of $10,000,000 to DS in exchange for a 7-year note paying interest at 8 percent per annum.

(ii) Because FP has the effective right to force payment of the ''interest'' on the perpetual subordinated debt, the instrument constitutes a financing transaction within the meaning of paragraph (a)(2)(ii)(A)(*2*) of this section. Moreover, because the note between FX and DS is a financing transaction within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section, together the transactions are a financing arrangement within the meaning of (a)(2)(i) of this section. Without regard to this section, 90 percent of each interest payment received by FX would be treated as exempt from U.S. withholding tax because it is beneficially owned by G, while 10 percent would be subject to a 30 percent withholding tax because beneficially owned by FP. If FP held directly the note issued by DS, 100 percent of the interest payments on the note would have been subject to the 30 percent withholding tax. The significant reduction in the tax imposed by section 881 resulting from the participation of FX in the financing arrangement is evidence that the participation of FX in the financing arrangement is pursuant to a tax avoidance plan. However, other facts relevant to the presence of such a plan must also be taken into account.

Example 16. Time period between transactions. (i) On January 1, 1995, FP lends $10,000,000 to FS in exchange for a 10-year note that pays no interest annually. When the note matures, FS is obligated to pay $24,000,000 to FP. On January 1, 1996, FS lends $10,000,000 to DS in exchange for a 10-year note that pays interest annually at a rate of 10 percent per annum.

(ii) The FS note held by FP and the DS note held by FS are financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section and together constitute a financing arrangement within the meaning of (a)(2)(i) of this section. Pursuant to paragraph (b)(2)(iii) of this section, the short period of time (twelve months) between the loan by FP to FS and the loan by FS to DS is evidence that the participation of FS in the financing arrangement is pursuant to a tax avoidance plan. However, other facts relevant to the presence of such a plan must also be taken into account.

Example 17. Financing transactions in the ordinary course of business. (i) FP is a holding company. FS is actively engaged in country T in the business of manufacturing and selling product A. DS manufactures product B, a principal component in which is product A. FS' business activity is substantial. On January 1, 1995, FP lends $100,000,000 to FS to finance FS' business operations. On January 1, 1996, FS ships $30,000,000 of product A to DS. In return, FS creates an interest-bearing account receivable on its books. FS' shipment is in the ordinary course of the active conduct of its trade or business (which is complementary to DS' trade or business.)

(ii) The loan from FP to FS and the accounts receivable opened by FS for a payment owed by DS are financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section and together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section. Pursuant to paragraph (b)(2)(iv) of this section, the fact that DS' liability to FS is created in the ordinary course of the active conduct of DS' trade or business that is complementary to a business actively engaged in by DS is evidence that the participation of FS in the financing arrangement is not pursuant to a tax avoidance plan. However, other facts relevant to the presence of such a plan must also be taken into account.

Example 18. Tax avoidance plan—other factors. (i) On February 1, 1995, FP issues debt in Country N that is in registered form within the meaning of section 881(c)(3)(A). The FP debt would satisfy the requirements of section 881(c) if the debt were issued by a U.S. person and the withholding agent received the certification required by section 871(h)(2)(B)(ii). The purchasers of the debt are financial institutions and there is no reason to believe that they would not furnish Forms W–8. On March 1, 1995, FP lends a portion of the proceeds of the offering to DS.

(ii) The FP debt and the loan to DS are financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section and together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section. The owners of the FP debt are the financing entities, FP is the intermediate entity and DS is the financed entity. Interest payments on the debt issued by FP would be subject to withholding tax if the debt were issued by DS, unless DS received all necessary Forms W–8. Therefore, the participation of FP in the financing arrangement potentially reduces the tax imposed by section 881(a). However, because it is reasonable to assume that the purchasers of the FP debt would have provided certifications in order to avoid the withholding tax imposed by section 881, there is not a tax avoidance plan. Accordingly, FP is not a conduit entity.

Example 19. Tax avoidance plan—other factors. (i) Over a period of years, FP has maintained a deposit with BK, a bank organized in the United States, that is unrelated to FP and its subsidiaries. FP often sells goods and purchases raw materials in the United States. FP opened the bank account with BK in order to facilitate this business and the amounts it maintains in the account are reasonably related to its dollar-denominated working capital needs. On January 1, 1995, BK lends $5,000,000 to DS. After the loan is made, the balance in FP's bank account remains within a range appropriate to meet FP's working capital needs.

(ii) FP's deposit with BK and BK's loan to DS are financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section and together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section. Pursuant to section 881(i), interest paid by BK to FP with respect to the bank deposit is exempt from withholding tax. Interest paid directly by DS to FP would not be exempt from withholding tax under section 881(i) and therefore would be subject to a 30% withholding tax. Accordingly, there is a significant reduction in the tax imposed by section 881, which is evidence of the existence of a tax avoidance plan. See paragraph (b)(2)(i) of this section. However, the district director also will consider the fact that FP historically has maintained an account with BK to meet its working capital needs and that, prior to and after BK's loan to DS, the balance within the account remains within a range appropriate to meet those business needs as evidence that the participation of BK in the FP–BK–DS financing arrangement is not pursuant to a tax avoidance plan. In determining the presence or absence of a tax avoidance plan, all relevant facts will be taken into account.

Example 20. Tax avoidance plan—other factors. (i) Assume the same facts as in *Example 19*, except that on January 1, 2000, FP's deposit with BK substantially exceeds FP's expected working capital needs and on January 2, 2000, BK lends additional funds to DS. Assume also that BK's loan to DS provides BK with a right of offset against FP's deposit. Finally, assume that FP would have lent the funds to DS directly but for the imposition of the withholding tax on payments made directly to FP by DS.

(ii) As in *Example 19*, the transactions in paragraph (i) of this *Example 20* are a financing arrangement within the meaning of paragraph (a)(2)(i) and the participation of the BK reduces the section 881 tax. In this case, the presence of funds substantially in excess of FP's working capital needs and the fact that FP would have been willing to lend funds directly to DS if not for the withholding tax are evidence that the participation of BK in the FP-BK-FS financing arrangement is pursuant to a tax avoidance plan. However, other facts relevant to the presence of such a plan must also be taken into account. Even if the district director determines that the participation of BK in the financing arrangement is pursuant to a tax avoidance plan, BK may not be treated as a conduit entity unless BK would not have participated in the financing arrangement on substantially the same terms in the absence of FP's deposit with BK. BK's right of offset against FP's deposit (a form of guarantee of BK's loan to DS) creates a presumption that BK would not have made the loan to DS on substantially the same terms in the absence of FP's deposit with BK. If the taxpayer overcomes the presumption by clear and convincing evidence, BK will not be a conduit entity.

Example 21. Significant financing activities. (i) FS is responsible for coordinating the financing of all of the subsidiaries of FP, which are engaged in substantial trades or businesses and are located in country T, country N, and the United States. FS maintains a centralized cash management accounting system for FP and its subsidiaries in which it records all

intercompany payables and receivables; these payables and receivables ultimately are reduced to a single balance either due from or owing to FS and each of FP's subsidiaries. FS is responsible for disbursing or receiving any cash payments required by transactions between its affiliates and unrelated parties. FS must borrow any cash necessary to meet those external obligations and invests any excess cash for the benefit of the FP group. FS enters into interest rate and foreign exchange contracts as necessary to manage the risks arising from mismatches in incoming and outgoing cash flows. The activities of FS are intended (and reasonably can be expected) to reduce transaction costs and overhead and other fixed costs. FS has 50 employees, including clerical and other back office personnel, located in country T. At the request of DS, on January 1, 1995, FS pays a supplier $1,000,000 for materials delivered to DS and charges DS an open account receivable for this amount. On February 3, 1995, FS reverses the account receivable from DS to FS when DS delivers to FP goods with a value of $1,000,000.

(ii) The accounts payable from DS to FS and from FS to other subsidiaries of FP constitute financing transactions within the meaning of paragraph (a)(2)(ii)(A)(*1*) of this section, and the transactions together constitute a financing arrangement within the meaning of paragraph (a)(2)(i) of this section. FS's activities constitute significant financing activities with respect to the financing transactions even though FS did not actively and materially participate in arranging the financing transactions because the financing transactions consisted of trade receivables and trade payables that were ordinary and necessary to carry on the trades or businesses of DS and the other subsidiaries of FP. Accordingly, pursuant to paragraph (b)(3)(i) of this section, FS' participation in the financing arrangement is presumed not to be pursuant to a tax avoidance plan.

Example 22. Significant financing activities—active risk management. (i) The facts are the same as in Example 21, except that, in addition to its short-term funding needs, DS needs long-term financing to fund an acquisition of another U.S. company; the acquisition is scheduled to close on January 15, 1995. FS has a revolving credit agreement with a syndicate of banks located in Country N. On January 14, 1995, FS borrows ¥10 billion for 10 years under the revolving credit agreement, paying yen LIBOR plus 50 basis points on a quarterly basis. FS enters into a currency swap with BK, an unrelated bank that is not a member of the syndicate, under which FS will pay BK ¥10 billion and will receive $100 million on January 15, 1995; these payments will be reversed on January 15, 2004. FS will pay BK U.S. dollar LIBOR plus 50 basis points on a notional principal amount of $100 million semi-annually and will receive yen LIBOR plus 50 basis points on a notional principal amount of ¥10 billion quarterly. Upon the closing of the acquisition on January 15, 1995, DS borrows $100 million from FS for 10 years, paying U.S. dollar LIBOR plus 50 basis points semiannually.

(ii) Although FS performs significant financing activities with respect to certain financing transactions to which it is a party, FS does not perform significant financing activities with respect to the financing transactions between FS and the syndicate of banks and between FS and DS because FS has eliminated all material market risks arising from those financing transactions through its currency swap with BK. Accordingly, the financing arrangement does not benefit from the presumption of paragraph (b)(3)(i) of this section and the district director must determine whether the participation of FS in the financing arrangement is pursuant to a tax avoidance plan on the basis of all the facts and circumstances. However, if additional facts indicated that FS reviews its currency swaps daily to determine whether they are the most cost efficient way of managing their currency risk and, as a result, frequently terminates swaps in favor of entering into more cost efficient hedging arrangements with unrelated parties, FS would be considered to perform significant financing activities and FS' participation in the financing arrangements would not be pursuant to a tax avoidance plan.

Example 23. Significant financing activities—presumption rebutted. (i) The facts are the same as in *Example 21*, except that, on January 1, 1995, FP lends to FS DM 15,000,000 (worth $10,000,000) in exchange for a 10 year note that pays interest annually at a rate of 5 percent per annum. Also, on March 15, 1995, FS lends $10,000,000 to DS in exchange for a 10-year note that pays interest annually at a rate of 8 percent per annum. FS would not have had sufficient funds to make the loan to DS without the loan from FP. FS does not enter into any long-term hedging transaction with respect to these financing transactions, but manages the interest rate and currency risk arising from the transactions on a daily, weekly or quarterly basis by entering into forward currency contracts.

(ii) Because FS performs significant financing activities with respect to the financing transactions between FS, DS and FP, the participation of FS in the financing arrangement is presumed not to be pursuant to a tax avoidance plan. The district director may rebut this presumption by establishing that the participation of FS is pursuant to a tax avoidance plan, based on all the facts and circumstances. The mere fact that FS is a resident of country T is not sufficient to establish the existence of a tax avoidance plan. However, the existence of a plan can be inferred from other factors in addition to the fact that FS is a resident of country T. For example, the loans are made within a short time period and FS would not have been able to make the loan to DS without the loan from FP.

Example 24. Determination of amount of tax liability. (i) On January 1, 1996, FP makes two three-year installment loans of $250,000 each to FS that pay interest at a rate of 9 percent per annum. The loans are self-amortizing with payments on each loan of $7,950 per month. On the same date, FS lends $1,000,000 to DS in exchange for a two-year note that pays interest semi-annually at a rate of 10 percent per annum, beginning on June 30, 1996. The FS-DS loan is not self-amortizing. Assume that for the period of January 1, 1996 through June 30, 1996, the average principal amount of the financing transactions between FP and FS that comprise the financing arrangement is $469,319. Further, assume that for the period of July 1, 1996 through December 31, 1996, the average principal amount of the financing transactions between FP and FS is $393,632. The average principal amount of the financing transaction between FS and DS for the same periods is $1,000,000. The district director determines that the financing transactions between FP and FS, and FS and DS, are a conduit financing arrangement.

(ii) Pursuant to paragraph (d)(1)(i) of this section, the portion of the $50,000 interest payment made by DS to FS on June 30, 1996, that is recharacterized as a payment to FP is $23,450 computed as follows: ($50,000 x $469,319/$1,000,000) = $23,450. The portion of the interest payment made on December 31, 1996 that is recharacterized as a payment to FP is $19,650, computed as follows: ($50,000 x $393,632/$1,000,000) = $19,650. Furthermore, under § 1.1441–3(j), DS is liable for withholding tax at a 30 percent rate on the portion of the $50,000 payment to FS that is recharacterized as a payment to FP, i.e., $7,035 with respect to the June 30, 1996 payment and $5,895 with respect to the December 31, 1996 payment.

Example 25. Determination of principal amount. (i) FP lends DM 10,000,000 to FS in exchange for a ten year note that pays interest semi-annually at a rate of 8 percent per annum. Six months later, pursuant to a tax avoidance plan, FS lends DM 5,000,000 to DS in exchange for a 10 year note that pays interest semi-annually at a rate of 10 percent per annum. At the time FP make its loan to FS, the exchange rate is DM 1.5/$1. At the time FS makes its loan to DS the exchange rate is DM 1.4/$1.

(ii) FP's loan to FS and FS' loan to DS are financing transactions and together constitute a financing arrangement. Furthermore, because the participation of FS reduces the tax imposed under section 881 and FS' participation is pursuant to a tax avoidance plan, the financing arrangement is a conduit financing arrangement.

(iii) Pursuant to paragraph (d)(1)(i) of this section, the amount subject to recharacterization is a fraction the numerator of which is the average principal amount advanced from FS to DS and the denominator of which is the average principal amount advanced from FP to FS. Because the property advanced in these financing transactions is the same type of fungible property, under paragraph (d)(1)(ii)(A) of this section, both are valued on the date of the last financing transaction. Accordingly, the portion of the payments of interest that is recharacterized is ((DM 5,000,000×DM 1.4/$1)/(DM 10,000,000×DM 1.4/$1) or 0.5.

(f) *Effective date.* This section is effective for payments made by financed entities on or after September 11, 1995. This section shall not apply to interest payments covered by section 127(g)(3) of the Tax Reform Act of 1984, and to interest payments with respect to other debt obligations issued prior to October

15, 1984 (whether or not such debt was issued by a Netherlands Antilles corporation).

§ 1.881–4 Recordkeeping requirements concerning conduit financing arrangements.

(a) *Scope.* This section provides rules for the maintenance of records concerning certain financing arrangements to which the provisions of § 1.881–3 apply.

(b) *Recordkeeping requirements*—(1) *In general.* Any person subject to the general recordkeeping requirements of section 6001 must keep the permanent books of account or records, as required by section 6001, that may be relevant to determining whether that person is a party to a financing arrangement and whether that financing arrangement is a conduit financing arrangement.

(2) *Application of Sections 6038 and 6038A.* A financed entity that is a reporting corporation within the meaning of section 6038A(a) and the regulations under that section, and any other person that is subject to the recordkeeping requirements of § 1.6038A–3, must comply with those recordkeeping requirements with respect to records that may be relevant to determining whether the financed entity is a party to a financing arrangement and whether that financing arrangement is a conduit financing arrangement. Such records, including records that a person is required to maintain pursuant to paragraph (c) of this section, shall be considered records that are required to be maintained pursuant to section 6038 or 6038A. Accordingly, the provisions of sections 6038 and 6038A (including, without limitation, the penalty provisions thereof), and the regulations under those sections, shall apply to any records required to be maintained pursuant to this section.

(c) *Records to be maintained*—(1) *In general.* An entity described in paragraph (b) of this section shall be required to retain any records containing the following information concerning each financing transaction that the entity knows or has reason to know comprises the financing arrangement—

(i) The nature (e.g., loan, stock, lease, license) of each financing transaction;

(ii) The name, address, taxpayer identification number (if any) and country of residence of—

(A) Each person that advanced money or other property, or granted rights to use property;

(B) Each person that was the recipient of the advance or rights; and

(C) Each person to whom a payment was made pursuant to the financing transaction (to the extent that person is a different person than the person who made the advance or granted the rights);

(iii) The date and amount of—

(A) Each advance of money or other property or grant of rights; and

(B) Each payment made in return for the advance or grant of rights;

(iv) The terms of any guarantee provided in conjunction with a financing transaction, including the name of the guarantor; and

(v) In cases where one or both of the parties to a financing transaction are related to each other or another entity in the financing arrangement, the manner in which these persons are related.

(2) *Additional documents.* An entity described in paragraph (b) of this section must also retain all records relating to the circumstances surrounding its participation in the financing transactions and financing arrangements. Such documents may include, but are not limited to—

(i) Minutes of board of directors meetings;

(ii) Board resolutions or other authorizations for the financing transactions;

(iii) Private letter rulings;

(iv) Financial reports (audited or unaudited);

(v) Notes to financial statements;

(vi) Bank statements;

(vii) Copies of wire transfers;

(viii) Offering documents;

(ix) Materials from investment advisors, bankers and tax advisors; and

(x) Evidences of indebtedness.

(3) *Effect of record maintenance requirement.* Record maintenance in accordance with paragraph (b) of this section generally does not require the original creation of records that are ordinarily not created by affected entities. If, however, a document that is actually created is described in this paragraph (c), it is to be retained even if the document is not of a type ordinarily created by the affected entity.

(d) *Effective date.* This section is effective September 11, 1995. This section shall not apply to interest payments covered by section 127(g)(3) of the Tax Reform Act of 1984, and to interest payments with respect to other debt obligations issued prior to October 15, 1984 (whether or not such debt was issued by a Netherlands Antilles corporation).

Par. 4. In § 1.1441–3, the OMB parenthetical at the end of the section is removed and paragraph (j) is added to read as follows:

§ 1.1441–3 Exceptions and rules of special application.

* * * * *

(j) *Conduit financing arrangements*—(1) *Duty to withhold.* A financed entity or other person required to withhold tax under section 1441 with respect to a financing arrangement that is a conduit financing arrangement within the meaning of § 1.881–3(a)(2)(iv) shall be required to withhold under section 1441 as if the district director had determined, pursuant to § 1.881–3(a)(3), that all conduit entities that are parties to the conduit financing arrangement should be disregarded. The amount of tax required to be withheld shall be determined under § 1.881–3(d). The withholding agent may withhold tax at a reduced rate if the financing entity establishes that it is entitled to the benefit of a treaty that provides a reduced rate of tax on a payment of the type deemed to have been paid to the financing entity. Section 1.881–3(a)(3)(ii)(E) shall not apply for purposes of determining whether any person is required to deduct and withhold tax pursuant to this paragraph (j), or whether any party to a financing arrangement is liable for failure to withhold or entitled to a refund of tax under sections 1441 or 1461 to 1464 (except to the extent the amount withheld exceeds the tax liability determined under § 1.881–3(d)). See § 1.1441–7(d) relating to withholding tax liability of the withholding agent in conduit financing arrangements subject to § 1.881–3.

(2) *Effective date.* This paragraph (j) is effective for payments made by financed entities on or after September 11, 1995. This paragraph shall not apply to interest payments covered by section 127(g)(3) of the Tax Reform Act of 1984, and to interest payments with respect to other debt obligations issued prior to October 15, 1984 (whether or not such debt was issued by a Netherlands Antilles corporation).

Par. 5. In § 1.1441–7, the OMB parenthetical at the end of the section is removed and paragraph (d) is added to read as follows:

§ 1.1441–7 General provisions relating to withholding agents.

* * * * *

(d) *Conduit financing arrangements*—(1) *Liability of withholding agent.* Subject to paragraph (d)(2) of this section, any person that is required to deduct and withhold tax under § 1.1441–3(j) is made liable for that tax by section 1461. A person that is required to deduct and withhold tax but fails to do so is liable for the payment

of the tax and any applicable penalties and interest.

(2) *Exception for withholding agents that do not know of conduit financing arrangement*—(i) *In general.* A withholding agent will not be liable under paragraph (d)(1) of this section for failing to deduct and withhold with respect to a conduit financing arrangement unless the person knows or has reason to know that the financing arrangement is a conduit financing arrangement. This standard shall be satisfied if the withholding agent knows or has reason to know of facts sufficient to establish that the financing arrangement is a conduit financing arrangement, including facts sufficient to establish that the participation of the intermediate entity in the financing arrangement is pursuant to a tax avoidance plan. A withholding agent that knows only of the financing transactions that comprise the financing arrangement will not be considered to know or have reason to know of facts sufficient to establish that the financing arrangement is a conduit financing arrangement.

(ii) *Examples.* The following examples illustrate the operation of paragraph (d)(2) of this section.

Example 1. (i) DS is a U.S. subsidiary of FP, a corporation organized in Country N, a country that does not have an income tax treaty with the United States. FS is a special purpose subsidiary of FP that is incorporated in Country T, a country that has an income tax treaty with the United States that prohibits the imposition of withholding tax on payments of interest. FS is capitalized with $10,000,000 in debt from BK, a Country N bank, and $1,000,000 in capital from FS.

(ii) On May 1, 1995, C, a U.S. person, purchases an automobile from DS in return for an installment note. On July 1, 1995, DS sells a number of installment notes, including C's, to FS in exchange for $10,000,000. DS continues to service the installment notes for FS and C is not notified of the sale of its obligation and continues to make payments to DS. But for the withholding tax on payments of interest by DS to BK, DS would have borrowed directly from BK, pledging the installment notes as collateral.

(iii) The C installment note is a financing transaction, whether held by DS or by FS, and the FS note held by BK also is a financing transaction. After FS purchases the installment note, and during the time the installment note is held by FS, the transactions constitute a financing arrangement, within the meaning of § 1.881–3(a)(2)(i). BK is the financing entity, FS is the intermediate entity, and C is the financed entity. Because the participation of FS in the financing arrangement reduces the tax imposed by section 881 and because there was a tax avoidance plan, FS is a conduit entity.

(iv) Because C does not know or have reason to know of the tax avoidance plan (and by extension that the financing arrangement is a conduit financing arrangement), C is not required to withhold tax under section 1441. However, DS, who knows that FS's participation in the financing arrangement is pursuant to a tax avoidance plan and is a withholding agent for purposes of section 1441, is not relieved of its withholding responsibilities.

Example 2. Assume the same facts as in *Example, 1* except that C receives a new payment booklet on which DS is described as ''agent''. Although C may deduce that its installment note has been sold, without more C has no reason to know of the existence of a financing arrangement. Accordingly, C is not liable for failure to withhold, although DS still is not relieved of its withholding responsibilities.

Example 3. (i) DC is a U.S. corporation that is in the process of negotiating a loan of $10,000,000 from BK1, a bank located in Country N, a country that does not have an income tax treaty with the United States. Before the loan agreement is signed, DC's tax lawyers point out that interest on the loan would not be subject to withholding tax if the loan were made by BK2, a subsidiary of BK1 that is incorporated in Country T, a country that has an income tax treaty with the United States that prohibits the imposition of withholding tax on payments of interest. BK1 makes a loan to BK2 to enable BK2 to make the loan to DC. Without the loan from BK1 to BK2, BK2 would not have been able to make the loan to DC.

(ii) The loan from BK1 to BK2 and the loan from BK2 to DC are both financing transactions and together constitute a financing arrangement within the meaning of § 1.881–3(a)(2)(i). BK1 is the financing entity, BK2 is the intermediate entity, and DC is the financed entity. Because the participation of BK2 in the financing arrangement reduces the tax imposed by section 881 and because there is a tax avoidance plan, BK2 is a conduit entity.

(iii) Because DC is a party to the tax avoidance plan (and accordingly knows of its existence), DC must withhold tax under section 1441. If DC does not withhold tax on its payment of interest, BK2, a party to the plan and a withholding agent for purposes of section 1441, must withhold tax as required by section 1441.

Example 4. (i) DC is a U.S. corporation that has a long-standing banking relationship with BK2, a U.S. subsidiary of BK1, a bank incorporated in Country N, a country that does not have an income tax treaty with the United States. DC has borrowed amounts of as much as $75,000,000 from BK2 in the past. On January 1, 1995, DC asks to borrow $50,000,000 from BK2. BK2 does not have the funds available to make a loan of that size. BK2 considers BK1 to enter into a loan with DC but rejects this possibility because of the additional withholding tax that would be incurred. Accordingly, BK2 borrows the necessary amount from BK1 with the intention of on-lending to DC. BK1 does not make the loan directly to DC because of the withholding tax that would apply to payments of interest from DC to BK1. DC does not negotiate with BK1 and has no reason to know that BK1 was the source of the loan.

(ii) The loan from BK2 to DC and the loan from BK1 to BK2 are both financing transactions and together constitute a financing arrangement within the meaning of § 1.881–3(a)(2)(i). BK1 is the financing entity, BK2 is the intermediate entity, and DC is the financed entity. The participation of BK2 in the financing arrangement reduces the tax imposed by section 881. Because the participation of BK2 in the financing arrangement reduces the tax imposed by section 881 and because there was a tax avoidance plan, BK2 is a conduit entity.

(iii) Because DC does not know or have reason to know of the tax avoidance plan (and by extension that the financing arrangement is a conduit financing arrangement), DC is not required to withhold tax under section 1441. However, BK2, who is also a withholding agent under section 1441 and who knows that the financing arrangement is a conduit financing arrangement, is not relieved of its withholding responsibilities.

(3) *Effective date.* This paragraph (d) is effective for payments made by financed entities on or after September 11, 1995. This paragraph shall not apply to interest payments covered by section 127(g)(3) of the Tax Reform Act of 1984, and to interest payments with respect to other debt obligations issued prior to October 15, 1984 (whether or not such debt was issued by a Netherlands Antilles corporation).

Par. 6. In § 1.6038A–3, paragraphs (b)(5) and (c)(2)(vii) are added to read as follows:

§ 1.6038A–3 Record maintenance.

* * * * *

(b) * * *

(5) *Records relating to conduit financing arrangements.* See § 1.881–4 relating to conduit financing arrangements.

(c) * * *

(2) * * *

(vii) *Records relating to conduit financing arrangements.* See § 1.881–4 relating to conduit financing arrangements.

* * * * *

Par. 7. Section 1.7701(l)–1 is added to read as follows:

§ 1.7701(l)–1 Conduit financing arrangements.

(a) *Scope.* Section 7701(l) authorizes the issuance of regulations that recharacterize any multiple-party financing transaction as a transaction directly among any two or more of such parties where the Secretary determines that such recharacterization is appropriate to prevent avoidance of any tax imposed by title 26 of the United States Code.

(b) *Regulations issued under authority of section 7701(l).* The following regulations are issued under the authority of section 7701(l)—

(1) § 1.871–1(b)(7);
(2) § 1.881–3;
(3) § 1.881–4;
(4) § 1.1441–3(j);
(5) § 1.1441–7(d);
(6) § 1.6038A–3(b)(5); and
(7) § 1.6038A–3(c)(2)(vii).

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 8. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 9. In § 602.101, paragraph (c) is amended by adding an entry in numerical order and revising an entry to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(c) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.881–4	1545–1440
* * * * *	
§ 1.6038A–3	1545–1191 1545–1440
* * * * *	

Margaret Milner Richardson,
Commissioner of Internal Revenue.
Approved: July 26, 1995.
Leslie Samuels,
Assistant Secretary of the Treasury.
[FR Doc. 95–19446 Filed 8–10–95; 8:45 am]
BILLING CODE 4830–01–U

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 20

Federal Claims Collection; Collection of Debts by Federal Income Tax Refund Offset

AGENCY: Office of the Secretary, Labor.

ACTION: Final rule; interim rule adopted as final with changes.

SUMMARY: The Department of Labor is completing its rulemaking to implement the requirement of the Cash Management Improvement Act Amendments of 1992 that Federal agencies refer delinquent debt to the Internal Revenue Service (IRS) for collection by offset from a Federal income tax refund that may be due to the delinquent debtor. These regulations are necessary for the Department's participation in the IRS offset program. The IRS offset program has proven to be a cost-effective mechanism for collection of delinquent debt.

EFFECTIVE DATE: These regulations are effective September 11, 1995.

FOR FURTHER INFORMATION CONTACT: Robert Barnhard, Division of Planning and Internal Control, Office of Financial Integrity, Office of the Chief Financial Officer, Department of Labor, Room S–4502, 200 Constitution Avenue, NW., Washington, DC 20210, telephone number 202/219–8184.

SUPPLEMENTARY INFORMATION: In 1992 the Congress passed and the President signed into law the Cash Management Improvement Act Amendments of 1992, which requires Federal agencies to participate in the IRS income tax refund offset program. On September 15, 1994 the Department of Labor published in the **Federal Register** an interim rule with request for comments implementing the IRS income tax refund offset program. The interim rule established a new Subpart E which specifies the procedures the Department of Labor will follow with regard to referral by its constituent offices, administrations and bureaus of past-due legally enforceable debts to IRS for collection by income tax refund offset.

The interim rule also established a new title for 29 CFR part 20: Federal Claims Collection. In addition to the new subpart E, part 20 contains the Department's regulations implementing the Debt Collection Act of 1982 (DCA). Subpart A implements the credit reporting provisions of the DCA; Subpart B, adminstrative offset; Subpart C, assessment of interest, penalties and administrative costs; and Subpart D, salary offset.

No comments were received in response to the notice of interim rulemaking with request for comments. Comments were to be submitted on or before November 14, 1994. However, two changes are made with the adoption of the interim rule as final due to changes in IRS requirements for participation in the offset program. In § 20.105 the specified minimum amounts for individual debts and business debts otherwise eligible for referral have been deleted. Section 10.106(b) is amended to delete reference to the requirement that business debts be referred to a commercial credit reporting agency.

Publication in Final

The Department of Labor has determined pursuant to 5 U.S.C. 553(b)(B) that good cause exists for waiving public comment on the changes to § 20.105 and § 20.106(b) set forth in this document. These changes merely reflect the change or elimination of certain IRS requirements for participation in the offset program. Therefore, public comment is unnecessary.

Executive Order 12866

This final rule is not classified as a ''significant rule'' under Executive Order 12866 on Federal regulations, because it will not result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or foreign markets. Accordingly, no regulatory impact assessment is required.

Regulatory Flexibility Act

Because no notice of proposed rulemaking has occurred during this rulemaking, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) pertaining to regulatory analyses do not apply.

Paperwork Reduction Act

This final rule is not subject to Section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3501) since it does not contain any new information collection requirements.

List of Subjects in 19 CFR Part 20

Government employees, Loan programs, Credit, Administrative practice and procedure, Claims.

Accordingly, the interim rule amending part 20 of title 29 of the Code of Federal Regulations which was published at 59 FR 47249 on September 15, 1994 is adopted as a final rule with the following changes:

PART 20—FEDERAL CLAIMS COLLECTION

1. The authority citation for Part 20 continues to read as follows:

Authority: 31 U.S.C. 3711 *et seq.;* Subpart D is also issued under 5 U.S.C. 5514; Subpart E is also issued under 31 U.S.C. 3720A.

2. Section 20.105 is revised to read as follows:

§ 20.105 Minimum referral amount.

The IRS annually establishes the minimum amount for debts otherwise eligible for referral. Minimum referral amounts are established separately for individual debts and business debts, as set forth in the memorandum of understanding. The amount referred may include the principal portion of the debt, as well as any accrued interest, penalties and/or administrative cost charges.

3. Section 20.106(b) is revised to read as follows:

§ 20.106 Relation to other collection efforts.

* * * * *

(b) The debts of individuals of $100 or more will be reported to a consumer credit reporting agency before referral for tax refund offset.

* * * * *

Signed at Washington, DC, this 27th day of July, 1995.

Robert B. Reich,

Secretary of Labor.

[FR Doc. 95–19876 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–23–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD02–95–016]

RIN 2115–AA97

Safety Zone; Lower Mississippi River, Mile 593.0 to Mile 597.0

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Lower Mississippi River between mile 593.0 and mile 597.0. The zone is needed to protect vessel traffic from a collision hazard during weir dike construction operations. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port.

EFFECTIVE DATES: This regulation is effective from 7 a.m. on August 10, 1995, and terminates at 11:55 p.m. on September 30, 1995.

FOR FURTHER INFORMATION CONTACT: LTJG Roberts, Assistant Chief Operations Officer, Captain of the Port, 200 Jefferson Avenue, Suite 1301, Memphis, TN 38103, Phone: (901) 544–3941.

SUPPLEMENTARY INFORMATION:

Background and Purpose

At approximately 7 a.m. on August 10, 1995, the U.S. Army Corps of Engineers will commence weir dike construction operations at Lower Mississippi River mile 595.2 on the left descending bank. The construction is expected to be completed within 50 days from the commencement date. The navigable channel will be blocked during the operations. A safety zone has been established on the Lower Mississippi River from mile 593.0 to mile 597.0 in order to facilitate safe vessel passage. All vessels shall establish passing arrangements with the contact pilot aboard the M/V KATE, via VHF Marine Band Radio, Channel 13, prior to entering the safety zone and shall abide by the conditions of the arrangement. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Publication of a notice of proposed rulemaking and delay of effective date would be contrary to the public interest because immediate action is necessary. Specifically, immediate action is necessary to facilitate construction operations during the present low water level of the river. Harm to the public or environment may result if vessel traffic is not controlled during construction operations. As a result, the Coast Guard deems it to be in the public's best interest to issue a regulation immediately.

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 not been reviewed 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 proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Collection of Information

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

Federalism

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

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under paragraph 2.B.2. of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary section 165.T02–200 is added to read as follows:

§ 165.T02–200 Safety Zone; Lower Mississippi River.

(a) *Location.* The following area is a Safety Zone: Lower Mississippi River mile 593.0 to mile 597.0.

(b) *Effective dates.* This section is effective from 7 a.m. on August 10, 1995, and terminates at 11:55 p.m. on September 30, 1995.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited except as authorized by the Captain of the Port. The captain of the Port, Memphis, Tennessee, will notify the maritime community of conditions affecting the area covered by this safety zone by Marine Safety Information Radio Broadcast on VHF Marine Band Radio, Channel 22 (157.1 MHz).

Dated: July 28, 1995.

A.L. Thompson, Jr.,

Commander, USCG, Captain of the Port.

[FR Doc. 95–19825 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–14–M

33 CFR Part 165

[CGD02–95–015]

RIN 2115–AA97

Safety Zone; Lower Mississippi River, mile 840.0 to mile 835.0

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Lower Mississippi River between mile 840.0 and mile 835.0. The zone is needed to restrict vessel traffic in the regulated area to provide a safe work area for emergency responders and salvage personnel. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port.

EFFECTIVE DATES: This regulation is effective from 11 p.m. on July 23, 1995 and terminates at 11:55 p.m. on December 31, 1995.

FOR FURTHER INFORMATION CONTACT: LTJG Roberts, Assistant Chief Operations Officer, Captain of the Port, 200 Jefferson Avenue, Suite 1301, Memphis, TN 38103, Phone: (901) 544–3941.

SUPPLEMENTARY INFORMATION:

Background and Purpose

On July 23, 1995 the Coast Guard was notified that a towing vessel with 35 barges allided with the I–155 bridge at Lower Mississippi River mile 838.9. After further investigation by Marine Safety Office Memphis personnel, it was recommended that a safety zone be issued in order to prevent additional damage that could be caused by a tow striking a submerged barge and to aid in the safe location and salvage of the barges. The barges are believed to be located in the channel and pose a substantial threat to navigation. The safety zone will be limited to Lower Mississippi River mile 840.0 to mile 835.0.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Publication of a notice of proposed rulemaking and delay of effective date would be contrary to the public interest because immediate action is necessary. Specifically, emergency response crews and salvage personnel require the area to be secured in order to aid in the location and salvage of the sunken barges. As a result, the Coast Guard deems it to be in the public's best interest to issue a regulation immediately.

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 not been reviewed 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 proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Collection of Information

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

Federalism

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

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under paragraph 2.B.2 of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water) Reporting and recordkeeping requirements, Security measures. Waterways.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary section 165.T02–015 is added to read as follows:

§ 165.T02–015 Safety Zone; Lower Mississippi River.

(a) *Location.* The following area is a Safety Zone: Lower Mississippi River mile 840.0 to mile 835.0.

(b) *Effective dates.* This section is effective from 11 p.m. on July 23, 1995 and terminates at 11:55 p.m. on December 31, 1995.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited except as authorized by the Captain of the Port. The Captain of the Port, Memphis, Tennessee, will notify the maritime community of conditions affecting the area covered by this safety zone by Marine Safety Information Radio Broadcast on VHF Marine Band Radio, Channel 22 (157.1 MHZ).

Dated: July 23, 1995.

A.L. Thompson, Jr.,

Commander, USCG, Captain of the Port.

[FR Doc. 95–19824 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1, 2, and 7

[Docket No. 950501124–5185–02]

RIN 0651–AA74

Revision of Patent and Trademark Fees

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office (PTO) is amending the rules of practice in patent and trademark cases, Parts 1, 2 and 7 of title 37, Code of Federal Regulations, to adjust certain patent and trademark fee amounts to reflect fluctuations in the Consumer Price Index (CPI) and to recover costs of operation, and is amending the requirements for recording documents on the Government Register. This rule also includes information relating to the availability of patent and trademark information products provided by the PTO.

EFFECTIVE DATE: October 1, 1995.

FOR FURTHER INFORMATION CONTACT: Robert Kopson by telephone at (703) 305–8510, fax at (703) 305–8525, or by mail marked to his attention and addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

SUPPLEMENTARY INFORMATION: This rule change is designed to adjust PTO fees in accordance with the applicable provisions of title 35, United States Code; section 31 of the Trademark (Lanham) Act of 1946 (15 U.S.C. 1113); and section 10101 of the Omnibus Budget Reconciliation Act of 1990 (as amended by section 8001 of Public Law 103–66), all as amended by the Patent and Trademark Office Authorization Act of 1991 (Pub. L. 102–204).

The cover sheet referenced in 37 CFR 7.1(c) must be in a format approved by the Office. The Office of Public Records will maintain a list of approved formats that will meet this requirement. Contact the Office of Public Records at (703) 308–9743 regarding specific questions relating to this requirement and to seek approval of additional formats.

Background

Statutory Provisions

Patent fees are authorized by 35 U.S.C. 41 and 35 U.S.C. 376. A fifty percent reduction in the fees paid under 35 U.S.C. 41(a) and (b) by independent inventors, small business concerns, and nonprofit organizations who meet prescribed definitions is required by 35 U.S.C. 41(h).

Subsection 41(f) of title 35, United States Code, provides that fees established under 35 U.S.C. 41(a) and (b) may be adjusted on October 1, 1992, and every year thereafter, to reflect fluctuations in the Consumer Price Index (CPI) over the previous 12 months.

Section 10101 of the Omnibus Budget Reconciliation Act of 1990 (amended by section 8001 of Pub. L. 103–66) provides that there shall be a surcharge on all fees established under 35 U.S.C. 41(a) and (b) to collect $111 million in fiscal year 1996.

Subsection 41(d) of title 35, United States Code, authorizes the Commissioner to establish fees for all other processing, services, or materials related to patents to recover the average cost of providing these services or materials, except for the fees for recording a document affecting title, for each photocopy, and for each black and white copy of a patent.

Section 376 of title 35, United States Code, authorizes the Commissioner to set fees for patent applications filed under the Patent Cooperation Treaty (PCT).

Subsection 41(g) of title 35, United States Code, provides that new fee amounts established by the Commissioner under section 41 may take effect thirty days after notice in the **Federal Register** and the *Official Gazette of the Patent and Trademark Office.*

Section 31 of the Trademark (Lanham) Act of 1946, as amended (15 U.S.C. 1113), authorizes the Commissioner to establish fees for the filing and processing of an application for the registration of a trademark or other mark, and for all other services and materials relating to trademarks and other marks.

Section 31(a) of the Trademark (Lanham) Act of 1946 (15 U.S.C. 1113(a)), as amended, allows trademark fees to be adjusted once each year to reflect, in the aggregate, any fluctuations during the preceding 12 months in the CPI.

Section 31 also allows new trademark fee amounts to take effect thirty days after notice in the **Federal Register** and the *Official Gazette of the United States Patent and Trademark Office.*

Recovery Level Determinations

This rule adjusts patent and trademark fees for a planned recovery of $643,014,000 in fiscal year 1996, as proposed in the Administration's budget request to the Congress.

The patent statutory fees established by 35 U.S.C. 41(a) and (b) are being adjusted on October 1, 1995, to reflect any fluctuations occurring during the previous 12 months in the Consumer Price Index (CPI–U). In calculating these fluctuations, the Office of Management and Budget (OMB) has determined that the PTO should use CPI–U data as determined by the Secretary of Labor. However, the Department of Labor does not make public the CPI–U until approximately 21 days after the end of the month being calculated. Therefore, the latest CPI–U information available is for the month of May 1995. In accordance with previous rulemaking methodology, the PTO uses the Administration's projected CPI–U for the 12-month period ending September 30, 1995, which is 3.2 percent. Based on this projection, patent statutory fees will be adjusted by 3.2 percent. Before the final fee schedule is published, the fees may be slightly adjusted based on actual data available from the Department of Labor.

Certain non-statutory patent processing fees established under 35 U.S.C. 41(d) and PCT processing fees established under 35 U.S.C. 376 are being adjusted to recover their estimated average costs in fiscal year 1996. Three patent service fees that are set by statute will not be adjusted. The three fees that are not being adjusted are assignment recording fees, printed patent copy fees and photocopy charge fees.

Certain trademark service fees established under 15 U.S.C. 1113 are being adjusted to recover their estimated average costs in fiscal year 1996.

The fee amounts were rounded by applying standard arithmetic rules so that the amounts rounded would be convenient to the user. Fees of $100 or more were rounded to the nearest $10. Fees between $2 and $99 were rounded to an even number so that the comparable small entity fee would be a whole number.

Workload Projections

Determination of workloads varies by fee. Principal workload projection techniques are as follows:

Patent application workloads are projected from statistical regression models using recent application filing trends. Patent issues are projected from an in-house patent production model and reflect examiner production achievements and goals. Patent maintenance fee workloads utilize patents issued 3.5, 7.5 and 11.5 years prior to payment and assume payment rates of 79 percent, 55 percent and 32 percent, respectively. Service fee workloads follow linear trends from prior years' activities.

General Procedures

Any fee amount that is paid on or after the effective date of the fee increase would be subject to the new fees then in effect. For purposes of determining the amount of the fee to be paid, the date of mailing indicated on a proper Certificate of Mailing or Transmission, where authorized under 37 CFR 1.8, will be considered to be the date of receipt in the PTO. A Certificate of Mailing or Transmission under Section 1.8 is not ''proper'' for items which are specifically excluded from the provisions of Section 1.8. Section 1.8 should be consulted for those items for which a Certificate of Mailing or Transmission is not ''proper.'' Such items include, inter alia, the filing of national and international applications for patents and the filing of trademark applications. However, the provisions of 37 CFR 1.10 relating to filing papers and fees with an ''Express Mail'' certificate do apply to any paper or fee (including patent and trademark applications) to be filed in the PTO. If an application or fee is filed by ''Express Mail'' with a proper certificate dated on or after the effective date of the rules, as amended, the amount of the fee to be paid would be fee established by the amended rules.

A notice of final rulemaking was published at 60 FR 20195 (April 25, 1995) wherein several new fee provisions were made to implement the 20-year patent term and provisional applications. Language changes were made in 37 CFR 1.16 (a), (b), (d), (f), and (g) which are reproduced in this final rule package. In addition, fees involving 37 CFR 1.17 (r) and (s) are being adjusted by changes in the CPI to remain equal to the basic filing fee for a utility patent application.

PTO Information Dissemination Products

The PTO provides information to the public in the Patent Search Room and

the Trademark Search Library in Arlington, Virginia, and at 78 Patent and Trademark Depository Libraries around the country. A list of the libraries is included in each issue of the *Official Gazette of the Patent and Trademark Office*. In addition, a number of patent and trademark search tools and document-delivery products, published on paper and on various machine-readable media, are sold directly to the public.

Printed PTO publications may be ordered from the Government Printing Office (GPO) or one of its Book Stores located throughout the country. A list of patent and trademark-related publications with current prices and ordering information is available from the GPO (Subject Bibliography SB 021). Superintendent of Documents, P.O. Box 371984, Pittsburgh, PA 15250–7954, Voice: 202–512–1800, Fax: 202–512–2250.

Machine-readable publications, including magnetic tapes and CD–ROMs, may be ordered directly from the PTO. A printed catalog of machine-readable products, including current prices and ordering information, is available from the Office of Information Products Development. US Patent and Trademark Office, Office of Information Products Development, Crystal Park 3, Room 412, Washington, DC 20231, Voice: 703–308–0322, Fax: 703–308–0493.

The catalog of machine-readable products is published in the Official Gazette of the Patent and Trademark Office in late December each year and may also be viewed on, or downloaded from, the PTO electronic bulletin board (703–305–8950, 8/no/1) or from the PTO's home page on the Internet (http://www.uspto.gov/).

In order to ensure clarity in the implementation of the new fees, a discussion of specific sections is set forth below.

Discussion of Specific Rules

37 CFR 1.16 National Application Filing Fees

Section 1.16, paragraphs (a), (b), (d), and (f)–(i), is revised to adjust fees established therein to reflect fluctuations in the CPI.

Section 1.16, paragraphs (a), (b), (d), and (g) include language changes relating to provisional patent applications (see 60 FR 20195, dated April 25, 1995).

37 CFR 1.17 Patent Application Processing Fees

Section 1.17, paragraphs (b)–(g) (m), (r), and (s), is revised to adjust fees established therein to reflect fluctuations in the CPI.

Section 1.17, paragraphs (j) and (n)–(p), is revised to adjust fees established therein to recover costs.

37 CFR 1.18 Patent Issue Fees

Section 1.18, paragraphs (a)–(c), is revised to adjust fees established therein to reflect fluctuations in the CPI.

37 CFR 1.19 Document Supply Fees

Section 1.19, paragraphs (a)(1)(ii) and (a)(1)(iii) is revised to amend the language to reflect the PTO's most recent business practices.

Section 1.19, paragraph (b)(1), is revised to adjust fees established therein to reflect fluctuations in the CPI.

37 CFR 1.20 Post-Issuance Fees

Section 1.20, paragraphs (c), (i), and (j), is revised to adjust fees established therein to recover costs.

Section 1.20, paragraphs (e)–(g), is revised to adjust fees established therein to reflect fluctuations in the CPI.

37 CFR 1.21 Miscellaneous Fees and Charges

Section 1.21, paragraph (a)(1), is revised to adjust fees established therein to recover costs.

37 CFR 1.445 International Application Filing, Processing, and Search Fees

Section 1.445, paragraph (a), is revised to adjust the fees authorized by 35 U.S.C. 376 to recover costs.

37 CFR 1.482 International Preliminary Examination Fees

Section 1.482, paragraphs (a)(1)(i), (a)(1)(ii), and (a)(2)(ii), is revised to adjust the fees authorized by 35 U.S.C. 376 to recover costs.

37 CFR 1.492 National Stage Fees

Section 1.492, paragraphs (a), (b) and (d), is revised to adjust fees established therein to reflect fluctuations in the CPI.

37 CFR 2.6 Trademark Fees

Section 2.6, paragraphs (b)(1)(ii) and (b)(1)(iii), is revised to amend the language to reflect the PTO's most recent business practices.

Section 2.6, paragraph (b)(2), is revised to adjust fees therein to recover costs.

37 CFR 7.1 Requirements

Section 7.1, is revised to designate the current language as paragraph (a), and to add new paragraphs (b)–(j) to clarify that the requirements for patent and patent application assignment documents, including the requirement for the fee set forth in § 1.21(h), submitted for recording also apply to instruments submitted for recording on the Government Register. Sections 7.1(b)–(d) and (f)–(i) contain language similar to that in §§ 3.21, 3.28, 3.31, 3.34, 3.26, 3.27, and 3.41, respectively.

Section 7.1(b), is added to provide that an instrument relating to a patent must identify the patent by the patent number, that an instrument relating to a national patent application must identify the national patent application by the application number (consisting of the series code and the serial number, *e.g.*, 07/123,456) or the serial number and filing date, that an instrument relating to an international patent application which designates the United States of America must identify the international application by the international application number (*e.g.*, PCT/US90/01234), and that if an assignment is executed concurrently with, or subsequent to, the execution of the patent application, but before the patent application is filed, it must identify the patent application by its date of execution, name of each inventor, and title of the invention so that there can be no mistake as to the patent application intended.

Section 7.1(c), is added to provide that each instrument submitted to the PTO for recording must be accompanied by a cover sheet referring to those patent applications and patents against which the instrument is to be recorded, that one set of instruments and cover sheets to be recorded should be filed, and that if an instrument to be recorded is not accompanied by a completed cover sheet, the instrument and any incomplete cover sheet will be returned for proper completion of a cover sheet and resubmission of the instrument and a completed cover sheet.

Section 7.1(d), is added to provide that each cover sheet must contain: (1) the name of the party conveying the interest; (2) the name and address of the party receiving the interest; (3) a description of the interest conveyed or transaction to be recorded; (4) each application number or patent number against which the instrument is to be recorded, or an indication that the instrument is filed together with a patent application; (5) the name and address of the party to whom correspondence concerning the request to record the instrument should be mailed; (6) the number of applications or patents identified in the cover sheet and the total fee; (7) the date the instrument was executed; (8) a statement by the party submitting the instrument that to the best of the person's knowledge and belief, the information contained on the cover

sheet is true and correct and any copy submitted is a true copy of the original instrument; and (9) the signature of the party submitting the instrument.

Section 7.1(e), is added that each patent cover sheet required by paragraph (c) of this section seeking to record a governmental interest as provided by paragraph (a) of this section must: (1) indicate that the instrument is to be recorded on the governmental register, and, if applicable, that the instrument is to be recorded on the Secret Register. See § 7.7, and (2) indicate, if applicable, that the instrument to be recorded is not an instrument affecting title. See paragraph (j) of this section.

Section 7.1(f), is added to provide for the correction of errors in the cover sheet. Specifically, § 7.1(e), provides that an error in a cover sheet recorded pursuant to this Part will be corrected only if: (1) the error is apparent when the cover sheet is compared with the recorded instrument to which it pertains, and (2) a corrected cover sheet accompanied by the recording fee set forth in paragraph (i) of this section and either the original recorded instrument or a copy of the original recorded instrument is filed for recordation.

Section 7.1(g), is added to provide that the Office will accept and record non-English language instruments only if accompanied by a verified English translation signed by the individual making the translation.

Section 7.1(h), is added to provide that instruments and cover sheets to be recorded should be addressed to the Commissioner of Patents and Trademarks, Box Assignment, Washington, D.C. 20231.

Section 7.1(i) is added to provide that all requests, except as provided by paragraph (j) of this section, to record instruments must be accompanied by the recording fee set forth in § 1.21(h) of this chapter, and that the fee set forth in § 1.21(h) of this chapter is required for each application and patent against which the instrument is recorded as identified in the cover sheet.

Section 7.1(j), is added to provide that no fee is required for each patent application and patent against which an instrument required by Executive Order 9424 (3 CFR 1943–1948 Comp.) to be filed if: (1) the instrument does not affect title and is so identified in the cover sheet (see paragraph (e) of this section); and (2) the cover sheet is filed in a format approved by the Office.

Response to Comments on the Rules

A notice of proposed rulemaking to adjust certain patent and trademark fee amounts and to amend the requirements for recording an assignment to apply to documents forwarded for recording on the Government Register was published in the **Federal Register** on May 26, 1995, at 60 FR 27934, and in the *Official Gazette of the United States Patent and Trademark Office* on May 30, 1995, at 1174 OG 134.

A public hearing was held June 29, 1995. Nine comments were received and considered in adopting the rules set forth herein. No oral testimony was presented.

Comment: Two respondents stated that the proposed inflationary increase of patent and trademark fees is unnecessary because the PTO is already operating at a surplus.

Response: Current PTO resources include carryover funds from fiscal year 1994. These carryover funds are partly unobligated balances to be carried forward, but primarily advanced fee payments for work to be done in fiscal year 1995. Furthermore, this carryover includes fee income generated from trademark-related products and services which, according to 35 U.S.C. 42(c), may be used only for trademark-related activities. Therefore, to recover all costs associated with the processing of patent applications, and to remain consistent with the current rate of inflation, the PTO is increasing certain patent fees by 3.2 percent as authorized by 35 U.S.C. 41(f).

In addition, two trademark service fees were proposed to be increased. The adopted fee amounts will recover the average cost of providing the service as authorized by 35 U.S.C. 41(d), and will also remain consistent with the equivalent patent service fee amounts.

Comments: Seven respondents objected to the proposal to amend the requirements for recording an assignment to apply to documents forwarded for recording on the Government Register. The respondents stated that not only are Government agencies required by Executive Order 9424 to forward an assignment to the PTO for recordation, but also the PTO lacks the authority under Title 35 of the United States Code to impose a fee for recording an assignment on the Government Register.

Response: 35 U.S.C. 41(d)(1) provides that the Commissioner shall charge a fee of $40 per property for recording any document affecting title. An assignment is a document affecting title. Therefore, the Office must require a $40 recording fee for recording any assignment, even those being recorded on the Government Register. If a document to be recorded on the Government Register does not affect title and if it is accompanied by the appropriate cover sheet, then no fee is required.

Other Considerations

This final rule change is in conformity with the requirements of Executive Order 12612, and the Paperwork Reduction Act of 1980, 44 U.S.C. 3501, et seq. This rulemaking contains no information collection within the meaning of the Paperwork Reduction Act. This final rule has been determined not to be significant for purposes of Executive Order 12866.

The PTO has determined that this final rule change has no Federalism implications affecting the relationship between the National Government and the States as outlined in Executive Order 12612.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that the final rule change would not have a signficiant impact on a substantial number of small entities (Regulatory Flexibility Act, Pub. L. 96–354). The final rule change increases fees to reflect the change in the CPI as authorized by 35 U.S.C. 42(f). Further, the principal impact of the major patent fees has already been taken into account in 35 U.S.C. 41(h), which provides small entities with a 50-percent reduction in the major patent fees.

A comparison of existing and new fee amounts is included as an Appendix to this notice of final rulemaking.

Lists of Subjects

37 CFR Part 1

Administrative practice and procedure, Inventions and patents, Reporting and record keeping requirements, Small businesses.

37 CFR Part 2

Administrative practice and procedure, Courts, Lawyers, Trademarks.

37 CFR Part 7

Administrative practice and procedure, Inventions, and patents, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the PTO is amending title 37 of the Code of Federal Regulations, Chapter 1, Part 1, as set forth below.

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 would continue to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.16 is amended by revising paragraphs (a), (b), (d), and (f) through (i), to read as follows:

§ 1.16 National application filing fees.

(a) Basic fee for filing each application for an original patent, except provisional, design or plant applications:

By a small entity (§ 1.9(f))....$375.00
By other than a small entity $750.00

(b) In addition to the basic filing fee in an original application, except provisional applications, for filing or later presentation of each independent claim in excess of 3:

By a small entity (§ 1.9(f))....$39.00
By other than a small entity $78.00

* * * * *

(d) In addition to the basic filing fee in an original application, except provisional applications, if the application contains, or is amended to contain, a multiple dependent claim(s), per application:

By a small entity (§ 1.9(f))....$125.00
By other than a small entity $250.00

(If the additional fees required by paragraphs (b), (c), and (d) of this section are not paid on filing or on later presentation of the claims for which the additional fees are due, they must be paid or the claims canceled by amendment prior to the expiration of the time period set for response by the Office in any notice of fee deficiency.)

* * * * *

(f) Basic fee for filing each design application:

By a small entity (§ 1.9(f))....$155.00
By other than a small entity $310.00

(g) Basic fee for filing each plant application, except provisional applications:

By a small entity (§ 1.9(f))....$255.00
By other than a small entity $510.00

(h) Basic fee for filing each reissue application:

By a small entity (§ 1.9(f))....$375.00
By other than a small entity $750.00

(i) In addition to the basic filing fee in a reissue application, for filing or later presentation of each independent claim which is in excess of the number of independent claims in the original patent:

By a small entity (§ 1.9(f))....$39.00
By other than a small entity $78.00

* * * * *

3. Section 1.17 is amended by revising paragraphs (b) through (g), (j), (m) through (p), (r), and (s) to read as follows:

§ 1.17 Patent application processing fees.

* * * * *

(b) Extension fee for response within second month pursuant to § 1.136(a):

By a small entity (§ 1.9(f))....$190.00
By other than a small entity $380.00

(c) Extension fee for response within third month pursuant to § 1.136(a):

By a small entity (§ 1.9(f))....$450.00
By other than a small entity $900.00

(d) Extension fee for response within fourth month pursuant to § 1.136(a)

By a small entity (§ 1.9(f))....$700.00
By other than a small entity $1,400.00

(e) For filing a notice of appeal from the examiner to the Board of Patent Appeals and Interferences:

By a small entity (§ 1.9(f))....$145.00
By other then a small entity $290.00

(f) In addition to the fee for filing a notice of appeal, for filing a brief in support of an appeal:

By a small entity (§ 1.9(f))....$145.00
By other than a small entity 290.00

(g) For filing a request for an oral hearing before the Board of Patent Appeals and Interferences in an appeal under 35 U.S.C. 134:

By a small entity (§ 1.9(f))....$125.00
By other than a small entity $250.00

* * * * *

(j) For filing a petition to institute a public use proceeding under

§ 1.292 ....$1,430.00

* * * * *

(m) For filing a petition:

(1) For revival of an unintentionally abandoned application, or

(2) For the unintentionally delayed payment of the fee for issuing a patent:

By a small entity (§ 1.9(f))....$625.00
By other than a small entity $1,250.00

(n) For requesting publication of a statutory invention registration prior to the mailing of the first examiner's action pursuant to § 1.104—$870.00 reduced by the amount of the application basic filing fee paid.

(o) For requesting publication of a statutory invention registration after the mailing of the first examiner's action pursuant to § 1.104—$1,740.00 reduced by the amount of the application basic filing fee paid.

(p) For submission of an information disclosure statement under

§ 1.97(c) $220.00

* * * * *

(r) For entry of a submission after final rejection under § 1.129(a):

By a small entity (§ 1.9(f))....375.00
By other than a small entity $750.00

(s) For each additional invention requested to be examined under § 1.129(b):

By a small entity (§ 1.9(f))....$375.00
By other than a small entity $750.00

4. Section 1.18 is revised to read as follows:

§ 1.18 Patent issue fees.

(a) Issue fee for issuing each original or reissue patent, except a design or plant patent:

By a small entity (§ 1.9(f))....$625.00
By other than a small entity $1,250.00

(b) Issue fee for issuing a design patent:

By a small entity (§ 1.9(f))....$215.00
By other than a small entity $430.00

(c) Issue fee for issuing a plant patent:

By a small entity (§ 1.9(f))....$315.00
By other than a small entity $630.00

5. Section 1.19 is amended by revising paragraphs (a)(1)(ii), (a)(1)(iii), (b)(1)(i), and (b)(1)(ii) to read as follows:

§ 1.19 Document supply fees.

* * * * *

(a) * * *

(1) * * *

* * * * *

(ii) Overnight delivery to PTO Box or overnight fax $6.00

(iii) Expedited service for copy ordered by expedited mail or fax delivery service and delivered to the customer within two workdays $25.00

* * * * *

(b) * * *

(1) * * *

(i) Regular service $15.00

(ii) Expedited regular service $30.00

* * * * *

6. Section 1.20 is amended by revising paragraphs (c), (e) through (g), (i)(1), (i)(2), and (j) to read as follows:

§ 1.20 Post issuance fees.

* * * * *

(c) For filing a request for reexamination (§ 1.510(a))....$2,390.00

* * * * *

(e) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond four years; the fee is due by three years and six months after the original grant:

By a small entity (§ 1.9(f)) $495.00
By other than a small entity $990.00

(f) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond eight years; the fee is due by seven years and six months after the original grant:

By a small entity (§ 1.9(f))....$995.00
By other than a small entity $1,990.00

(g) For maintaining an original or reissue patent, except a design or plant patent, based on an application filed on or after December 12, 1980, in force beyond twelve years; the fee is due by eleven years and six months after the original grant:

By a small entity (§ 1.9(f))....$1,495.00
By other than a small entity $2,990.00

* * * * *

(i) * * *

(1) unavoidable $660.00

(2) Unintentional $1,550.00

* * * * *

(j) For filing an application for extension of the term of a patent

(§ 1.740) $1,060.00

7. Section 1.21 is amended by revising paragraph (a)(1) to read as follows:

§ 1.21 Miscellaneous fees and charges.

* * * * *

(a) * * *

(1) For admission to examination for registration to practice: fee payable upon application $310.00

* * * * *

8. Section 1.445 is amended by revising paragraph (a) to read as follows:

§ 1.445 International application filing, processing and search fees.

(a) The following fees and charges for international applications are established by the Commissioner under the authority of 35 U.S.C. 376:

(1) A transmittal fee (see 35 U.S.C. 361(d) and PCT Rule 14) $220.00

(2) A search fee (see 35 U.S.C. 361(d) and PCT Rule 16) where:

(i) No corresponding prior United States national application with basic filing fee has been filed $660.00

(ii) A corresponding prior United States national application with basic filing fee has been filed $430.00

(3) A supplemental search fee when required, per additional invention $190.00

* * * * *

9. Section 1.482 is amended by revising paragraphs (a)(1) and (a)(2)(ii) to read as follows:

§ 1.482 International preliminary examination fees.

(a) * * *

(1) A preliminary examination fee is due on filing the Demand:

(i) Where an international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office as an International Searching Authority, a preliminary examination fee of $470.00

(ii) Where the International Searching Authority for the international application was an authority other than the United States Patent and Trademark Office, a preliminary examination fee of $710.00

(2) * * *

(ii) Where the International Searching Authority for the International application was an authority other than the United States Patent and Trademark Office.....$250.00

* * * * *

10. Section 1.492 is amended by revising paragraphs (a), (b), and (d) to read as follows:

§ 1.492 National stage fees.

* * * * *

(a) The basic national fee:

(1) Where an international preliminary examination fee as set forth in § 1.482 has been paid on the international application to the United States Patent and Trademark Office:

By a small entity (§ 1.9(f)).....$340.00
By other than a small entity $680.00

(2) Where no international preliminary examination fee as set forth in § 1.482 has been paid to the United States Patent and Trademark Office, but an international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office as an International Searching Authority:

By a small entity (§ 1.9(f)).....$375.00
By other than a small entity $750.00

(3) Where no international preliminary examination fee as set forth in § 1.482 has been paid and no international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office:

By a small entity (§ 1.9(f)).....$505.00
By other than a small entity $1,010.00

(4) Where an international preliminary examination fee as set forth in § 1.482 has been paid to the United States Patent and Trademark Office and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness), and industrial applicability, as defined in PCT Article 33 (1) to (4) have been satisfied for all the claims presented in the application entering the national stage (see § 1.496(b)):

By a small entity (§ 1.9(f)).....$47.00
By other than a small entity $94.00

(5) Where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office:

By a small entity (§ 1.9(f)).....$440.00
By other than a small entity $880.00

(b) In addition to the basic national fee, for filing or later presentation of each independent claim in excess of 3:

By a small entity (§ 1.9(f)).....$39.00
By other than a small entity $78.00

* * * * *

(d) In addition to the basic national fee, if the application contains, or is amended to contain, a multiple dependent claim(s), per application:

By a small entity (§ 1.9(f)).....$125.00
By other than a small entity $250.00

* * * * *

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

1. The authority citation for 37 CFR Part 2 would continue to read as follows:

Authority: 15 U.S.C. 1123; 35 U.S.C. 6, unless otherwise noted.

2. Section 2.6 is amended by revising paragraphs (b)(1)(ii), (b)(1)(iii), (b)(2)(i), and (b)(2)(ii) to read as follows:

§ 2.6 Trademark fees.

* * * * *

(b) * * *

(1) * * *

* * * * *

(ii) Overnight delivery to PTO Box or overnight fax $6.00

(iii) Expedited service for copy ordered by expedited mail or fax delivery service and delivered to the customer within two work days $25.00

* * * * *

(2) * * *

(i) Regular service $15.00

(ii) Expedited local service.....$30.00

* * * * *

PART 7—REGISTER OF GOVERNMENT INTERESTS IN PATENTS

1. The authority citation for 37 CFR Part 7 would continue to read as follows:

Authority: E.O. 9424, February 18, 1944, 9 FR 1959; 3 CFR 1943–1948 Comp.

2. Section 7.1 is revised to read as follows:

§ 7.1 Requirements.

(a) Executive Order 9424 (3 CFR 1943–1948 Comp.) requires the several departments and other executive agencies of the Government, including Government-owned or Government-controlled corporations, to forward promptly to the Commissioner of Patents and Trademarks for recording all licenses, assignments, or other interests of the Government in or under patents or applications for patents.

(b) An instrument relating to a patent must identify the patent by the patent number. An instrument relating to a national patent application must identify the national patent application by the application number (consisting of the series code and the serial number, e.g., 07/123,456) or the serial number and filing date. An instrument relating to an international patent application which designates the United States of America must identify the international applications by the international application number (e.g., PCT/US90/01234). If an assignment is executed concurrently with, or subsequent to, the execution of the patent application, but before the patent application is filed, it must identify the patent application by its date of execution, name of each inventor, and title of the invention so that there can be no mistake as to the patent application intended.

(c) Each instrument submitted to the Office for recording must be accompanied by at least one cover sheet as specified in paragraph (d) of this section referring to those patent applications and patents against which the instrument is to be recorded. Only one set of instruments and cover sheets

to be recorded should be filed. If an instrument to be recorded is not accompanied by a completed cover sheet, the instrument and any incomplete cover sheet will be returned for proper completion of a cover sheet and resubmission of the instrument and a completed cover sheet.

(d) Each cover sheet required by paragraph (c) of this section must contain:

(1) the name of the party conveying the interest;

(2) the name and address of the party receiving the interest;

(3) a description of the interest conveyed or transaction to be recorded;

(4) each application number or patent number against which the instrument is to be recorded, or an indication that the instrument is filed together with a patent application;

(5) the name and address of the party to whom correspondence concerning the request to record the instrument should be mailed;

(6) the number of applications or patents identified in the cover sheet and the total fee;

(7) the date the instrument was executed;

(8) a statement by the party submitting the instrument that to the best of the person's knowledge and belief, the information contained on the cover sheet is true and correct and any copy submitted is a true copy of the original instrument; and

(9) the signature of the party submitting the instrument.

(e) Each patent cover sheet required by paragraph (c) of this section seeking to record a governmental interest as provided by paragraph (a) of this section must:

(1) indicate that the instrument is to be recorded on the governmental register, and, if applicable, that the instrument is to be recorded on the Secret Register. See § 7.7.

(2) indicate, if applicable, that the instrument to be recorded is not an instrument affecting title. See paragraph (j) of this section.

(f) An error in a cover sheet recorded pursuant to this Part will be corrected only if:

(1) the error is apparent when the cover sheet is compared with the recorded instrument to which it pertains, and

(2) a corrected cover sheet accompanied by the recording fee set forth in paragraph (i) of this section and either the original recorded instrument or a copy of the original recorded instrument is filed for recordation.

(g) The Office will accept and record non-English language instruments only if accompanied by a verified English translation signed by the individual making the translation.

(h) Instruments and cover sheets to be recorded should be addressed to the Commissioner of Patents and Trademarks, Box Assignment, Washington, D.C. 20231.

(i) All requests to record instruments must be accompanied by the appropriate fee. Except as provided in paragraph (j) of this section, a recording fee set forth in § 1.21(h) of this chapter fee is required for each application and patent against which the instrument is recorded as identified in the cover sheet.

(j) No fee is required for each patent application and patent against which an instrument required by Executive Order 9424 (3 CFR 1943–1948 Comp.) to be filed if:

(1) the instrument does not affect title and is so identified in the cover sheet (see paragraph (e) of this section); and

(2) the cover sheet is filed in a format approved by the Office.

Dated: August 4, 1995.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

Note. The following appendix will not appear in the Code of Federal Regulations.

Appendix A—Comparison of Existing and Revised Fee Amounts

37 CFR Sec.	Description	Pre-Oct. 1995	Oct. 1995
1.16(a)	Basic Filing Fee	$730	$750
1.16(a)	Basic Filing Fee (Small Entity)	365	375
1.16(b)	Independent Claims	76	78
1.16(b)	Independent Claims (Small Entity)	38	39
1.16(c)	Claims in Excess of 20	22	.....
1.16(c)	Claims in Excess of 20 (Small Entity)	11	.....
1.16(d)	Multiple Dependent Claims	240	250
1.16(d)	Multiple Dependent Claims (Small Entity)	120	125
1.16(e)	Surcharge—Late Filing Fee	130	.....
1.16(e)	Surcharge—Late Filing Fee (Small Entity)	65	.....
1.16(f)	Design Filing Fee	300	310
1.16(f)	Design Filing Fee (Small Entity)	150	155
1.16(g)	Plant Filing Fee	490	510
1.16(g)	Plant Filing Fee (Small Entity)	245	255
1.16(h)	Reissue Filing Fee	730	750
1.16(h)	Reissue Filing Fee (Small Entity)	365	375
1.16(i)	Reissue Independent Claims	76	78
1.16(i)	Reissue Independent Claims (Small Entity)	38	39
1.16(j)	Reissue Claims in Excess of 20	22	.....
1.16(j)	Reissue Claims in Excess of 20 (Small Entity)	11	.....
1.16(k)	Provisional Application Filing Fee	150	.....
1.16(k)	Provisional Application Filing Fee (Small Entity)	75	.....
1.16(l)	Surcharge—Incomplete Provisional App. Filed	50	.....
1.16(l)	Surcharge—Incomplete Provisional App. Filed (Small Entity)	25	.....
1.17(a)	Extension—First Month	110	.....
1.17(a)	Extension—First Month (Small Entity)	55	.....
1.17(b)	Extension—Second Month	370	380
1.17(b)	Extension—Second Month (Small Entity)	185	190

37 CFR Sec.	Description	Pre-Oct. 1995	Oct. 1995
1.17(c)	Extension—Third Month	870	900
1.17(c)	Extension—Third Month (Small Entity)	435	450
1.17(d)	Extension—Fourth Month	1,360	1,400
1.17(d)	Extension—Fourth Month (Small Entity)	680	700
1.17(e)	Notice of Appeal	280	290
1.17(e)	Notifce of Appeal (Small Entity)	140	145
1.17(f)	Filing a Brief	280	290
1.17(f)	Filing a Brief (Small Entity)	140	145
1.17(g)	Request for Oral Hearing	240	250
1.17(g)	Request for Oral Hearing (Small Entity)	120	125
1.17(h)	Petition—Not All Inventors	130	
1.17(h)	Petition—Correction of Inventorship	130	
1.17(h)	Petition—Decision on Questions	130	
1.17(h)	Petition—Suspend Rules	130	
1.17(h)	Petition—Expedited License	130	
1.17(h)	Petition—Scope of License	130	
1.17(h)	Petition—Retroactive License	130	
1.17(h)	Petition—Refusing Maintenance Fee	130	
1.17(h)	Petition—Refusing Maintenance Fee—Expired Patent	130	
1.17(h)	Petition—Interference	130	
1.17(h)	Petition—Reconsider Interference	130	
1.17(h)	Petition—Late Filing of Interference	130	
1.20(b)	Petition—Correction of Inventorship	130	
1.17(h)	Petition—Refusal to Publish SIR	130	
1.17(i)	Petition—For Assignment	130	
1.17(i)	Petition—For Application	130	
1.17(i)	Petition—Late Priority Papers	130	
1.17(i)	Petition—Suspend Action	130	
1.17(i)	Petition—Divisional Reissues to Issue Separately	130	
1.17(i)	Petition—For Interference Agreement	130	
1.17(i)	Petition—Amendment After Issue	130	
1.17(i)	Petition—Withdrawal After Issue	130	
1.17(i)	Petition—Defer Issue	130	
1.17(i)	Petition—Issue to Assignee	130	
1.17(i)	Petition—Accord a Filing Date Under § 1.53	130	
1.17(i)	Petition—Accord a Filing Date Under § 1.62	130	
1.17(i)	Petition—Make Application Special	130	
1.17(j)	Petition—Public Use Proceeding	1,390	1,430
1.17(k)	Non-English Specification	130	
1.17(l)	Petition—Revive Abandoned Appl	110	
1.17(l)	Petition—Revive Abandoned Appl. (Small Entity)	55	
1.17(m)	Petition—Revive Unintentionally Abandoned Appl	1,210	1,250
1.17(m)	Petition—Revive Unintent Abandoned Appl. (Small Entity)	605	625
1.17(n)	SIR—Prior to Examiner's Action	840	870
1.17(o)	SIR—After Examiner's Action	1,690	1,740
1.17(p)	Submission of an Information Disclosure Statement (§ 1.97)	210	220
1.17(q)	Petition—Correction of Inventorship (Prov. App.)	50	
1.17(q)	Petition—Accord a filing date (Prov. App.)	50	
1.17(r)	Filing a submission after final rejection (1.129(a))	730	750
1.17(r)	Filing a submission after final rejection (1.129(a)) (Small Entity)	365	375
1.17(s)	Per add'l invention to be examined (1.129(b))	730	750
1.17(s)	Per add'l invention to be examined (1.129(b)) (Small Entity)	365	375
1.18(a)	Issue Fee	1,210	1,250
1.18(a)	Issue Fee (Small Entity)	605	625
1.18(b)	Design Issue Fee	420	430
1.18(b)	Design Issue Fee (Small Entity)	210	215
1.18(c)	Plant Issue Fee	610	630
1.18(c)	Plant Issue Fee (Small Entity)	305	315
1.19(a)(1)(i)	Copy of Patent	3	
1.19(a)(1)(ii)	Patent Copy—Overnight delivery to PTO Box or overnight fax	6	
1.19(a)(1)(iii)	Patent Copy Ordered by Expedited Mail or Fax—Exp. service	25	
1.19(a)(2)	Plant Patent Copy	12	
1.19(a)(3)(i)	Copy of Utility Patent or SIR in Color	24	
1.19(b)(1)(i)	Certified Copy of Patent Application as Filed	12	15
1.19(b)(1)(ii)	Certified Copy of Patent Application as Filed, Expedited	24	30
1.19(b)(2)	Cert or Uncert Copy of Patent-Related File Wrapper/Contents	150	
1.19(b)(3)	Cert. or Uncert. Copies of Office Records, per Document	25	
1.19(b)(4)	For Assignment Records, Abstract of Title and Certification	25	
1.19(c)	Library Service	50	
1.19(d)	List of Patents in Subclass	3	
1.19(e)	Uncertified Statement-Status of Maintenance Fee Payment	10	

37 CFR Sec.	Description	Pre-Oct. 1995	Oct. 1995
1.19(f)	Copy of Non-U.S. Patent Document	25	
1.19(g)	Comparing and Certifying Copies, Per Document, Per Copy	25	
1.19(h)	Duplicate or Corrected Filing Receipt	25	
1.20(a)	Certificate of Correction	100	
1.20(c)	Reexamination	2,320	2,390
1.20(d)	Statutory Disclaimer	110	
1.20(d)	Statutory Disclaimer (Small Entity)	55	
1.20(e)	Maintenance Fee—3.5 Years	960	990
1.20(e)	Maintenance Fee—3.5 Years (Small Entity)	480	495
1.20(f)	Maintenance Fee—7.5 Years	1,930	1,990
1.20(f)	Maintenance Fee—7.5 Years (Small Entity)	965	995
1.20(g)	Maintenance Fee—11.5 Years	2,900	2,990
1.20(g)	Maintenance Fee—11.5 Years (Small Entity)	1,450	1,495
1.20(h)	Surcharge—Maintenance Fee—6 Months	130	
1.20(h)	Surcharge—Maintenance Fee—6 Months (Small Entity)	65	
1.20(i)(1)	Surcharge—Maintenance After Expiration—Unavoidable	640	660
1.20(i)(2)	Surcharge—Maintenance After Expiration—Unintentional	1,500	1,550
1.20(j)	Extension of Term of Patent	1,030	1,060
1.21(a)(1)	Admission to examination	300	310
1.21(a)(2)	Registration to Practice	100	
1.21(a)(3)	Reinstatement to Practice	15	
1.21(a)(4)	Certificate of Good Standing	10	
1.21(a)(4)	Certificate of Good Standing, Suitable Framing	20	
1.21(a)(5)	Review of Decision of Director, OED	130	
1.21(a)(6)	Regrading of Examination	130	
1.21(b)(1)	Establish Deposit Account	10	
1.21(b)(2)	Service Charge Below Minimum Balance	25	
1.21(b)(3)	Service Charge Below Minimum Balance	25	
1.21(c)	Filing a Disclosure Document	10	
1.21(d)	Box Rental	50	
1.21(e)	International Type Search Report	$40	
1.21(g)	Self-Service Copy Charge	.25	
1.21(h)	Recording Patent Property	40	
1.21(i)	Publication in the OG	25	
1.21(j)	Labor Charges for Services	30	
1.21(k)	Unspecified Other Services		
1.21(k)	Terminal Use APS–CSIR (per hour)	50	
1.21(m)	Processing Returned Checks	50	
1.21(n)	Handling Fee—Incomplete Application	130	
1.21(o)	Terminal Use APS–TEXT	40	
1.24	Coupons for Patent and Trademark Copies	3	
1.296	Handling Fee—Withdrawal SIR	130	
1.445(a)(1)	Transmittal Fee	210	$220
1.445(a)(2)(i)	PCT Search Fee—No U.S. Application	640	660
1.445(a)(2)(ii)	PCT Search Fee—Prior U.S. Application	420	430
1.445(a)(3)	Supplemental Search	180	190
1.482(a)(1)(i)	Preliminary Exam Fee	460	470
1.482(a)(1)(ii)	Preliminary Exam Fee	690	710
1.482(a)(2)(i)	Additional Invention	140	
1.482(a)(2)(ii)	Additional Invention	240	250
1.492(a)(1)	Preliminary Examining Authority	660	680
1.492(a)(1)	Preliminary Examining Authority (Small Entity)	330	340
1.492(a)(2)	Searching Authority	730	750
1.492(a)(2)	Searching Authority (Small Entity)	365	375
1.492(a)(3)	PTO Not ISA nor IPEA	980	1,010
1.492(a)(3)	PTO Not ISA nor IPEA (Small Entity)	490	505
1.492(a)(4)	Claims—IPEA	92	94
1.492(a)(4)	Claims—IPEA (Small Entity)	46	47
1.492(a)(5)	Filing with EPO/JPO Search Report	850	880
1.492(a)(5)	Filing with EPO/JPO Search Report (Small Entity)	425	440
1.492(b)	Claims—Extra Individual (Over 3)	76	78
1.492(b)	Claims—Extra Individual (Over 3) (Small Entity)	38	39
1.492(c)	Claims—Extra Total (Over 20)	22	
1.492(c)	Claims—Extra Total (Over 20) (Small Entity)	11	
1.492(d)	Claims—Multiple Dependents	240	250
1.492(d)	Claims—Multiple Dependents (Small Entity)	120	125
1.492(e)	Surcharge	130	
1.492(e)	Surcharge (Small Entity)	65	
1.492(f)	English Translation—After 20 Months	130	
2.6(a)(1)	Application for Registration, Per Class	245	
2.6(a)(2)	Amendment to Allege Use, Per Class	100	

37 CFR Sec.	Description	Pre-Oct. 1995	Oct. 1995
2.6(a)(3)	Statement of Use, Per Class	100	
2.6(a)(4)	Extension for Filing Statement of Use, Per Class	100	
2.6(a)(5)	Application for Renewal, Per Class	300	
2.6(a)(6)	Surcharge for Late Renewal, Per Class	100	
2.6(a)(7)	Publication of Mark Under § 12(c), Per Class	100	
2.6(a)(8)	Issuing New Certificate of Registration	100	
2.6(a)(9)	Certificate of Correction of Registrant's Error	100	
2.6(a)(10)	Filing Disclaimer to Registration	100	
2.6(a)(11)	Filing Amendment to Registration	100	
2.6(a)(12)	Filing Affidavit Under Section 8, Per Class	100	
2.6(a)(13)	Filing Affidavit Under Section 15, Per Class	100	
2.6(a)(14)	Filing Affidavit Under Sections 8 & 15, Per Class	200	
2.6(a)(15)	Petitions to the Commissioner	100	
2.6(a)(16)	Petition to Cancel, Per Class	200	
2.6(a)(17)	Notice of Opposition, Per Class	200	
2.6(a)(18)	Ex Parte Appeal to the TTAB, Per Class	100	
2.6(a)(19)	Dividing an Application, Per New Application Created	100	
2.6(b)(1)(i)	Copy of Registered Mark	3	
2.6(6)(1)(ii)	Copy of Registered Mark, overnight delivery to PTO box or fax	6	
2.6(b)(1)(iii)	Copy of Reg. Mark Ordered Via Exp. Mail or Fax, Exp. Svc	25	
2.6(b)(2)(i)	Certified Copy of TM Application as Filed	12	15
2.6(b)(2)(ii)	Certified Copy of TM Application as Filed, Expedited	24	30
2.6(b)(3)	Cert. or Uncert. Copy of TM-Related File Wrapper/Contents	50	
2.6(b)(4)(i)	Cert. Copy of Registered Mark, Title or Status	10	
2.6(b)(4)(ii)	Cert. Copy of Registered Mark, Title or Status—Expedited	20	
2.6(b)(5)	Certified or Uncertified Copy of TM Records	25	
2.6(b)(6)	Recording Trademark Property, Per Mark, Per Document	40	
2.6(b)(6)	For Second and Subsequent Marks in Same Document	25	
2.6(b)(7)	For Assignment Records, Abstracts of Title and Cert	25	
2.6(b)(8)	Terminal Use X–SEARCH	40	
2.6(b)(9)	Self-Service Copy Charge	0.25	
2.6(b)(10)	Labor Charges for Services	30	
2.6(b)(11)	Unspecified Other Services	[1]	

These fees are not affected by this rulemaking.
[1] Actual cost.

[FR Doc. 95–19763 Filed 8–10–95; 8:45 am]
BILLING CODE 3510–16–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 95–62; RM–8601]

Radio Broadcasting Services; Linden, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Cass County Radio, allots Channel 257C3 to Linden, Texas, as the community's first local aural transmission service. *See* 60 FR 26018, May 16, 1995. Channel 257C3 can be allotted to Linden, Texas, in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction. The coordinates for Channel 257C3 at Linden are 33–00–44 and 94–21–55. With this action, this proceeding is terminated.

DATES: Effective September 21, 1995. The window period for filing applications will open on September 21, 1995, and close on October 23, 1995.

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. 95–62, adopted August 1, 1995, and released August 7, 1995. 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 Texas, is amended by adding Linden, Channel 257C3.

Federal Communications Commission.

Andrew J. Rhodes,

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

[FR Doc. 95–19830 Filed 8–10–95; 8:45 am]
BILLING CODE 6712–01–F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 1–21, Notice 14]

RIN 2127–AE99

Federal Motor Vehicle Safety Standards; Theft Protection; Correction

AGENCY: National Highway Traffic Safety Administration, Department of Transportation.

ACTION: Final rule; correction.

In Docket No. 1–21, Notice 13, Federal Motor Vehicle Safety Standards; Theft Protection; Final Rule; on page 30006 in the issue of Wednesday, June 7, 1995, making the following corrections:

On page 30011 in the first column, in the authority citation, 30162 should be replaced with 30115, 30117, and 30166.

On page 30011 in the first column, in 5.4.2.1(a)(1), introductory text, S5(a) should be replaced with S5.2.

On page 30011 in the first column, in S.4.2.1(a)(2), S5(b) should be replaced with S5.3.

Authority: 49 U.S.C. 322, 30111, 30162; delegation of authority at 49 CFR 1.50.

Issued: August 8, 1995.

Barry Felrice,

Associate Administrator for Safety Performance Standards.

[FR Doc. 95–19896 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–59–M

Proposed Rules

Federal Register
Vol. 60, No. 155
Friday, August 11, 1995

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.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 308, 310, 318, 320, 325, 326, 327, and 381

[Docket No. 95–034N]

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems—Public Scoping Session for Issue-Focused Public Meetings on Proposed Regulation

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Meeting notice; reopening of comment period.

SUMMARY: The U.S. Department of Agriculture is holding a public scoping session for a series of issue-focused public meetings to be held in September 1995 on the FSIS proposed rule, ''Pathogen Reduction, Hazard Analysis and Critical Control Point (HACCP) Systems.'' The purpose of the scoping session is to discuss with all interested parties the agenda and format for the September meetings.

DATES: The scoping session will be held on August 23, 1995 from 9:00 AM to 4:00 PM. The scoping session will be convened by the Secretary.

The comment period for the proposed rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems'' (60 FR 6674, February 3, 1995) will reopened as of August 11, 1995, and will extend until 30 days following the last September meeting. FSIS will publish notice of the comment period closing date.

ADDRESSES: The scoping session will be held at the U.S. Department of Agriculture, 14th and Independence Avenue, Back of the South Building Cafeteria (between the 2nd and 3rd Wings).

Send an original and two copies of written comments to: FSIS Docket Clerk, DOCKET 93–016P, Docket Room 4352, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Mr. Charles Danner, Director, Planning Office, Policy Evaluation and Planning Staff, FSIS, USDA, Room 6904, Franklin Court, Washington, DC 20250, (202) 501–7138. If you plan to attend, please contact Ms. Lisa Parks at (202) 501–7138.

SUPPLEMENTARY INFORMATION: USDA will hold a public scoping session on August 23, 1995 at the U.S. Department of Agriculture, 14th and Independence Avenue, Back of the South Building Cafeteria (between the 2nd and 3rd Wings) from 9:00 AM to 4:00 PM to discuss the agenda and format for a series of issue-focused public meetings to be held in September 1995 on the proposed rule, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems'' (60 FR 6674, February 3, 1995).

August Public Scoping Session

The August 23, 1995 scoping session announced in this notice will be convened by Secretary of Agriculture Dan Glickman and will begin with a discussion of the topics to be included on the agenda for the September meetings, both those tentatively identified by FSIS, and those suggested for inclusion by interested parties. The meeting participants will then consider what format would best ensure that these issues will be fairly, frankly, and fully explored in September. After the August 23 scoping session, FSIS will issue a notice announcing the schedule, agenda and format for the September meetings.

Those wishing to attend the August session should contact Ms. Lisa Parks at (202) 501–7138. Also contact Ms. Parks if you require a sign language interpreter or other special accommodations. Those unable to attend the scoping session may submit comments or suggestions for planning the September meetings to FSIS no later than August 18, 1995.

Purpose and Nature of the September Meeting

The September meetings will provide an opportunity for interested persons to directly discuss the key concerns that were raised during the comment period on the proposed rule with USDA officials and with one another. To comply with the Administrative Procedure Act, these issue-focused meetings will be open to the public and announced in advance in the **Federal Register**. The proceedings will be transcribed, and the transcripts will be made a part of the rulemaking record.

These meetings will be plenary meetings, so that all interested parties can attend and participate in all the discussions. Interested parties with common concerns and positions on a particular issue are encouraged to designate a representative to speak for them on that issue. This will help foster focused, substantive dialogue on the key issues.

Tentatively identified agenda items for consideration at the September meetings include: (1) Tthe relationship between the proposed HACCP system and existing regulatory requirements (the layering issue); (2) options to reduce the expected economic impact of the proposed rule on small businesses, while still achieving desired food safety goals; (3) the proposed interim targets for pathogen reduction and the use of microbial testing to verify achievement of the targets; (4) the role of antimicrobial treatments and other technological interventions to improve food safety; (5) temperature/time requirements for chilling red meat; and (6) FSIS oversight of HACCP.

Reopening of Comment Period

FSIS is reopening the comment period for the proposed regulation, effective August 11, 1995, and extending until 30 days following the last September meeting, in order to include in the administrative record the transcript of the scoping session and the public meetings, written comments submitted by persons unable to attend the meetings, and other written comments submitted by interested parties on the matters addressed at the public meetings.

Done at Washington, DC, on August 8, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

[FR Doc. 95–19930 Filed 8–9–95; 9:23 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 91–CE–45–AD]

Airworthiness Directives; de Havilland DHC–6 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 78–26–02, which currently requires repetitively inspecting the fuselage side frame flanges at Fuselage Station (FS) 218.125 and FS 219.525 for cracks on certain de Havilland DHC–6 series airplanes, and repairing or replacing any cracked part. The Federal Aviation Administration's policy on aging commuter-class aircraft is to eliminate or, in certain instances, reduce the number of certain repetitive short-interval inspections when improved parts or modifications are available. The proposed action would require modifying the fuselage side frames at the referenced FS areas as terminating action for the repetitive inspections that are currently required by AD 78–26–02. The actions specified in the proposed AD are intended to prevent failure of the fuselage because of cracks in the fuselage side frames, which, if not detected and corrected, could result in loss of control of the airplane.

DATES: Comments must be received on or before October 16, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91–CE–45–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from de Havilland, Inc., 123 Garratt Boulevard, Downsview, Ontario, Canada, M3K 1Y5. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Jon Hjelm, Aerospace Engineer, FAA, New York Aircraft Certification Office, 10 Fifth Street, 3rd Floor, Valley Stream, New York 11581; telephone (516) 256–7523; facsimile (516) 568- 2716.

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 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, 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 that summarizes 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 No. 91–CE–45–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, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91–CE–45–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The FAA has determined that reliance on critical repetitive inspections on aging commuter-class airplanes carries an unnecessary safety risk when a design change exists that could eliminate or, in certain instances, reduce the number of those critical inspections. In determining what inspections are critical, the FAA considers (1) the safety consequences if the known problem is not detected by the inspection; (2) the reliability of the inspection such as the probability of not detecting the known problem; (3) whether the inspection area is difficult to access; and (4) the possibility of damage to an adjacent structure as a result of the problem.

These factors have led the FAA to establish an aging commuter-class aircraft policy that requires incorporating a known design change when it could replace a critical repetitive inspection. With this policy in mind, the FAA conducted a review of existing AD's that apply to de Havilland DHC–6 series airplanes. Assisting the FAA in this review were (1) de Havilland; (2) the Regional Airlines Association (RAA); and (3) several operators of the affected airplanes.

From this review, the FAA has identified AD 78–26–02, Amendment 39–3370, as one that should be superseded with a new AD that would require a modification that could eliminate the need for short-interval and critical repetitive inspections. AD 78–26–02 currently requires repetitively inspecting the fuselage side frame flanges at Fuselage Station (FS) 218.125 and FS 219.525 on certain de Havilland DHC–6 series airplanes, and repairing or replacing any cracked part.

De Havilland Service Bulletin (SB) No. 6/371, dated June 2, 1978, specifies procedures for inspecting, repairing, and modifying (Modification Nos. 6/1461 and 6/1462) the fuselage side frame flanges at FS 218.125 and FS 219.525. Modification No. 6/1461 introduces fuselage side frames manufactured from material having improved stress corrosion properties at FS 218.125, and Modification No. 6/1462 introduces fuselage side frames of this material at FS 219.525.

This airplane model is manufactured in Canada and is type certificated for operation in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the bilateral airworthiness agreement between the United States and Canada. Pursuant to this bilateral airworthiness agreement, Transport Canada has kept the FAA informed of the situation described above.

Based on its aging commuter-class aircraft policy and after reviewing all available information, the FAA has determined that AD action should be taken to eliminate the repetitive short-interval inspections required by AD 78–26–02, Amendment 39–3370, and to prevent failure of the fuselage because of cracks in the fuselage side frames, which, if not detected and corrected, could result in loss of control of the airplane.

Since an unsafe condition has been identified that is likely to exist or develop in other de Havilland DHC-6 series airplanes of the same type design without Modification Nos. 6/1461 and 6/1462 incorporated, the proposed AD

would supersede AD 78–26–02 with a new AD that would (1) retain the current requirement of repetitively inspecting the fuselage side frame flanges at FS 218.125 and FS 219.525, as applicable, and repairing or replacing any cracked part; and (2) require modifying the fuselage side frame flanges in the referenced FS areas (Modification Nos. 6/1461 and 6/1462) as terminating action for the repetitive inspections. Accomplishment of the proposed actions would be in accordance with de Havilland SB No. 6/371, dated June 2, 1978.

The FAA estimates that 94 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 300 workhours per airplane to accomplish the proposed modification, and that the average labor rate is approximately $60 an hour. Parts cost approximately $16,200 (average) per airplane. Based on these figures, the total cost impact of the proposed modification on U.S. operators is estimated to be $3,214,800 or $34,200 per airplane. This cost figure is based upon the assumption that none of the affected airplane owners/operators have incorporated Modification Nos. 6/1461 and 6/1462.

The intent of the FAA's aging commuter airplane program is to ensure safe operation of commuter-class airplanes that are in commercial service without adversely impacting private operators. Of the approximately 94 airplanes in the U.S. registry that would be affected by the proposed AD, the FAA has determined that approximately 45 percent are operated in scheduled passenger service. A significant number of the remaining 55 percent are operated in other forms of air transportation such as air cargo and air taxi.

The proposed AD allows 4,800 hours time-in-service (TIS) after the proposed AD would become effective before mandatory accomplishment of the design modification. The average utilization of the fleet for those airplanes in commercial commuter service is approximately 25 to 50 hours TIS per week. Based on these figures, operators of commuter-class airplanes involved in commercial operation would have to accomplish the proposed modification within 24 to 48 calendar months after the proposed AD would become effective. For private owners, who typically operate between 100 to 200 hours TIS per year, this would allow 24 to 48 years before the proposed modification would be mandatory.

The following paragraphs present cost scenarios for airplanes where no cracks were found and where cracks were found during the inspections, and where the remaining airplane life is 15 years with an average annual utilization rate of 1,600 hours TIS. A copy of the full Cost Analysis and Regulatory Flexibility Determination for the proposed action may be examined at the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91–CE–45–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri.

- No Cracks Scenario: Under the provisions of AD 78–26–02, an owner/operator of an affected de Havilland DHC–6 series airplane in scheduled service who operates an average of 1,600 hours TIS annually would inspect every 400 hours TIS. This would amount to a remaining airplane life (estimated 15 years) cost of $18,420; this figure is based on the assumption that no cracks are found during the inspections. The proposed AD would incur the same inspections except at 600-hour TIS intervals until 4,800 hours TIS after the proposed AD would become effective where the operator would have to replace the fuselage side frame flanges (eliminating the need for further repetitive inspections), which would result in a present value cost of $31,433. The incremental cost of the proposed AD for such an airplane would be $13,013 or $4,959 annualized over the three years it would take to accumulate 4,800 hours TIS. An owner of a general aviation airplane who operates 800 hours TIS annually without finding any cracks during the 600-hour TIS inspections would incur a present value incremental cost of $7,598. This would amount to a per year amount of $1,594 over the six years it would take to accumulate 4,800 hours TIS.
- Limited Cracking Found Scenario: Under the provisions of AD 78–26–02, an owner/operator of an affected de Havilland DHC–6 series airplane who found limited cracking (as defined in SB No. 6/371) during an inspection would have to inspect each 300 hours TIS or 45 days, whichever occurs first, and replace the part within 360 days after finding the cracking. The proposed AD would require inspections every 300 hours TIS, and then require replacement at 4,800 hours TIS after the proposed AD would become effective. This would result in a present value total cost of $34,908 per airplane in scheduled service, which would make immediate replacement more economical ($32,400) than repetitively inspecting. With this scenario, the proposed AD would result in an incremental present value cost savings over that required in AD 78–26–02 of $1,491 per airplane in scheduled service (or $568 annualized over 3 years) and $6,517 ($1,367 annualized over 6 years) for airplanes operating in general aviation service.
- Excessive cracking scenario: AD 78–26–02 requires repairing or replacing the fuselage side frames if excessive cracking is found (as defined by SB No. 6/371), as would the proposed AD. The difference is that AD 78–26–02 requires immediate crack repair and then replacement within 360 days after finding the crack, and the proposed AD would require immediate repair and mandatory replacement of the fuselage side frames within 4,800 hours TIS after the proposed AD would become effective. This would result in a present value total cost of $34,709 per airplane in scheduled service, which would make immediate replacement more economical ($32,400) than repetitively inspecting. With this scenario, the proposed AD would average a present value cost savings over that required in AD 78–26–02 of $2,083 ($794 annualized over 3 years) for each airplane operated in scheduled service, and $6,607 ($1,386 annualized over 6 years) for each airplane operated in general aviation service.

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to ensure that small entities are not unnecessarily or disproportionally burdened by government regulations. The RFA requires government agencies to determine whether rules would have a ''significant economic impact on a substantial number of small entities,'' and, in cases where they would, conduct a Regulatory Flexibility Analysis in which alternatives to the rule are considered. FAA Order 2100.14A, Regulatory Flexibility Criteria and Guidance, outlines FAA procedures and criteria for complying with the RFA. Small entities are defined as small businesses and small not-for-profit organizations that are independently owned and operated or airports operated by small governmental jurisdictions. A ''substantial number'' is defined as a number that is not less than 11 and that is more than one-third of the small entities subject to a proposed rule, or any number of small entities judged to be substantial by the rulemaking official. A ''significant economic impact'' is defined by an annualized net compliance cost, adjusted for inflation, which is greater than a threshold cost level for defined entity types. FAA Order 2100.14A sets the size threshold for small entities operating aircraft for hire at 9 aircraft owned and the annualized cost thresholds, adjusted to 1994 dollars, at $69,000 for scheduled operators and $5,000 for unscheduled operators.

Of the 94 U.S.-registered airplanes affected by the proposed AD, 4 airplanes are owned by the federal government. Of the other 90, one business owns 26 airplanes, two businesses own 7 airplanes each, one business owns 3 airplanes, seven businesses own 2 airplanes each, and thirty-three businesses own 1 airplane each.

Because the FAA has no readily available means of obtaining data on sizes of these entities, the economic analysis for the proposed AD utilizes the worst case scenario using the lower annualized cost threshold of $5,000 for operators in unscheduled service instead of $69,000 for operators in scheduled service. With this in mind and based on the above ownership distribution, the 33 entities owning two or fewer airplanes would not experience a ''significant economic impact'' as defined by FAA Order 2100.14A. Since the remaining 11 entities do not constitute a ''substantial number'' as defined in the Order, the proposed AD would not have a ''significant economic impact on a substantial number of small entities.''

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 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) 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 has been placed 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), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing AD 78–26–02, Amendment 39–3370, and adding the following new AD to read as follows:

De Havilland: Docket No. 91–CE–45–AD. Supersedes AD 78–26–02, Amendment 39–3370.

Applicability: Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes (serial numbers 1 through 411), certificated in any category, that do not have Modification Nos. 6/1461 and 6/1462 incorporated.

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 use the authority provided in paragraph (e) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless already accomplished.

To prevent failure of the fuselage because of cracks in the fuselage side frames, which, if not detected and corrected, could result in loss of control of the airplane, accomplish the following:

(a) Within the next 200 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished (compliance with AD 78–26–02), and thereafter as indicated below, inspect the fuselage side frames for cracks at Fuselage Station (FS) 218.125 and FS 219.525, as applicable (see chart below) in accordance with the Accomplishment Instructions section of de Havilland Service Bulletin (SB) No. 6/371, dated June 2, 1978. Utilize the following chart to determine which fuselage stations are affected:

Serial Nos.	Modification 6/1553 incorporated	Fuselage stations affected (both sides)
1 through 395	No	218.125 and 219.525.
1 through 395	Yes	219.525 only.
396 through 411 .	N/A	219.525 only.

Note 2: Modification 6/1553 incorporates fuselage side frames of improved stress corrosion resistant material at FS 218.125.

(1) If cracks are found that exceed the limits specified in Figure 3 of de Havilland SB No. 6/371, prior to further flight, accomplish one of the following:

(i) Repair the cracks in accordance with the Accomplishment Instructions: *Repair:* section of de Havilland SB No. 6/371, dated June 2, 1978. Reinspect thereafter at intervals not to exceed 600 hours TIS until the modification specified in paragraph (b) of this AD is incorporated; or

(ii) Replace the cracked fuselage side frame in accordance with the Accomplishment Instructions: *Replacement:* section of de Havilland SB No. 6/371, dated June 2, 1978. Reinspect any fuselage side frame not replaced at intervals not to exceed 600 hours TIS until the modification specified in paragraph (b) of this AD is incorporated.

(2) If cracks are found that are within the limits specified in Figure 3 of de Havilland SB No. 6/371, reinspect at intervals not to exceed 300 hours TIS until the modification specified in paragraph (b) of this AD is incorporated.

(3) If no cracks are found, reinspect thereafter at intervals not to exceed 600 hours TIS until the modification specified in paragraph (b) of this AD is incorporated.

(b) Within the next 4,800 TIS after the effective date of this AD, incorporate Modification Nos. 6/1461 and 6/1462 in accordance with the Accomplishment Instructions: *Replacement:* section of de Havilland SB No. 6/371, dated June 2, 1978. This consists of replacing all fuselage side frames required as specified in the following chart:

Serial Nos.	Modification 6/1553 incorporated	Fuselage stations affected (both sides)
1 through 395	No	218.125 and 219.525.
1 through 395	Yes	219.525 only.
396 through 411 .	N/A	219.525 only.

(c) Incorporating Modification Nos. 6/1461 and 6/1462 as specified in paragraph (b) of this AD is considered terminating action for the inspection requirement of this AD.

(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.

(e) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, New York Aircraft Certification Office (ACO), FAA, 10 Fifth Street, 3rd Floor, Valley Stream, New York 11581. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, New York Aircraft ACO.

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

(f) All persons affected by this directive may obtain copies of the document referred to herein upon request to de Havilland, Inc., 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5 Canada; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(g) This amendment supersedes AD 78–26–02, Amendment 39–3370.

Issued in Kansas City, Missouri, on August 7, 1995.

Gerald W. Pierce,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–19917 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–13–U

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2615

RIN 1212–AA77

Reportable Events

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to form a negotiated rulemaking advisory committee.

SUMMARY: The Pension Benefit Guaranty Corporation intends to form a negotiated rulemaking advisory committee under the Negotiated Rulemaking Act of 1990. The committee will develop proposed amendments to the PBGC's regulations governing reportable events, *i.e.*, events that may be indicative of a need to terminate a pension plan. These amendments will, among other things, implement recent amendments contained in the Retirement Protection Act of 1994.

DATES: Comments and applications or nominations for membership must be received on or before September 15, 1995.

ADDRESSES: Comments and nominations or applications for membership may be mailed to the Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026, or delivered to Suite 340 at the above address. Comments, nominations, and applications will be available for public inspection at the PBGC's Communications and Public Affairs Department, Suite 240.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, or James L. Beller, Attorney, Office of the General Counsel, PBGC, 1200 K Street, NW., Washington, DC 20005–4026, 202–326–4024 (202–326–4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION:

Background

Section 4043 of the Employee Retirement Income Security Act of 1974, as amended by the Retirement Protection Act of 1994, requires the reporting to the PBGC of certain events (''reportable events'') that may be indicative of a need to terminate the plan. The PBGC's existing regulations on reportable events (29 CFR part 2615, subpart A) specify the events that must be reported, the circumstances under which reporting is waived, and the information that must be included in a reportable event filing.

RPA amended section 4043 of ERISA by (1) establishing the reporting obligation, which was previously placed solely on plan administrators, on contributing sponsors as well; (2) adding four new reportable events; (3) establishing a new obligation on contributing sponsors of certain underfunded plans to provide 30 days' advance notice of certain reportable events; and (4) protecting reportable event filings from public disclosure.

The PBGC intends to publish a proposed rule that would amend its existing regulations on reportable events to reflect RPA and to make other appropriate changes. Two major issues the PBGC intends to address in these regulations are: (1) The conditions under which the regulations should provide for waivers of reporting requirements (based on, *e.g.*, the size or funding status of the plan); and (2) the information the regulations should require as part of the reportable event filing (including, *e.g.*, plan actuarial and employer financial information). Other issues may be addressed as well.

The PBGC intends to use the negotiated rulemaking procedure in accordance with the Negotiated Rulemaking Act of 1990. The PBGC will form an advisory committee consisting of representatives of the affected interests and the agency for the purpose of reaching a consensus on the text of a proposed rule.

A number of interests (including employers, service providers, and participants) are likely to be significantly affected by new regulations on reportable events. The effect of the regulations is likely to vary, depending primarily on the size and funding status of the plan and the size, corporate structure, and financial condition of the employer.

Regulatory Negotiation

Negotiated rulemaking is a consensus-based approach to the development of agency rules, in which representatives of affected interests work together to reach consensus on the content of a proposed rule. The PBGC believes that these proposed regulations are appropriate for regulatory negotiation because of the various interests likely to be significantly affected and the complexity of the subject matter.

Formation of the committee is in the public interest in connection with developing rules concerning reportable events. The PBGC hopes to be able to use the consensus of the committee as the basis for the proposed rule.

The PBGC invites comments on the appropriateness of regulatory negotiation for these proposed regulations.

Committee Membership

The PBGC tentatively has identified the following interests and list of possible committee members:

Employer Representatives:
- Association of Private Pension and Welfare Plans
- Chamber of Commerce of the United States of America
- The ERISA Industry Committee
- Financial Executives Institute

Service Provider Representatives:
- American Academy of Actuaries
- American Bar Association
- American Institute of Certified Public Accountants
- American Society of Pension Actuaries

Participant Representatives:
- Air Line Pilots Association
- American Association of Retired Persons
- American Federation of Labor-Council of Industrial Organizations
- International Union, United Automobile, Aerospace & Implement Workers of America
- United Steelworkers of America

Pension Benefit Guaranty Corporation:
- Ellen A. Hennessy, Deputy Executive Director and Chief Negotiator
- William Posner, Deputy Executive

Director and Chief Operating Officer
Stuart A. Sirkin, Director, Corporate Policy and Research Department
Andrea E. Schneider, Director, Corporate Finance and Negotiations Department
James J. Keightley, General Counsel

The PBGC will use a neutral facilitator for the committee. The facilitator's role is to chair negotiating sessions and to help committee members define and reach consensus. The PBGC will nominate for the committee's consideration Kate Blunt, Special Assistant to the Deputy Executive Director and Chief Management Officer, to serve as the facilitator of the committee. Ms. Blunt has extensive experience in facilitating meetings, conducting focus groups, and mediating disputes. She will perform her duties as facilitator in an impartial manner.

All committee meetings will be open to the public.

Requests for Representation

Persons who will be significantly affected by the planned proposed rule on reportable events and who believe that their interests will not be adequately represented by the persons identified above may apply, or nominate another person, for membership on the committee to represent their interests. Each application or nomination must include: (1) The name of the applicant or nominee and a description of the interests that person will represent; (2) evidence that the applicant or nominee is authorized to represent parties related to the interests the person proposes to represent; (3) a written commitment that the applicant or nominee will actively participate in good faith in the development of proposed regulations; and (4) the reasons that the persons identified above do not adequately represent the interests of the person submitting the application or nomination.

Committee Expenses and Administrative Support

In most cases, committee members are responsible for their own expenses of participation. The PBGC may pay for certain expenses, in accordance with section 7(d) of the Federal Advisory Committee Act, if (1) a member certifies a lack of adequate financial resources to participate in the committee; and (2) the PBGC determines that such member's participation in the committee is necessary to assure adequate representation of the member's interest.

The PBGC will provide logistical, administrative, and management support to the committee. All meetings will be held at the PBGC's offices in Washington, D.C.

Proposed Agenda and Schedule

The proposed agenda and schedule for the committee's activities will be determined by the committee at the first meeting, which the PBGC anticipates will be held in October of 1995.

The PBGC's goal is to issue a proposed rule on reportable events by the spring of 1996. If it appears that the committee is unable to reach consensus in time to meet this goal, the PBGC may proceed with rulemaking based in part on information gained through the negotiated rulemaking process.

Notice of Establishment of Committee

After reviewing any comments on this Notice of Intent and any requests for representation, the PBGC will issue a notice announcing the establishment of a negotiated rulemaking advisory committee and the date of the first meeting, unless the PBGC decides, based on comments and other relevant considerations, that establishment of the committee is inappropriate. Notice of future meetings will be published in the **Federal Register**.

Issued in Washington, D.C., this 8th day of August, 1995.

Martin Slate,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 95–19929 Filed 8–10–95; 8:45 am]

BILLING CODE 7708–01–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 250 and 256

RIN 1010–AC04

Pipeline Right-of-Way Applications and Assignment Fees; Requirements for Filing of Transfers

AGENCY: Minerals Management Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Minerals Management Service (MMS) proposes to amend its regulations governing the filing fees charged for processing pipeline right-of-way applications and assignments, and applications for approval of instruments of transfer of a lease or interest. This amendment proposes to increase the filing fees for these documents, which will allow MMS to recover the full processing costs. MMS further proposes to adjust the filing fees by indexing them to the Consumer Price Index ''U'' which will enable MMS to continue to recover the processing costs of these documents. MMS will periodically publish these filing fee increases in the **Federal Register**.

DATES: Comments must be received or postmarked no later than October 10, 1995 to be consider in this rulemaking.

ADDRESSES: Comments should be mailed or hand-carried to the Department of the Interior; Minerals Management Service; Mail Stop 4700; 381 Elden Street; Herndon, Virginia 22070–4817; Attention: Chief, Engineering and Standards Branch.

FOR FURTHER INFORMATION CONTACT: Andy Radford, telephone (703) 787–1144 or Jo Ann Lauterbach, telephone (703) 787–1606.

SUPPLEMENTARY INFORMATION:

Background

MMS last increased the filing fees for pipeline right-of-way applications and assignments on April 1, 1988. At that time, the fee for a pipeline right-of-way application was increased to $1,400, and the fee for a pipeline right-of-way assignment was increased to $50. MMS has not changed the $25 filing fee for instruments of transfer of a lease or interest since the administration of regulations concerning Outer Continental Shelf minerals and rights-of-way was transferred to MMS from the Bureau of Land Management under Amendment No. 1 to Secretarial Order No. 3071, dated May 10, 1982.

During the years since MMS last adjusted these filing fees, the costs to process these documents have increased. MMS conducted in-house cost analyses based on the costs of salaries and benefits, computer time, and overhead in each of the regional offices to determine the average processing cost for each of these documents. The results showed that MMS is undercharging for these services, and therefore, MMS is proposing to increase the fees.

This amendment proposes to increase the filing fee for a pipeline right-of-way application from $1,400 to $2,350; the filing fee for a pipeline right-of-way assignment from $50 to $60; and the filing fee for instruments of transfer of a lease or an interest from $25 to $185. Further, the amendment proposes to index the filing fees to the Consumer Price Index ''U''. The MMS will announce subsequent changes to the filing fee in the **Federal Register**.

Authors: The principal authors for this proposed rule are Andy Radford and Jo Ann Lauterbach, Engineering and Standards Branch, MMS.

Executive Order (E.O.) 12866

The Department of the Interior (DOI) reviewed this proposed rule under E.O. 12866 and determined that this document is not a significant rule.

Regulatory Flexibility Act

The DOI has determined that this proposed rule will not have a significant economic effect on a substantial number of small entities. Any direct effects of this rulemaking will primarily affect OCS lessees and operators—entities that are generally not small due to the technical complexities and financial resources necessary to conduct OCS activities.

Paperwork Reduction Act

The Office of Management and Budget (OMB) approved the collections of information contained in this proposed rule under 44 U.S.C. 3501 et seq., and assigned clearance numbers 1010–0050 and 1010–0006.

Takings Implication Assessment

The DOI certifies that the proposed rule does not represent a governmental action capable of interference with constitutionally protected property rights. This action does not require a Takings Implication Assessment prepared pursuant to E.O. 12630, Government Action and Interference with Constitutionally Protected Property Rights.

E.O. 12778

The DOI has certified to OMB that this proposed rule meets the applicable civil justice reform standards provided in Sections 2(a) and 2(b)(2) of E.O. 12778.

National Environmental Policy Act

The DOI has determined that this action does not constitute a major Federal action significantly affecting the quality of the human environment; therefore, this action does not require the preparation of an Environmental Impact Statement.

List of Subjects

30 CFR Part 250

Continental shelf, Environmental impact statements, Environmental protection, Government contracts, Incorporation by reference, Investigations, Mineral royalties, Oil and gas development and production, Oil and gas exploration, Oil and gas reserves, Penalties, Pipelines, Public lands—mineral resources, Public lands—rights-of-way, Reporting and recordkeeping requirements, Sulphur development and production, Sulphur exploration, Surety bonds.

30 CFR Part 256

Administrtive practice and procedure, Continental shelf, Government contracts, Incorporation by reference, Oil and gas exploration, Public lands—mineral resources, Reporting and recordkeeping requirements, Surety bonds.

Dated: May 12, 1995.

Bob Armstrong,

Assistant Secretary, Land and Minerals Management.

For the reasons set out in the preamble, 30 CFR parts 250 and 256 are proposed to be amended as follows:

PART 250—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

1. The authority citation for part 250 is amended to read as follows:

Authority: 43 U.S.C. 1334.

2. Section 250.160 is amended by revising the fifth sentence and adding a new sentence following the fifth sentence in paragraph (a) to read as follows:

§ 250.160 Applications for a pipeline right-of-way grant.

(a) * * * A nonrefundable filing fee of $2,350 and the rental required under § 250.159(c)(2) of this part must accompany a new right-of-way application. MMS will periodically make technical amendments to adjust the filing fee according to the Consumer Price Index ''U''. * * *

* * * * *

3. Section 250.163 is amended by revising the last sentence in paragraph (b) and adding a new sentence following the last sentence to read as follows;

§ 250.163 Assignment of a right-of-way grant.

* * * * *

(b) * * * A nonrefundable filing fee of $60 must accompany the application for the approval of an assignment. MMS will periodically make technical amendments to adjust the filing fee according to the Consumer Price Index ''U''.

PART 256—LEASING OF SULPHUR OR OIL AND GAS IN THE OUTER CONTINENTAL SHELF

4. The authority citation for part 256 continues to read as follows:

Authority: 43 U.S.C. 1331 *et seq.*

5. Section 256.64 is amended by revising the first sentence in paragraph (a)(2) and adding a new sentence following the first sentence to read as follows:

§ 256.64 Requirements for filing of transfers.

(a) * * *

(2) A nonrefundable filing fee of $185 must accompany an application for approval of any instrument of transfer required to be filed. MMS will periodically make technical amendments to adjust the filing fee according to the Consumer Price Index ''U''. * * *

[FR Doc. 95–19233 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–MR–M

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. 95–0720187–5187–01]

RIN 0651–AA79

Rules of Practice in Patent Cases; Reexamination Proceedings

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Patent and Trademark Office (Office) is proposing to amend its rules of practice in patent cases to provide revised procedures for the reexamination of patents. H.R. 1732 proposes to authorize the extension of reexamination proceedings as a means for improving the quality of United States patents. The Office intends, through this proposed amendment of its rules, to provide patent owners and the public with guidance on the procedures the Office would follow in conducting reexamination proceedings.

DATES: A public hearing will be held on Wednesday, September 20, 1995, at the Stouffer Renaissance Crystal City Hotel, 2399 Jefferson Davis Highway, Arlington, Virginia, 22202 at 9:30 a.m. Those wishing to present oral testimony must request an opportunity to do so no later than September 14, 1995. Written comments must be submitted on or before September 22, 1995.

ADDRESSES: Written comments concerning the rule changes should be addressed to the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231, marked to the attention of Gerald A. Dost, Senior Legal Advisor, Special Program Law Office, Crystal Park 1, Suite 520. In addition, written comments may also be sent by facsimile transmission to (703) 308–6919 with a confirmation copy mailed to the above address, or by electronic mail messages over the Internet to reexamrule@uspto.gov.

Written comments concerning reexamination rule matters will be available for public inspection on October 2, 1995, in Room 520 of Crystal Park One, 2011 Crystal Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Gerald A. Dost or Lawrence E. Anderson by telephone at (703) 305–9285, by electronic mail at landerso@uspto.gov, or by mail to Gerald A. Dost to his attention addressed to the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231.

SUPPLEMENTARY INFORMATION:

Background

This proposed rulemaking sets forth distinct procedures directed towards determining and improving the quality and reliability of United States patents. The procedures are proposed to provide for the expanded reexamination of patents as proposed in H.R. 1732.

Discussion of General Issues Involved

The proposals are in response to H.R. 1782 which resulted from suggestions and comments to the Administration by the public, bar groups, and the August 1992 Advisory Commission on Patent Law Reform suggesting more participation in the reexamination proceeding by third party requesters. Under the rules proposed herein, third party requesters will have greater opportunity to participate in reexamination proceedings in keeping with the spirit and intent of the proposed law. At the same time, participation will be limited to minimize the costs and other effects of reexamination requests on patentees.

If H.R. 1732 is amended during the legislative process, the final rules will comply with this legislation as enacted. If H.R. 1732 is not enacted, the proposed rules for expanded reexamination of patents would be withdrawn.

Because reexamination filed before the proposed law takes effect will continue to be governed by 37 CFR 1.501–1.570, to avoid confusion between the new and old rules the newly proposed reexamination rules have been numbered 37 CFR 1.901–1.997.

Regarding the reexamination fee, 35 U.S.C. 41(d) requires the Commissioner to set the fee for reexamination at a level which will recover the estimated average cost to the Office. The estimated average cost is $4,500 per patent owner requested reexamination and $11,000 for third party requested reexaminations. The difference in price takes into account the estimate that the examiner will spend twice the amount of time examining a case where a third party requester is present and additional costs incurred during the appellate stages incident to additional processing steps required in the third party proceedings.

Discussion of the Major Specific Issues Involved

The proposed rules relating to reexamination proceedings are directed to the procedures set forth in proposed Chapter 30 of Title 35 of the United States Code (35 U.S.C. 301–307). This proposed Chapter provides for the citation of prior art in patents, filing of requests for reexamination, decisions on such requests, reexamination and appeal from reexamination decisions, and the issuance of a certificate at the termination of the reexamination proceedings.

Section 1.4 is proposed to be amended so that paragraph (a)(2) includes the reexamination §§ 1.901–1.997.

Section 1.6 is proposed to be amended so that paragraph (d)(5) includes § 1.913, which related to the exception of the use of facsimile transmission for filing the request for reexamination.

Section 1.11 is proposed to be amended so that paragraph (c), which relates to reexaminations at the initiative of the Commissioner, includes the reference to reexamination § 1.929.

Section 1.17 is proposed to be amended so that paragraph (l) reflects the fact that in the case of reexaminations filed after January 1, 1996, petitions for revival of a reexamination proceeding terminated for an unavoidable failure to respond require the fees of $55.00 for a small entity and $110.00 for other than small entity. Also, § 1.17 is proposed to be amended so that paragraph (m) reflects the fact that in the case of reexaminations filed after January 1, 1996, petitions for revival of a reexamination proceeding terminated for an unintentional failure to respond require the fees of $605.00 for a small entity and $1,1210.00 for other than small entity. The Office has proposed an increase in the fee set by § 1.17(m). See ''Revision of Patent and Trademark Fees'' published in the **Federal Register** at 60 FR 27934 (May 26, 1995) and in the Patent and Trademark Office *Official Gazette* at 1174 Off. Gaz. Pat. Office 134 (May 30, 1995).

Section 1.20 is proposed to be amended so that paragraph (c) reflects the fact that in the case of reexaminations filed after January 1, 1996, there is a two tier fee scale in which patent owner requesters will be charged $4,500 and third party requesters will be charged $11,000.

Section 1.25 is proposed to be amended so that paragraph (b), which relates to requests for reexaminations, includes the reference to reexamination § 1.913.

Section 1.26 is proposed to be amended so as to reflect that in the case of reexaminations filed after January 1, 1996, a refund of seventy-five percent (75%) of the fee paid for filing the request for reexamination will be made to the requester.

Section 1.112 is proposed to be amended so that the last sentence reflects the fact that in the case of reexamination filed after January 1, 1996, the examiner may close prosecution prior to making the action final. Section 1.113, which provides for a final rejection or action in a reexamination proceeding, is proposed to be amended so that its application is limited to applicants and patent owners in reexaminations filed before January 1, 1996. For reexaminations filed after January 1, 1996, the new reexamination rules will apply.

Section 1.115, which provides for amendments by the patent owner in a reexamination proceeding, is proposed to be amended so that its application is limited to applicants and patent owners in reexaminations filed before January 1, 1996. For reexaminations filed after January 1, 1996, the new reexamination rules will apply.

Section 1.116, which provides for amendments after final action in reexamination proceedings, is proposed to be amended so that its application is permissible after an action closing prosecution for patent owners in reexaminations filed on or after January 1, 1996. Also, for clarity, the rule is amended to provide that for reexaminations filed after January 1, 1996, no appeal is permitted until a right of appeal notice has been issued.

Section 1.136, which provides for filing of timely responses with petitions and fee for extension of time and extensions of time for cause, is amended to make it clear that for reexamination proceedings filed on or after January 1, 1996, § 1.957 is controlling for extensions of time.

Section 1.137, which provides for revival of abandoned applications or lapsed patents, is proposed to be amended to change the title and add new paragraphs (g) and (h). Paragraph (f) is proposed to be utilized for provisional applications. Paragraph (g) is proposed to be added to provide for revival of unavoidably terminated proceedings for reexamination proceedings filed before January 1,

1996. Paragraph (h) is proposed to be added to make it clear that for reexamination proceedings filed on or after January 1, 1996, § 1.958 is controlling.

Section 1.191, which provides for appeal to the Board of Patent Appeals and Interferences by the patent owner from any decision adverse to patentability, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.959 is controlling.

Section 1.192, which provides two months from the date of the Notice of Appeal for the patent owner to file an appeal brief in a reexamination proceeding, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.965 is controlling.

Section 1.193, which provides for the Examiner's answer and reply brief, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, §§ 1.969 and 1.971 are controlling.

Section 1.194, which provides for the oral hearing, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.973 is controlling.

Section 1.195, which provides for the affidavits or declarations after appeal, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.975 is controlling.

Section 1.196, which provides for the decision of the Board of Patent Appeals and Interferences, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.977 is controlling.

Section 1.197, which provides for action following the decision, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.979 is controlling.

Section 1.198, which provides for reopening after the decision, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.981 is controlling.

Section 1.301, which provides for appeal by the owner of a patent in reexamination proceedings to the U.S. Court of Appeals for the Federal Circuit, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.983 is controlling.

Section 1.303, which provides for remedy by civil action under 35 U.S.C. 145 for the owner of a patent in reexamination proceedings, is proposed to be amended so as to be applicable to reexaminations filed before January 1, 1996. For reexamination proceedings filed on or after January 1, 1996, § 1.993 is controlling.

Section 1.304 which provides for time for appeal or civil action, is proposed to be amended so as to refer also to § 1.957.

The title to Subpart D is proposed to be amended to provide that the reexamination rules in this part apply only to reexamination proceedings filed before January 1, 1996.

The proposed title to Subpart H provides that the reexamination rules in this part apply only to reexamination proceedings filed on or after January 1, 1996.

Proposed § 1.901 provides a system for citation of patents and printed publications to the Office for placement in the patent file by an person during the period of enforceability of the patent in accordance with 35 U.S.C. 301. The section provides for citations limited to patents and printed publications when the person making the citation states the pertinency and applicability of the citation to the patent and the bearing the citation has on the patentability of at lease one claim of the patent. The rule provides that a citation made by the patent owner may include an explanation of how the claims differ from the prior art cited. Any citations which include items other than patents and printed publications will not be entered in the patent file. This does not, of course, limit in any manner the kinds and types of information which can be relied upon in protests against pending patent applications, whether such be original applications or reissue applications. The term ''period of enforceability of a patent'' includes any period for which recovery can be had for infringement. Under usual circumstances, this would be the term of the patent plus the six years provided by 35 U.S.C. 286.

Proposed § 1.902 provides for the processing of prior art citations during a reexamination proceeding.

Proposed § 1.903 provides for the service of papers on parties.

Proposed § 1.904 provides that the notices published in the Official Gazette will be considered to be constructive notice.

Proposed § 1.905 provides for submission of papers by the public.

Proposed § 1.906 covers the scope of reexamination in a reexamination proceeding. While it is not intended that the examiners will routinely complete a new search when conducting reexamination, the examiners will be free to, and will, very likely, conduct additional searches and cite and apply additional prior patents and publications when they consider it is appropriate and beneficial to do so. Insofar as the actual reexamination is concerned, the examination is only on the basis of patents or printed publications and on the basis of the requirements of 35 U.S.C. 112, except for the best mode requirement. Claims in a reexamination proceeding must not enlarge the scope of the claims of the patent and must not introduce new matter. Paragraph (c) provides that questions relating to matters other than those indicated in paragraphs (a) and (b) of this section will not be resolved in a reexamination proceeding, but will be noted by the examiner as being an open question in the record. Patent owners could then file a reissue application if they wish such questions to be resolved.

Proposed § 1.907 sets forth when reexamination is prohibited. Once an order to reexamine has been issued under § 1.931, neither the patent owner nor the third party requester, if any, nor privies of either, may file a subsequent request for reexamination of the patent until a reexamination certificate is issued under § 1.997, unless authorized by the Commissioner. Once a final decision has been entered against a party in a civil action arising in whole or in part under 28 U.S.C. 1338 in which the party did not sustain its burden of proving invalidity of any patent claim in suit, then neither that party nor its privies may thereafter request reexamination of any such patent claim on the basis of issues which that party or its privies raised or could have raised in such civil action, and reexamination requested by that party or its privies on the basis of such issues may not thereafter be maintained by the Office.

Proposed § 1.909 provides for estoppel of their party requesters from previous reexamination proceedings. A third party requester, or its privy, who,

during a reexamination proceeding, has filed a notice of appeal to the Court of Appeals for the Federal Circuit, or who has participated as a party to an appeal by the patent owner, under the provisions of 35 U.S.C. 141 to 144, is estopped from later asserting, in a subsequent reexamination proceeding, the invalidity of any claim determined to be patentable on appeal on any ground which the third party requester, or its privy, raised or could have raised during the prior reexamination proceeding. A third party requester, or its privy, is deemed not to have participated as a party to an appeal by the patent owner unless, within twenty days after the patent owner has filed notice of appeal, the third party (or its privy) files notice with the Commissioner electing to participate.

Proposed § 1.911 provides factors for consideration of privies and persons bound. For the purposes of § 1.907, a determination of whether person is a privy with respect to the patent owner shall include consideration of whether there is: (1) a mutual, concurrent or successive relationship to the same property rights in the patent involved in the reexamination proceeding; or (2) representation of the interests of the patent owner concerning the patent. For the purposes of §§ 1.907 and 1.909, a determination of whether a person is a privy with respect to a third party requester shall include consideration of whether there is: (1) a mutual, concurrent or successive relationship to the same property rights which are or may be affected by and/or infringe the patent involved in the reexamination proceeding; or (2) representation of the interests of the other party which are or may be affected by and/or potentially infringe the patent. For the purposes of §§ 1.907 and 1.909, a person who is not a party to the reexamination proceeding but who controls or substantially participates in the control of the presentation of the reexamination proceeding on behalf of a party is bound by the determination of issues decided as though he or she were a named party. To have control of the presentation requires that person to have effective choice as to the legal theories and/or grounds of rejection or defenses to be advanced on behalf of the party to the reexamination proceeding. Under this section a party would be precluded from hiring another law firm and having that firm file a subsequent reexamination request in order to avoid the prohibitions of 35 U.S.C. 307(c) or 308.

Proposed § 1.913 sets forth procedures for any person to request reexamination in accordance with 35 U.S.C. 302 and limits the period for such request to the period of enforceability of the patent for which the request is filed.

Proposed § 1.915(a) requires payment of the fee for requesting reexamination. Paragraph (b) of new § 1.915 indicates what each request for reexamination must include. Paragraph (c) of new § 1.915 covers amendments which a patent owner can propose. Such amendments can accompany a request for reexamination by the patent owner. Paragraph (d) indicates that requests for reexamination may be filed by attorneys or agents on behalf of a requester, but it is noted that the real party in interest must be identified in accordance with § 1.915(b)(10).

Proposed § 1.917 indicates what will be done if the request is incomplete.

Proposed § 1.919 indicates the date on which the entire fee is received will be considered to be the date of the request for reexamination.

Proposed § 1.921 provides that prior art submissions by the third party requester filed after the reexamination order shall be limited solely to prior art which is used to rebut a finding a fact by the examiner or a response of the patent owner.

Proposed § 1.923 relates to a determination as to whether the request has presented a substantial new question of patentability under 35 U.S.C. 303 and requires that the determination be made within 3 months of the filing date of the request.

Proposed § 1.925 refers to the refund provisions.

Proposed § 1.927 provides for review by petition to the Commissioner of any decision refusing reexamination.

Proposed § 1.929 provides for reexamination at the initiative of the Commissioner under the provisions of the last sentence of paragraph (a) of 35 U.S.C. 303.

Proposed § 1.931 provides for ordering reexamination where a substantial new question of patentability has been found pursuant to §§ 1.923 or 1.929. Under paragraph (b), the only limitation placed on the selection of the examiner by the Office is that the same examiner whose decision was reversed on petition ordinarily will not conduct the reexamination.

Proposed § 1.933 covers the duty of disclosure by a patent owner in a reexamination proceeding involving the owner's patent.

Proposed § 1.935 indicates that the initial Office action normally accompanies the reexamination order.

Proposed § 1.937 provides that in accordance with 35 U.S.C. 305(c), unless otherwise provided by the Commissioner for good cause, all reexamination proceedings will be conducted with special dispatch. Paragraph (b) covers the basic items relating to the conduct of reexamination proceedings.

Proposed § 1.939 provides that no paper shall be filed before the first Office action.

Proposed § 1.941 provides for proposed amendments provided for the second sentence of 35 U.S.C. 305. Amendments submitted by the patent owner cannot enlarge the scope of a claim in the patent. Amendments will not be effectively entered into the patent until the certificate under § 1.997 and 35 U.S.C. 307 is issued.

Proposed § 1.943 provides a page limit for responses and briefs of 50 pages. Prior art references and Appendix of claims would not be included in this total.

Proposed § 1.945 provides that a patent owner will be given at least thirty days to respond to any Office action. Although problems may arise in certain cases and extensions of time may be granted, it is felt that relatively short response times are necessary in order to process reexaminations with ''special dispatch.''

Proposed § 1.9347 provides that in accordance with 35 U.S.C. 305(b)(3), if a patent owner files a response to any Office action on the merits, the third party requester may once file written comments.

Proposed § 1.949 provides when prosecution may be closed.

Proposed § 1.951 provides for responses by the parties after an Office action closing prosecution. The responses and time periods provided for by paragraphs (a) and (b) may run concurrently.

Proposed § 1.953 provides that, following the responses or expiration of the time for response in § 1.951, the examiner may issue a right of appeal notice which shall include a final rejection or final decision favorable to patentability in accordance with 35 U.S.C. 134. The intent of limiting the appeal rights until after the examiner issues a ''Right of Appeal Notice'' is to specifically preclude the possibility of one party attempting to appeal prematurely while prosecution before the examiner is being continued by the other party.

Proposed § 1.955 relates to the conduct of interviews in reexamination proceedings. The third party requested is permitted to attend all interviews. Interviews are permitted before the first Office action only when initiated by the examiner.

Proposed § 1.957 relates to extensions of time and termination of

reexamination proceedings. In circumstances where the response by the patent owner is not required by the examiner and is merely discretionary, such as when all claims are allowed or their patentability is confirmed and the patent owner is merely given the opportunity for comment, such a failure to comment is not type of lack of response contemplated by paragraphs (b) and (c) and, therefore, not grounds for termination or limiting prosecution.

Proposed § 1.958 relates to revival of terminated proceedings.

Proposed § 1.959 relates to appeals and cross appeals to the Board of Patent Appeals and Interferences. Both patent owners and third party requesters are given appeal rights in accordance with 35 U.S.C. 306.

Proposed § 1.961 relates to time of transfer of the jurisdiction of the appeal over to the Board of Patent Appeals and Interferences.

Proposed § 1.962 relates to the definition of appellant and respondent.

Proposed § 1.963 relates to the time periods for filing briefs.

Proposed § 1.965 relates to the appellant brief.

Proposed § 1.967 relates to the respondent brief.

Proposed § 1.969 relates to the examiner's answer.

Proposed § 1.971 relates to the reply brief.

Proposed § 1.973 relates to the oral hearing.

Proposed § 1.975 relates to affidavits or declarations after appeal.

Proposed § 1.977 relates to the decision by the Board of Patent Appeals and Interferences.

Proposed § 1.979 relates to the procedures following the decision by the Board of Patent Appeals and Interferences.

Proposed § 1.981 relates to the procedure for reopening prosecution following the decision by the Board of Patent Appeals and Interferences.

Proposed § 1.983 relates to appeals to the United States Court of Appeals for the Federal Circuit, in accordance with 35 U.S.C. 306. Under H.R. 1732, civil actions under 35 U.S.C. 145 are not permitted in reexamination proceedings filed on or after January 1, 1996.

Proposed § 1.985 relates to notification or prior or concurrent proceedings.

Proposed § 1.987 relates to the stay of concurrent proceedings. Decisions as to whether to delay or combine cases will be made on a case-by-case basis to minimize delays and to protect the interests of all parties concerned.

Proposed § 1.989 relates to the merger of concurrent proceedings.

Proposed § 1.991 relates to the merger of a concurrent reissue application and a reexamination proceeding.

Proposed § 1.993 relates to the stay of a concurrent interference and reexamination proceeding.

Proposed § 1.995 relates to a third party requester's participation rights being preserved in merged proceeding.

Proposed § 1.997 concerns the issuance of the reexamination certificate under 35 U.S.C. 307 after the conclusion of reexamination proceedings. The certificate will cancel any patent claims determined to be unpatentable, confirm any patent claims determined to be patentable, and incorporate into the patent any amended or new claim determined to be patentable. Once all of the claims have been canceled from the patent, the patent ceases to be enforceable for any purpose. Accordingly, any pending reissue or other Office proceeding relating to a patent in which such a certificate has been issued will be terminated.

This provides a degree of assurance to the public that patents with all the claims canceled via reexamination proceedings will not again be asserted. It is intended that copies of the certificate will continue to be part of subsequently sold copies of the patent.

Other Considerations

The proposed rule changes are in conformity with the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), Executive Order 12612, and the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* It has been determined that this rulemaking is not significant for the purposes of Executive Order 12866.

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that these proposed rule changes will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The principal impacts of these proposed changes are to expand the grounds for requesting a reexamination and to permit the third party to participate more extensively during the reexamination proceeding as well as having appeal rights.

The Office has also determined that this notice has no Federalism implications affecting the relationship between the National Government and the States as outlined in Executive Order 12612.

These rule changes contain collection of information requirements subject to the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, which is currently approved by the Office of Management and Budget under Control No. 0651–0033. The public reporting burden for the collection of information for requests for reexamination is estimated to average 2.0 hours each including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Office of System Quality and Enhancement, Patent and Trademark Office, Washington, D.C. 20231, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (ATTN: Paperwork Reduction Act Project 0651–0033).

Notice is hereby given that pursuant to the authority granted to the Commissioner of Patents and Trademarks by 35 U.S.C. 6, the Patent and Trademark Office proposed to amend Title 37 of the Code of Federal Regulations as set forth below.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small Businesses.

For the reasons set out in the preamble and under the authority given to the Commissioner of Patents and Trademarks by 35 U.S.C. 6, Part I of Title 37 CFR is proposed to be amended as set forth below.

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 would continue to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.4(a)(2) is proposed to be revised to read as follows:

§ 1.4 Nature of correspondence and signature requirements.

(a) * * *

(2) Correspondence in and relating to a particular application or other proceeding in the Office. See particularly the rules relating to the filing, processing, or other proceedings of national applications in Subpart B, §§ 1.31 to 1.378; of international applications in Subpart C, §§ 1.401 to 1.499; or reexamination of patents filed before January 1, 1996, in Subpart D,

1.501 to 1.570, and of reexaminations filed on or after January 1, 1996, in Subpart H, §§ 1.901–1.997; of interferences in Subpart E; §§ 1.601 to 1.690; of extension of patent term in Subpart F, §§ 1.710 to 1.785; and of trademark applications §§ 2.11 to 2.189.

* * * * *

3. Section 1.6(d)(5) is proposed to be revised to read as follows:

§ 1.6 Receipt of correspondence.

* * * * *

(d) (5) A request for reexamination under § 1.510 or § 1.913.

* * * * *

4. Section 1.11(c) is proposed to be revised to read as follows:

§ 1.11 Files open to the public.

* * * * *

(c) All requests for reexamination for which the fee under 1.20(c) has been paid, will be announced in the Official Gazette. Any reexaminations at the initiative of the Commissioner pursuant to 1.520 or 1.929 will also be announced in the Official Gazette. The announcement shall include at least the date of the request, if any, the reexamination request control number of the Commissioner initiated order control number, patent number, title, class and subclass, name of the inventor, name of the patent owner of record, and the examining group to which the reexamination is assigned.

* * * * *

5. Section 1.17 (l) and (m) are proposed to be revised to read as follows:

§ 1.17 Patent application processing fees.

* * * * *

(l) For filing a petition:

(1) For the revival of an unavoidably abandoned application under 35 U.S.C. 111, 133, 364, or 371,

(2) For delayed payment of the issue fee under 35 U.S.C. 151, or,

(3) For the revival of an unavoidably terminated reexamination proceeding:

By a small entity (§ 1.9(f)).....55.00
By other than a small entity 110.00

(m) For filing a petition:

(1) For revival of an unintentionally abandoned application,

(2) For the unintentionally delayed payment of the fee for issuing a patent, or

(3) For reexamination proceedings filed on or after January 1, 1996, for the revival of an unintentionally terminated reexamination proceeding:

By a small entity (§ 1.9(f)).....605.00
By other than a small entity 1,210.00

* * * * *

6. Section 1.20(c) is proposed to be revised to read as follows:

§ 1.20 Post issuance fees.

* * * * *

(c) For filing a request for reexamination (§ 1.915(a)):

By a patent owner $4,500.00
By a third party requester.....$11,000.00

* * * * *

7. Section 1.25(b) is proposed to be revised to read as follows:

§ 1.25 Deposit accounts.

* * * * *

(b) Filing, issue, appeal, international-type search report, international application processing, petition, and post-issuance fees may be charged against these accounts if sufficient funds are on deposit to cover such fees. A general authorization to charge all fees, or only certain fees, set forth in §§ 1.16 to 1.18 to a deposit account containing sufficient funds may be filed in an individual application, either for the entire pendency of the application or with respect to a particular paper filed. An authorization charge to a deposit account the fee for a request for reexamination pursuant to § 1.510 or § 1.915 and any other fees required in a reexamination proceeding in a patent may also be filed with the request for reexamination. An authorization to charge a fee to a deposit account will not be considered payment of the fee on the date the authorization to charge the fee is effective as to the particular fee to be charged unless sufficient funds are present in the account to cover the fee.

8. Section 1.26(c) is proposed to be revised to read as follows:

§ 1.26 Refunds.

* * * * *

(c) If the Commissioner decides not to institute a reexamination proceeding, for reexaminations filed on or after January 1, 1996, a refund of seventy-five percent (75%) of the fee paid for filing the request for reexamination will be made to the requester. Reexamination requesters should indicate whether any refund should be made by check or by credit to a deposit account.

9. Section 1.112 is proposed to be revised to read as follows:

§ 1.112 Reconsideration.

After response by applicant or patent owner (§ 1.111), the application or patent under reexamination will be reconsidered and again examined. The applicant or patent owner will be notified if claims are rejected, or objections or requirements made, in the same manner as after the first examination. Applicant or patent owner may respond to such Office action in the same manner provided in § 1.111, with or without amendment. Any amendments after the second Office action must ordinarily be restricted to the rejection or to the objections or requirements made. The application or patent under reexamination will be again considered, and so on repeatedly, unless the examiner has indicated that the action is final or is an action closing prosecution.

10. Section 1.113(a) is proposed to be revised to read as follows:

§ 1.113 Final rejection or action.

(a) On the second or any subsequent examination or consideration the rejection or other action may be made final, whereupon applicant's or (for reexaminations filed before January 1, 1996) patent owner's response is limited to appeal in the case of rejection of any claim (§ 1.191), or to amendment as specified in § 1.116. Petition may be taken to the Commissioner in the case of objections or requirements not involved in the rejection of any claim (§ 1.181). Response to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim. If any claim stands allowed, the response to a final rejection or action must comply with any requirements or objection as to form.

* * * * *

11. Section 1.115 is proposed to be revised to read as follows:

§ 1.115 Amendment.

The applicant may amend before or after the first examination and action and also after the second or subsequent examination or reconsideration as specified in § 1.112 or when and as specifically required by the examiner. For reexaminations filed before January 1, 1996, the patent owner may amend in accordance with §§ 1.510(e) and 1.530(b) prior to reexamination, and during reexamination proceedings in accordance with §§ 1.112 and 1.116. For reexaminations filed on or after January 1, 1996, the patent owner may amend in accordance with § 1.915(c) prior to reexamination, and during reexamination proceedings in accordance with §§ 1.941 and 1.945.

12. Section 1.116(a) is proposed to be revised to read as follows:

§ 1.116 Amendments after final action.

(a) After final rejection or action (§ 1.113) or action closing prosecution (§ 1.949) for reexaminations filed on or after January 1, 1996, amendments may be made cancelling claims or complying with any requirement of form which has been made. Amendments presenting

rejected claims in better form for consideration on appeal may be admitted. The admission of, or refusal to admit, any amendment after final rejection, and any proceedings relative thereto, shall not operate to relieve the application or patent under reexamination from its condition as subject to appeal or to save the application from abandonment under § 1.135. Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, no appeal may be had until a right of appeal notice has been issued pursuant to § 1.953.

* * * * *

13. Section 1.136(a)(2) and (b) are proposed to be revised to read as follows:

§ 1.136 Filing of timely responses with petition and fee for extension of time and extensions of time for cause.

(a) * * *

(2) The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for purposes of determining the period of extension and the corresponding amount of the fee. The expiration of the time period is determined by the amount of the fee paid. In no case may an applicant respond later than the maximum time period set by statute, or be granted an extension of time under paragraph (b) of this section when the provisions of this paragraph are available. See § 1.136(b) for extensions of time relating to proceedings pursuant to § 1.193(b), 1.194, 1.196 or 1.197. See § 1.304 for extension of time to appeal to the U.S. Court of Appeals for the Federal Circuit or to commence a civil action. See § 1.550(c) for extension of time in reexamination proceedings filed before January 1, 1996, § 1.957 for extension of time in reexamination proceedings filed on or after January 1, 1996, and § 1.645 for extension of time in interference proceedings.

(b) When a response with petition and fee for extension of time cannot be filed pursuant to paragraph (a) of this section, the time for response will be extended only for sufficient cause and for a reasonable time specified. Any request for such extension must be filed on or before the day on which action by the applicant is due, but in no case will the mere filing of the request effect any extension. In no case can any extension carry the date on which response to an Office action is due beyond the maximum time period set by statute or be granted when the provisions of paragraph (a) of this section are available. See § 1.304 for extension of time to appeal to the U.S. Court of Appeals for the Federal Circuit or to commence a civil action, § 1.645 for extension of time in interference proceedings, § 1.550(c) for extension of time in reexamination proceedings filed before January 1, 1996, and § 1.957 for extension of time in reexamination proceedings filed on or after January 1, 1996.

14. Section 1.137 (g) and (h) are proposed to be added and the Section heading revised to read as follows:

§ 1.137 Revival of abandoned application, lapsed patent or terminated reexamination.

* * * * *

(g) A reexamination proceeding filed before January 1, 1996, which is terminated for failure to prosecute may be revised as a pending proceeding if it is shown to the satisfaction of the Commissioner that the delay was unavoidable. A petition to revive an unavoidably terminated reexamination proceeding must be promptly filed after the patent owner is notified of, or otherwise becomes aware of, the termination of the proceeding, and must be accompanied by:

(1) a proposed response to continue prosecution of that proceeding unless it has been previously filed;

(2) the petition fee as set forth in § 1.17(1); and

(3) a showing that the delay was unavoidable. The showing must be a verified showing if made by a person not registered to practice before the Patent and Trademark Office.

(h) For reexamination proceedings filed on or after January 1, 1996, see § 1.958.

15. Section 1.191(a) is proposed to be revised to read as follows:

§ 1.191 Appeal to Board of Patent Appeals and Interferences.

(a) Every applicant for a patent or for reissue of a patent, or every owner of a patent under reexamination (for reexaminations filed before January 1, 1996), any of the claims of which have been twice rejected or who has been given a final rejection (§ 1.113), may, upon the payment of the fee set forth in § 1.17(e), appeal from the decision of the examiner to the Board of Patent Appeals and Interferences within the time allowed for response. Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, § 1.959 et seq., is controlling.

* * * * *

16. Section 1.192(a) is proposed to be revised to read as follows:

§ 1.192 Applicant's brief.

(a) The appellant shall, within 2 months from the date of the notice of appeal under § 1.191 in an application, reissue application, or patent under reexamination (for reexaminations filed before January 1, 1996), or within the time allowed for response to the action appealed from, if such time is later, file a brief in triplicate. The brief must be accompanied by the requisite fee set forth in § 1.17(f) and must set forth the authorities and arguments on which the appellant will rely to maintain the appeal. Any arguments or authorities not included in the brief may be refused consideration by the Board of Patent Appeals and Interferences. Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, § 1.965 is controlling.

* * * * *

17. Section 1.193 is proposed to be amended by adding a paragraph (c) to read as follows:

§ 1.193 Examiner's answer.

* * * * *

(c) Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, §§ 1.969 and 1.971 are controlling.

18. Section 1.194 is proposed to be amended by adding a paragraph (d) to read as follows:

§ 1.194 Oral hearing.

* * * * *

(d) Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, § 1.973 is controlling.

19. Section 1.195 is proposed to be revised to read as follows:

§ 1.195 Affidavits or declarations after appeal.

Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented. Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, § 1.975 is controlling.

20. Section 1.196 is proposed to be amended by adding a paragraph (g) to read as follows:

§ 1.196 Decision by the Board of Patent Appeals and Interferences.

* * * * *

(g) Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, § 1.977 is controlling.

21. Section 1.197 is proposed to be amended by adding a paragraph (d) to read as follows:

§ 1.197 Action following decision.

* * * * *

(d) Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, § 1.979 is controlling.

22. Section 1.198 is proposed to be revised to read as follows:

§ 1.198 Reopening after decision.

Cases which have been decided by the Board of Patent Appeals and Interferences will not be reopened or reconsidered by the primary examiner except under the provisions of § 1.196 without the written authority of the Commissioner, and then only for the consideration of matters not already adjudicated, sufficient cause being shown. Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, § 1.981 is controlling.

23. Section 1.301 is proposed to be revised to read as follows:

§ 1.301 Appeal to U.S. Court of Appeals for the Federal Circuit.

Any applicant or any owner of a patent involved in a reexamination proceeding (filed before January 1, 1996) dissatisfied with the decision of the Board of Patent Appeals and Interferences, and any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences, may appeal to the U.S. Court of Appeals for the Federal Circuit. The appellant must take the following steps in such an appeal: In the Patent and Trademark Office file a written notice of appeal directed to the Commissioner (see §§ 1.302 and 1.304); and in the Court, file a copy of the notice of appeal and pay the fee for appeal as provided by the rules of the Court. Notwithstanding the above, for reexamination proceedings filed on or after January 1, 1996, § 1.983 is controlling.

24. Section 1.303 is proposed to be amended by revising paragraphs (a) and (b) and adding a new paragraph (d) to read as follows:

§ 1.303 Civil action under 35 U.S.C. 145, 146, 306.

(a) Any applicant or any owner of a patent involved in a reexamination proceeding (filed before January 1, 1996) dissatisfied with the decision of the Board of Patent Appeals and Interferences, and any party dissatisfied with the decision of the Board of Patent Appeals and Interferences may, instead of appealing to the U.S. Court of Appeals for the Federal Circuit (§ 1.301), have remedy by civil action under 35 U.S.C. 145 or 146, as appropriate. Such civil action must be commenced within the time specified in § 1.304.

(b) If an applicant in an ex parte case or an owner of a patent involved in a reexamination proceeding (filed before January 1, 1996) has taken an appeal to the U.S. Court of Appeals for the Federal Circuit, he or she thereby waives his or her right to proceed under 35 U.S.C. 145.

* * * * *

(d) For reexamination proceedings filed on or after January 1, 1996, no remedy by civil action under 35 U.S.C. 145 is available.

25. Section 1.304(a)(2) is proposed to be revised to read as follows:

§ 1.304 Time for appeal or civil action.

(a) * * *

(2) The time periods set forth in this section are not subject to the provisions of §§ 1.136, 1.550(c), 1.957 or 1.645 (a) or (b).

* * * * *

26. The heading for Subpart D is proposed to be revised to read as follows:

Subpart D—Reexamination of Patents for Proceedings Filed Before January 1, 1996 (For Proceeding beginning on or after January 1, 1996, see Subpart H)

27. Subpart H is proposed to be added to read as follows:

Subpart H—Reexamination of Patents for Proceedings Filed On or After January 1, 1996 (For Proceedings beginning Before January 1, 1996, see Subpart D)

Sec.

1.901 Citation of prior art in patents file.
1.902 Processing of prior art citations in patent files during a reexamination proceeding.

Reexamination Proceedings

1.903 Service of papers on parties.
1.904 Notice of reexamination in Official Gazette.
1.905 Submission of papers by public.
1.906 Scope of reexamination in reexamination proceeding.
1.907 Reexamination prohibited.
1.909 Estoppel of third party requester from previous reexamination proceedings.
1.911 Privies and persons bound.

Determining if Reexamination Will Be Ordered

1.913 Persons eligible.
1.915 Content of request.
1.917 Omission of a requirement in the request for reexamination.
1.919 Filing date for request for reexamination.
1.921 Submission of prior art by third party following the order for reexamination.
1.923 Examiner's consideration of the request for reexamination.
1.925 Partial refund if request is denied.
1.927 Petition to review denial of the request for reexamination.

Reexamination of Patients

1.929 Reexamination at the initiative of the Commissioner.
1.931 Order to reexamine.

Information Disclosure

1.933 Information material to patentability in reexamination proceedings.

Office Actions and Responses (Before the Examiner)

1.935 Initial Office action normally accompanies order to reexamine.
1.937 Conduct of Reexamination.
1.939 Unauthorized papers.
1.941 Amendments by patent owner and their effective date.
1.943 Length of responses and briefs.
1.945 Response by patent owner.
1.947 Response by third party requester to patent owner's response.
1.949 Examiner's Office action closing prosecution.
1.951 Responses after Office action closing prosecution.
1.953 Examiner's Right of Appeal Notice.

Interviews

1.955 Interviews in reexamination proceedings.

Extensions of Time and Revival of Proceedings

1.957 Extensions of time and cause for termination in reexamination proceedings.
1.958 Revival of terminated proceedings.

Appeal to the Board of Patent Appeals and Interferences

1.959 Notice of appeal and cross appeal to Board of Patent Appeals and Interferences.
1.961 Jurisdiction over appeal.
1.962 Appellant and respondent defined.
1.963 Time for filing briefs.
1.965 Appellant brief.
1.967 Respondent brief.
1.969 Examiner's answer.
1.971 Reply brief.
1.973 Oral hearing.
1.975 Affidavits or declarations after appeal.
1.977 Decision by the Board of Patent Appeals and Interferences.
1.979 Action following decision.
1.981 Reopening after decision.

Appeal to the United States Court of Appeals for the Federal Circuit

1.983 Appeal to the United States Court of Appeals for the Federal Circuit.

Proceedings Including Same Patient as in Reexamination

1.985 Notification of prior or concurrent proceedings.
1.987 Stay of concurrent proceeding.
1.989 Merger of concurrent reexamination proceedings.

1.991 Merger of concurrent reissue application and reexamination proceeding.
1.993 Stay of concurrent interference and reexamination proceeding.
1.995 Third party requester's participation rights preserved in merged proceedings.

Certificate

1.997 Issuance of reexamination certificate after reexamination proceedings.

§ 1.901 Citation of prior art in patent files.

(a) At any time during the period of enforceability of a patent, any person may cite to the Patent and Trademark Office in writing prior art consisting of patents or printed publications which that person states to be pertinent and applicable to the patent and believes to have a bearing on the patentability of any claim of a particular patent. If the citation is made by the patent owner, the explanation of pertinency and applicability may include an expansion of how the claims differ from the prior art.

(b) If the person making the citation wishes his or her identity to be excluded from the patent file and kept confidential, the citation papers must be submitted without any identification of the person making the submission.

(c) Citations of patent or printed publications by the public in patent files should either:

(1) reflect that a copy of the same has been mailed to the patent owner at the address as provided in § 1.33(c); or in the event service is not possible,

(2) be filed with the Office in duplicate.

(d) Except as provided in § 1.902, citations submitted in accordance with this section will be placed and made of record in the patent file.

§ 1.902 Processing of prior art citations in patent files during a reexamination proceeding.

Citations by the patent owner in accordance with § 1.933 and by a reexamination third party requester under § 1.915 will be entered in the patent file. The entry in the patent file of other citations submitted after the date of an order to reexamine pursuant to § 1.931 will be delayed until the reexamination proceeding has been terminated.

Reexamination Proceedings

§ 1.903 Service of papers on parties.

The patent owner and any third party requester will be sent copies of Office actions issued during the reexamination proceeding. After filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on every other party in the reexamination proceeding in the manner provided in § 1.248. Any document must reflect service or the document may be refused consideration by the Office. The failure of the third party requester, if any, to timely file or serve documents may result in their being refused consideration.

§ 1.904 Notice of reexamination in Official Gazette.

A notice of the filing of a reexamination request or initiation of a Commissioner-ordered reexamination will be published in the Official Gazette. The notice in the Official Gazette under § 1.11(c) will be considered to be constructive notice of the reexamination proceeding and reexamination will proceed.

§ 1.905 Submission of papers by public.

Unless specifically provided for, no submissions on behalf of any third parties other than third party requesters as defined in 35 U.S.C. 100(e) will be considered unless such submissions are in accordance with § 1.915 or entered in the patent file prior to the date of the order to reexamine pursuant to § 1.931. Submissions by third parties, other than third party requesters, filed after the date of the order to reexamine pursuant to § 1.931, must meet the requirements of § 1.901 (a) through (c) and will be treated in accordance with § 1.902.

§ 1.906 Scope of reexamination in reexamination proceeding.

(a) Claims in a reexamination proceeding will be examined on the basis of patents or printed publications and on the basis of the requirements of 35 U.S.C. 112 except for the best mode requirement.

(b) Claims in a reexamination proceeding must not enlarge the scope of the claims of the patent.

(c) Questions other than those indicated in paragraphs (a) and (b) of this section will not be resolved in a reexamination proceeding. If such questions are raised by the patent owner or third party requester during a reexamination proceeding, the existence of such questions will be noted by the examiner in the next Office action, in which case the patent owner may desire to consider the advisability of filing a reissue application to have such questions considered and resolved.

§ 1.907 Reexamination prohibited.

(a) Once an order to reexamine has been issued under § 1.931, neither the patent owner nor the third party requester, if any, nor privies of either, may file a subsequent request for reexamination of the patent until a reexamination certificate is issued under § 1.997, unless authorized by the Commissioner.

(b) Once a final decision has been entered against a party in a civil action arising in whole or in part under 28 U.S.C. 1338 that the party has not sustained its burden of proving invalidity of any patent claim in suit, then neither that party nor its privies may thereafter request reexamination of any such patent claim on the basis of issues which that party or its privies raised or could have raised in such civil action, and a reexamination requested by that party, or its privies, on the basis of such issues may not thereafter be maintained by the Office.

§ 1.909 Estoppel of third party requester from previous reexamination proceedings.

A third party requester, or its privy, who, during a reexamination proceeding, has filed a notice of appeal to the Court of Appeals for the Federal Circuit, or who has participated as a party to an appeal by the patent owner, under the provisions of 35 U.S.C. 141 to 144, is estopped from later serving, in a subsequent reexamination proceeding, the invalidity of any claim determined to be patentable on appeal on any ground which the third party requester, or its privy, raised or could have raised during the prior reexamination proceeding. A third party requester, or its privy, is deemed not to have participated as a party to an appeal by the patent owner unless, within twenty days after the patent owner has filed notice of appeal, the third party, or its privy, files notice with the Commissioner's electing to participate.

§ 1.911 Privies and persons bound.

(a) For the purposes of § 1.907, a determination of whether a person is a privy with respect to the patent owner shall include consideration of whether there is:

(1) a mutual, concurrent or successive relationship to the same property rights in the patent involved in the reexamination proceeding; or

(2) representation of the interests of the patent owner concerning the patent.

(b) For the purposes of §§ 1.907 and 1.909, a determination of whether a person is a privy with respect to a third party requester shall include consideration of whether there is:

(1) a mutual, concurrent or successive relationship to the same property rights which are or may be affected by and/or infringe the patent involved in the reexamination proceeding; or

(2) representation of the interests of the other party which are or may be

affected by and/or potentially infringe the patent.

(c) For the purposes of §§ 1.907 and 1.909, a person who is not a party to the reexamination proceeding but who controls or substantially participates in the control of the presentation of the reexamination proceeding on behalf of a party is bound by the determination of issues decided as though he or she were a named party. To have control of the presentation requires that person to have effective choice as to the legal theories and/or grounds of rejection or defenses to be advanced on behalf of the party to the reexamination proceeding.

Determining if Reexamination Will Be Ordered

§ 1.913 Persons eligible.

Except as otherwise provided, any person may, at any time during the period of enforceability of a patent, file a request for reexamination by the Patent and Trademark Office of any claim of the patent on the basis of prior art patents or printed publications cited under § 1.901 or on the basis of the requirements of 35 U.S.C. 112 except for the best mode requirement.

§ 1.915 Content of request.

(a) The request must be accompanied by the fee for requesting reexamination set in § 1.20(c).

(b) Any request for reexamination must include the following parts:

(1) A statement pointing out each substantial new question of patentability based on prior patents and printed publications or based on the manner in which the patent specification or claims fail to comply with the requirements of 35 U.S.C. 112 except for the best mode requirement.

(2) An identification of every claim for which reexamination is requested.

(3) A detailed explanation of the pertinency and manner of applying the cited prior art to every claim for which reexamination is requested or a detailed explanation of the manner in which the specification or claim(s) fail to comply with 35 U.S.C. 112 except for the best mode requirement. If appropriate, the party requesting reexamination may also point out how claims distinguish over cited prior art or how 35 U.S.C. 112 requirements are complied with except for the best mode requirement.

(4) A copy of every patent or printed publication relied upon or referred to in paragraphs (b) (1) and (3) of this section accompanied by an English language translation of all the necessary and pertinent parts of any non-English language document.

(5) The entire patent for which reexamination is requested must be furnished in the form of cut-up copies of the original patent with only a single column of the printed patent securely mounted or reproduced in permanent form on one side of a separate paper. A copy of any disclaimer, certificate of correction, or reexamination certificate issued in the patent must also be included.

(6) A certification that a copy of the request filed by a person other than the patent owner has been served in its entirety on the patent owner at the address as provided for in § 1.33(c). The name and address of the party served must be indicated. If service was not possible, a duplicate copy must be supplied to the Office.

(7) If the patent is currently involved in a reexamination proceeding for which a reexamination certificate has not been issued, a certification that the person making the request is not a privy of the patent owner or third party requester, unless otherwise authorized by the Commissioner.

(8) In a request filed by a third party requester, a certification that

(i) no final decision has been entered against that party or its privies in a civil action arising in whole or in part under 28 U.S.C. 1338 in which that party or its privies did not sustain its burden of proving the invalidity of any patent claim in suit, and

(ii) neither that party nor its privies are requesting reexamination of any such patent claim on the basis of issues which that party or its privies raised or could have raised in such civil action.

(9) In a request filed by a third party requester, a certification that the request does not assert the invalidity of any claim determined to be patentable on appeal on any ground which the third party requester or its privy raised or could have raised during a prior reexamination proceeding in which that party or its privies filed a notice of appeal to the Court of Appeals for the Federal Circuit and/or participated as a party to an appeal by the patent owner, under the provisions of 35 U.S.C. 141 to 144.

(10) A statement identifying the real party in interest to the extent necessary for a subsequent person filing a reexamination request to determine whether that person is a privy.

(c) A request filed by the patent owner may include a proposed amendment in accordance with § 1.121(f).

(d) If a request is filed by an attorney or agent identifying another party on whose behalf the request is being filed, the attorney or agent must have a power of attorney from that party or be acting in a representative capacity pursuant to § 1.34(a).

§ 1.917 Omission of a requirement in the request for reexamination.

If the request is not accompanied by the fee for requesting reexamination or all of the other parts required by § 1.915, the person identified as requesting reexamination will be so notified and given an opportunity to complete the request within a specified time. If the fee for requesting reexamination has been paid but the defect in the request is not corrected within the specified time, the determination whether or not to institute reexamination will be made on the request as it then exists. If the fee for requesting reexamination has not been paid, no determination will be made and the request will be placed in the patent file as a citation if it complies with the requirements of § 1.901 and/or § 1.902.

§ 1.919 Filing date for request for reexamination.

The filing date of the request is the date on which the request including the entire fee for requesting reexamination is received; or, if the request is not initially accompanied by the entire fee, the date on which the last portion of the fee is received in the Patent and Trademark Office.

§ 1.921 Submission of prior art by third party following the order for reexamination.

Prior art submissions by the third party requester filed after the reexamination order shall be limited solely to prior art which is used to rebut a finding of fact by the examiner or a response of the patent owner.

§ 1.923 Examiner's consideration of the request for reexamination.

Within three months following the filing date of a request for reexamination, an examiner will consider the request and determine whether or not a substantial new question of patentability affecting any claim of the patent is raised by the request and the prior art cited therein, with or without consideration of other patents or printed publications, or by the failure of the patent specification or claim(s) to comply with the requirements of 35 U.S.C. 112 except for the best mode requirement. The examiner's determination will be used on the claims in effect at the time of the determination and will become a part of the official file of the patent and will be mailed to the patent owner at the address as provided for in § 1.33(c) and to the person requesting reexamination.

§ 1.925 Partial refund if request is denied.

Where no substantial new question of patentability has been found, a refund of a portion of the fee for requesting

reexamination will be made to the requester in accordance with § 1.26(c).

§ 1.927 Petition to review denial of the request for reexamination.

The requester may seek review by a petition to the Commissioner under § 1.181 within one month of the mailing date of the examiner's determination refusing reexamination. Any such petition must comply with § 1.181(b). If no petition is timely filed or if the decision on petition affirms that no substantial new question of patentability has been raised, the determination shall be final and nonappealable.

Reexamination of Patents

§ 1.929 Reexamination at the initiative of the Commissioner.

The Commissioner, at any time during the period of enforceability of a patent, may determine whether or not a substantial new question of patentability is raised by patents or printed publications which have been discovered by the Commissioner or which have been brought to the Commissioner's attention or by the failure of the patent specification or claim(s) to comply with the requirements of 35 U.S.C. 112 except for the best mode requirement. The Commissioner may order reexamination even though no request for reexamination has been filed in accordance with § 1.915. Normally requests from outside the Patent and Trademark Office that the Commissioner undertake reexamination on his or her own initiative will not be considered. Any determination to initiate reexamination under this section will become a part of the official file of the patent and will be given or mailed to the patent owner at the address as provided for in § 1.33(c).

§ 1.931 Order to reexamine.

(a) If a substantial new question of patentability is found, the determination will include an order for reexamination of the patent for resolution of the question.

(b) If the order for reexamination resulted from a petition pursuant to § 1.927, the reexamination will ordinarily be conducted by an examiner other than the examiner responsible for the initial determination under § 1.923.

Information Disclosure

§ 1.933 Information material to patentability in reexamination proceedings.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective reexamination occurs when, at the time a reexamination proceeding is being conducted, the Office is aware of and evaluates the teachings of all information material to patentability in a reexamination proceeding. Each individual associated with the patent owner in a reexamination proceeding has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability in a reexamination proceeding. The individuals who have a duty to disclose to the Office all information known to them to be material to patentability in a reexamination proceeding are the patent owner, each attorney or agent who represents the patent owner, and every other individual who is substantively involved on behalf of the patent owner in a reexamination proceeding. The duty to disclose the information exists with respect to each claim pending in the reexamination proceeding until the claim is cancelled. Information material to the patentability of a cancelled claim need not be submitted if the information is not material to patentability of any claim remaining under consideration in the reexamination proceeding. The duty to disclose all information known to be material to patentability in a reexamination proceeding is deemed to be satisfied if all information known to be material to patentability of any claim in the patent after issuance of the reexamination certificate was cited by the Office or submitted to the Office in an information disclosure statement. However, the duties of candor, good faith, and disclosure have not been complied with if any fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct by, or on behalf of, the patent owner in the reexamination proceeding. Any information disclosure statement must be filed with the items listed in § 1.98(a) as applied to individuals associated with the patent owner in a reexamination proceeding, and should be filed within two months of the date of the order for reexamination, or as sooner thereafter as possible.

(b) Under this section, information is material to patentability in a reexamination proceeding when it is not cumulative to information of record or being made of record in the reexamination proceeding, and

(1) It is a patent or printed publication that establishes, by itself or in combination with other patents or printed publications, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the patent owner takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability of a claim pending in a reexamination proceeding is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) The responsibility for compliance with this section rests upon the individuals designated in paragraph (a) of this section, and no evaluation will be made by the Office in the reexamination proceeding as to compliance with this section. If questions of compliance with this section are discovered during a reexamination proceeding, they will be noted as unresolved questions in accordance with § 1.906(c).

Office Actions and Responses (Before the Examiner)

§ 1.935 Initial Office action normally accompanies order to reexamine.

The order for reexamination will normally be accompanied by the initial Office action on the merits of the reexamination.

§ 1.937 Conduct of Reexamination.

(a) All reexamination proceedings, including any appeals to the Board of Patent Appeals and Interference, will be conducted with special dispatch within the Office, unless the Commissioner makes a determination that there is good cause for suspending the reexamination proceding. A final determination that good cause exists shall not be made until the patent owner and third party requesters (if any) have had a reasonable opportunity to comment on or oppose any suspension.

(b) Except as otherwise provided, the reexamination proceeding will be conducted in accordance with the sections governing the application examination process; §§ 1.104 through 1.119, and will result in the issuance of a reexamination certificate under § 1.997.

§ 1.939 Unauthorized papers.

Unless authorized by the reexamination regulations (§§ 1.901–

1.997), no paper shall be filed prior to the first Office action. If an unauthorized paper is filed by the patent owner or third party requester, it will not be considered in making the determination under § 1.923 and will be returned.

§ 1.941 Amendments by patent owner and their effective date.

(a) Any proposed amendment to the description and claims must be made in accordance with § 1.121(f) and be accompanied by an explanation of the support for the proposed amendment in the disclosure of the patent. No amendment may enlarge the scope of the claims of the patent or introduce new matter. No amendment may be proposed for entry in an expired patent. Moreover, no amendment will be incorporated into the patent by certificate issued after the expiration of the patent.

(b) Amendments made to a patent during a reexamination proceeding will not be effective until a reexamination certificate is issued.

§ 1.943 Length of responses and briefs.

Responses and appellant briefs by the patent owner (including amendments) and third party requester, if any, shall not exceed 50 pages in length, excluding Appendix of claims and reference materials such as prior art references. All further briefs by any party shall not exceed 35 pages in length.

§ 1.945 Response by patent owner.

The patent owner will be given at least thirty (30) days to respond to any Office action. Such response may include arguments in response to any rejections and/or proposed amendments or new claims to place the patent in condition where all claims, if amended as proposed, would be patentable.

§ 1.947 Response by third party requester to patent owner's response.

If the patent owner files a response to an Office action, any third party requester may once file written comments within a period of one month from the date of service of the patent owner's response. These comments shall be limited to issues covered by the action or the patent owner's response.

§ 1.949 Examiner's Office action closing prosecution.

Upon consideration of the issues and/or grounds of rejection a second or subsequent time, or upon allowance of all claims, the examiner shall issue an Office action treating all claims present in the reexamination proceeding, which may be an action closing prosecution. An action will not normally close prosecution if it includes a new ground of rejection which was not previously addressed by the patent owner, unless the new ground was necessitated by an amendment.

§ 1.951 Responses after Office action closing prosecution.

After any action closing prosecution issued by the examiner, the third party requester may once file written comments limited to the issues raised in the Office action closing prosecution. Such comments must be filed within the time set for response in the action closing prosecution. When the third party requester does file such comments, the patent owner may file comments responding to the third party requester's comments within one month from the date of service of the third party requester's comments on the patent owner.

(b) After any action closing prosecution issued by the examiner, the patent owner may once file written comments limited to the issues raised in the reexamination proceeding and/or present a proposed amendment to the claims which amendment will be subject to the criteria of § 1.116 as to whether it shall be entered and/or considered. Such comments and/or proposed amendments must be filed within the time set for response in the action closing prosecution. Where the patent owner does file such comments and/or proposed amendment, the third party requester may file comments responding to such comments and/or proposed amendments by the patent owner within one month from the date of service of patent owner's comments and/or proposed amendment on the third party requester.

§ 1.953 Examiner's Right of Appeal Notice.

Upon considering the responses of the patent owner and any third party requester subsequent to the Office action closing prosecution, or upon expiration of the time for submitting such responses, the examiner shall issue a ''Right of Appeal Notice,'' unless the examiner reopens prosecution. The ''Right of Appeal Notice'' shall include a final rejection and/or final decision favorable to patentability which shall identify the status of each claim and reasons for patentability or grounds of rejection for each claim. It shall set a 30-day or one month time period, whichever is longer, for either party to appeal. If no appeal follows, the reexamination proceeding will be terminated and the Commissioner will proceed to issue a certificate under § 1.997 in accordance with the last action of the Office.

Interviews

§ 1.955 Interviews in reexamination proceedings.

(a) Interviews in reexamination proceedings pending before the Office between examiners and the owners of such patents or their attorneys or agents of record must be had in the Office at such times, within Office hours, as the respective examiners may designate. Interviews will not be permitted at any other time or place without the authority of the Commissioner. Interviews should be arranged for in advance. A third party requester may not initiate an interview. A third party requester has a right to participate in an interview initiated by the patent owner or the examiner and must be given adequate notice and opportunity to participate. A senior level Office official will be present when the interview is attended by a third party requester.

(b) Interviews for the discussion of the patentability of claims in patents involved in reexamination proceedings will not be initiated by the patent owner prior to the first Office action thereon.

(c) In every instance of an interview with an examiner, each party must present a statement of the issues which were discussed. An interview does not remove the necessity for response to Office actions as specified in § 1.111.

Extensions of Time and Revival of Proceedings

§ 1.957 Extensions of time and cause for termination in reexamination proceedings.

(a) The time for taking any action by a patent owner or third party requester in a reexamination proceeding will be extended only for sufficient cause, and for a reasonable time specified. Any request for such extension must be filed on or before the day on which action by the patent owner or third party requester is due, but in no case will the mere filing of a request effect any extension. See § 1.304(a) for extensions of time for filing a notice of appeal to the U.S. Court of Appeals for the Federal Circuit.

(b) If the patent owner fails to file a timely and appropriate response to any Office action in a reexamination proceeding, the reexamination proceeding will be terminated and the Commissioner will proceed to issue a certificate under § 1.997 in accordance with the last action of the Office, unless there is a third party requester and claims are found patentable.

(c) If there is a third party requester and claims are found patentable, and the patent owner fails to file a timely and appropriate response to any action in a reexamination proceeding,

prosecution will be limited to claims found patentable at the time of the failure to respond and to claims which do not enlarge the scope of the claims found patentable at that time.

§ 1.958 Revival of terminated proceedings.

(a) A reexamination proceeding terminated for failure to prosecute may be revived as a pending proceeding if it is shown to the satisfaction of the Commissioner that the delay was unavoidable. A petition to revive an unavoidably terminated reexamination proceeding must be promptly filed after the patent owner is notified of, or otherwise becomes aware of, the termination of the proceeding, and must be accompanied by:

(1) a proposed response to continue prosecution of that proceeding unless it has been previously filed;

(2) the petition fee as set forth in § 1.17(l); and

(3) a showing that the delay was unavoidable. The showing must be a verified showing if made by a person not registered to practice before the Patent and Trademark Office.

(b) A reexamination proceeding terminated for failure of the patent owner to prosecute may be revived as a pending proceeding if the delay in prosecution was unintentional. A petition to revive an unintentionally terminated reexamination proceeding must be:

(1) accompanied by a proposed response to continue prosecution of that proceeding unless it has been previously filed;

(2) accompanied by the petition fee as set forth in § 1.17(m);

(3) accompanied by a statement that the delay was unintentional. The statement must be a verified statement if made by a person not registered to practice before the Patent and Trademark Office. The Commissioner may require additional information where there is a question whether the delay was unintentional; and

(4) filed either:

(i) within two months of the date of the first Office notification that the proceeding has been terminated; or

(ii) within two months of the date of the first decision on a petition to revive under paragraph (a) of this section which was timely filed within the time period set forth in paragraph (b)(4)(i) of this section.

(c) Any request for reconsideration or review of a decision refusing to revive a proceeding upon petition filed pursuant to paragraph (a) or (b) of this section, to be considered timely, must be filed within two months of the decision refusing to revive or within such time as set in the decision.

(d) The time periods set forth in this section cannot be extended, except that the time period set forth in paragraph (c) of this section may be extended under the provisions of § 1.957(a).

Appeal to the Board of Patent Appeals and Interferences

§ 1.959 Notice of appeal and cross appeal to Board of Patent Appeals and Interferences.

(a) (1) Once a ''Right of Appeal Notice'' has been issued, by filing a notice of appeal within the time provided in § 1.953 and paying the fee set forth in § 1.17(e), the patent owner may appeal to the Board of Patent Appeals and Interferences with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.

(2) Once a ''Right of Appeal Notice'' has been issued, by filing a notice of appeal within the time provided in § 1.953 and paying the fee set forth in § 1.17(e), a third party requester involved in a reexamination proceeding may appeal to the Board of Patent Appeals and Interferences with respect to any final decision favorable to the patentability of any original or proposed amended or new claim of the patent.

(b) (1) Within fourteen days of service of a third party requester's notice of appeal, and upon payment of the fee set forth in § 1.17(e), a patent owner who has not filed a notice of appeal may file a notice of cross appeal with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.

(2) Within fourteen days of service of a patent owner's notice of appeal, and upon payment of the fee set forth in § 1.17(e), a third party requester who has not filed a notice of appeal may file a notice of cross appeal with respect to any final decision favorable to the patentability of any original or proposed amended or new claim of the patent.

(c) The appeal in a reexamination proceeding must identify the claim(s) appealed, and must be signed by the patent owner or third party requester, or their duly authorized attorney or agent.

(d) An appeal when taken must be taken from the rejection of all claims under rejection in a Right of Appeal Notice which the patent owner proposes to contest, or from the determination of patentability of all claims indicated as patentable in a Right of Appeal Notice which the third party requester proposes to contest. Questions relating to matters not affecting the merits of the invention may be required to be settled before an appeal can be considered.

(e) The time periods set forth in §§ 1.959 through 1.969 are subject to the provisions of § 1.957(a) for reexamination proceedings. See § 1.304(a) for extensions of time for filing a notice of appeal of the U.S. Court of Appeals for the Federal Circuit.

§ 1.961 Jurisdiction over appeal.

Jurisdiction over the patent under reexamination passes to the Board of Patent Appeals and Interferences upon transmittal of the file, including all briefs and examiner's answers, to the Board. Prior to the entry of a decision on the appeal, the Commissioner may sua sponte order the patent remanded to the examiner, for action consistent with the Commissioner's order.

§ 1.962 Appellant and respondent defined.

For the purposes of reexamination, appellant is any party filing a notice of appeal. A respondent is any opposing party responding to the appeal of the appellant. If more than one party appeals, each is an appellant with respect to the claims to which his or her appeal is directed and, to the extent each responds, each is a respondent with respect to the claims to which his or her opponent's appeal is directed.

§ 1.963 Time for filing briefs.

(a) If a party files a notice of appeal or cross appeal, the party must file an appellant brief within two months of the date of filing of their notice of appeal or cross appeal. However, if another party files a notice of appeal or cross appeal subsequent to that of the party, then the party must file an appeal brief within two months of the date of filing of the subsequent notice of appeal or cross appeal, so that the appellant briefs of all parties filing a notice of appeal or cross appeal will be due no later than two months after the last-filed notice.

(b) Once an appellant brief has been properly filed, an opposing party may file a respondent brief within one month from the date of service of the appellant brief. The examiner will consider both the appellant and respondent briefs and prepare an examiner's answer.

(c) The third party requester and the patent owner may each file a reply brief within one month of the date of the examiner's answer. No further brief will be acknowledged or considered.

§ 1.965 Applellant brief.

(a) Appellant(s) shall, within time limits for filing set forth in § 1.963, file a brief in triplicate and serve the brief on all parties in accordance with § 1.903. The brief must be accompanied by the requisite fee set forth in § 1.17(f) and must set forth the authorities and

arguments on which appellant will rely to maintain the appeal. Any arguments or authorities not included in the brief will be refused consideration by the Board of Patent Appeals and Interferences, unless good cause is shown.

(b) On failure of a party to file the brief, accompanied by the requisite fee, within the time allowed, the appeal shall stand dismissed with respect to the claims appealed by that party.

(c) The brief shall contain the following items under appropriate headings and in the order indicated below unless the brief is filed by a party who is not represented by a registered practitioner:

(1) *Real Party in Interest.* A statement identifying the real party in interest, if the party named in the caption of the brief is not the real party in interest.

(2) *Related Appeals and Interferences.* A statement identifying by number and filing date all other appeals or interferences known to the appellant, the appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) *Status of Claims.* A statement of the status of all the claims, pending or cancelled, and identifying the claims appealed.

(4) *Status of Amendments.* A statement of the status of any amendment filed subsequent to final rejection.

(5) *Summary of Invention.* A concise explanation of the invention or subject matter defined in the claims involved in the appeal, which shall refer the specification by column and line number, and to the drawing(s), if any, by reference characters.

(6) *Issues.* A concise statement of the issues presented for review.

(7) *Grouping of Claims.* For each ground of rejection, or, in the case where the appeal is by a third party requester, each determination of patentability or determination of inapplicability of a proposed rejection, which appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together and, in the argument under paragraph (c)(8) of this section, appellant explains why the claims of this group are believed to be separately patentable or unpatentable. Merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable.

(8) *Argument.* The contentions of appellant with respect to each of the issues presented for review in paragraph (c)(6) of this section, and the basis therefor, with citations of the authorities, statues, and parts of the record relief on. Each issue should be treated under a separate heading.

(i) For each rejection or, in the case where the appeal is by a third party requester, any other determination under 35 U.S.C. 112, first paragraph, the argument shall specify the errors in the rejection or other determination and how the first paragraph of 35 U.S.C. 112 is or is not complied with, including, as appropriate, how the specification and drawings, if any,

(A) describe or fail to describe the subject matter defined by each of the appealed claims, and

(B) enable or fail to enable any person skilled in the art to make and use the subject matter defined by each of the appealed claims, and

(ii) For each rejection, or in the case where the appeal is filed by a third party requester, any determination, under 35 U.S.C. 112, second paragraph, the argument shall specify the errors in the rejection or other determination and how the claims do or do not particularly point out and distinctly claim the subject matter which appellant regards as the invention.

(iii) For each rejection or, in the case where the appeal is by a third party requester, each determination of patentability, under 35 U.S.C. 102, the argument shall specify the errors in the rejection or determination and why the appealed claims are or are not patentable under 35 U.S.C. 102, including any specific limitations in the appealed claims which are not described in the prior art.

(iv) For each rejection or, in the case where the appeal is by a third party requester, each determination of patentability under 35 U.S.C. 103, the argument shall specify the errors in the rejection or determination and, if appropriate, the specific limitations in the appealed claims which are or are not described in the prior art, and shall explain how such limitations render the claimed subject matter obvious or unobvious over the prior art. If the rejection or determination is based upon a combination of references, the argument shall explain why the references, taken as a whole, do or do not suggest the claimed subject matter, and shall include, as may be appropriate, an explanation of why features disclosed in one reference may or may not properly be combined with features disclosed in another reference. A general argument that all the limitations are or are not described in a single reference does not satisfy the requirements of this paragraph.

(v) For any rejection or, in the case where the appeal is by a third party requester, any determination of patentability, other than those referred to in paragraphs (c)(8)(i) to (iv) of this section, the argument shall specify the errors in the rejection or other determination and the specific limitations in the appealed claims, if appropriate, or other reasons, which cause the rejection or other determination to be in error.

(9) *Appendix.* An appendix containing a copy of the claims involved in the appeal.

(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and provided with a period of one month within which to file an amended brief. If the appellant does not file an amended brief during the one-month period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed as to that party.

§ 1.967 Respondent brief.

(a) The brief(s) if the respondent(s) specified in § 1.963 must be filed in triplicate, served on all other parties in accordance with § 1.903 and be accompanied by the requisite fee set forth in § 1.17(f). Any arguments or authorities not included in the brief will be refused consideration by the Board of Patent Appeals and Interferences, unless good cause is shown. The respondent brief shall be limited to issues raised in the appellant brief to which the respondent brief is directed.

(b) The respondent brief shall contain the following items under appropriate headings and in the order here indicated, and may include an appendix containing portions of the record on which reliance is made:

(1) *Real party in Interest.* A statement identifying the real party in interest, if the party named as the respondent in the brief is not the real party in interest.

(2) *Related Appeals and Interferences.* A statement identifying by number and filing date all other appeals or interferences known to the respondent, the respondent's legal representative, or assignee (if any) which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) *Status of claims.* A statement accepting or disputing appellant's

statement of the status of claims. If appellant's statement of the status of claims is disputed, the errors in appellant's statement must be specified with particularity.

(4) *Status of amendments.* A statement accepting or disputing appellant's statement of the status of amendments. If appellant's statement of the status of amendments is disputed, the errors in appellant's statement must be specified with particularity.

(5) *Summary of invention.* A statement accepting or disputing appellant's summary of the invention or subject matter defined in the claims involved in the appeal. If appellant's summary of the invention or subject matter defined in the claims involved in the appeal is disputed, the errors in appellant's summary must be specified with particularity. A counter explanation of the invention may be made.

(6) *Issues.* A statement accepting or disputing appellant's statement of the issues presented for review and identifying any examiner's determination not to make a rejection proposed by the third party requester. If appellant's statement of the issues presented for review is disputed, the errors in appellant's statement must be specified with particularity. A counter statement of the issues for review may be made.

(7) *Grouping of claims.* A statement accepting or disputing any statement by appellant that allowed or rejected claims stand or fall together. If appellant's statement is disputed, the errors in appellant's statement must be specified with particularity. A counter statement may be made.

(8) *Argument.* A statement accepting or disputing the contentions of the appellant with respect to each of the issues. If a contention of the appellant or a determination of the examiner not to make a rejection proposed by the requester is disputed, the errors in appellant's argument or examiner's determination must be specified with particularity, stating the basis therefor, with citations of the authorities, statutes and parts of the record relied on. Each issue should be treated under a separate heading. An argument may be made with respect to each of the issues stated in the counter statement of the issues, with each counter stated issue being treated under a separate heading. The provisions of §§ 1.965(c)(8)(iii) and (iv) of these regulations shall apply to any argument raised under 35 U.S.C. 102 or 103.

(c) If a respondent brief is filed which does not comply with all the requirements of paragraph (b) of this section, respondent will be notified of the reasons for non-compliance and provided with a period of one month within which to file an amended brief. If the respondent does not file an amended brief during the one-month period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the respondent brief will not be received into the record and will not be considered.

§ 1.969 Examiner's answer.

The primary examiner may, within such time as may be directed by the Commissioner, furnish a written statement in answer to the patent owner's and/or third party requester's appellant brief or respondent brief including such explanation of the invention claimed and of the references and grounds of rejection or reasons for patentability as may be necessary, supplying a copy to the patent owner and each third party requester, if any. If the primary examiner shall find that the appeal is not regular in form or does not relate to an appealable action, he or she shall so state and a petition from such decision may be taken to the Commissioner as provided in § 1.181.

§ 1.971 Reply brief.

(A) The patent owner and any third party requester may each file a reply brief directed only to such new points of argument as may be raised in the examiner's answer, within one month from the date of such answer. The new points of argument shall be specifically identified in the reply brief. If the examiner determines that the reply brief is not directly only to new points of argument raised in the examiner's answer, the examiner may refuse entry of the reply brief and will so notify the appellant.

(b) If the examiner's answer expressly states that it includes a new ground of rejection or allowance of claims not previously allowed, the party adversely affected must file a reply thereto within one month from the date of such answer to avoid dismissal of the appeal as to the claims subject to the new ground of rejection or allowance; such reply may be accompanied by any amendment (in the case of the patent owner) or material appropriate to the new ground. See § 1.957 for extensions of time for filing a reply brief.

§ 1.973 Oral hearing.

(a) An oral hearing should be requested only in those circumstances in which the appellant, or a respondent who has filed a respondent brief under § 1.967, considers such a hearing necessary or desirable for a proper presentation of the appeal. An appeal decided without an oral hearing will receive the same consideration by the Board of Patent Appeals and Interferences as an appeal decided after oral hearing.

(b) If appellant, or a respondent who has filed a respondent brief under § 1.967, desires an oral hearing, he or she must file a written request for such hearing accompanied by the fee set forth in § 1.17(g) within one month after the date of the examiner's answer. If appellant, or a respondent who has filed a respondent brief under § 1.967, requests an oral hearing and submits therewith the fee set forth in § 1.17(g), an oral argument may be presented by, or on behalf of, the primary examiner if considered desirable by either the primary examiner or the Board. See § 1.957 for extensions of time in a reexamination proceeding.

(c) If no request and fee for oral hearing have been timely filed by an appellant or a respondent who has filed a respondent brief under § 1.967, the appeal will be assigned for consideration and decision. If an appellant or respondent who has filed a respondent brief under § 1.967 has requested an oral hearing and has submitted the fee set forth in § 1.17(g), a hearing date will be set, and notice thereof given to each appellant, to the primary examiner and to each respondent who has filed a respondent brief under § 1.967. The notice shall set a period within which all requests for oral hearing shall be submitted. Hearing will be held as stated in the notice, and oral argument will be limited to twenty minutes for each appellant and respondent, and fifteen minutes for the primary examiner unless otherwise ordered before the hearing begins.

§ 1.975 Affidavits or declarations after appeal.

Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented.

§ 1.977 Decision by the Board of Patent Appeals and Interferences.

(a) The Board of Patent Appeals and Interferences, in its decision, may affirm or reverse the decision of the examiner in whole or in part on the grounds and on the claims specified by the examiner, or on the grounds presented by a third party requester, or remand the reexamination proceeding to the examiner for further consideration. The affirmance of the rejection or allowance of a claim on any of the grounds

specified constitutes a general affirmance of the decision of the examiner on that claim, except as to any ground specifically reversed or otherwise stated. A rejection of claims by the examiner may also be affirmed on the basis of the arguments presented by the third party requester.

(b) Should the Board of Patent Appeals and Interferences have knowledge of any grounds for rejecting any appealed claim not raised in the appeal, it may include in the decision a statement to that effect with its reasons for so holding, which statement shall constitute a new rejection of the claims. A new rejection shall not be considered final for purposes of judicial review. When the Board of Patent Appeals and Interferences makes a new rejection of an appealed claim, the patent owner may exercise one of the following two options with respect to the new ground:

(1) The patent owner may submit an appropriate amendment of the claims so rejected or a showing of facts, or both, and have the matter reconsidered by the examiner, in which event the patent will be remanded to the examiner. The statement of the Board of Patent Appeals and Interferences shall be binding upon the examiner unless an amendment or showing of facts not previously of record be made which, in the opinion of the examiner, overcomes the new ground for rejection stated in the decision. Should the examiner again reject the claims, the patent owner may again appeal to the Board of Patent Appeals and Interferences.

(2) The patent owner may have the case reconsidered under § 1.979(b) by the Board of Patent Appeals and Interferences upon the same record. The request for reconsideration shall address the new ground for rejection and state with particularity the points believed to have been misapprehended or overlooked in rendering the decision and also state all other grounds upon which reconsideration is sought. Where request for such reconsideration is made, the Board of Patent Appeals and Interferences shall reconsider the new ground for rejection and, if necessary, rendered a new decision which shall include all grounds upon which a patent is refused. The decision on reconsideration is deemed to incorporate the earlier decision, except for those portions specifically withdrawn on reconsideration, and is final for the purpose of judicial review.

(c) Should the decision of the Board of Patent Appeals and Interferences include an explicit statement that a claim may be allowed in amended form, patent owner shall have the right to amend in conformity with such statement which shall be binding on the examiner in the absence of new references or grounds of rejection.

(d) Although the Board of Patent Appeals and Interferences normally will confine its decision to a review of rejections and allowances made by the examiner and/or arguments of the third party requester, should it have knowledge of any grounds for rejecting any allowed claim not advanced by the examiner or third party requester, it may recommend a rejection of the claim in its decision and remand the case to the examiner. In such event, the Board shall set a period, not less than one month, within which the patent owner may submit to the examiner an appropriate amendment, a showing of facts or reasons, or both, in order to avoid any grounds for rejection set forth in the recommendation of the Board of Patent Appeals and Interferences. The examiner shall be bound by any such recommended rejection and shall enter and maintain the recommended rejection unless an amendment or showing of facts not previously of record is filed which, in the opinion of the examiner, overcomes the recommended rejection. Should the examiner make the recommended rejection final the patent owner may again appeal to the Board of Patent Appeals and Interferences.

(e) Whenever a decision of the Board of Patent Appeals and Interferences includes a remand, that decision shall not be considered a final decision. When appropriate, upon conclusion of proceedings on remand before the examiner, the Board of Patent Appeals and Interferences may enter an order otherwise making its decision final.

(f) See § 1.957(a) for extensions of time to take action under this section.

§ 1.979 Action following decision.

(a) After decision by the Board of Patent Appeals and Interferences, the case shall be returned to the examiner, subject to a right of appeal or other review by the appellant or respondent, for such further action by the patent owner or by the examiner, as the condition of the case may require, to carry into effect the decision.

(b) Each party may file a single request for reconsideration or modification of the decision if filed within one month from the date of the original decision, unless that decision is so modified by the decision on reconsideration as to become, the effect, a new decision, and the Board of Patent Appeals and Interferences so states. The request for reconsideration shall state with particularity the points believed to have been misapprehended or overlooked in rendering the decision and also state all other grounds upon which reconsideration is sought. See § 1.957(a) for extensions of time for seeking reconsideration.

(c) The appeal proceedings are considered terminated by the dismissal of an appeal or the failure to timely file an appeal to the U.S. Court of Appeals for the Federal Circuit. The date of termination of proceedings is the date on which the appeal is dismissed or the date on which the time for appeal to the Federal Circuit expires. If an appeal to the Federal Circuit has been filed, proceedings are considered terminated when the appeal is terminated. An appeal to the Federal Circuit is terminated when the mandate is received by the Office. Upon termination of the reexamination proceeding, the Commission will issue a certificate under § 1.997.

§ 1.981 Reopening after decision.

(a) Cases which have been decided by the Board of Patent Appeals and Interferences will not be reopened or reconsidered by the primary examiner except under the provisions of § 1.979 without the written authority of the Commissioner, and then only for the reconsideration of matters not already adjudicated, sufficient cause being shown.

(b) In the event prosecution is reopened or the case is reconsidered by the primary examiner after decision by the Board of Patent Appeals and Interferences or by the U.S. Court of Appeals for the Federal Circuit, any third party requester who appealed or responded under § 1.967 may again present comments pursuant to § 1.947 and may appeal or participate in an appeal by the patent owner pursuant to § 1.959.

Appeal to the United States Court of Appeals for the Federal Circuit

§ 1.983 Appeal to the United States Court of Appeals for the Federal Circuit.

Any third party requester or patent owner involved in a reexamination proceeding who is a party to any appeal to the Board of Patent Appeals and Interferences and who is dissatisfied with the decision of the Board of Patent Appeals and Interferences may appeal to the U.S. Court of Appeals for the Federal Circuit and may be a party to any appeal thereto taken from a reexamination decision of the Board of Patent Appeals and Interferences. The appellant must take the following steps in such an appeal:

(a) in the Patent and Trademark Office file a written notice of appeal directed

to the Commissioner (see §§ 1.302 and 1.304); and

(b) in the Court, file a copy of the notice of appeal and pay the fee, as provided for in the rules of the Court. A third party requester is deemed not to have participated as a party to an appeal by the patent owner, and thereby not subject to § 1.909, unless within twenty days after the patent owner has filed notice of appeal pursuant to § 1.983(a), the third party requester files notice with the Commissioner electing to participate.

Proceedings Involving Same Patent as in Reexamination

§ 1.985 Notification of prior or concurrent proceedings.

Any person at any time may file a paper in a reexamination proceeding notifying the Office of a prior or concurrent proceeding in which the same patent is or was involved, such as interferences, reissues, reexaminations, or litigation and the results of such proceedings. Such paper must be limited to merely providing notice of the other proceeding without discussion of issues of the current reexamination proceeding.

§ 1.987 Stay of concurrent proceeding.

If a patent in the process of reexamination is or becomes involved in litigation or a reissue application for the patent is filed or pending, the Commissioner shall determine whether or not to stay the reexamination or reissue proceeding.

§ 1.989 Merger of concurrent reexamination proceedings.

(a) If reexamination is ordered while a prior reexamination proceeding is pending for the same patent, the reexamination proceedings will be merged and result in the issuance of a single certificate under § 1.997.

(b) A reexamination proceeding filed under § 1.915 which is merged with a reexamination proceeding filed under § 1.510 will result in the merged proceeding being governed by §§ 1.901–1.997.

§ 1.991 Merger of concurrent reissue application and reexamination proceeding.

If a reissue application and a reexamination proceeding on which an order pursuant to § 1.931 has been mailed are pending on a patent, a decision may be made to merge the two proceedings or to stay one of the two proceedings. Where merger is a reissue application and a reexamination proceeding is ordered, the merged examination will be conducted in accordance with §§ 1.171 through 1.179 and the patent owner will be required to place and maintain the same claims in the reissue application and the reexamination proceeding during the pendency of the merged proceeding. In a merged proceeding, participation by the third party requester shall be limited to issues within the scope of reexamination. The examiner's actions and any responses by the patent owner or third party requester in a merged proceeding will apply to both the reissue application and the reexamination proceeding and be physically entered into both files. Any reexamination proceeding merged with a reissue application shall be terminated by the grant of the reissue patent.

§ 1.993 Stay of concurrent interference and reexamination proceeding.

If a patent in the process of reexamination is or becomes involved in an interference, the Commissioner may stay reexamination or the interference. The Commissioner will not consider a request to stay an interference unless a motion (§ 1.635) to stay the interference has been presented to and denied by an administrative patent judge and the request is filed within ten (10) days of a decision by an administrative patent judge denying the motion for a stay or such other time as the administrative patent judge may set.

§ 1.995 Third party requester's participation rights preserved in merged proceeding.

When a third party requester is involved in one or more proceedings including a reexamination proceeding, the merger of such proceedings will be accomplished so as to preserve the third party requester's right to participate to the extent specifically provided for in these regulations. In merged proceedings involving different requesters, any paper filed by one party in the merged proceeding shall be served on all other parties of the merged proceeding.

Certificate

§ 1.997 Issuance of reexamination certificate after reexamination proceedings.

(a) Upon the conclusion of a reexamination proceeding, the Commissioner will issue a certificate in accordance with 35 U.S.C. 307 setting forth the results of the reexamination proceeding and the content of the patent following the reexamination proceeding.

(b) A certificate will be issued in each patent in which a reexamination proceeding has been ordered under § 1.931. Any statutory disclaimer filed by the patent owner will be made part of the certificate.

(c) The certificate will be mailed on the day of its date to the patent owner at the address as provided for in § 1.33(c). A copy of the certificate will also be mailed to the requester of the reexamination proceeding.

(d) If a certificate has been issued which cancels all of the claims of the patent, no further Office proceedings will be conducted with regard to that patent or any reissue applications or reexamination requests relating thereto.

(e) If the reexamination proceeding is terminated by the grant of a reissued patent as provided in § 1.965(d), the reissued patent will constitute the reexamination certificate required by this section and 35 U.S.C. 307.

(f) A notice of the issuance of each certificate under this section will be published in the Official Gazette on its date of issuance.

Dated: August 1, 1995.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 95–19488 Filed 8–10–95; 8:45 am]

BILLING CODE 3510–16–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5269–7]

National Oil and Hazardous Substance Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete Ossineke Groundwater Contamination Site.

SUMMARY: The Environmental Protection Agency (EPA) announces its intent to delete the Ossineke Groundwater Contamination Site (the ''OGC Site''), from the National Priorities List (NPL), 40 CFR part 300, appendix B, and requests public comment on this action. The NPL constitutes appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. This action to delete the OGC Site from the NPL is proposed because EPA's Office of Superfund (OSF) and the State of Michigan Department of Natural Resources (MDNR) have determined that using the Hazardous Substance Superfund (the ''Fund'') to fund further

remedial action under CERCLA at this Site is not appropriate. Either OUST or the State of Michigan will undertake any necessary corrective actions at the OGC Site under the authorities of the Michigan Leaking Underground Storage Tank (LUST) Statute, the Michigan Environmental Response Act (MERA), or Subtitle I of the Resource Conservation and Recovery Act (RCRA). MDNR evaluates and responds to sites according to a State specific priority ranking scheme. The OGC site will be evaluated and addressed consistent with this scheme.

DATES: Comments concerning the OGC Site may be submitted on or before September 11, 1995.

ADDRESSES: Comments to be considered by EPA in making this decision should be mailed to: Linda Nachowicz: Remedial Project Manager; Waste Management Division; Remedial Response Branch WI/MI; U.S. Environmental Protection Agency, Region 5; 77 West Jackson Boulevard; Chicago, IL 60604–3507.

FOR FURTHER INFORMATION CONTACT: Linda Nachowicz: Remedial Project Manager; Waste Management Division; Remedial Response Branch WI/MI; U.S. Environmental Protection Agency, Region 5; 77 West Jackson Boulevard; Chicago, IL 60604–3507; telephone (312) 886–6337.

SUPPLEMENTARY INFORMATION: Comprehensive information on the OGC Site is available for public review in the deletion docket that EPA Region 5 has prepared. The deletion docket contains the documents and information EPA reviewed in the decision to propose to delete the OGC Site from the NPL. The docket is available for public review during normal business hours at the EPA Region 5 docket room at the above address and at the NBD Alpena Bank; 11686 U.S. Highway 23 South; Ossineke, MI 49766.

Table of Contents

I. Introduction.
II. NPL Deletion Criteria.
III. Deletion Procedures.
IV. Basis for the Intended Deletion of the OGC Site.

I. Introduction

The Environmental Protection Agency (EPA) announces its intent to delete the Ossineke Groundwater Contamination Site in Ossineke, Michigan (the ''OGC Site''), from the National Priorities List (NPL), which constitutes appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan, 40 CFR Part 300 (NCP), and requests comments on this action.

The EPA identifies sites which may present a significant risk to public health, welfare, or the environment, and maintains the NPL as the list of those sites. Sites on the NPL may be the subject of remedial action financed by the Hazardous Substance Superfund Response Trust Fund (the ''Fund'') or by responsible parties. Pursuant to the NCP at 40 CFR 300.425(e)(3), any site deleted from the NPL remains eligible for future Fund-financed response actions and for re-listing on the NPL, if conditions at the site ever warrant such action.

The EPA will accept comments concerning the proposal to delete the OGC Site from the NPL for thirty (30) calendar days after 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 the history of the OGC Site and explains how the OGC Site meets the deletion criteria.

II. NPL Deletion Criteria

The NCP establishes the criteria that the Agency uses to delete sites from the NPL. In accordance with the NCP at 40 CFR 300.425(e), sites may be deleted from the NPL where no further response under CERCLA is appropriate. In making this determination, EPA considers, in consultation with the State, whether any of the following criteria have been met: Whether responsible or other parties have implemented all appropriate and required response action; whether 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 whether the release of hazardous substances poses no significant threat to public health or the environment, and, therefore, taking of remedial measures is not appropriate. (55 FR 8813, March 8, 1990.)

In the past, EPA has indicated that in some cases it may be appropriate to delete from the NPL those sites that meet all the criteria for deferral to RCRA, and, in addition, present circumstances that otherwise make deletion appropriate. See 51 FR 21059 (June 10, 1986); 53 FR 30008 (August 9, 1988). On August 9, 1988 (53 FR 30009), EPA indicated that while it would not systematically review sites already on the NPL to see whether they are eligible for deletion on this basis, it would consider requests for deletion that showed the circumstances to be appropriate.

The Underground Storage Tanks (UST) Program was established by Subtitle I of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA) and as amended by SARA. The UST Program has authority to address releases of petroleum from leaking underground storage tanks.

Deletion under this approach does not indicate that the cleanup has been completed, but rather that no further Superfund involvement is appropriate, and that EPA has determined that any necessary corrective action will be considered under another statutory authority, RCRA Subtitle I.

As discussed further below, the EPA has determined that the above criteria for deletion of the OGC Site from the NPL have been fulfilled. Any necessary corrective action at the OGC Site will be considered under either the EPA's UST Program or the Michigan Department of Natural Resources, pursuant to RCRA Subtitle I and the Michigan Leaking Underground Storage Tank statute. No further Fund-financed action, pursuant to CERCLA, at the OGC Site is deemed appropriate at this time.

III. Deletion Procedures

The NCP at 40 CFR 300.425(e) specifies the procedures to be followed in deleting sites from the NPL. Prior to proposing deletion from the NPL and prior to developing the Notice of Intent to Delete, EPA must consult with the State. The EPA, in consultation with the State, must decide whether the criteria for deletion of § 300.425(e) have been met.

Section 300.425(e) also directs that the Notice of Intent to Delete be published in the **Federal Register**, and that a concurrent notice be published in a local newspaper of general circulation near the site. By publication of this **Federal Register** notice for the OGC Site, EPA is extending to the public a period of thirty (30) calendar days after publication to comment on the proposed deletion. Information supporting the EPA's intent to delete the OGC Site is contained in the information repository and deletion docket, and is available to the public for inspection.

EPA will accept and evaluate public comments before making a final decision, and will address all significant comments made and significant data provided in a Responsiveness Summary. The Responsiveness Summary will be placed in the deletion docket. If, after consideration of these comments, EPA decides to proceed with the deletion, EPA will publish in the **Federal**

Register a final notice announcing the deletion.

The following procedures are being used for the intended deletion of the OGC Site:

The State of Michigan has concurred with this decision to address contamination under RCRA, Subtitle I authority.

Concurrent with this national Notice of Intent to Delete, a local notice will be published in the local newspaper and will be distributed to appropriate federal, state and local officials and other interested parties. This local notice will specify a 30 day comment period.

The Region has made all relevant documents available in the Regional Office and local site information repository.

IV. Basis for the Intended Deletion of the OGC Site

The Ossineke Groundwater Contamination Site is located in the southern portion of the Village of Ossineke near the intersection of U.S. Route 23 and Nicholson Hill Road in Alpena County, Michigan. The Site lies approximately 1.8 miles southwest of Lake Huron.

In June 1977, the Alpena County Health Department (ACHD) began receiving complaints from Ossineke residents about odors in their drinking water. Sampling confirmed the presence of hydrocarbons. The ACHD advised residents using the upper aquifer to stop using their wells as a drinking water source. On April 13, 1982, the Michigan State Police responded to a report of gas odors in the basements of several businesses. These reports were verified and it was discovered that a snow plow had hit a self-service gasoline pump during the winter, causing the release of an unknown amount of gasoline.

The Site was evaluated by U.S. EPA's OSF in July 1982 and placed on the National Priorities List (NPL) in September 1983. In June 1986, residential wells affected by contamination were replaced by the Michigan Department of Public Health.

The final Remedial Investigation (RI) Report was issued on January 31, 1991. Field work for the RI began in May 1989 and was completed in March 1990. The results of the RI show that contaminants of concern at the OGC Site are petroleum-related and were likely caused by petroleum or petroleum product releases from leaking USTs in the area. A CERCLA Feasibility Study was not conducted for the OGC Site.

On June 28, 1991, a Record of Decision for the OGC Site was signed by the Regional Administrator of EPA Region 5. The ROD selected the remedy of no further action.

On the basis of the RI and ROD, the OGC Site was referred to the EPA UST Program established by Subtitle I of the Resource Conservation and Recovery Act (RCRA). The State of Michigan also has regulatory authority and jurisdiction to address releases from petroleum USTs, under Michigan's Leaking Underground Storage Tank (LUST) statute enacted in 1988, and has been delegated the authority to address this facility under its Cooperative Agreement under Subtitle I of RCRA. The State of Michigan, through the Michigan Department of Natural Resources, concurs with the ROD for the OGC Site.

Responsibility for the determining whether future clean-up of the OGC Site shall be taken is with the State of Michigan DNR under a cooperative agreement and the EPA's UST Program. Any petroleum-related contamination currently at the OGC Site as a result of leaking USTs may be addressed, if appropriate, either by the EPA's UST Program or by the Michigan Department of Natural Resources. Such actions may include corrective actions and/or enforcement actions under the authority of RCRA Subtitle I, the Michigan LUST statute, or the Michigan Environmental Response Act (MERA) (1982 P.A. 307, as amended).

Based on the above circumstances, EPA has concluded that in this case deletion from the NPL of the OGC Site is appropriate. In this case, EPA can make a finding that all appropriate Fund-financed response under CERCLA has been implemented and that no further CERCLA response action by responsible parties is appropriate. Deletion under this approach does not indicate that the clean-up has been completed, but rather that no further Superfund involvement is necessary at the OGC Site, and that EPA expects any necessary response actions to be completed under RCRA, Subtitle I.

Dated: December 8, 1994.

Valdas V. Adamkus,

Regional Administrator, U.S. EPA Region 5.

[FR Doc. 95–19003 Filed 8–10–95; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 60, No. 155

Friday, August 11, 1995

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

Forest Service

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Bureau of Land Management

[WO–1550–00–7111–111–24–1A]

Fish and Wildlife Service

National Biological Service

National Park Service

Federal Wildland Fire Management Policy and Program Review

AGENCIES: Forest Service, Agriculture; Bureau of Indian Affairs, Bureau of Land Management, Fish and Wildlife Service, National Biological Service, National Park Service, Interior.

ACTION: Notice; opening of public comment period.

SUMMARY: On June 22, 1995, the Departments of Agriculture and the Interior gave notice in the **Federal Register** (60 FR 32485) of a draft report of the Federal Wildland Fire Management Policy and Program Review and invited public comment. The period for commenting on this draft report ended July 24, 1995. However, the agencies have received numerous requests from reviewers for additional time to complete the review and prepare responses. Accordingly, an additional 45-day comment period is hereby established to allow reviewers to submit comments on the draft report.

DATES: Comments must be submitted in writing by September 25, 1995.

ADDRESSES: Comments should be directed to Federal Wildland Fire Policy and Program Review, Department of the Interior, 1849 C Street NW, Mail Stop 7356; Washington, D.C. 20240, or via FAX to (202) 208–5078.

FOR FURTHER INFORMATION CONTACT: Tim Hartzell, Bureau of Land Management, (202) 208–5472; John Chambers, USDA Forest Service, (202) 205–1505. Additional copies of the draft report may be obtained by calling BLM's National Office of Fire and Aviation, (208) 387–5150, or the National Interagency Fire Center, (208) 387–5457.

For the Department of Agriculture.

Jack Ward Thomas,

Chief, Forest Service.

Dated: August 3, 1995.

For the Department of the Interior.

Claudia P. Schechter,

Director of Operations, USDOI.

Dated: August 3, 1995.

[FR Doc. 95–19892 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 760]

Revision of Grant of Authority, for Subzone 87B, CITGO Petroleum Corp., Lake Charles, LA

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Board (the Board) authorized subzone status at the refinery complex of CITGO Petroleum Corporation in Lake Charles, Louisiana, in 1989, subject to two conditions (Subzone 87B, Board Order 420, 54 FR 27660, 6/30/89);

Whereas, the Lake Charles Harbor & Terminal District, grantee of FTZ 87, has requested, pursuant to § 400.32(b)(1)(i), a revision (filed 6/12/95, A(32b1)–9–95; FTZ Doc. 38–95, assigned 7/19/95) of the grant of authority for FTZ Subzone 87B which would make its scope of authority identical to that recently granted for FTZ Subzone 199A at the refinery complex of Amoco Oil Company, Texas City, Texas (Board Order 731, 60 FR 13118, 3/10/95); and,

Whereas, the request has been reviewed and the Assistant Secretary for Import Administration, acting for the Board pursuant to § 400.32(b)(1), concurs in the recommendation of the Executive Secretary, and approves the request;

Now therefore, the Board hereby orders that, subject to the Act and the Board's regulations, including § 400.28, Board Order 420 is revised to replace the two conditions currently listed in the Order with the following conditions:

1. Foreign status (19 CFR 146.41, 146.42) products consumed as fuel for the refinery shall be subject to the applicable duty rate.

2. Privileged foreign status (19 CFR 146.41) shall be elected on all foreign merchandise admitted to the subzone, except that non-privileged foreign (NPF) status (19 CFR 146.42) may be elected on refinery inputs covered under HTSUS Subheadings # 2709.00.1000–# 2710.00.1050 and # 2710.00.2500 which are used in the production of:

—Petrochemical feedstocks and refinery by-products (FTZ staff report, Appendix B);
—Products for export; and,
—Products eligible for entry under HTSUS # 9808.00.30 and 9808.00.40 (U.S. Government purchases).

3. The authority with regard to the NPF option is initially granted until September 30, 2000, subject to extension.

Signed at Washington, DC, this 4th day of August 1995.

Susan G. Esserman,

Assistant Secretary of Commerce for Import Administration Alternate Chairman Foreign-Trade Zones Board.

[FR Doc. 95–19940 Filed 8–10–95; 8:45 am]

BILLING CODE 3510–DS–P

U.S. DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 759]

Revision of Grant Authority, Subzone 122I, CITGO Refining and Chemicals Inc., Corpus Christi, TX

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Board (the Board) authorized subzone status at the refinery complex of CITGO Refining and Chemicals Inc. (formerly owned by Champlin Refining Company) in Corpus Christi, Texas, in 1988, subject to two conditions (Subzone 122I, Board Order 407, 53 FR 52457, 12/28/88);

Whereas, the Port of Corpus Christi Authority, grantee of FTZ 122, has requested, pursuant to § 400.32(b)(1)(i), a revision (filed 6/12/95, A(32b1)–8–95; FTZ Doc. 37–95, assigned 7/19/95) of the grant of authority for FTZ Subzone 122I which would make its scope of authority identical to that recently granted for FTZ Subzone 199A at the refinery complex of Amoco Oil Company, Texas City, Texas (Board Order 731, 60 FR 13118, 3/10/95); and,

Whereas, the request has been reviewed and the Assistant Secretary for Import Administration, acting for the Board pursuant to § 400.32(b)(1), concurs in the recommendation of the Executive Secretary, and approves the request;

Now Therefore, the Board hereby orders that, subject to the Act and the Board's regulations, including § 400.28, Board Order 407 is revised to replace the two conditions currently listed in the Order with the following conditions:

1. Foreign status (19 CFR 146.41, 146.42) products consumed as fuel for the refinery shall be subject to the applicable duty rate.

2. Privileged foreign status (19 CFR 146.41) shall be elected on all foreign merchandise admitted to the subzone, except that non-privileged foreign (NPF) status (19 CFR 146.42) may be elected on refinery inputs covered under HTSUS Subheadings # 2709.00.1000—# 2710.00.1050 and # 2710.00.2500 which are used in the production of:

—Petrochemical feedstocks and refinery by-products (FTZ staff report, Appendix B);

—Products for export; and,

—Products eligible for entry under HTSUS # 9808.00.30 and 9808.00.40 (U.S. Government purchases).

3. The authority with regard to the NPF option is initially granted until September 30, 2000, subject to extension.

Signed at Washington, DC, this 4th day of August 1995.

Susan G. Esserman,

Assistant Secretary of Commerce for Import Administration Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 95–19941 Filed 8–10–95; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–357–810]

Antidumping Duty Order: Oil Country Tubular Goods From Argentina

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 11, 1995.

FOR FURTHER INFORMATION CONTACT: John Beck or Jennifer Stagner, Office of Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–3464 or (202) 482–1673, respectively.

Scope of Order

The merchandise covered by this order are oil country tubular goods (OCTG), hollow steel products of circular cross-section, including oil well casing, tubing, and drill pipe, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished or unfinished (including green tubes and limited service OCTG products). This scope does not cover casing, tubing, or drill pipe containing 10.5 percent or more of chromium. The OCTG subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers:

7304.20.10.10, 7304.20.10.20, 7304.20.10.30, 7304.20.10.40, 7304.20.10.50, 7304.20.10.60, 7304.20.10.80, 7304.20.20.10, 7304.20.20.20, 7304.20.20.30, 7304.20.20.40, 7304.20.20.50, 7304.20.20.60, 7304.20.20.80, 7304.20.30.10, 7304.20.30.20, 7304.20.30.30, 7304.20.30.40, 7304.20.30.50, 7304.20.30.60, 7304.20.30.80, 7304.20.40.10, 7304.20.40.20, 7304.20.40.30, 7304.20.40.40, 7304.20.40.50, 7304.20.40.60, 7304.20.40.80, 7304.20.50.15, 7304.20.50.30, 7304.20.50.45, 7304.20.50.60, 7304.20.50.75, 7304.20.60.15, 7304.20.60.30, 7304.20.60.45, 7304.20.60.60, 7304.20.60.75, 7304.20.70.00, 7304.20.80.30, 7304.20.80.45, 7304.20.80.60, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.20.10.30, 7306.20.10.90, 7306.20.20.00, 7306.20.30.00, 7306.20.40.00, 7306.20.60.10, 7306.20.60.50, 7306.20.80.10, and 7306.20.80.50.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994.

Antidumping Duty Order

On August 2, 1995, in accordance with section 735(d) of the Tariff Act of 1930, as amended (the Act), the U.S. International Trade Commission (ITC) notified the Department of its final determination in this investigation. In its determination, the ITC found two like products: (1) Drill pipe; and (2) OCTG other than drill pipe (*i.e.*, casing and tubing). The ITC determined that imports of drill pipe from Argentina threaten material injury to a U.S. industry. Because there was no suspension of liquidation between the Department's preliminary and final determinations due to the Department's negative amended preliminary determination, the ITC did not determine, pursuant to section 735(b)(4)(B) of the Act, that, but for the suspension of liquidation of entries of drill pipe from Argentina, the domestic industry would have been materially injured.

When the ITC finds threat of material injury, and makes a negative ''but for'' finding, the ''Special Rule'' provision of section 736(b)(2) applies. Therefore, all unliquidated entries of drill pipe from Argentina, entered or withdrawn from warehouse, for consumption on or after the date on which the ITC published its notice of final determination of threat of material injury in the **Federal Register**, are subject to the assessment of antidumping duties.

Regarding OCTG other than drill pipe, the ITC determined that imports of such merchandise are materially injuring a U.S. industry. Therefore, all unliquidated entries of OCTG other than drill pipe from Argentina, entered or withdrawn from warehouse, are also subject to assessment of antidumping duties.

Therefore, the Department will direct the Customs Service to terminate the suspension of liquidation for entries of drill pipe imported from Argentina entered, or withdrawn from warehouse, for consumption before the date on which the ITC published its notice of final determination of threat of material injury in the **Federal Register**, and to release any bond or other security, and refund any cash deposit, posted to secure the payment of estimated antidumping duties with respect to these entries.

In accordance with section 736 of the Act, the Department will also direct the Customs Service to assess antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all

entries of OCTG from Argentina. These antidumping duties will be assessed on all unliquidated entries of: (1) drill pipe from Argentina entered, or withdrawn from warehouse, for consumption on or after the date on which the ITC published its notice of final determination of threat of material injury in the **Federal Register**; and (2) OCTG other than drill pipe from Argentina entered, or withdrawn from warehouse, for consumption on or after June 28, 1995, the date on which the Department published its final determination notice in the **Federal Register** (60 FR 33539).

On or after the date of publication of this notice in the **Federal Register**, the Customs Service must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Manufacturer/producer/exporter	Weighted-average margin percentage
Siderca S.A.I.C	1.36
All Others	1.36

This notice constitutes the antidumping duty order with respect to OCTG from Argentina, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, Room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: August 7, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–19933 Filed 8–10–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–201–817]

Antidumping Duty Order: Oil Country Tubular Goods From Mexico

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 11, 1995.

FOR FURTHER INFORMATION CONTACT: Jennifer Stagner or John Beck, Office of Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1673 or (202) 482–3464, respectively.

Scope of Order

The merchandise covered by this order are oil country tubular goods (OCTG), hollow steel products of circular cross-section, including oil well casing, tubing, and drill pipe, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished or unfinished (including green tubes and limited service OCTG products). This scope does not cover casing, tubing, or drill pipe containing 10.5 percent or more of chromium. The OCTG subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers:

7304.20.10.10, 7304.20.10.20, 7304.20.10.30, 7304.20.10.40, 7304.20.10.50, 7304.20.10.60, 7304.20.10.80, 7304.20.20.10, 7304.20.20.20, 7304.20.20.30, 7304.20.20.40, 7304.20.20.50, 7304.20.20.60, 7304.20.20.80, 7304.20.30.10, 7304.20.30.20, 7304.20.30.30, 7304.20.30.40, 7304.20.30.50, 7304.20.30.60, 7304.20.30.80, 7304.20.40.10, 7304.20.40.20, 7304.20.40.30, 7304.20.40.40, 7304.20.40.50, 7304.20.40.60, 7304.20.40.80, 7304.20.50.15, 7304.20.50.30, 7304.20.50.45, 7304.20.50.60, 7304.20.50.75, 7304.20.60.15, 7304.20.60.30, 7304.20.60.45, 7304.20.60.60, 7304.20.60.75, 7304.20.70.00, 7304.20.80.30, 7304.20.80.45, 7304.20.80.60, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.20.10.30, 7306.20.10.90, 7306.20.20.00, 7306.20.30.00, 7306.20.40.00, 7306.20.60.10, 7306.20.60.50, 7306.20.80.10, and 7306.20.80.50.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994.

Antidumping Duty Order

On August 2, 1995, in accordance with section 735(d) of the Tariff Act of 1930, as amended (the Act), the U.S. International Trade Commission (ITC) notified the Department of its final determination in this investigation. In its determination, the ITC found two like products: (1) Drill pipe; and (2) OCTG other than drill pipe (*i.e.*, casing and tubing). The ITC determined that imports of drill pipe from Mexico threaten material injury to a U.S. industry. Because there was no suspension of liquidation between the Department's preliminary and final determinations due to the Department's negative preliminary determination, the ITC did not determine, pursuant to section 735(b)(4)(B) of the Act, that, but for the suspension of liquidation of entries of drill pipe from Mexico, the domestic industry would have been materially injured.

When the ITC finds threat of material injury, and makes a negative ''but for'' finding, the ''Special Rule'' provision of section 736(b)(2) applies. Therefore, all unliquidated entries of drill pipe from Mexico, entered or withdrawn from warehouse, for consumption on or after the date on which the ITC published its notice of final determination of threat of material injury in the **Federal Register**, are subject to the assessment of antidumping duties.

Regarding OCTG other than drill pipe, the ITC determined that imports of such merchandise are materially injuring a U.S. industry. Therefore, all unliquidated entries of OCTG other than drill pipe from Mexico, entered or withdrawn from warehouse, are also subject to the assessment of antidumping duties.

Therefore, the Department will direct the Customs Service to terminate the suspension of liquidation for entries of drill pipe imported from Mexico entered, or withdrawn from warehouse, for consumption before the date on which the ITC published its notice of final determination of threat of material injury in the **Federal Register**, and to release any bond or other security, and refund any cash deposit, posted to secure the payment of estimated antidumping duties with respect to these entries.

In accordance with section 736 of the Act, the Department will also direct the Customs Service to assess antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of OCTG from Mexico. These antidumping duties will be assessed on all unliquidated entries of: (1) Drill pipe from Mexico entered, or withdrawn from warehouse, for consumption on or after the date on which the ITC published its notice of final determination of threat of material injury in the **Federal Register**; and (2) OCTG other than drill pipe from Mexico entered, or withdrawn from warehouse, for consumption on or after June 28, 1995, the date on which the Department published its final determination notice in the **Federal Register** (60 FR 33567).

On or after the date of publication of this notice in the **Federal Register**, the Customs Service must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Manufacturer/producer/exporter	Weighted-average margin percentage
Tubos de Acero de Mexico, S.A.	23.79
All Others	23.79

This notice constitutes the antidumping duty order with respect to OCTG from Mexico, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, Room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: August 7, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–19934 Filed 8–10–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–475–816]

Antidumping Duty Order: Oil Country Tubular Goods from Italy

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 11, 1995.

FOR FURTHER INFORMATION CONTACT: William Crow or Brian Smith, Office of Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC. 20230; telephone (202) 482–0116 or (202) 482–1766, respectively.

Scope of Order

In its final determination, the Department determined that oil country tubular goods (OCTG) comprised one class or kind of merchandise. In its final determination, the International Trade Commission (ITC) found two like products: (1) Drill pipe and (2) OCTG other than drill pipe (*i.e.*, casing and tubing). The ITC did not find material injury, or threat of material injury with regard to drill pipe. Consequently, the antidumping duty order covers only OCTG other than drill pipe.

The merchandise covered by this order are OCTG, hollow steel products of circular cross-section, including only oil well casing and tubing pipe, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished or unfinished (including green tubes and limited service OCTG products). This scope does not cover casing or tubing pipe containing 10.5 percent or more of chromium, or drill pipe. The OCTG subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers:

7304.20.10.10, 7304.20.10.20, 7304.20.10.30, 7304.20.10.40, 7304.20.10.50, 7304.20.10.60, 7304.20.10.80, 7304.20.20.10, 7304.20.20.20, 7304.20.20.30, 7304.20.20.40, 7304.20.20.50, 7304.20.20.60, 7304.20.20.80, 7304.20.30.10, 7304.20.30.20, 7304.20.30.30, 7304.20.30.40, 7304.20.30.50, 7304.20.30.60, 7304.20.30.80, 7304.20.40.10, 7304.20.40.20, 7304.20.40.30, 7304.20.40.40, 7304.20.40.50, 7304.20.40.60, 7304.20.40.80, 7304.20.50.15, 7304.20.50.30, 7304.20.50.45, 7304.20.50.60, 7304.20.50.75, 7304.20.60.15, 7304.20.60.30, 7304.20.60.45, 7304.20.60.60, 7304.20.60.75, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.20.10.30, 7306.20.10.90, 7306.20.20.00, 7306.20.30.00, 7306.20.40.00, 7306.20.60.10, 7306.20.60.50, 7306.20.80.10, and 7306.20.80.50.

Drill pipe is classifiable under HTSUS item numbers 7304.20.70.00, 7304.20.80.30, 7304.20.80.45, and 7304.20.80.60. However, pursuant to the ITC's negative determination regarding drill pipe, we have deleted these numbers from the scope of this order.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994.

Antidumping Duty Order

On August 2, 1995, in accordance with section 735(d) of the Act, the U.S. International Trade Commission (ITC) notified the Department that imports of drill pipe from Italy do not cause or threaten material injury to a U.S. industry. Therefore, the scope of this order does not include drill pipe.

However, the ITC did find that imports of OCTG other than drill pipe from Italy materially injure a U.S. industry. Therefore, in accordance with section 736 of the Act, the Department will direct U.S. Customs officers to assess, upon further advice by the administering authority pursuant to section 736(a)(1) of the Act, antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of OCTG other than drill pipe from Italy. These antidumping duties will be assessed on all unliquidated entries of OCTG other than drill pipe from Italy entered, or withdrawn from warehouse, for consumption on or after February 2, 1995, the date on which the Department published its preliminary determination notice in the **Federal Register** (60 FR 6515).

The Department will also direct U.S. Customs officers to terminate the suspension of liquidation of entries of drill pipe from Italy entered, or withdrawn from warehouse, for consumption on or after February 2, 1995, and to release any bond or other security, and refund any cash deposit, posted to secure the payment of estimated antidumping duties with respect to these entries.

On or after the date of publication of this notice in the **Federal Register**, U.S. Customs officers must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Manufacturer/producer/exporter	Weighted-average margin percentage
Dalmine S.p.A	49.78
Acciaierie Tubificio Arvedi S.p.A.	49.78
General Sider Europa S.p.A.	49.78
All Others	49.78

This notice constitutes the antidumping duty order with respect to OCTG other than drill pipe from Italy, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, Room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: August 4, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–19935 Filed 8–10–95; 8:45 am]

BILLING CODE 3510–DS-P

[A–580–825]

Antidumping Duty Order: Oil Country Tubular Goods From Korea

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 11, 1995.

FOR FURTHER INFORMATION CONTACT: Brian C. Smith or John Beck, Office of

Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC. 20230; telephone (202) 482–1766 or (202) 482–3464, respectively.

Scope of Order

In its final determination, the Department determined that oil country tubular goods (OCTG) comprised one class or kind of merchandise. In its final determination, the International Trade Commission (ITC) found two like products: (1) Drill pipe and (2) OCTG other than drill pipe (*i.e.*, casing and tubing). The ITC did not find material injury, or threat of material injury with regard to drill pipe. Consequently, the antidumping duty order covers only OCTG other than drill pipe.

The merchandise covered by this order are OCTG, hollow steel products of circular cross-section, including only oil well casing and tubing, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished or unfinished (including green tubes and limited service OCTG products). This scope does not cover casing or tubing pipe containing 10.5 percent or more of chromium, or drill pipe. The OCTG subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers:

7304.20.10.10, 7304.20.10.20, 7304.20.10.30, 7304.20.10.40, 7304.20.10.50, 7304.20.10.60, 7304.20.10.80, 7304.20.20.10, 7304.20.20.20, 7304.20.20.30, 7304.20.20.40, 7304.20.20.50, 7304.20.20.60, 7304.20.20.80, 7304.20.30.10, 7304.20.30.20, 7304.20.30.30, 7304.20.30.40, 7304.20.30.50, 7304.20.30.60, 7304.20.30.80, 7304.20.40.10, 7304.20.40.20, 7304.20.40.30, 7304.20.40.40, 7304.20.40.50, 7304.20.40.60, 7304.20.40.80, 7304.20.50.15, 7304.20.50.30, 7304.20.50.45, 7304.20.50.60, 7304.20.50.75, 7304.20.60.15, 7304.20.60.30, 7304.20.60.45, 7304.20.60.60, 7304.20.60.75, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.20.10.30, 7306.20.10.90, 7306.20.20.00, 7306.20.30.00, 7306.20.40.00, 7306.20.60.10, 7306.20.60.50, 7306.20.80.10, and 7306.20.80.50.

Drill pipe is classifiable under HTSUS item numbers 7304.20.70.00, 7304.20.80.30, 7304.20.80.45, and 7304.20.80.60. However, pursuant to the ITC's negative determination regarding drill pipe, we have deleted these numbers from the scope of this order.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994.

Antidumping Duty Order

On August 2, 1995, in accordance with section 735(d) of the Act, the U.S. International Trade Commission (ITC) notified the Department of its final determination in this investigation that imports of drill pipe from Korea do not cause or threaten material injury to a U.S. industry. Therefore, the scope of this order does not include drill pipe.

However, the ITC did find that imports of OCTG other than drill pipe from Korea materially injure a U.S. industry. Therefore, in accordance with section 736 of the Act, the Department will direct U.S. Customs officers to assess, upon further advice by the administering authority pursuant to section 736(a)(1) of the Act, antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of OCTG other than drill pipe from Korea except those entries of Hyundai Steel Pipe Company, Ltd. These antidumping duties will be assessed on all unliquidated entries of OCTG other than drill pipe from Korea, except those entries from Hyundai Steel Pipe Company, Ltd., entered, or withdrawn from warehouse, for consumption on or after February 2, 1995, the date on which the Department published its preliminary determination notice in the **Federal Register** (60 FR 6507).

On or after the date of publication of this notice in the **Federal Register**, U.S. Customs officers must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Manufacturer/producer/exporter	Weighted-average margin percentage
Hyundai Steel Pipe Company, Ltd.	00.00
Union Steel Manufacturing Company	12.17
All Others	12.17

This notice constitutes the antidumping duty order with respect to OCTG other than drill pipe from Korea, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, Room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Dated: August 4, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–19936 Filed 8–10–95; 8:45 am]

BILLING CODE 3510–DS–P

[A–588–835]

Antidumping Duty Order: Oil Country Tubular Goods From Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: August 11, 1995.

FOR FURTHER INFORMATION CONTACT: Brian Smith or John Beck, Office of Antidumping Duty Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1766 or (202) 482–3464, respectively.

Scope of Order

The merchandise covered by this order are oil country tubular goods (OCTG), hollow steel products of circular cross-section, including only oil well casing, tubing and drill pipe, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, whether or not conforming to American Petroleum Institute (API) or non-API specifications, whether finished or unfinished (including green tubes and limited service OCTG products). This scope does not cover casing, tubing, or drill pipe containing 10.5 percent or more of chromium. The OCTG subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers:

7304.20.10.10, 7304.20.10.20, 7304.20.10.30, 7304.20.10.40, 7304.20.10.50, 7304.20.10.60, 7304.20.10.80, 7304.20.20.10, 7304.20.20.20, 7304.20.20.30, 7304.20.20.40, 7304.20.20.50, 7304.20.20.60, 7304.20.20.80, 7304.20.30.10, 7304.20.30.20, 7304.20.30.30, 7304.20.30.40, 7304.20.30.50, 7304.20.30.60, 7304.20.30.80, 7304.20.40.10, 7304.20.40.20, 7304.20.40.30, 7304.20.40.40, 7304.20.40.50, 7304.20.40.60, 7304.20.40.80, 7304.20.50.15, 7304.20.50.30, 7304.20.50.45, 7304.20.50.60, 7304.20.50.75, 7304.20.60.15, 7304.20.60.30, 7304.20.60.45, 7304.20.60.60, 7304.20.60.75, 7304.20.70.00, 7304.20.80.30, 7304.20.80.45, 7304.20.80.60, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.20.10.30, 7306.20.10.90, 7306.20.20.00, 7306.20.30.00, 7306.20.40.00, 7306.20.60.10, 7306.20.60.50, 7306.20.80.10, and 7306.20.80.50.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994.

Antidumping Duty Order

On August 2, 1995, in accordance with section 735(d) of the Tariff Act of 1930 (the Act), the U.S. International Trade Commission (ITC) notified the Department of its final determination in this investigation. In its determination, the ITC found two like products: (1) Drill pipe; and (2) OCTG other than drill pipe (*i.e.*, casing and tubing). The ITC determined that imports of drill pipe from Japan threaten material injury to a U.S. industry. However, the ITC did not determine that but for the suspension of liquidation of entries of drill pipe from Japan, the domestic industry would have been materially injured, pursuant to section 735(b)(4)(B) of the Act.

When the ITC finds threat of material injury, and makes a negative ''but for'' finding, the ''Special Rule'' provision of section 736(b)(2) applies. Therefore, all unliquidated entries of drill pipe from Japan, entered or withdrawn from warehouse, for consumption on or after the date on which the ITC published its notice of final determination of threat of material injury in the **Federal Register**, are liable for the assessment of antidumping duties.

Pursuant to section 736(b)(2), the Department will direct the Customs Service to terminate the suspension of liquidation for entries of drill pipe imported from Japan entered, or withdrawn from warehouse, for consumption before the date on which the ITC published its notice of final determination of threat of material injury in the **Federal Register**, and to release any bond or other security, and to refund any cash deposit, posted to secure the payment of estimated antidumping duties with respect to entries of the merchandise entered or withdrawn from warehouse for consumption before that date.

Regarding OCTG other than drill pipe, the ITC determined that imports of such merchandise are materially injuring a U.S. industry. Therefore, in accordance with section 736(a) of the Act, the Department will direct the Customs Service to assess antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the United States price for all entries of OCTG other than drill pipe from Japan. These antidumping duties will be assessed on all unliquidated entries of OCTG other than drill pipe from Japan entered, or withdrawn from warehouse, for consumption on or after February 2, 1995, the date on which the Department published its preliminary determination notice in the **Federal Register** (60 FR 6506).

On or after the date of publication of this notice in the **Federal Register**, the Customs Service must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Manufacturer/producer/exporter	Weighted-Average Margin Percentage
Nippon Steel Corporation	44.20
Sumitomo Metal Industries, Ltd.	44.20
All Others	44.20

This notice constitutes the antidumping duty order with respect to OCTG from Japan, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, Room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect. This order is published in accordance with section 736(a) of the Act and 19 CFR 353.21.

Paul L. Joffe,

Deputy Assistant Secretary for Import Administration.

Dated: August 7, 1995.

[FR Doc. 95–19937 Filed 8–10–95; 8:45 am]

BILLING CODE 3510–DS–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds to the Procurement List a commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List commodities previously furnished by such agencies.

EFFECTIVE DATE: September 11, 1995.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On April 28, May 5 and June 16, 1995, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (60 F.R. 20971, 22372 and 31705) of proposed additions to and deletions from the Procurement List:

Additions

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity and services, fair market price, and impact of the additions on the current or most recent contractors, the Committee has determined that the commodity and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity and services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodity and services.

3. The action will result in authorizing small entities to furnish the commodity and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for addition to the Procurement List.

Accordingly, the following commodity and services are hereby added to the Procurement List:

Commodity

Cover Assembly, Generator
2805–00–356–1985

Services

Janitorial/Custodial, U.S. Army Reserve Center, Buildings 104, 105, 106, 107, 108, 109, 140, 141, 144 and 145, Arlington Heights, Illinois

Operation of Postal Service Center, Fairchild Air Force Base, Washington

Parts Sorting, Defense Reutilization and Marketing Office, Fort Lewis, Washington

This action does not affect current contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action will not have a severe economic impact on future contractors for the commodities.
3. The action will result in authorizing small entities to furnish the commodities to the Government.
4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48d) in connection with the commodities deleted from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Accordingly, the following commodities are hereby deleted from the Procurement List:

Aerosol Paint, Lacquer
8010–00–936–8366
8010–00–936–8367
8010–00–936–8369
8010–00–936–8370
8010–00–936–8371

Beverly L. Milkman,

Executive Director.

[FR Doc. 95–19915 Filed 8–10–95; 8:45 am]

BILLING CODE 6820–33–P

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletion from Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete a commodity furnished by such an agency.

COMMENTS MUST BE RECEIVED ON OR BEFORE: September 11, 1995.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.
2. The action does not appear to have a severe economic impact on current contractors for the commodities and services.
3. The action will result in authorizing small entities to furnish the commodities and services to the Government.
4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Executive/Personal Time Management System

7520–00–NSH–0087 (1″ binder, with or without specialized logo, seven sections, velcro closure)
7520–00–NSH–0091 (1″ binder, with or without specialized logo, seven sections, zipper closure)
7520–00–NSH–0092 (1.5″ binder, with or without specialized logo, five sections, no closure)
(up to 46,000 annually)
NPA: The Easter Seal Society of Allegheny County, Pittsburgh, Pennsylvania

Floor Finish
7930–01–183–8584
7930–01–183–8585
7930–01–184–3905
NPA: Diversified Industrial Concepts, Inc., Virginia Beach, Virginia

Floor Wax
7930–00–205–2870
7930–00–205–2871
7930–00–141–5888
NPA: Diversified Industrial Concepts, Inc., Virginia Beach, Virginia

Bag, Plastic, General Purpose
8105–00–579–8451
NPA: Wichita Industries and Services for the Blind, Inc., Wichita, Kansas

Services

Administrative Services, Social Security Administration, 1221 Nevin Avenue, Richmond, California. NPA: Solano Developmental Services, Inc., Vallejo, California

Administrative Services, Department of the Treasury, U.S. Mint Headquarters, 633 3rd Street, NW., Washington, DC. NPA: Fairfax Opportunities Unlimited, Inc., Springfield, Virginia

Grounds Maintenance, Lake Sonoma/Warm Springs Dam, Geyserville, California. NPA: Rubicon Programs, Inc., Richmond, California

Janitorial/Custodial, for the following Huntsville, Alabama locations: Ballistic Missile Center, 106 Wynn Drive, U.S. Post Office & Courthouse, 101 Holmes Avenue. NPA: Phoenix Service, Inc., Huntsville, Alabama

Janitorial/Custodial, Child Care Buildings 2414, 2501, 3830 and West 3rd Street Facility, McGuire Air Force Base, New Jersey. NPA: Occupational Training Center of Burlington County, Mt. Holly, New Jersey

Janitorial/Custodial, Federal Aviation Administration, Air Traffic Control Tower Facility, Newark International Airport, Newark, New Jersey. NPA: The First Occupational Center of New Jersey, Orange, New Jersey

Janitorial/Custodial, U.S. Army Reserve Center, Hoyt Avenue, Binghamton, New York. NPA: Sheltered Workshop for the Disabled, Inc., Binghamton, New York

Janitorial/Custodial, Eafratti U.S. Army Reserve Center, Front Street, Terrace Heights, Weirton, West Virginia. NPA: Hancock County Sheltered Workshop, Weirton, West Virginia

Deletion

If the Committee approved the proposed deletion, all entities of the Federal Government will no longer be required to procure the commodity listed below from nonprofit agencies employing people who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action does not appear to have a severe economic impact on future contractors for the commodity.

3. The action will result in authorizing small entities to furnish the commodity to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity proposed for deletion from the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodity has been proposed for deletion from the Procurement List:

Paper, Toilet Tissue
8540–00–530–3770

Beverly L. Milkman,

Executive Director.

[FR Doc. 95–19916 Filed 8–10–95; 8:45 am]

BILLING CODE 6820–33–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2047 New York]

Niagara Mohawk Power Corporation; Notice of Intent To File an Application for a New License

August 7, 1995

Take notice that the Niagara Mohawk Power Corporation, the existing licensee for the Stewarts Bridge Hydroelectric Project No. 2047, filed a timely notice of intent to file an application for a new license, pursuant to 18 CFR 16.6 of the Commission's Regulations. The original license for Project No. 2047 was issued effective July 1, 1950, and expires July 1, 2000.

The project is located on the Sacandaga River in Saratoga County, New York. The principal works of the Stewarts Bridge Project include an earth dam about 1,650 feet long and 112 feet high with a concrete gated spillway and penstock intake structure; a reservoir of about 475 acres at elevation 705 feet USGS datum; a steel penstock to a brick powerhouse with one generator rated at 36,000 kW; an outdoor transformer, switching station and 400-foot-long transmission line; and appurtenant facilities.

Pursuant to 18 CFR 16.7, the licensee is required henceforth to make available certain information to the public. This information is available from the licensee at 300 Erie Boulevard West, Syracuse, New York 13202.

Pursuant to 18 CFR 16.8, 16.9 and 16.10, each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by July 1, 1998.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19842 Filed 8–10–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER95–1050–000]

Sonat Power Marketing, Inc; Notice of Filing

August 7, 1995.

Take notice that on June 13, 1995, Sonat Power Marketing, Inc. tendered for filing an amendment in the above-referenced docket.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before August 11, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19888 Filed 8–10–95; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 11545–000, MA]

Allen Ross; Notice of Scoping Pursuant to the National Environmental Policy Act of 1969, Notice Requesting Interventions and Protests, and Notice Not Ready for Environmental Analysis

August 7, 1995.

On July 31, 1995, the Federal Energy Regulatory Commission (Commission) issued a letter accepting the Allen Ross' application for the Book Mill Project, located on the Sawmill River in Franklin County, Massachusetts. The application is not ready for environmental analysis at this time. A public notice will be issued in the future indicating its readiness for environmental analysis and soliciting comments, recommendations, terms and conditions, or prescriptions on the application and the applicant's reply comments.

The purpose of this notice is to (1) Invite interventions and protests; (2) advise all parties as to the proposed scope of the staff's environmental analysis, including cumulative effects, and to seek additional information pertinent to this analysis; and (3) advise all parties of their opportunity for comment.

Interventions and Protests

All filings must: (1) Bear in all capital letters the title ''PROTEST,'' ''MOTION TO INTERVENE,'' ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' or ''COMPETING APPLICATION;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426.

An additional copy must be sent to: Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, Room 1027, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

All filings for any protest or motion to intervene must be received 60 days from the issuance date of this notice.

Scoping Process

The Commission's scoping objectives are to:

- Identify significant environmental issues;
- Determine the depth of analysis appropriate to each issue;
- Identify the resource issues not requiring detailed analysis; and
- Identify reasonable project alternatives.

The purpose of the scoping process is to identify significant issues related to the proposed action and to determine what issues should be covered in the environmental document pursuant to the National Environmental Policy Act of 1969 (NEPA). The document entitled ''Scoping Document I'' (SDI) will be circulated shortly to enable appropriate federal, state, and local resource agencies, developers, Indian tribes, non-governmental organizations (NGO's), and other interested parties to effectively participate in and contribute to the scoping process. SDI provides a brief description of the proposed action, project alternatives, the geographic and temporal scope of a cumulative effects analysis, and a list of preliminary issues identified by staff.

Project Site Visit

The applicant and the Commission staff will conduct a project site visit of the Book Mill Project on August 28, 1995, at 10:00 a.m., meeting at the Book Mill Building, Greenfield Rd., Montague Center, Franklin County, Massachusetts 01351. All interested individuals, NGO's and agencies are invited to attend. All participants are responsible for their own transportation and should bring a hard hat. For more details, interested parties should contact Jay Boeri, agent for Allen Ross, at (802) 436–2521, prior to the site visit date.

Scoping Meetings

The Commission staff will conduct two scoping meetings, both on the same day. All interested individuals, organizations, and agencies are invited to attend and assist the staff in identifying the scope of environmental issues that should be analyzed in the NEPA document.

The afternoon agency scoping meeting will be held on August 28, 1995, from 2:00 P.M. to 4:00 P.M., at the Book Mill Building, Greenfield Road, Montague Center, Franklin County, Massachusetts 01352.

The evening public scoping meeting will be held on August 28, 1995, from 7:00 P.M. to 10:00 P.M. at the above-mentioned location.

The Commission will decide, based on the application, and agency and public comments at the scoping session, whether licensing the Book Mill Project constitutes a major federal action significantly impacting the quality of the human environment. Irrespective of the Commission's determination to prepare an environmental assessment or an environmental impact statement for the Book Mill Project, the Commission staff will not hold additional scoping meetings other than those scheduled, as listed above.

Objectives

At the scoping meetings, the Commission staff will: (1) Summarize the environmental issues tentatively identified for analysis in the NEPA document; (2) solicit from the meeting participants all available information, especially quantified data, on the resources at issue, and (3) encourage statements from experts and the public on issues that should be analyzed in the NEPA document. Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meetings and to assist the staff in defining and clarifying the issues to be addressed.

Meeting Procedures

The meetings will be recorded by a stenographer and become a part of the formal record of the Commission proceeding on the Book Mill Project. Individuals presenting statements at the meetings will be asked to identify themselves for the record.

Concerned parties are encouraged to offer us verbal guidance during public meetings. Speaking time allowed for individuals will be determined before each meeting, based on the number of persons wishing to speak and the approximate amount of time available for the session, but all speakers will be provided at least 5 minutes to present their views.

All those attending the meeting are urged to refrain from making any communications concerning the merits of the application to any member of the Commission staff outside of the established process for developing the record as stated in the record of the proceeding.

Persons choosing not to speak but wishing to express an opinion, as well as speakers unable to summarize their positions within their allotted time, may submit written statements for inclusion in the public record up until the closing date for SDI.

All filings should contain an original and 8 copies. Failure to file an original and 8 copies may result in appropriate staff not receiving the benefit of your comments in a timely manner. See 18 C.F.R. 4.34(h). In addition, commenters may submit a copy of their comments on a 3½-inch diskette formatted for MS–DOS based computers. In light of our ability to translate MS–DOS based materials, the text need only be submitted in the format and version that it was generated (i.e., MS Word, WordPerfect 5.1/5.2, ASCII, etc.). It is not necessary to reformat word processor generated text to ASCII. For Macintosh users, it would be helpful to save the documents in Macintosh word processor format and then write them to files on a diskette formatted for MS–DOS machines. All comments should be submitted to the Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, and should clearly show the following captions on the first page: Book Mill Project, FERC No. 11545.

Further, interested persons are reminded of the Commission's Rules of Practice and Procedures, requiring parties or interceders (as defined in 18 C.F.R. 385.2010) to file documents on each person whose name is on the official service list for this proceeding. See 18 C.F.R. 4.34(b).

The Commission staff will consider all written comments and may issue a Scoping Document II (SDII). SDII will include a revised list of issues, based on the scoping sessions.

For further information regarding the scoping process, please contact Mary Golato, Federal Energy Regulatory Commission, Office of Hydropower Licensing, 825 North Capitol Street, NE., Washington, DC 20426 at (202) 219–2804.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19841 Filed 8–10–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP95–643–000, et al.]

East Tennessee Natural Gas Company, et al.; Natural Gas Certificate Filings

August 3, 1995.

Take notice that the following filings have been made with the Commission:

1. East Tennessee Natural Gas Company

[Docket No. CP95–643–000]

Take notice that on July 27, 1995, East Tennessee Natural Gas Company (East Tennessee), P.O. Box 2511, Houston,

Texas 77252, filed in Docket No. CP95–643–000 a request pursuant to Sections 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212) for authorization to install a delivery point in Unicoi County, Tennessee for interruptible transportation service for Southern Gas Services, Inc (Southern Gas), formerly C.B.M. International Inc., under East Tennessee's blanket certificate issued in Docket No. CP82–412–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

East Tennessee proposes a delivery point at M.P. 3307C–202+6.12 in Unicoi County, Tennessee. The installed two-inch hot tap assembly and interconnecting pipe will be located on East Tennessee's existing right-of-way and the measurement facilities will be located on a site provided by Southern Gas. East Tennessee will inspect Southern Gas's installation of the interconnecting pipe and measurement facilities. East Tennessee will own, operate and maintain the hot tap assembly and will operate the measurement facilities. Southern Gas will own, operate and maintain the interconnecting pipe and own and maintain the measurement facilities. The estimated cost is $12,300 reimbursable to East Tennessee by Southern Gas.

East Tennessee states that the total quantities to be delivered to Southern Gas will not exceed those authorized, that the proposed delivery point is not prohibited by its existing tariff, and that there is sufficient capacity for the proposed deliveries without detriment or disadvantage to other customers.

Comment date: September 18, 1995, in accordance with the Standard Paragraph G at the end of this notice.

2. Colorado Interstate Gas Company

[Docket No. CP95–645–000]

Take notice that on July 27, 1995, Colorado Interstate Gas Company (CIG), P.O. Box 1087, Colorado Springs, Colorado 80944, filed an application pursuant to Sections 7(b) of the Natural Gas Act for an order permitting and approving the abandonment of approximately 4.3 miles of a 10-inch lateral pipeline located in Sweetwater County, Wyoming and certain certificated gathering lines connected to the lateral, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

CIG states the facilities were originally certificated in Docket Nos. G–16904 and G–18430.[1] CIG states that it has an agreement with Texaco Exploration and Production Inc. (Texaco) whereby the pressure of the lateral that is the subject of the abandonment will be lowered. Currently, the lateral is connected to the discharge of CIG's Table Rock Compressor Station and is part of CIG's transmission system. CIG proposes to lower the pressure in the lateral by making minor changes to the pipes and valves and thereby allowing additional production from seven Texaco wells connected to the lateral. CIG also proposes to reclassify the lateral from transmission function to the gathering function because of the proposed reconfiguration of the lateral. CIG states that the current net book value of the lateral is $33,453, as of May 31, 1995.

Comment date: August 24, 1995, in accordance with Standard Paragraph F at the end of this notice.

3. Columbia Gas Transmission Corporation

[Docket No. CP95–646–000]

Take notice that on July 28, 1995, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314, filed in Docket No. CP95–646–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to construct and operate an additional delivery point for interruptible transportation service to Columbia Gas of Kentucky, Inc. (CKY) in Mason County, Kentucky, under Columbia's blanket certificate issued in Docket No. CP83–76–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Specifically, Columbia proposes to construct and operate a new delivery point for interruptible transportation service to CKY which will deliver gas to the Maysville Materials asphalt plant. Columbia will provide the service to CKY under Rate Schedule SST and states that the volumes delivered are within certificated entitlements. The estimated cost to establish this point is $50,000, which amount, CKY has agreed to reimburse Columbia.

Comment date: September 18, 1995, in accordance with the Standard Paragraph G at the end of this notice.

[1] See, Opinion No. 393, 30 FPC 77, 93–94 (1963) and 31 FPC 694 (1964), respectively.

4. Koch Gateway Pipeline Company

[Docket No. CP95–654–000]

Take notice that on August 1, 1995, Koch Gateway Pipeline Company (KGPC), P.O. Box 1478, Houston, Texas 77251–1478, filed in Docket No. CP95–654–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to operate as a jurisdictional facility, a delivery tap placed in service under Section 311(a) of the Natural Gas Policy Act (NGPA) and Section 284.3(c) of the Commission's Regulations, under KGPC's blanket certificate issued in Docket No. CP82–430–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

KGPC states that the proposed certification of facilities will enable KGPC to provide transportation services under its blanket transportation certificate through an existing delivery tap serving Entex, Inc. (Entex), a local distribution company, in Jones County, Mississippi.

KGPC also states that it will operate the proposed facilities in compliance with 18 CFR Part 157, Subpart F and that it has sufficient capacity to render the proposed service without detriment or disadvantage to its other existing customers.

Comment date: September 18, 1995, in accordance with the Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or to make any protest with reference to said application should on or before the comment date, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission

by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and/or permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19840 Filed 8–10–95; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. CP93–613–004, et al.]

Northwest Pipeline Corporation, et al.; Natural Gas Certificate Filings

August 4, 1995.

Take notice that the following filings have been made with the Commission:

1. Northwest Pipeline Corporation

[Docket Nos. CP93–613–004, CP93–673–004]

Take notice that on July 24, 1995, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84158, filed an abbreviated petition, pursuant to Sections 7(b) and 7(c) of the Natural Gas Act in Docket Nos. CP93–613–004 and CP93–673–004, to amend the Commission order issued April 19, 1995 in the referenced dockets. Northwest requests authorization to downsize or eliminate certain components of the Expansion II Project; revise the allocation of certificated facilities between the Expansion II and Northwest Natural Expansion Projects; and extend the time for construction of the Weyerhaeuser Lateral and Weyerhaeuser Meter Station; all as more fully set forth in the petition to amend which is on file with the Commission and open to the public inspection.

Northwest states that the Northwest Natural Expansion Project will still provide 102,000 Dth per day of mainline capacity for Northwest Natural Gas Company. Further, Northwest says the only impacts of the proposed design changes on the Northwest Natural Expansion Project are new requirements for 1,241 additional horsepower at the existing Goldendale Compressor Station and restaging of existing units at the Albany and Eugene Compressor Stations. Northwest states that these requirements will be satisfied by allocating to the Northwest Natural Expansion Project the Albany and Eugene restaging and a $3.4 million share of an additional Goldendale compressor unit, all already authorized to be installed at Goldendale for the Northwest Expansion II Project. Northwest states that these allocations from the Northwest Expansion II Project, along with updated cost estimates for all components of the project, results in a revised estimated cost for the Northwest Natural Expansion Project of $52.5 million.

Northwest indicates that, for the Northwest Expansion II Project, which now will provide 42,175 Dth per day of mainline capacity for 11 shippers (reduced from 62,175 Dth per day), the proposed design changes include:

(1) The aforementioned allocation of previously authorized facilities to the Northwest Natural Expansion Project from the Expansion II Project;

(2) A 3.1 mile reduction in the length of the 24-inch Soda Springs North Loop and elimination of the Soda Springs Meter Station crossover tap;

(3) Elimination of various modifications to existing compression facilities at the Roosevelt, Washougal, Oregon City, McMinnville and Lava Hot Springs Compressor Stations; and

(4) Elimination of a tap and associated piping and valves at the Longview Meter Station (Northwest says these facilities were previously installed as part of a Section 284.3(c) exempt facility).

Northwest states that the foregoing facility reductions, along with updated cost estimates for the remaining project components, result in a current estimated cost for the Northwest Expansion II Project of $64.0 million ($53.1 million for mainline facilities plus $10.9 million for two incremental laterals).

Finally, Northwest requests the Commission to grant a 30 month extension of time, until October 19, 1998, for construction of the authorized Weyerhaeuser Lateral and Meter Station to be completed, consistent with Weyerhaeuser's current schedule for building its cogeneration plant which will require service through these facilities.

Comment date: August 25, 1995, in accordance with the first paragraph of Standard Paragraph F at the end of this notice.

2. Panhandle Eastern Pipe Line Company

[Docket No. CP95–648–000]

Take notice that on July 31, 1995, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP95–648–000 a request pursuant to §§ 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.216) for authorization to abandon in place approximately 6,911 feet of 3-inch diameter pipeline and appurtenant facilities under Panhandle's blanket certificate issued in Docket No. CP83–83–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Panhandle proposes to abandon 6,911 feet of 3-inch diameter pipeline on Panhandle's Marblehead lateral, line No. 45–05–001–27 and appurtenant facilities located in Quincy, Adams County, Illinois.

Comment date: September 18, 1995, in accordance with Standard Paragraph G at the end of this notice.

3. National Fuel Gas Supply Corporation

[Docket No. CP95–649–000]

Take notice that on July 31, 1995, National Fuel Gas Supply Corporation (National), 10 Lafayette Square, Buffalo, New York 14203, filed in Docket No. CP95–649–000, an application pursuant to §§ 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (NGA) (18 CFR 157.205, and 157.211) for authorization to construct and operate a sales tap for delivery of gas to a new residential customer of National Fuel Gas Distribution Corporation (Distribution) under authorization issued in Docket

No. CP83–4–000, pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

National proposes to construct and operate a new residential sales tap in North East Township, Erie County, Pennsylvania. The total proposed estimated deliveries for this sales tap are 150 Mcf annually and would be transported and delivered under National's Rate Schedule EFT. National states that the gas volumes would have a minimal impact on National's peak day and annual deliveries.

National further states that the estimated cost of the proposed new delivery point is $1,500. It is stated that Distribution would reimburse National for the cost of the construction of the tap.

Comment date: September 18, 1995, in accordance with Standard Paragraph G at the end of this notice.

4. CNG Transmission Corporation

[Docket No. CP95–651–000]

Take notice that on July 31, 1995, CNG Transmission Corporation (CNGT), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP95–651–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211) for authorization to construct and operate a measuring and regulation station under CNGT's blanket certificate issued in Docket No. CP82–537–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

CNGT proposes to construct a new measuring and regulation station in Chemung County, New York. The facilities will serve as a new interconnection to New York State Electric and Gas Corporation, for receipt and delivery on a firm basis of up to 80,000 Dth of natural gas per day.

Comment date: September 18, 1995, in accordance with Standard Paragraph G at the end of this notice.

5. Columbia Gas Transmission Corporation

[Docket No. CP95–657–000]

Take notice that on August 2, 1995, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314–1273, filed in Docket No. CP95–657–000 a petition pursuant to Rule 207 of the Commission's Rules of Practice and Procedure (18 CFR 385.207) for a declaratory order: (1) Finding that certain meter facilities which Columbia functionalized as gathering facilities in fact perform a transmission function and should be refunctionalized as transmission facilities for rate and accounting purposes, (2) authorizing Columbia to record these facilities and related costs on its accounting books and records as transmission facilities, and (3) confirming that these facilities do not require Section 7(c) certificate authority, all as more fully set forth in the petition on file with the Commission and open to public inspection.

Columbia requests that 644 receipt meters located within the states of Kentucky, New York, Ohio, Pennsylvania and West Virginia be refunctionalized from the gathering function to the transmission function for rate and accounting purposes. Columbia states that in each case the meter represents the point of entry into Columbia's system and serves the purpose of measuring the flow of gas from a facility owned by a third party into a Columbia-owned transmission line. Columbia states that the proposed refunctionalization is reflected in its rate case filed on August 1, 1995 in Docket No. RP95–408–000.

Columbia also requests that the Commission confirm that the 644 receipt meters do not require Section 7(c) authority, as they are not ''facilities'' within the meaning of the Natural Gas Act, and are exempt pursuant to Commission's Regulations (18 CFR 2.55).

Comment date: August 25, 1995, in accordance with the first paragraph of Standard Paragraph F at the end of this notice.

6. Virginia Gas Storage Company

[Docket No. CP95–660–000]

Take notice that on August 2, 1995, Virginia Gas Storage Company (VGS) tendered for filing under Section 7(c) of the Natural Gas Act (NGA) and Section 284.224 of the Regulations of the Federal Energy Regulatory Commission (Commission), an application for a certificate of public convenience and necessity authorizing VGS to participate in storage of natural gas authorized under 18 CFR Part 284 of the Commission's Regulations, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

VGS states that it is an intrastate facility whose rates, services, and facilities are subject to the regulation of the State Corporation Commission of the Commonwealth of Virginia (VSCC), with its rates and tariffs subject to the jurisdiction of the VSCC. VGS further states that it is exempt from the Commission's Regulations under Section 1(c) of the NGA.

VGS states that it is proposing to provide storage service from the Early Grove underground storage field located in Scott and Washington Counties in Virginia. VGS proposes to provide open-access conditions set forth in § 284.224 of the Commission's Regulations.

Comment date: August 25, 1995, in accordance with the first paragraph of Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or to make any protest with reference to said application should on or before the comment date, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and/or permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR

385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 95–19887 Filed 8–10–95; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5275–3]

California State Motor Vehicles Pollution Control Standards; Opportunity for Public Hearing

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice of opportunity for public hearing and public comment period.

SUMMARY: The California Air Resources Board (CARB) has notified EPA that it has adopted regulations regarding on-board diagnostic system requirements for 1994 and later model year passenger cars, light-duty trucks, and medium-duty vehicles (OBD II). On-board diagnostics consist of a computer-based system incorporated into the vehicle electronics for the purpose of detecting operational malfunctions within the emission control system. When malfunctions are detected, a malfunction light is illuminated on the instrument panel and a trouble code is stored in the computer memory identifying the system in which the fault has occurred. CARB initially requested that EPA find its OBD II regulations within the scope of existing waivers of Federal preemption pursuant to section 209 of the Clean Air Act (Act), 42 U.S.C. 7543(b), as amended. Subsequently, CARB twice amended the subject regulations. On June 14, 1995, California requested that, pursuant to section 209(b) of the Clean Air Act, EPA waive Federal preemption for its onboard diagnostics amendments including the December 1994 revisions. This notice announces that EPA has tentatively scheduled a public hearing for October 17, 1995, to hear comments from the general public concerning CARB's request.

DATES: EPA has tentatively scheduled a public hearing for October 17, 1995, beginning at 9:30 a.m. Any person who wishes to testify on the record at the hearing must notify EPA by September 29, 1995, that it wishes to present oral testimony regarding CARB's request. Any party may submit written comments regarding CARB's request by November 17, 1995. If EPA receives one or more requests to testify on the pending request, a hearing will be held. Please note that if no one notifies EPA that they wish to testify, no hearing will be held. Therefore, any person who plans to attend the hearing should call Leila Holmes Cook of EPA's Manufacturers Operation Division at (202) 233–9252, on or after October 2, 1995, to determine if a request for a hearing has been received by the Agency and thus whether a hearing will be held. Regardless of whether or not a hearing is held, written comments regarding CARB's request will be accepted through November 17, 1995.

ADDRESSES: If a request is received, a public hearing will be held at: Sheraton Inn, 3200 Boardwalk, Ann Arbor, Michigan 48108. Parties wishing to testify at the hearing should provide written notice to: Charles N. Freed, Director, Manufacturers Operations Division (6405J), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. In addition, written comments, in duplicate, should be sent to Mr. Freed at the same address. Copies of material relevant to the waiver request (Docket No. A–90–28) will be available for public inspection during the working hours of 8:30 AM to 12:00 PM and 1:30 PM to 3:30 PM, Monday through Friday, at: U.S. Environmental Protection Agency, Air Docket (LE–131), Room M1500, First Floor Waterside Mall, 401 M Street, S.W., Washington, D.C. 20460 [Telephone (202) 260–7548].

FOR FURTHER INFORMATION CONTACT: Leila Holmes Cook, Attorney/Advisor, Manufacturers Operations Division (6405J), U.S. Environmental Protection Agency, Washington, DC. 20460, Telephone: (202) 233–9252.

SUPPLEMENTARY INFORMATION:

I. Background and Discussion

Section 209(a) of the Act as amended, 42 U.S.C. 7543(a), provides in part: ''No State or any political subdivision thereof shall adopt or attempt to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part * * * [or] require certification, inspection, or any other approval relating to the control of emissions * * * as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment.''

Section 209(b) of the Act requires the Administrator, after notice and an opportunity for public hearing, to waive application of the prohibitions of section 209(a) for California ''* * * if the State determines that the State standards will be, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. No such waiver shall be granted if the Administrator finds that—(A) the determination of the State is arbitrary and capricious, (B) [California] does not need such * * * standards to meet compelling and extraordinary conditions, or (C) [its] standards and accompanying enforcement procedures are not consistent with section 202(a) of [the Act].''

As previous decisions granting waivers of federal preemption have explained, State standards are inconsistent with section 202(a) if there is inadequate lead time to permit the development of the necessary technology given the cost of compliance within that time period or if the Federal and state test procedures impose inconsistent certification requirements.

With regard to enforcement procedures accompanying standards, I must grant the requested waiver unless I find that these procedures may cause the California standards, in the aggregate, to be less protective of public health and welfare than the applicable Federal standards promulgated pursuant to section 202(a), or unless the California and Federal certification test procedures are inconsistent.

Once California has been granted waiver for a set of standards and enforcement procedures for a class of vehicles, it may adopt other conditions precedent to initial retail sale, titling or registration of the subject class of vehicles without having to receive a further waiver of Federal preemption.

CARB initially requested that EPA find its OBD II regulations within the scope of existing waivers of federal preemption pursuant to section 209 of the Clean Air Act (Act), 42 U.S.C. 7543(b), as amended. Subsequently, CARB twice amended the subject regulations. EPA finalized its On-Board Diagnostics Rule on January 29, 1993 [58 FR 9468 (February 19, 1993)]. By letter dated June 14, 1995, California requested that, pursuant to section 209(b) of the Clean Air Act, EPA waive Federal preemption for its onboard diagnostics amendments including the December 1994 revisions. These

amendments, which apply to 1994 and later model year passenger cars, light-duty trucks, and medium-duty vehicles require the monitoring of essentially all emission control systems, and emission related components. In addition, it addresses deficiencies in the OBD I requirements that have become apparent since their adoption, and establishes new testing protocol and standardization procedures.

OBD II provides for new monitoring requirements covering: catalyst system condition, engine misfire detection, evaporative control system operation, supplementary air system function, the exhaust gas recirculation (EGR) system flow rate, chloroflourocarbon loss (air conditioning refrigerant), and monitoring of other components and systems controlled by the on-board engine control computer. In general the California OBD II regulations require that a deteriorated component or system be detected as malfunctioning by the time its lack of performance causes vehicle emissions to exceed 1.5 times any of the standards to which the vehicle is certified or when a component is completely non-functioning. Therefore, permissible emission increases are a function of the standards to which the vehicle is certified.

A number of changes to requirements initially established under OBD I were made to increase the effectiveness of the monitoring systems in detecting emission-related malfunctions. These requirements include tampering deterrence features, as well as, improvements to the malfunction detection effectiveness of the fuel system, oxygen sensor, EGR system, other emission-related electronic components.

Manufacturers are required to perform emission tests on a durability demonstration vehicle equipped with deteriorated emission-critical parts and show that the on-board diagnostic system will identify when an emission standard is exceeded by 1.5 times the applicable standard.

In order to facilitate vehicle repairs and assist Inspection and Maintenance Programs in utilizing the OBD system, CARB has required standardized vehicle communication systems that interface with a relatively low-cost, hand-held, universal diagnostic tool. The tool will be able to read specific diagnostic information such as fault codes which lead service personnel to the likely area of any malfunctions, and will provide continuously updated engine parameter data that will further help to isolate fault codes and ensure proper repairs.

In response to a Petition from Ford Motor Company, dated March 29, 1993, CARB modified its OBD II regulations to give the Executive Officer, upon request from a manufacturer, the authority to waive one or more of the OBD II requirements for vehicle models or engine families introduced prior to April 1, 1994. In making this determination the Executive Officer would consider, among other things, the overall extent to which the OBD II requirements will be met, and whether the manufacturer made good-faith efforts to comply with the regulation. For 1995 model year vehicles for which production begins after March 31, 1994, per vehicle penalties in increments of $25 or $50 per vehicle for the third and subsequently identified deficiency not to exceed $500 per vehicle are possible.

On December 8, 1994, CARB approved amendments which addressed manufacturer concerns with developing fully compliant monitoring systems by the 1996 model year. Specifically, these amendments give additional compliance flexibility for manufacturers having difficulty creating enhanced diagnostic systems which monitor catalysts used in low-emission vehicles (LEV) and adequate misfire detection. In addition, the amendments also address monitoring requirements for evaporative system leaks and for the monitoring of diesel and alternate fuel vehicles.

In its request letter dated, June 14, 1995, California has stated that regardless of whether the EPA views the subject regulation as accompanying enforcement procedures or new standards, the requisite findings to support a grant of a waiver of federal preemption have been made. That is, as accompanying enforcement procedures, the regulations do not endanger the protectiveness finding that the ARE has made for previously granted waiver determinations and the regulations are consistent with the intent of section 202(a) of the federal CAA. In the alternative, if the OBD II regulations are viewed as new emission standards, a waiver should be granted because the regulations (as amended) are, in the aggregate, at least as stringent as the comparable federal OBD regulations, California needs its own motor vehicle program to meet compelling and extraordinary conditions in the state, and the regulations are consistent with section 202(a) of the CAA. Section 202(a) requires that the procedures provide sufficient lead time to permit the development and application of requisite technology, giving appropriate consideration to the cost of compliance within such period. In addition, the Agency has held that to avoid inconsistency with section 202(a), California's procedures may not impose inconsistent certification requirements such that manufacturers would be unable to meet both the California and Federal requirements with the same test vehicle.

Once California has been granted waiver of Federal preemption for a set of standards and enforcement procedures for a class of vehicles, it may adopt other conditions precedent to the initial retail sale, titling or registration of the subject class of vehicles without having to receive a further waiver of Federal preemption.

California's request will be considered according to the procedures for a waiver decision, which includes providing the opportunity for a public hearing. Any party wishing to present testimony at the hearing should address the following issues:

(1) Whether California's OBD II regulations are appropriately considered accompanying enforcement procedures or new emission standards;

(2) If CARB's regulations are accompanying enforcement procedures, address (A) whether these procedures may cause the California standards, in the aggregate, to be less protective of public health and welfare than the applicable Federal standards promulgated pursuant to section 202(a), and (B) whether the California and Federal certification test procedures are inconsistent.

(3) If CARB's regulations are standards, address (A) whether California's determination that the amended standards are at least as protective of public health and welfare as applicable Federal standards is arbitrary and capricious; (B) whether California needs separate standards to meet compelling and extraordinary conditions; and, (C) whether California's standards and accompanying enforcement procedures are consistent with section 202(a) of the Act.

II. Procedures for Public Participation

Any person desiring to make an oral statement on the record should file ten (10) copies of their proposed testimony and other relevant material with the Director of EPA's Manufacturers Operations Division at the Director's address listed above not later than October 13, 1995. In addition, that person should submit 25 copies, if feasible, of the planned statement to the presiding officer at the time of the hearing.

Because a public hearing is designed to give interested parties an opportunity to participate in this proceeding, there are no adverse parties as such.

Statements by participants will not be subject to cross-examination by other participants without special approval by the presiding officer. The presiding officer is authorized to strike from the record statements which he or she deems irrelevant or repetitious and to impose reasonable limits on the duration of the statement of any witness.

If a hearing is held, the Agency will make a verbatim record of the proceedings. Interested persons may arrange with the reporter at the hearing to obtain a copy of the transcript at their own expense.

Regardless of whether a public hearing is held, EPA will keep the record open until November 17, 1995. The Administrator will then render her decision on CARB's request based on the record of the public hearing, if one is held, relevant written submissions, and other information which is deemed pertinent. All information will be available for public inspection at the EPA Air Docket.

Dated: August 3, 1995.

Ann E. Goode,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 95–19902 Filed 8–10–95; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5275–8]

Acid Rain Program: Acid Rain Compliance Plans & Exemptions

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice of draft nitrogen oxides compliance plans and written exemptions.

SUMMARY: The U.S. Environmental Protection Agency is issuing draft nitrogen oxides (NO_X) compliance plans and written exemptions from the Acid Rain Program permitting and monitoring requirements to a total of 74 utility units at 30 plants in accordance with the Acid Rain Program regulations (40 CFR parts 72 and 76). Because the Agency does not anticipate receiving adverse comments, these NO_X compliance plans and exemptions are also being issued as a direct final action in the notice of nitrogen oxides compliance plans and written exemptions published elsewhere in today's **Federal Register**.

DATES: Comments on the NO_X compliance plans and written exemptions proposed by this action must be received on or before September 11, 1995, or within 30 days after notice is given in a publication of general circulation in the area where the source is located, whichever is later.

ADDRESSES: Send comments to the following addresses:

For plants in Maryland, Pennsylvania, and West Virginia: Thomas Maslany, Director, Air, Radiation and Toxics Division, EPA Region 3, 841 Chestnut Building, Philadelphia, PA 19107.

For plants in Ohio and Wisconsin: David Kee, Director, Air and Radiation Division, EPA Region 5, Ralph H. Metcalfe Federal Bldg., 77 West Jackson Blvd., Chicago, IL 60604.

For plants in Arkansas, New Mexico, and Texas: Samuel Coleman, Director, Compliance Assurance and Enforcement Division, EPA Region 6, First Interstate Bank Tower, 1445 Ross Ave. (6EN–AA), Dallas, TX 75202–2733.

For plants in Iowa: William A. Spratlin, Director, Air and Toxics Division, EPA Region 7, 726 Minnesota Ave., Kansas City, KS 66101.

For plants in Arizona and California: Celia Bloomfield, EPA Region 9, Air and Toxics Division (A–5–2), 75 Hawthorne Street, San Francisco, CA, 94105.

Submit comments in duplicate and identify the NO_X compliance plan or written exemption to which the comments apply, the commenter's name, address, and telephone number, and the commenter's interest in the matter and affiliation, if any, to the owners and operators of the unit covered by the NO_X compliance plan or written exemption.

FOR FURTHER INFORMATION CONTACT: For plants in Maryland, Pennsylvania, and West Virginia: Linda Miller, (215) 597–7547, EPA Region 3; for plants in Wisconsin: Beth Valenziano, (312) 886–2703, EPA Region 5; for plants in Ohio: Franklin Echevarria, (312) 886–9653, EPA Region 5; for plants in Arkansas, New Mexico, and Texas: Daniel Meyer, (214) 665–7233, EPA Region 6; for plants in Iowa: Jon Knodel, (913) 551–7622, EPA Region 7; for plants in Arizona and California: Celia Bloomfield, (415) 744–1249, EPA Region 9.

SUPPLEMENTARY INFORMATION: If no significant, adverse comments are timely received, no further activity is contemplated in relation to these draft NO_X compliance plans and written exemptions, and the NO_X compliance plans and written exemptions issued as a direct final action in the notice of NO_X compliance plans and written exemptions published elsewhere in today's **Federal Register** will automatically become final on the date specified in that notice. If significant, adverse comments are timely received on any NO_X compliance plan or written exemption, that NO_X compliance plan or written exemption in the notice of NO_X compliance plans and written exemptions will be withdrawn and all public comment received on that NO_X compliance plan or written exemption will be addressed in a subsequent final action based on the relevant NO_X compliance plan or written exemption in this notice of draft NO_X compliance plans and written exemptions. Because the Agency will not institute a second comment period on this notice of draft NO_X compliance plans and written exemptions, any parties interested in commenting should do so during this comment period.

For further information and a detailed description of the NO_X compliance plans and written exemptions, see the information provided in the notice of NO_X compliance plans and written exemptions elsewhere in today's **Federal Register**.

Dated: August 7, 1995.

Joseph A. Kruger,

Acting Director, Acid Rain Division, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 95–19900 Filed 8–10–95; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5275–9]

Acid Rain Program: Acid Rain Compliance Plans & Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of nitrogen oxides compliance plans and written exemptions.

SUMMARY: The U.S. Environmental Protection Agency is issuing, as a direct final action, nitrogen oxides (NO_X) compliance plans and written exemptions from the Acid Rain Program permitting and monitoring requirements to a total of 74 utility units at 30 plants in accordance with the Acid Rain Program regulations (40 CFR parts 72 and 76). Because the Agency does not anticipate receiving adverse comments, these compliance plans and exemptions are being issued as a direct final action.

DATES: Each NO_X compliance plan and written exemption issued in this direct final action, will be final on September 21, 1995, or 40 days after notice is also given in a publication of general circulation in the area where the source is located, whichever is later, unless significant, adverse comments are received by September 11, 1995, or 30 days after the aforementioned local notice is published, whichever is later. If significant, adverse comments are timely received on any NO_X compliance plan or on any exemption in this direct

final action, that compliance plan or exemption will be withdrawn through a notice in the **Federal Register**.

ADDRESSES: Administrative Records. The administrative record for the NO_X compliance plans and written exemptions, except information protected as confidential, may be viewed during normal operating hours at the following locations:

For plants in Maryland, Pennsylvania, and West Virginia: EPA Region 3, 841 Chestnut Building, Philadelphia, PA 19107.

For plants in Ohio and Wisconsin: EPA Region 5, Ralph H. Metcalfe Federal Bldg., 77 West Jackson Blvd., Chicago, IL 60604.

For plants in Arkansas, New Mexico, and Texas: EPA Region 6, First Interstate Bank Tower, 1445 Ross Ave. (6EN–AA), Dallas, TX 75202–2733.

For plants in Iowa: EPA Region 7 Library, 726 Minnesota Ave., Kansas City, KS 66101 or Iowa Dept. of Natural Resources, Henry A. Wallace Bldg., 900 E. Grand, Des Moines, IA 50319.

For plants in Arizona and California: EPA Region 9, Air and Toxics Division, 75 Hawthorne Street, San Francisco, CA, 94105.

Comments. Send comments to the following address:

For plants in Maryland, Pennsylvania, and West Virginia: Thomas Maslany, Director, Air, Radiation and Toxics Division, EPA Region 3 (address above).

For plants in Ohio and Wisconsin: David Kee, Director, Air and Radiation Division, EPA Region 5 (address above).

For plants in Arkansas, New Mexico, and Texas: Samuel Coleman, Director, Compliance Assurance and Enforcement Division, EPA Region 6 (address above).

For plants in Iowa: William A. Spratlin, Director, Air and Toxics Division, EPA Region 7 (address above).

For plants in Arizona and California: Celia Bloomfield, Air and Toxics Division (A–5–2), EPA Region 9 (address above).

Submit comments in duplicate and identify the NO_X compliance plan or written exemption to which the comments apply, the commenter's name, address, and telephone number, and the commenter's interest in the matter and affiliation, if any, to the owners and operators of the unit covered by the NO_x compliance plan or written exemption.

FOR FURTHER INFORMATION CONTACT: For plants in Maryland, Pennsylvania, and West Virginia: Linda Miller, (215) 597–7547, EPA Region 3; for plants in Wisconsin: Beth Valenziano, (312) 886–2703, EPA Region 5; for plants in Ohio: Franklin Echevarria, (312) 886–9653, EPA Region 5; for plants in Arkansas, New Mexico, and Texas: Daniel Meyer, (214) 665–7233, EPA Region 6; for plants in Iowa: Jon Knodel, (913) 551–7622, EPA Region 7; for plants in Arizona and California: Celia Bloomfield, (415) 744–1249, EPA Region 9.

SUPPLEMENTARY INFORMATION: All public comment received on any NOx compliance plan or written exemption in this direct final action on which significant, adverse comments are timely received will be addressed in a subsequent approval or denial of the compliance plan or exemption. Such approval or denial will be based on the relevant draft compliance plan or exemption in the notice of draft compliance plans and exemptions that is published elsewhere in today's **Federal Register** and that is identical to this direct final action.

New Unit Exemptions

Under the Acid Rain Program regulations (40 CFR 72.7), utilities may petition EPA for an exemption from permitting and monitoring requirements for any new utility unit that serves one or more generators with total nameplate capacity of 25 MW or less and burns only fuels with a sulfur content of 0.05 percent or less by weight. On the earlier of the date an exempted new unit burns any fuel with a sulfur content in excess of 0.05 percent by weight or 24 months prior to the date the exempted unit first serves one or more generators with total nameplate capacity in excess of 25 MW, the unit shall no longer be exempted under 40 CFR 72.7 and shall be subject to all permitting and monitoring requirements of the Acid Rain Program.

EPA is issuing written exemptions effective from January 1, 1995 through December 31, 1999, to the following new units:

Region 6

Animas, unit 5 in New Mexico, owned and operated by the City of Farmington. The Designated Representative for Animas is Michael R. Sims.

Retired Unit Exemptions

Additionally, under the Acid Rain Program regulations (40 CFR 72.8), utilities may petition EPA for an exemption from permitting requirements for units that are retired prior to the issuance of a Phase II Acid Rain permit. Units that are retired prior to the deadline for continuous emissions monitoring system (CEMS) certification may also petition for an exemption from monitoring requirements. Exempted retired units must not emit any sulfur dioxide or nitrogen oxides on or after the date the units are exempted, and the units must not resume operation unless the Designated Representative submits an application for an Acid Rain permit and installs and certifies its monitors by the applicable deadlines.

EPA is approving retired unit exemptions, effective January 1, 1996 through December 31, 1999, and exemptions from monitoring requirements, effective January 1, 1995 through December 31, 1999, to the following retired units:

Region 6

Cecil Lynch Steam Electric Station, unit 1 in Arkansas, owned and operated by Arkansas Power and Light Company. The Designated Representative for Cecil Lynch is Frank F. Gallaher.

Person Generating Station, units 3 and 4 in New Mexico, owned and operated by Public Service Company of New Mexico. The Designated Representative for Person is Patrick J. Goodman.

Concho Power Station, unit 4 in Texas, owned by West Texas Utilities Company and operated by Central and South West Services, Inc. The Designated Representative for Concho is E. Michael Williams.

Region 7

Sixth Street Generating Station, unit 1 in Iowa, owned and operated by IES Utilities. The Designated Representative for Sixth Street is Roger Lessly.

Region 9

DeMoss Petrie, unit 4 in Arizona, owned and operated by Tucson Electric Power Company. The Designated Representative for DeMoss Petrie is Cosimo DeMasi.

Avon Power Plant, units 1, 2, and 3 in California, owned and operated by Pacific Gas and Electric Company. The Designated Representative for Avon is James K. Randolph.

Harbor Generating Station, units 1–5 in California, owned and operated by the Los Angeles Department of Water and Power. The Designated Representative for Sixth Street is Dennis B. Whitney.

Huntington Beach Generating Station, units 3 and 4 in California, owned and operated by Southern California Edison Company. The Designated Representative for Huntington is John R. Fielder.

Martinez Power Plant, units 1, 2, and 3 in California, owned and operated by Pacific Gas and Electric Company. The Designated Representative for Martinez is James K. Randolph.

Oleum Power Plant, units 1–6 in California, owned and operated by Pacific Gas and Electric Company. The Designated Representative for Oleum is James K. Randolph.

Redondo Generating Station, units 11–16 in California, owned and operated by Southern California Edison Company. The Designated Representative for Redondo is John R. Fielder.

NO_X Compliance Plans

Lastly, EPA is approving NO_X compliance plans under which units will comply with the applicable emission limitations for NO_X under 40 CFR 76.5 (referred to as ''standard emission limitations'') or with a NO_X averaging plan under 40 CFR 76.10, for the following utility plants:

Region 3

R. Paul Smith in Maryland: Standard emission limitation of 0.50 lbs/MMBtu for unit 9 and 0.45 lbs/MMBtu for unit 11. The Designated Representative is David C. Benson.

Bruce Mansfield in Pennsylvania: Units 1 and 2 will each comply with 4 averaging plans, one for calendar year 1996, and three for each calendar year 1997–1999. For each year under these plans, the actual annual average emission rate for NO_X for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.45 lbs/MMBtu, and the actual annual heat input for units 1 and 2 shall not be less than the annual heat input limits of 63,306,398 MMBtu and 62,726,184 MMBtu, respectively. The other units designated in the plans are Edgewater unit 13, Gorge units 25 and 26, New Castle units 1 and 2, R.E. Burger units 7 and 8, Toronto units 10 and 11, and W.H. Sammis units 5 and 6. The Designated Representative is Howard C. Couch, Jr.

New Castle in Pennsylvania: units 1 and 2 will each comply with 4 averaging plans, one for calendar year 1996, and three for each calendar year 1997–1999. For each year under these plans, the actual annual average emission rate for NO_X for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.50 lbs/MMBtu, and there are no annual heat input limits. The other units designated in the plans are Bruce Mansfield units 1 and 2, Edgewater unit 13, Gorge units 25 and 26, R.E. Burger units 7 and 8, Toronto units 10 and 11, and W.H. Sammis units 5 and 6. The Designated Representative is Howard C. Couch, Jr.

Albright in West Virginia: Standard emission limitation of 0.50 lbs/MMBtu for units 1 and 2, and 0.45 lbs/MMBtu for unit 3. The Designated Representative is David C. Benson.

Pleasants in West Virginia: Standard emission limitation of 0.50 lbs/MMBtu for units 1 and 2. The Designated Representative is David C. Benson.

Region 5

Edgewater in Ohio: Unit 13 will comply with four averaging plans, one for calendar year 1996, and three for each calendar year 1997–1999. For each year under these plans, the actual annual average emission rate for NO_X for this unit shall not exceed the alternative contemporaneous annual emission limitation of 0.20 lbs/MMBtu, and the actual annual heat input for unit 13 shall not be less than the annual heat input limit of 2,034,422 MMBtu. The other units designated in the plans are Bruce Mansfield units 1 and 2, Gorge units 25 and 26, New Castle units 1 and 2, R.E. Burger units 7 and 8, Toronto units 10 and 11, and W.H. Sammis units 5 and 6. The Designated Representative is Howard C. Couch, Jr.

Gorge in Ohio: Units 25 and 26 will each comply with four averaging plans, one for calendar year 1996, and three for each calendar year 1997–1999. For each year under these plans, the actual annual average emission rate for NOx for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.50 lbs/MMBtu, and there are no annual heat input limits. The other units designated in the plans are Bruce Mansfield units 1 and 2, Edgewater unit 13, New Castle units 1 and 2, R.E. Burger units 7 and 8, Toronto units 10 and 11, and W.H. Sammis units 5 and 6. The Designated Representative is Howard C. Couch, Jr.

R.E. Burger in Ohio: Units 7 and 8 will each comply with three averaging plans for each calendar year 1997–1999. For each year under these plans, the actual annual average emission rate for NOx for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.65 lbs/MMBtu, and the actual annual heat input for units 7 and 8 shall not be greater than the annual heat input limits of 8,636,386 MMBtu and 8,716,740 MMBtu, respectively. The other units designated in the plans are Bruce Mansfield units 1 and 2, Edgewater unit 13, Gorge units 25 and 26, New Castle units 1 and 2, Toronto units 10 and 11, and W.H. Sammis units 5 and 6. The Designated Representative is Howard C. Couch, Jr.

W.H. Sammis in Ohio: Units 5 and 6 will each comply with four averaging plans, one for calendar year 1996, and three for each calendar year 1997–1999. For each year under these plans, the actual annual average emission rate for NO_X for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.55 lbs/MMBtu for unit 5, and 0.45 lbs/MMBtu for unit 6. The actual annual heat input for unit 5 shall not be greater than the annual heat input limits of 16,570,591 MMBtu in 1996 and 18,708,732 MMBtu in 1997–1999. The actual annual heat input for unit 6 shall not be less than the annual heat input limits of 31,884,315 MMBtu in 1996 and 35,427,017 MMBtu in 1997–1999. The other units designated in the plans are Bruce Mansfield units 1 and 2, Edgewater unit 13, Gorge units 25 and 26, New Castle units 1 and 2, R.E. Burger units 7 and 8, and Toronto units 10 and 11. The Designated Representative is Howard C. Couch, Jr.

Toronto in Ohio: Units 10 and 11 will each comply with four averaging plans, one for calendar year 1996, and three for each calendar year 1997–1999. For each year under these plans, the actual annual average emission rate for NO_X for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.50 lbs/MMBtu, and there are no annual heat input limits. The other units designated in the plans are Bruce Mansfield units 1 and 2, Edgewater unit 13, Gorge units 25 and 26, New Castle units 1 and 2, R.E. Burger units 7 and 8, and W.H. Sammis units 5 and 6. The Designated Representative is Howard C. Couch, Jr.

Alma in Wisconsin: Units B4 and B5 will each comply with four averaging plans, one for each calendar year 1996–1999. For each year under these plans, the actual annual average emission rate for NO_X for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.80 lbs/MMBtu, and the actual annual heat input for units B4 and B5 shall not be greater than the annual heat input limits of 3,200,000 MMBtu and 5,100,000 MMBtu, respectively. The other units designated in the plans are Genoa unit 1 and J.P. Madgett unit B1. The Designated Representative is John P. Leifer.

Genoa in Wisconsin: Unit 1 will comply with four averaging plans, one for each calendar year 1996–1999. For each year under these plans, the actual annual average emission rate for NO_X for this unit shall not exceed the alternative contemporaneous annual emission limitation of 0.38 lbs/MMBtu, and the actual annual heat input for unit 1 shall not be less than the annual heat input limit of 13,500,000 MMBtu. The other units designated in the plans are Alma units B4 and B5 and J.P. Madgett

unit B1. The Designated Representative is John P. Leifer.

J.P. Madgett in Wisconsin: Unit B1 will comply with four averaging plans, one for each calendar year 1996–1999. For each year under these plans, the actual annual average emission rate for NO_X for this unit shall not exceed the alternative contemporaneous annual emission limitation of 0.39 lbs/MMBtu, and the actual annual heat input for unit B1 shall not be less than the annual heat input limit of 13,700,000 MMBtu. The other units designated in the plans are Alma units B4 and B5 and Genoa unit 1. The Designated Representative is John P. Leifer.

Port Washington in Wisconsin: Units 1, 2, 3, and 4 will comply with four averaging plans, one for each calendar year 1996–1999. For each year under these plans, the actual annual average emission rate for NO_X for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.40 lbs/MMBtu. The actual annual heat input for units 1, 2, 3, and 4 shall not be less than the annual heat input limits of 583,213 MMBtu, 1,632,997 MMBtu, 1,924,604 MMBtu, and 874,320 MMBtu, respectively. The other units designated in the plans are South Oak Creek units 5, 6, 7, and 8 and Valley units 1, 2, 3, and 4. Port Washington unit 5 will meet the standard emission limit of 0.50 lbs/MMBtu for 1996–1999. The Designated Representative is Paul D. Schumacher.

Pulliam in Wisconsin: Units 7 and 8 will each comply with a NO_X averaging plan for 1996–1999. For each year under the plan, the actual annual average emission rate for NO_X for each of these units shall not exceed the alternative contemporaneous annual emission limitation of 0.40 lbs/MMBtu, and the actual annual heat input for units 7 and 8 shall not be less than the annual heat input limits of 5,400,000 MMBtu and 7,000,000 MMBtu, respectively. The other units designated in this plan are Weston units 1, 2, and 3. The Designated Representative is Gary T. Van Helvoirt.

South Oak Creek in Wisconsin: Units 5, 6, 7, and 8 will comply with four averaging plans, one for each calendar year 1996–1999. For each year under these plans, the actual annual average emission rate for NO_X for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.30 lbs/MMBtu for units 5 and 6, and 0.42 lbs/MMBtu for units 7 and 8. The actual annual heat input for units 5 and 6 shall not be less than the annual heat input limits of 6,220,245 MMBtu and 6,349,833 MMBtu respectively, and the actual annual heat input for units 7 and 8 shall not be less than the annual heat input limit of 7,553,054 MMBtu each. The other units designated in the plans are Valley units 1, 2, 3, and 4 and Port Washington units 1, 2, 3, and 4. The Designated Representative is Paul D. Schumacher.

Valley in Wisconsin: Units 1, 2, 3, and 4 will comply with four averaging plans, one for each calendar year 1996–1999. For each year under these plans, the actual annual average emission rate for NO_X for these units shall not exceed the alternative contemporaneous annual emission limitation of 0.65 lbs/MMBtu. The actual annual heat input for units 1 and 2 shall not be greater than the annual heat input limit of 5,497,537 MMBtu each, and the actual annual heat input for units 3 and 4 shall not be greater than the annual heat input limit of 6,062,205 MMBtu each. The other units designated in the plans are South Oak Creek units 5, 6, 7, and 8 and Port Washington units 1, 2, 3, and 4. The Designated Representative is Paul D. Schumacher.

Weston in Wisconsin: Units 1, 2, and 3 will each comply with a NO_X averaging plan for 1996–1999. For each year under the plan, the actual annual average emission rate for NO_X for each of these units shall not exceed the alternative contemporaneous annual emission limitation of 0.90 lbs/MMBtu for unit 1, 1.05 lbs/MMBtu for unit 2, and 0.25 lbs/MMBtu for unit 3, and the actual annual heat input for units 1, 2, and 3 shall not be greater than the annual heat input limits of 4,500,000 MMBtu and 6,500,000 MMBtu for units 1 and 2, respectively, and shall not be less than the annual heat input limit of 20,500,000 MMBtu for unit 3. The other units designated in this plan are Pulliam units 7 and 8. The Designated Representative is Gary T. Van Helvoirt.

Dated: August 7, 1995.

Joseph A. Kruger,

Acting Director, Acid Rain Division, Office of Atmospheric Programs, Office of Air and Radiation.

[FR Doc. 95–19901 Filed 8–10–95; 8:45 am]

BILLING CODE 6560–50–P

[ER-FRL–4725–5]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 260–5076 OR (202) 260–5075. Weekly receipt of Environmental Impact Statements Filed July 31, 1995 Through August 04, 1995 Pursuant to 40 CFR 1506.9.

EIS No. 950349, Revised Final EIS, AFS, ID, West Fork Papoose Timber Sale, Implementation, Clearwater National Forest, Powell Ranger District, Idaho County, ID, Due: September 11, 1995, Contact: Stewart Hoyt (208) 942–3113.

EIS No. 950350, Draft Supplement, FHW, VT, Burlington Southern Connector New and Additional Information, Champlain Park Way Project, Construction I–189 and US Route 7 to Battery Street, COE Section 10 and 404 Permits, Central Business District (CBD), Burlington, Chittenden County, VT, Due: September 25, 1995, Contact: Donald J. West (802) 828–4433.

EIS No. 950351, Draft EIS, FHW, NC, US 64 Bypass Transportation Improvements Project, from I–440 to US 64 west of Wendell and Eastern Wake Expressway from existing US 64 to NC–1007 (Poole Road), Funding and COE Section 404 Permit, Wake County, NC, Due: October 06, 1995, Contact: Nicholas L. Graf (919) 856–4346.

EIS No. 950352, Final EIS, AFS, UT, Jacob/Swale Vegetation Management Project, Implementation, Dixie National Forest, Escalante Ranger District, Garfield County, UT, Due: September 11, 1995, Contact: Kevin R. Schulkoski (801) 882–5400.

EIS No. 950353, Final EIS, DOE, WA, Puget Power Northwest Washington Electric Transmission Project, Construction and Operation, Whatcom and Skagit Counties, WA, Due: September 11, 1995, Contact: Ken Barnhart (503) 230–3667.

EIS No. 950354, Final EIS, AFS, ID, Tailholt Administrative Research Study, Timber Harvesting and Road Construction, Payette National Forest, Krassel Ranger District, Valley County, ID, Due: September 11, 1995, Contact: Rudy Vershchoor (208) 634–0706.

EIS No. 950355, Draft Supplement, AFS, AK, Central Prince of Wales Ketchikan Pulp Long-Term Timber Sale, Additional Information, Implementation, Tongass National Forest, Prince of Wales Island, AK, Due: September 25, 1995, Contact: David Arrasmith (907) 228–6304.

EIS No. 950356, Draft EIS, IBR, CA, South Bay Water Recycling Program (SBWRP), Development and Construction, Funding and COE Section 404 Permit, Golden Triangle Area, City of San Jose, Santa Clara County, CA, Due: September 25, 1995, Contact: Mona Jefferies-Soniea (916) 979–2297.

EIS No. 950357, Draft EIS, FHW, DC, Canal Road Entrance to the Georgetown University

Improvements, Reconstruction between Whitehurst Freeway and Foxhall Road, Washington, DC, Due: September 25, 1995, Contact: Arthur Hill (202) 523–0181.

EIS No. 950358, Final Supplement, RUS, FL, Hardee Unit 3 440 Megawatt (MW) Natural Gas and Oil Fired Combined Cycle Electric Power Station, Construction and Operation, Approval, Funding and NPDES Permit, Hardee County, FL, Due: September 11, 1995, Contact: Robert Quigel (202) 720–1784.

EIS No. 950359, Draft EIS, AFS, MT, Rock Creek Underground Copper/Silver Mine Project, Construction and Operation, Plan of Operations Approval and COE Section 404 Permit, Kootenai National Forest, Sander County, MT, Due: September 25, 1995, Contact: Paul Kaiser (406) 293–6211.

EIS No. 950360, Draft EIS, NPS, NM, Petroglyph National Monument, General Management Plan and Development Concept Plan, Implementation, Bernalillo County, NM, Due: November 06, 1995, Contact: Lawrence Beal (505) 839–4429.

Amended Notices

EIS No. 940364, Final EIS, AFS, ID, West Fork Papoose Timber Sale, Implementation, Clearwater National Forest, Powell Ranger District, Idaho County, ID, Due: October 10, 1994, Contact: Stewart Hoyt (208) 942–3113. Published FR 08–23–91—Officially Withdraw by Preparing Agency.

EIS No. 950326, Draft Supplement, NIH, MD, National Institutes of Health Bethesda Main Campus Comprehensive Master Plan, Implementation, Montgomery County, MD, Due: October 23, 1995, Contact: Janyce Hedetniemi (301) 496–3931. Published FR -07–28–95 Correction to Title and Due Date.

Dated: August 08, 1995

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 95–19938 Filed 8–10–95; 8:45 am]

BILLING CODE 6560–50–U

[ER-FRL–4725–6]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared June 24, 1995 Through June 28, 1995 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 14, 1995 (60 FR 19047).

Draft EISs

ERP No. D-AFS-J65233–MT

Rating EC2, Murphy Timber Sales, Harvesting Timber, Road Construction and Prescribed Burning, Kootenai National Forest, Fortine Ranger District, Lincoln County, MT.

Summary: EPA expressed environmental concerns about increased water yield and sediment production and resultant aquatic effects, particularly in the Deep Creek basin, and the lack of information regarding water quality monitoring, exceedances of open road density standards, and potential air quality impacts.

ERP No. D-AFS-J65234–MT

Rating EC2, Beaver Woods Vegetation Management Project, Implementation, Bitterroot National Forest, West Fork Ranger District, Ravalli County, MT.

Summary: EPA expressed environmental concerns about potential increased water and sediment yields and proposed activities in critical watersheds and in watersheds where peak stream flow thresholds are already being exceeded. EPA requested additional information to fully assess and mitigate potential environmental impacts of the management actions.

ERP No. D-AFS-J65235–MT

Rating EC2, Bass Lake Dam Reconstruction, Operation and Maintenance, Temporary-Use-Permit, Bitterroot National Forest, Stevensville Ranger District, Ravalli County, MT.

Summary: EPA expressed environmental concerns about the potential impacts resulting from equipment access along the old road and trail into the Wilderness Area, and impacts of the concrete maintenance program and pipe and concrete housing replacement. EPA requested additional information to fully assess and mitigate potential environmental impacts of the management actions.

ERP No. D-AFS-K65167–CA

Rating EO2, California Spotted Owl Habitat Management Plan, Implementation, Sierra Nevada National Forests, CA.

Summary: EPA had environmental objections with whether the proposed management framework would be successful given the complexity variability of Sierra Nevada forests ecosystems and the lack of information on these ecosystems. EPA requested additional information on potential impacts to aquatic species and habitat, as well as fire risk, salvage activities, monitoring methods, cumulative impacts, and management tradeoffs.

ERP No. D-GSA-A80027–AZ

Rating LO, Evo A. Deconcini Federal Building—United States Courthouse, Construction and Site Selection, Central Business Area (CBA), City of Tucson, Pima County, AZ.

Summary: EPA had no environmental objection to the project.

ERP No. D-NOA-A91062–00

Rating EC2, Atlantic Coast Weakfish Fishery, Fishery Management Plan, Implementation, Weakfish Harvest Control in the Atlantic Ocean Exclusive Economic Zone (EEZ), off the New England, Mid-Atlantic and South Atlantic Coast.

Summary: EPA had environmental concerns with some aspects of the regulations and requested that additional information be included in the FEIS on the exemption for the Block Island Sound area and on the impacts that other fisheries may have on the weakfish fishery.

ERP No. D–TVA–E32075–TN

Rating EC2, Upper Tennessee River Navigation Improvement Project, Rehabilitation and/or Construction, Ckickamauga Dam—Navigation Lock Structural Improvement Alternative, Funding, NPDES Permit, Coast Guard Bridge Permit and COE Section 404 Permits, Tennessee River, Hamilton County, TN.

Summary: EPA expressed environmental concerns over potential impacts to spawning fish populations, air quality, and wetlands. EPA also noted the need for additional analyses to support conclusions regarding potential environmental impacts.

ERP No. DS–FHW–E54009–NC

Rating EC2, US 117 Corridor Improvement Project, US 13/70 at Goldsboro, North to US 301 in Wilson, Funding and COE Section 404 Permit, Updated and Additional Information, Wayne and Wilson Counties, NC.

Summary: EPA continues to express environmental concerns about the preferred alternative. Potential impacts to the Little River need to be avoided in order to fully protect this aquatic resource.

ERP No. DS–NAS–A12031–00

Rating EC2, Programmatic EIS—Sounding Rocket Program (SRP), Updated Information concerning Programmatic Changes since the 1973 FEIS, Site-Specific to Wallops Flight Facility (WFF), Wallops Island, VA; Poker Flat Research Range (PFRR), Fairbanks, AK and White Sands Missile Range (WSMR), White Sands, NM and on a Global Scale.

Summary: EPA expressed environmental concerns that, while the Sounding Rocket Program (SRP) as a whole does not seem to have significant direct impacts on the environment, it may present cumulative impacts at the local level. As a result, EPA requests some additional information.

ERP No. DS–RUS–E08017–FL

Rating EC2, Hardee Unit 3; 440 Megawatt (MW) Natural Gas and Oil Fired Combined Cycle Electric Power Station Construction and Operation, Funding, Approval and NPDES Permit Issuance, Hardee County, FL.

Summary: EPA expressed environmental concerns regarding impacts to air and water quality, and requested that additional information be presented in the final EIS supplement.

Final EISs

ERP No. F–BLM–K67026–CA

Briggs Open Pit Heap Leach Gold Mine Project, Construction and Operation, NPDES Permit and COE Section 404 Permit, Inyo County, CA.

Summary: The final EIS fully addressed EPA's environmental concerns regarding potential impacts to surface water and wetlands, facilities design, closure, reclamation and maintenance of the heap leach pad, and contingency measures. EPA also commented that BLM should consider new information regarding Native American interests in the proposed project before a Record of Decision is issued.

ERP No. F–GSA–L81009–WA

Seattle Federal Courthouse Building (Project # ZWA 81061), Implementation, Site Selection, Construction and Operation, King County, WA.

Summary: EPA commented that the final EIS effectively addressed EPA's comments on the draft EIS.

Dated: August 8, 1995.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 95–19939 Filed 8–10–95; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL RESERVE SYSTEM

First Commerce Corporation; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 95-19369) published on page 40180 of the issue for Monday, August 7, 1995.

Under the Federal Reserve Bank of Atlanta heading, the entry for First Commerce Corporation, is revised to read as follows:

1. First Commerce Corporation, New Orleans, Louisiana; to acquire 9.85 percent of the voting shares of First United Bank of Farmerville, Farmerville, Louisiana.

Comments on this application must be received by August 31, 1995.

Board of Governors of the Federal Reserve System, August 7, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–19889 Filed 8–10–95; 8:45 am]

BILLING CODE 6210–01–F

Jackie Lynn Poulsen, et al.; 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 August 25, 1995.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Jackie Lynn Poulsen, Ericson, Nebraska, and Gregory Gene Jensen, Ord, Nebraska; each to acquire an additional 3.86 percent, for a total of 26.27 percent, of the voting shares of Wheeler County Bancshares, Inc., Ericson, Nebraska, and thereby indirectly acquire Ericson State Bank, Ericson, Nebraska.

Board of Governors of the Federal Reserve System, August 7, 1995.

William W. Wiles,

Deputy Secretary of the Board.

[FR Doc. 95–19890 Filed 8–10–95; 8:45 am]

BILLING CODE 6210–01–F

Security State Bank Holding Company, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is 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 to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than September 5, 1995.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Security State Bank Holding Company, Hannaford, North Dakota; to acquire 100 percent of the voting shares of Security State Bank of Jamestown, Jamestown, North Dakota, a *de novo* bank.

2. Western Dakota Holding Company, Timber Lake, South Dakota; to become a bank holding company by acquiring 50.02 percent of the voting shares of Dewey County Bank, Timber Lake, Minnesota.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. FirstBank Holding Company of Colorado Employee Stock Ownership Plan, Lakewood, Colorado; to acquire

27.2 percent of the voting shares of FirstBank Holding Company of Colorado, Lakewood, Colorado.

Board of Governors of the Federal Reserve System, August 7, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–19891 Filed 8–10–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Information Collection Under OMB Review

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Administration for Children and Families (ACF) is publishing the following summary(ies). To request copies of the proposed collection of information and the related instructions, call the ACF Reports Clearance Officer on (202) 401–6465.

Comments are invited on: (a) 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; (b) the accuracy of the agency's estimate of the burden of the of the proposed collection of information; (c) 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 through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Proposed Project(s)

Title: Title IV–E Foster Care and Adoption Assistance Financial Report.

OMB No.: 0980–0131.

Description: This form is used by States to report quarterly expenditures and estimates for Foster Care and Adoption Assistance grant programs under Title IV–E of the Social Security Act.

Respondents: State governments.

Title	No. of respondents	No. of responses per respondent	Average burden per response	Burden
ACF–431	51	4	204	612

Estimated Total Annual Burden Hours: 612.

Dated: August 2, 1995.

Roberta Katson,

Reports Clearance Officer.

[FR Doc. 95–19571 Filed 8–10–95; 8:45 am]

BILLING CODE 4184–01–M

[Program Announcement No. 93631–95–02A]

Developmental Disabilities: Availability of Financial Assistance for Projects of National Significance for Fiscal Year 1995

AGENCY: Administration on Developmental Disabilities, ACF, DHHS.

ACTION: Extension of due date for receipt of applications for the program announcement cited above.

SUMMARY: This notice amends program announcement number 93631–95–02 published in the **Federal Register** on June 19, 1995, by extending the due date for submission of applications to August 11, 1995.

FOR FURTHER INFORMATION CONTACT: Adele Gorelick (202) 690–5982.

SUPPLEMENTARY INFORMATION: On June 19, 1995, the Administration on Developmental Disabilities (ADD), Administration for Children and Families, published a program announcement in the **Federal Register** soliciting applications for funding of Fiscal Year 1995 Projects of National Significance in the following areas: ADD and ACYF, Family and Youth Services Bureau Collaboration Between Youth Service Providers and Disabilities Advocates to Enhance Services to Youth With Developmental Disabilities; Americans With Developmental Disabilities and the Criminal Justice System; First Jobs—Introducing Persons With/Without Developmental Disabilities to the World of Work and Community Service; Child Care and Early Intervention: Linkages for Successful Inclusion of Young Children With Disabilities; Building a Multi-Cultural Network Within the Developmental Disabilities System Which Increases Service Equity, Opportunities, and Inclusion for Individuals From Racial and Ethnic Minority Groups; Meeting the Mental Health Needs of Individuals With Developmental Disabilities; and Children at Risk: The Impact of Abuse and Violence on Children With Disabilities.

Because of the recent hurricane in Florida, which disrupted work, transportation, and communication, we are allowing all prospective applicants more time to submit their applications. Therefore, we are extending the due date for submission of applications to August 11, 1995.

(Catalog of Federal Domestic Assistance Program Number 93.631, Developmental Disabilities—Projects of National Significance)

Dated: August 7, 1995.

Bob Williams,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 95–19894 Filed 8–10–95; 8:45 am]

BILLING CODE 4184–01–M

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: July 1995

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: This notice lists new proposals for welfare reform and combined welfare reform/Medicaid demonstration projects submitted to the Department of Health and Human Services for the month of July, 1995. Federal approval for the proposals has been requested pursuant to section 1115 of the Social Security Act. This notice also lists proposals that were previously submitted and are still pending a decision and projects that have been approved since July 1, 1995. The Health

Care Financing Administration is publishing a separate notice for Medicaid only demonstration projects.

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: For specific information or questions on the content of a project contact the State contact listed for that project.

Comments on a proposal or requests for copies of a proposal should be addressed to: Howard Rolston, Administration for Children and Families, 370 L'Enfant Promenade, S.W., Aerospace Building, 7th Floor West, Washington DC 20447. FAX: (202) 205–3598. Phone: (202) 401–9220.

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) may approve research and demonstration project proposals with a broad range of policy objectives.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the **Federal Register** (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

II. Listing of New and Pending Proposals for the Month of July, 1995

As part of our procedures, we are publishing a monthly notice in the **Federal Register** of all new and pending proposals. This notice contains proposals for the month of July, 1995.

Project Title: California—Work Pays Demonstration Project (Amendment).

Description: Would amend Work Pays Demonstration Project by adding provisions to: reduce benefit levels by 10% (but retaining the need level); reduce benefits an additional 15% after 6 months on assistance for cases with an able-bodied adult; time-limit assistance to able-bodied adults to 24 months, and not increase benefits for children conceived while receiving AFDC.

Date Received: 3/14/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Glen Brooks, (916) 657–3291.

Project Title: California—Assistance Payments Demonstration Project (Amendment).

Description: Would amend the Assistance Payments Demonstration Project by: exempting certain categories of AFDC families from the State's benefit cuts; paying the exempt cases based on grant levels in effect in California on November 1, 1992; and renewing the waiver of the Medicaid maintenance of effort provision at section 1902(c)(1) of the Social Security Act, which was vacated by the Ninth Circuit Court of Appeals in its decision in *Beno* v. *Shalala.*

Date Received: 8/26/94.

Type: Combined AFDC/Medicaid.

Current Status: Pending.

Contact Person: Michael C. Genest, (916) 657–3546.

Project Title: California—Work Pays Demonstration Project (Amendment).

Description: Would amend the Work Pays Demonstration Project by adding provisions to not increasing AFDC benefits to families for additional children conceived while receiving AFDC.

Date Received: 11/9/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Eloise Anderson, (916) 657–2598.

Project Title: California—School Attendance Demonstration Project.

Description: In San Diego County, require AFDC recipients ages 16–18 to attend school or participate in JOBS.

Date Received: 12/5/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Michael C. Genest (916) 657–3546.

Project Title: California—Incentive to Self-Sufficiency Demonstration.

Description: Statewide, would require 100 hours CWEP participation per month for JOBS mandatory individuals who have received AFDC for 22 of the last 24 months and are working fewer than 15 hours per week after two years from JOBS assessment and: have failed to comply with JOBS without good cause, have completed CWEP or are in CWEP less than 100 hours per month, or have completed or had an opportunity to complete post-assessment education and training; provide Transitional Child Care and Transitional Medicaid to families who become ineligible for AFDC due to increased assets or income resulting from marriage or the reuniting of spouses; increase the duration of sanctions for certain acts of fraud.

Date Received: 12/28/94.

Type: Combined AFDC/Medicaid.

Current Status: Pending.

Contact Person: Michael C. Genest (916) 657–3546.

Project Title: Georgia—Work for Welfare Project.

Description: Work for Welfare Project. In 10 pilot counties would require every non-exempt recipient and non-supporting parent to work up to 20 hours per month in a state, local government, federal agency or nonprofit organization; extends job search; and increases sanctions for JOBS noncompliance. On a statewide basis, would increase the automobile exemption to $4,500 and disregard earned income of children who are full-time students.

Date Received: 6/30/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Nancy Meszaros, (404) 657–3608.

Project Title: Georgia—JOBS First Program.

Description: In ten pilot counties, would replace AFDC payment with paid employment; extend transitional Medicaid to 24 months; eliminate 100 hour employment rule for eligibility determination in AFDC–UP cases.

Date Received: 7/5/95.

Type: AFDC.

Current Status: New.

Contact Person: Nancy Meszaros, (404) 657–3608.

Project Title: Hawaii—Families Are Better Together.

Description: Statewide, would eliminate 100-hour, attachment to the work force, 30 day unemployment and principal wage earner criteria for AFDC–UP families.

Date Received: 5/22/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Patricia Murakami, (808) 586–5230.

Project Title: Illinois—Six Month Paternity Establishment Demonstration.

Description: In 20 counties, would require the establishment of paternity, unless good cause exists, within 6 months of application or redetermination as a condition of AFDC and Medicaid eligibility for both mother

and child; would deny Medicaid to children age 7 and under, exclude children from filing rules, and exempt Department from making protective payments to eligible children, when custodial parent has not cooperated in establishing paternity; delegate the establishment of paternity in uncontested cases to caseworkers who perform assistance payment or social service functions under title IV–A or XX.

Date Received: 7/18/95.

Title: AFDC Medicaid.

Current Status: New.

Contact Person: Karan D. Maxson, (217) 785–3300.

Project Title: Illinois—School Attendance Demonstration

Description: Statewide, would require the participation in a plan for poor elementary school attendance and, upon continuation of poor attendance, the establishment of a protective payee, progressing to the removal of the caretaker's portion of the AFDC grant.

Date Received: 7/18/95.

Type: AFDC.

Current Status: New.

Contact Person: Karan D. Maxson, (217) 785–3300.

Project Title: Illinois—Work and Responsibility Demonstration.

Description: The demonstration includes six components, five of which will be implemented statewide. (1) Targeted Work Initiative—would limit receipt of AFDC benefits to a total of 24 months without earnings for households whose youngest child is at least 13 years of age; any month with budgeted income due to employment will not be counted toward the 24 month time limit. (2) Get a Job Initiative—new applicants determined to be job ready and whose children are between 5 and 12 will be required to participate in job search for up to six months. (3) Family Accountability—assistance payments will not be increased as a result of the birth of children conceived while the parent was receiving assistance. (4) Job Track—exempt volunteers for JOBS will become subject to the same requirements and sanctions as non-exempt participants; participation in basic education or GED programs will be limited to two years unless the individual is working or participating in an approved work activity. (5) Self-Sufficiency Plan—all applicants and recipients will be required to complete a self-sufficiency plan as a condition of eligibility. (6) Quarterly Budgeting—in selected sites, cases with earned income will be required to report income quarterly; the information will be used to prospectively budget income for the next quarter. Failure to report earnings will result in case closure and overpayment recovery.

Date Received: 7/18/95.

Type: AFDC.

Current Status: New.

Contact Person: Karan D. Maxson, (217) 785–3300.

Project Title: Kansas—Actively Creating Tomorrow for Families Demonstration.

Description: Would, after 30 months of participation in JOBS, make adults ineligible for AFDC for 3 years; replace $30 and 1/3 income disregard with continuous 40% disregard; disregard lump sum income and income and resources of children in school; count income and resources of family members who receive SSI; exempt one vehicle without regard for equity value if used to produce income; allow only half AFDC benefit increase for births of a second child to families where the parent is not working and eliminate increase for the birth of any child if families already have at least two children; eliminate 100-hour rule and work history requirements for UP cases; expand AFDC eligibility to pregnant women in 1st and 2nd trimesters; extend Medicaid transitional benefits to 24 months; eliminate various JOBS requirements, including those related to target groups, participation rate of UP cases and the 20-hour work requirement limit for parents with children under 6; require school attendance; require minors in AFDC and NPA Food Stamps cases to live with a guardian; make work requirements and penalties in the AFDC and Food Stamp programs more uniform; and increase sanctions for not cooperating with child support enforcement activities.

Date Received: 7/26/94.

Type: Combined AFDC/Medicaid.

Current Status: Pending.

Contact Person: Faith Spencer, (913) 296–0775.

Project Title: Maine—Project Opportunity.

Description: Increase participation in Work Supplementation to 18 months; use Work Supplementation for any opening; use diverted grant funds for vouchers for education, training or support services; and extend transitional Medicaid and child care to 24 months.

Date Received: 8/5/94.

Type: Combined AFDC/Medicaid.

Current Status: Pending.

Contact Person: Susan L. Dustin, (207) 287–3106.

Project Title: Maryland—Welfare Reform Project.

Description: Statewide, require minor parents to reside with a guardian; eliminate increased AFDC benefit for additional children conceived while receiving AFDC, with provision for third party payment or voucher/vendor payment for amount of the difference make rent vendor payments to local housing authority when delinquency exceeds 30 days; and issue AFDC benefits 14 days after date of application. In pilot sites, eliminate JOBS exemptions for having a child under age 3 and for having a medical disability of more than 12 months, unless the recipient applies for SSI; require able-bodied recipients who have received AFDC for 3 months to meet a work requirement (unless there is good cause) which will consist of full-time unsubsidized employment, 30 hours of subsidized employment, or a total of at least 20 hours of community service and employment; impose full-family sanction when JOBS non-exempt parent fails to comply with JOBS for 6 months and require parent to comply with JOBS for 30 days before reopening case; provide three more months of aid through a third party payment after full-family sanction is imposed; eliminate work supplementation program restriction from filling unfilled positions; eliminate work history and 100-hour rule requirements for AFDC–UP; require minimum of 20 hours of CWEP after three months of benefit receipt; disregard stepparent income if below 100% of poverty, reduce grant by 50 percent of need standard if income is between 100 and 150% of poverty, and make case ineligible if income is above 150% of poverty; base grant for families with earnings at 85 percent of difference between need standard and earnings; increase both auto and resource limits to $5000; disregard income of dependent children; provide one-time payment in lieu of AFDC benefits; require teen parents to attend family health and parenting classes; extend JOBS services to unemployed non-custodial parents; and cash-out food stamps for work supplementation cases.

Date Received: 3/1/94 and 5/16/95 (Amendments).

Type: AFDC.

Current Status: Pending.

Contact Person: Katherine L. Cook, (410) 767–7338.

Project Title: Massachusetts—Welfare Reform '95.

Description: Statewide, would limit AFDC assistance to 24 months in a 60-month period, with provisions for extensions, for all non-exempt recipients; reduce benefits for non-exempt recipients by 2.75 percent, while increasing earned income

disregard to $30 and one-half indefinitely; establish the Work Program designed to end cash assistance to non-exempt families, requiring recipients who cannot find at least 20 hours per week of paid employment after 60 days of AFDC receipt to do community service and job search to earn a cash ''subsidy'' that would make family income equal to applicable payment standard; fund subsidized jobs from value of AFDC grant plus cash value of Food Stamps for limited number of volunteer recipients; sanction individuals who fail to comply with the Work Program by a reduction in assistance equal to the parent's portion of the grant; establish an Employment Development Plan (EDP) for non-exempt participants not required to participate in the Work Program, requiring community service for second failure to comply with EDP and full-family sanction for second failure to comply with community service; require teen parents to live with guardian or in supportive living arrangements and attend school; require children under age 14 to attend school; eliminate grandparent-deeming; strengthen paternity establishment requirements and allow the IV–D agency to determine if participants are cooperating; allow courts to order parents unable to pay child support to community service programs; exclude from the grant calculation children born to mothers while on AFDC; require child immunization; pay rent directly to landlords where caretaker has fallen behind six weeks in payments; increase asset level to $2,500; increase equity value of a vehicle to $5,000; establish wage assignment in cases of fraud or other overpayments; increased penalties for individuals who commit fraud, release AFDC fraud conviction information to Department of Revenue and the Social Security Administration for cross-check, and deny benefits to individuals with an outstanding default warrant issued by a State court; allow State to issue a clothing allowance voucher for each child; disregard the first $600 of lump sum income; require direct deposit of benefits for recipients with bank accounts; and disregard the 100-hour rule for eligibility for two-parent families.

Date Received: 4/4/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Valerie Foretra, (617) 348–5508.

Project Title: Mississippi—A New Direction Demonstration Program—Amendment.

Description: Statewide, would amend previously approved New Direction Demonstration Program by adding provision that a family's benefits would not increase as a result of additional children conceived while receiving AFDC.

Date Received: 2/17/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Larry Temple, (601) 359–4476.

Project Title: New Hampshire—Earned Income Disregard Demonstration Project.

Description: AFDC applicants and recipients would have the first $200 plus 1/2 the remaining earned income disregarded.

Date Received: 9/20/93.

Type: AFDC.

Current Status: Pending.

Contact Person: Avis L. Crane, (603) 271–4255.

Project Title: New Mexico—Untitled Project.

Description: Would increase vehicle asset limit to $4500; disregard earned income of students; develop an AFDC Intentional Program Violation procedure identical to Food Stamps; and allow one individual to sign declaration of citizenship for entire case.

Date Received: 7/7/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Scott Chamberlin, (505) 827–7254.

Project Title: North Dakota—Training, Education, Employment and Management Project.

Description: Would require families to develop a social contract specifying time-limit for becoming self-sufficient; combine AFDC, Food Stamps and LIHEAP into single cash payment with simplified uniform income, expense and resource exclusions; increase income disregards and exempt stepparent's income for six months; increase resource limit to $5000 for one recipient and $8000 for families with two or more recipients; exempt value of one vehicle; eliminate 100-hour rule for AFDC–UP; impose a progressive sanction for non-cooperation in JOBS or with child support; require a minimum of 32 hours of paid employment and non-paid work; require participation in EPSDT; and eliminate child support pass-through.

Date Received: 9/9/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Kevin Iverson, (701) 224–2729.

Project Title: Ohio—Learning, Earning and Parenting (LEAP) Program.

Description: Statewide, would modify and extend by 6 and ½ years the previously approved Learning, Earning, and Parenting Demonstration to require enrollment and regular school attendance by pregnant and parenting teens; provide a $62 bonus or sanction based on attendance; require continued participation in JOBS by LEAP participants who turn 20 and have a child over 6 weeks of age; provide a $62 grade completion bonus for those in high school; provide a graduation or GED completion bonus of $200; implement a progressive sanction leading to removal of the needs of the teen parent and her child/children in determining amount of AFDC; and continue the LEAP progressive sanction when the participant turns 20, if she remains JOBS mandatory.

Date Received: 6/19/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Jackie Martin, (614) 466–8530.

Project Title: Oregon—Oregon Option.

Description: As a statewide project, would incorporate waivers already approved in 1992 for JOBS Welfare Program and in 1994 for the JOBS Plus Demonstration with previously pending waiver requests to increase vehicle asset limit and extend transitional child care. Requests guaranteed level of federal funding, with funds not used for benefits to be used for other community support or prevention programs. Also would, with some exceptions, limit receipt of AFDC benefits to no more than 24 out of 84 months for families with employable parents; allow case manager to determine JOBS exemptions on an individual basis; eliminate the time restrictions on job search; impose progressive sanctions, leading to full-family ineligibility, for non-compliance with JOBS; require ineligible alien parents of AFDC children to participate in JOBS; require counseling for recipients with substance abuse problems; require teen parents to live in an adult-supervised setting; discontinue the AFDC–UP program from June through September each year and eliminate the 100-hour rule and work history requirements; increase asset limit to $2,500 for non-JOBS participants and $10,000 for JOBS participants, and treat lump-sum payments as an asset; require annual AFDC eligibility redetermination; modify the rules for potential liability under EBT.

Date Received: 7/10/95.

Type: AFDC Medicaid.

Current Status: New.

Contact Person: Jim Neely, (503) 945–5607.

Project Title: Oregon—Expansion of the Transitional Child Care Program.

Description: Provide transitional child care benefits without regard to months of prior receipt of AFDC and provide benefits for 24 months.

Date Received: 8/8/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Jim Neely, (503) 945–5607.

Project Title: Oregon—Increased AFDC Motor Vehicle Limit.

Description: Would increase automobile asset limit to $9000.

Date Received: 11/12/93.

Type: AFDC.

Current Status: Pending.

Contact Person: Jim Neely, (503) 945–5607.

Project Title: Pennsylvania—School Attendance Improvement Program.

Description: In 7 sites, would require school attendance as condition of eligibility.

Date Received: 9/12/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Patricia H. O'Neal, (717) 787–4081.

Project Title: Pennsylvania—Savings for Education Program.

Description: Statewide, would exempt as resources college savings bonds and funds in savings accounts earmarked for vocational or secondary education and disregard interest income earned from such accounts.

Date Received: 12/29/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Patricia H. O'Neal, (717) 787–4081.

Project Title: South Carolina—Family Independence Program.

Description: Statewide, would, with exceptions, time limit AFDC benefits to families with able bodied adults to 24 months out of 120 months, not to exceed 60 months in a lifetime; eliminate increase in AFDC benefit resulting from birth of children 10 or more months after the family begins AFDC receipt, but provide benefits to such children in the form of vouchers for goods and services permitting child's mother to participate in education, training, and employment-related activities; eliminate deprivation requirements, principal earner provisions, work history requirements, and 100-hour rule for AFDC–UP; increase AFDC resource limit to $2,500 and disregard as resources one vehicle with a market value up to $10,000, the balance in an Individual Development Account (IDA) up to $10,000, and the cash value of life insurance; disregard from income up to $10,000 in lump sum payments deposited in an IDA within 30 days of receipt, earned income of children attending school, and interest and dividend income up to $400; require participation in a family skills training program; require certain AFDC recipients to submit to random drug tests and/or participate in alcohol or drug treatment; require children to attend school; increase amount of child support passed through to AFDC recipients; require more extensive information for child support enforcement purposes; modify JOBS exemptions and good cause criteria, and increase sanctions for non-compliance; make job search a condition of eligibility; allow non-custodial parents of AFDC children to participate in JOBS; pay transitional grant equaling 3 percent of the maximum family grant following employment; and provide transitional grant Medicaid and child care for 12 months from the date of employment for cases previously closed due to time limit.

Date Received: 6/12/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Linda Martin, (804) 737–6010.

Project Title: Texas—Service Management and Resources for Teens (SMART).

Description: Would, in pilot site, require non-parenting AFDC youth, age 10 and over to participate in selected communities in schools programs.

Date Received:

Type: AFDC.

Current Status: Pending.

Contact Person: Kent Gummerman, (512) 450–3743.

Project Title: Washington—Success Through Employment Program.

Description: Statewide, would eliminate the 100-hour rule for AFDC–UP families; impose a 10 percent grant reduction for AFDC recipients who have received assistance for 48 out of 60 months, and impose an additional 10 percent grant reduction for every additional 12 months thereafter, and budget earnings against the original payment standard; and hold the food stamp benefit level constant for cases whose AFDC benefits are reduced due to length of stay on assistance.

Date Received: 2/1/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Liz Begert Dunbar, (206) 438–8350.

Project Title: Wisconsin—Self Sufficiency First (SSF).

Description: Statewide, would require applicant adults, as a condition of eligibility, to meet with a financial planning resource specialist prior to completing an application to examine alternatives to welfare; with some exceptions. If the applicant still wants to apply for assistance, as a condition of eligibility, individual must engage in at least 60 hours of JOB search activities during the 30 day application period. Would also limit JOBS exemptions.

Date Received: 4/18/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Jean Sheil, (608) 266–0613.

Project Title: Wisconsin—Pay for Performance (PFP).

Description: Statewide, adult recipients will be required to participate in JOBS up to 40 hours per week; for each hour of non-participation the AFDC grant will be reduced by the federal minimum wage rate; if the AFDC grant is fully exhausted then the remaining sanction will be taken against the Food Stamp (FS) allotment; FS allotments will not be adjusted to account for AFDC reductions resulting from not participating in JOBS activities; if hours of participation fall below 25% of assigned hours without good cause then no AFDC grant will be awarded and the FS amount will be $10. Would also limit JOBS exemptions.

Date Received: 4/18/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Jean Sheil, (608) 266–0613.

III. Listing of Approved Proposals since July 1, 1995

Project Title: Texas—Promoting Child Health in Texas.

Contact Person: Kent Gummerman, (512) 450–3743.

Project Title: Utah—Single Parent Employment Demonstration Program (Amendments).

Contact Person: Bill Biggs, (801) 538–4337.

Project Title: West Virginia—Joint opportunities for independence (JOIN).

Contact Person: Sharon Paterno, (304) 558–3186.

IV. Requests for Copies of a Proposal

Requests for copies of an AFDC or combined AFDC/Medicaid proposal should be directed to the Administration for Children and Families (ACF) at the address listed above. Questions concerning the content of a proposal should be directed to the State contact listed for the proposal.

(Catalog of Federal Domestic Assistance Program, No. 93562; Assistance Payments—Research.)

Dated: August 7, 1995.

Howard Rolston,

Director, Office of Policy and Evaluation.

[FR Doc. 95–19833 Filed 8–10–95; 8:45 am]

BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 95N-0232]

Animal Drug Export; PERCORTEN®-V (Desoxycorticosterone Pivalate) Sterile Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed an application requesting approval for export to Canada of the animal drug Percorten®-V (desoxycorticosterone pivalate) sterile suspension for use as an injectable for dogs.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Gregory S. Gates, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Ciba-Geigy Corp., Animal Health Div., P.O. Box 18300, Greensboro, NC 27419–8300, has filed application number 6321 requesting approval for export to Canada of the animal drug Percorten®-V (desoxycorticosterone pivalate) sterile suspension. The product is intended for use in dogs as partial mineralocorticoid replacement therapy in cases of adrenocortical insufficiency. The application was received and filed in the Center for Veterinary Medicine on July 20, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by August 21, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: July 26, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–19886 Filed 8–10–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0193]

The Dr. Oscar E. Carter, Jr., Memorial Rehabilitation Center, Inc.; Proposal to Revoke Approval of a Narcotic Addiction Treatment Program; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke approval of an ''Application for Approval of Use of Methadone in a Treatment Program'' (Form FDA–2632) (renamed ''Application for Approval for Use of Narcotic Drugs in a Treatment Program'') held by The Dr. Oscar E. Carter, Jr., Memorial Rehabilitation Center, Inc. (Carter). The grounds for the proposed revocation are that the three most recent FDA inspections of the program revealed recurring violations of the Federal narcotic addiction treatment regulations, and the sponsor has failed to demonstrate adequately the ability or willingness to correct and prevent the violations. This document is intended to provide the sponsor an opportunity for a hearing to show why approval should not be revoked.

DATES: Submit a written request for a hearing by September 11, 1995; data and information in support of the hearing request by October 10, 1995.

ADDRESSES: A written request for a hearing, supporting data, and other comments should be identified with Docket No. 95N–0193 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerald R. Hajarian, Center for Drug Evaluation and Research (HFD–342), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1029.

SUPPLEMENTARY INFORMATION:

I. Background

On September 12, 1974, FDA granted Carter approval to operate a narcotic addiction treatment program. Such programs are governed by the rules, standards, and procedures set forth in § 291.505 (21 CFR 291.505). Since the program received approval, FDA has conducted inspections to determine the program's compliance with § 291.505. This notice will document the specific violations revealed in the three most recent inspections, and the events leading to this proposed revocation.

FDA's inspection from September 12 through October 17, 1991, revealed violations of the narcotic addiction treatment regulation in the areas of urinalyses, attendance schedules, medical orders, admission evaluations, counseling, treatment plans, and drug dispensing.

The specific violations were as follows:

1. Failure to maintain drug dispensing records showing batch or code marks of the methadone dispensed, and failure to retain drug dispensing records for 3 years from the date of dispensing (§ 291.505(d)(13)(ii));

2. Failure to maintain methadone daily dispensing records in 5 of 20 patient records reviewed (§ 291.505(d)(13)(ii));

3. Failure to conduct initial drug screening urinalyses for opiates,

cocaine, methadone, amphetamines, and barbiturates in 17 of 20 patient records reviewed (§ 291.505(d)(2)(i));

4. Failure of the program to document who conducted the urinalyses in all 20 patients for which ''Urinalysis Record'' forms showed results of testing for methadone, opiates/opioids, and other drugs (§ 291.505(d)(2)(i) and (d)(13)(iii));

5. Failure to obtain FDA's approval of a change to an in-house laboratory for the detection of opiates and cocaine in human urine, and the failure to test patients for methadone, barbiturates, and amphetamines (§ 291.505(d)(2)(i));

6. Failure to conduct monthly urinalyses on six patients with 6-day take-home privileges (§ 291.505(d)(2)(i));

7. Failure to perform initial serological tests for syphilis and tuberculin skin tests in 19 of 20 patient records reviewed (§ 291.505(d)(3)(i));

8. Failure to maintain current annual treatment plan evaluations by the program physician in 11 of 20 patient records reviewed (§ 291.505(d)(3)(v)(C));

9. Failure to record vital signs (temperature, pulse, blood pressure, and respiratory rate) as part of the admission physical examination in 14 of 20 patient records reviewed (§ 291.505(d)(3)(i));

10. Failure to ensure that the initial dose of methadone did not exceed 30 milligrams (mg) in 3 of the 20 patients whose records were reviewed (§ 291.505(d)(6)(i)(A));

11. Failure to review, reevaluate, and alter as necessary treatment plans at least once each 90 days during the first year of treatment in 4 of the 20 patient records reviewed (§ 291.505(d)(3)(v)(A));

12. Failure of the program physician to sign one patient's medication order change and to record the correct date for another patient's medication order change (§ 291.505(d)(6)(i)(B)); and

13. Failure to comply with the take-home medication requirements for 2 of the 20 patients whose records were reviewed (§ 291.505(d)(6)(iv));

At the conclusion of the inspection, the FDA investigator presented a list of observations (Form FDA 483), and discussed the findings with the sponsor and his staff. Program management attributed the violations to a lack of good recordkeeping practices and the lack of knowledge of the regulation.

FDA issued a warning letter on December 6, 1991, listing the violations. The program sponsor submitted a response on December 14, 1991, listing a number of corrective measures that had been, or would be, implemented, and pledging that the violations would not recur.

FDA and the Drug Enforcement Administration (DEA) conducted a joint inspection of the program from July 9 through July 28, 1992. This inspection revealed recurring violations in the areas of urinalyses, attendance schedules, medical orders, admission evaluations, counseling, treatment plans, and drug dispensing.

The specific violations identified in this inspection were as follows:

1. Failure to conduct monthly urinalyses on 5 patients with 6-day take-home privileges (§ 291.505(d)(2)(i));

2. Failure of the program physician to document his review of initial drug screening reports in 5 of 10 patient records reviewed (§ 291.505(d)(1)(i)(C), (d)(2), and (d)(4)(ii)(C));

3. Failure to provide counseling to patients whose urinalyses showed an absence of methadone and/or continued use of drugs of abuse in 5 of 10 patient records reviewed (§ 291.505(d)(3)(v) and (d)(13)(iii));

4. Failure of the supervisory counselor to countersign treatment plans in 5 of 10 patient records reviewed (§ 291.505(d)(3)(iv)(C));

5. Failure of the program physician to record the rationale for authorizing take-home medication, and failure to record medication orders in 4 of 10 patient records reviewed (§ 291.505(d)(4)(ii)(D) and (d)(6)(iv)(A));

6. Failure to perform initial serological tests for syphilis in 3 of 10 patient records reviewed (§ 291.505(d)(3)(i));

7. Failure of program physician to ensure that initial serological tests for syphilis were reviewed in 3 of 10 patient records reviewed (§ 291.505(d)(4)(ii)(C));

8. Failure to perform an initial tuberculin skin test and vital signs in 1 of 10 patient records reviewed (§ 291.505(d)(3)(i)); and

9. Failure to maintain accurate drug dispensing records. For example, records failed to record dosages for five patients, which were given to the patients on the 31st of the month (in months with 31 days). Also, records failed to contain batch or code marks of the methadone dispensed traceable to specific patients (§ 291.505(d)(13)(ii)).

On the basis of recurring violations, FDA issued a ''Proposal To Revoke Narcotic Treatment Program Approval; Notice of Informal Conference'' on October 1, 1992, in accordance with § 291.505(h)(2). The October 1, 1992, notice summarized the violations observed during the last three inspections and offered the sponsor an opportunity to appear at an informal conference and explain why the program approval should not be revoked. The notice also invited the sponsor to submit a ''comprehensive action plan'' for correcting the deficiencies in the program.

The informal conference was held on January 6, 1993, at FDA's New Orleans District Office. The sponsor did not submit a comprehensive written corrective action plan at the conference. The sponsor indicated, however, that steps had been taken to make necessary corrections and that he had requested that the State and the Center for Substance Abuse Treatment (CSAT) provide technical assistance to the program. FDA's District Office gave the sponsor until February 20, 1993, to submit a written corrective action plan.

In a February 23, 1993, letter to the district office, the sponsor presented a corrective action plan and timeframes for implementation. The action plan included: (1) Installing a computerized dispensing system, (2) hiring additional personnel, and (3) obtaining a commitment for technical assistance. The sponsor asked FDA for one final opportunity to implement the recommendations of the technical assistance group.

FDA held its decision regarding revocation of approval in abeyance pending completion of the technical assistance from CSAT by June 30, 1993, and pending a reinspection of the program. FDA agreed to give the program one final opportunity to achieve regulatory compliance.

The most recent inspection of December 13, 1994, through January 24, 1995, revealed recurring violations in the areas of urinalyses, attendance schedules, medical orders, admission evaluations, counseling, treatment plans, and drug dispensing.

The specific violations were as follows:

1. Failure to provide the required services for two patients regarding pregnancy evaluation, prenatal counseling, and treatment outcome of the patient and offspring (§ 291.505(d)(4)(i)(B));

2. Failure to document in the 13 patient records reviewed that the program physician has considered, at a minimum, the following in determining whether a patient's frequency of clinic visits for observed drug ingesting may be reduced: Absence of recent drug abuse; regularity of clinic attendance; absence of behavioral problems; absence of recent criminal activity; stability of the patient; length of time in treatment; assurance that take-home medication can be safely handled by the patient; and whether the benefits of take-outs outweigh the risks of diversion (§ 291.505(d)(6)(iv)(B));

3. Failure to document that two patients on 6-day, take-home

medication had monthly drug screening urinalyses for opiates, methadone, amphetamines, cocaine, barbiturates, and other drugs of abuse performed by a certified clinical laboratory (§ 291.505(d)(2)(i));

4. Failure to justify medication in excess of a 6-day, take-home supply given to three patients; failure to require two patients to complete 3 consecutive years of maintenance treatment at the program before being permitted to reduce their attendance for observation to once weekly; and failure to place one patient, who was receiving a 6-day supply of take-home medication, on probation for 3 months after his urinalysis was positive for a drug of abuse (§ 291.505(d)(4)(ii)(F), (d)(6)(v)(A)(*3*), and (d)(6)(v)(B)(*2*));

5. Failure of the program to have a licensed physician record, date, and sign in 2 of 13 records reviewed a change in each patient's dosage schedule (§ 291.505(d)(6)(i)(B));

6. Failure to document drug addiction and conduct physical examinations on two patients and failure to ensure that a transferring patient received a physical examination and documentation of addiction prior to administering the initial dose of methadone (§ 291.505(d)(1)(i)(C), (d)(4)(ii)(A), and (d)(4)(ii)(B));

7. Failure to ensure that the initial dose of methadone dispensed to two patients did not exceed 30 mg (§ 291.505(d)(6)(i)(A));

8. Failure of the program physician to document his review of initial drug screening urinalysis reports with his signature for two patients; and failure to document the review of random drug-screening urinalysis reports for five patients (§ 291.505(d)(2) and (d)(4)(ii)(C));

9. Failure of the program's counselors to document that three patients received counseling regarding drug-screening urinalyses that showed continued use of illicit drugs or the absence of methadone in these patients while undergoing methadone treatment (§ 291.505(d)(13)(iii));

10. Failure to obtain a signed ''Consent to Treatment With an Approved Narcotic Drug'' Form from two patients prior to admission to the program (§ 291.505(d)(1)(ii));

11. Failure to document that five patients received counseling on HIV disease upon admission or readmission for treatment (§ 291.505(d)(4)(i)(C));

12. Failure of the admitting physician to document his review of tuberculin skin test reports with his signature in the patient record for four patients; failure of the program physician to include the results of initial serological tests for syphilis in the patient records for nine patients (§ 291.505(d)(3)(ii));

13. Failure of the primary counselor and/or the program physician to countersign treatment plans for eight patients; failure to properly date treatment plan for one patient; failure to have an initial treatment plan on file for readmission of one patient; and failure of the primary counselor or program physician to prepare and review the periodic treatment plan for one patient within the proper timeframes (§ 291.505(d)(3)(iv) and (d)(3)(v));

14. Failure of the program to maintain drug dispensing records that permit traceability of drug lot numbers to specific patients on those days when a change from one lot number to another occurs (§ 291.505(d)(13)(ii));

15. Failure of the program physician to document that he requested from the physician or hospital to which the program referred two pregnant patients a summary of the delivery outcome for the patients and the offspring (§ 291.505(d)(1)(iii)(B)(*3*) and (d)(4)(i)(B)(*2*));

16. Failure to require that a patient, who had only been admitted to the program for 1 month, demonstrate adherence to the program's rules for at least 2 years before allowing the patient to decrease his personal attendance to twice weekly (§ 291.505(d)(6)(v)(A)(*2*)); and

(17) Failure of the program to account for, and require the return of, six extra doses of take-home medication dispensed to a patient for use during out-of-town travel that was subsequently postponed (§ 291.505(d)(13)(ii) and (d)(14)).

At the conclusion of the inspection, the FDA investigator presented a list of observations (Form FDA 483), and discussed the inspectional findings with the sponsor and his staff. The program sponsor promised to respond to the inspectional findings in writing, but has failed to do so.

II. Conclusion, Findings, and Proposed Action

As discussed above, the three most recent inspections of Carter conducted by FDA from September 12 through October 17, 1991; July 9 through July 28, 1992; and December 13, 1994, through January 24, 1995, revealed recurring violations of the Federal narcotic addiction treatment regulation, which sets forth the standards for use of narcotic drugs for medical treatment of narcotic addiction. In letters of December 14, 1991, December 9, 1992, and February 23, 1993, and during the January 6, 1993, informal conference, the sponsor made promises to correct the violations. However, as the December 13, 1994, through January 24, 1995, inspection demonstrated, the sponsor has failed to abide by all of the narcotic addiction treatment regulations, has failed to monitor the activities of those employed in the program adequately, and has generally failed to correct the program's recurring problems.

Accordingly, as provided by § 291.505(h)(3) and (i), the Director, Center for Drug Evaluation and Research, proposed revocation of Carter's program approval to the Associate Commissioner for Regulatory Affairs. The Associate Commissioner for Regulatory Affairs has evaluated the available information and finds that the program sponsor has failed to submit adequate assurances justifying continued approval of the program.

III. Notice of Opportunity for a Hearing

Notice is hereby given to the sponsor of the Narcotic Treatment Program listed above, and to all other interested persons, that the Associate Commissioner for Regulatory Affairs, under authority delegated to him (21 CFR 5.20) proposes to issue an order under § 291.505(h)(3) revoking approval of the ''Application for Approval for Use of Narcotic Drugs in a Treatment Program'' (Form FDA–2632) held by The Dr. Oscar E. Carter, Jr., Memorial Rehabilitation Center, Inc., 5500 North Johnson St., New Orleans, LA 70117, on the grounds stated above. In accordance with part 314 (21 CFR part 314), the sponsor is hereby given an opportunity for a hearing to show why approval should not be revoked.

The sponsor who decides to seek a hearing shall file: (1) On or before September 11, 1995, a written notice of appearance and request for a hearing, and (2) on or before October 10, 1995, information and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, submissions of data, information, and analyses to justify a hearing, other comments, and the granting or denial of a hearing are contained in § 314.200.

The failure of the applicant to file a timely written notice of appearance and request for a hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed, and a waiver of any contentions concerning the legal status of that

person's narcotic addiction treatment program.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that precludes the revocation of approval of the application, or when a request for a hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in six copies. Except for data and information prohibited from public disclosure under 42 CFR part 2, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 4, 1995.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 95–19885 Filed 8–10–95; 8:45 am]

BILLING CODE 4160–01–F

Public Health Service

Agency Forms Undergoing Paperwork Reduction Act Review

Each Friday the Public Health Service (PHS) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the PHS Reports Clearance Office on (202) 690–7100.

The following requests have been submitted for review since the list was last published on July 21.

1. National Institutes of Health Construction Grants—42 CFR Part 52b–NPRM—New—Revised regulations governing NIH construction grants require the transfer of a facility or the owner of a facility, the use of which has changed, to provide written notice of the sale, transfer or change within 30 days. The regulations also require awardees to maintain and provide daily construction logs and provide a copy of the construction schedule; and applicants to provide cost data for projects involving the acquisition of existing facilities. *Respondents:* Federal agencies or employees, Non-profit institutions; *Number of Respondents:* 1; *Number of Responses per Respondent:* 1; *Average Burden per Response:* 1 hour; *Estimated Annual burden:* 1 hour. Send comments to Allison Eydt, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

2. AIDS Drug Discovery and Development Industry Survey—New—The National Task Force on AIDS Drug Development has identified inadequate levels of private sector activity in HIV/AIDS drug discovery targeting the human immunodeficiency virus (HIV) on molecular level as a significant obstacle to the development of new therapies. The Public Health Service is conducting this survey to determine the extent of private sector activity in this area, and to determine whether there are obstacles to further activity and collaboration in HIV/AIDS drug discovery and development between the public and private sectors. *Respondents:* Business or other for-profit; *Number of Respondents:* 300; *Number of Responses per Respondent:* 1; *Average Burden per Response:* 2 hours; *Estimated Annual burden:* 600 hours. Send comments to Allison Eydt, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

Written comments and recommendations concerning the proposed information collections should be sent within 30 days of this notice directly to the individual designated.

Dated: August 1, 1995.

James Scanlon,

Director, Data Policy Staff Office of the Assistant Secretary for Health and PHS Reports Clearance Officer.

[FR Doc. 95–19383 Filed 8–10–95; 8:45 am]

BILLING CODE 4160–01–M

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 60 FR 18607, April 12, 1995) is amended to reflect a reorganization within the Office of the Director, Office of Research Services (ORS). The reorganization consists of establishing the Office of Quality Development. This reorganization is consistent with Administration objectives related to the National Performance Review and the Continuous Improvement Program. This reorganization will enable ORS to better fulfill its mission by centralizing the focus of widespread reengineering, streamlining, and quality management efforts that are currently taking place within ORS.

Section HN–B, Organization and Functions, is amended as follows: Under the heading *Office of the Director (HNAL1), Office of Research Services (HNAL)*, insert the following:

Office of Quality Development (HNAL13). (1) Provides leadership and support to ORS management in developing methods to move ORS towards a total quality culture in customer service and customer and employee satisfaction; (2) promotes quality development initiatives across ORS through management consultation, reinvention efforts, organizational redesign, total quality management, team building, strategic planning, human resource development, and effective training of managers and employees; and (3) serves as the focal point for ORS streamlining initiatives aimed at achieving downsizing targets and achieving customer satisfaction through continuous process improvement, reengineering and other organizational quality improvement methods.

Dated: July 28, 1995.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 95–19873 Filed 8–10–95; 8:45 am]

BILLING CODE 4140–01–M

National Institutes of Health; Statement of Organizations, Functions and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 60 FR 18607, April 12, 1995), is amended to reflect the establishment of the Office of Information Systems Management (OISM) within the National Center for Human Genome Research (NCHGR). The establishment of the OISM will streamline organization within the NCHGR by bringing together all NCHGR staff with responsibility for information systems management under one umbrella organization and allow the Center to operate more effectively by making the most efficient use of manpower and resources.

Section HN-B, Organization and Functions is amended as follows:

Under the heading *National Center for Human Genome Research (HN4)*, add the title and functional statement for the OISM as follows:

Office of Information Systems Management (HN416): (1) Provides technical leadership and advice to all levels of Center management in order to obtain maximum utilization of current ADP resources and advancements in the field of information systems technology and telecommunications; (2) determines requirements, designs, implements and coordinates the Center's management information systems which collect, maintain, and report various types of administrative information; (3) advises the NCHGR Director, Deputy Director and Executive Officer, and other Center staff on the technological and policy impact and implications of developments in information systems and related fields within and outside the government; (4) coordinates staff activities with those of contractors, other components of NIH, and other Federal and non-Federal data processing agencies; (5) provides user support, including training, in LAN/information systems capabilities, programs and procedures.

Under the heading *Office of Policy Coordination (HN415)*, delete ''(6) plans and coordinates computer network operations'', since these activities have been incorporated into the functional statement for the OISM.

Under the heading *Office of Information Management (HN45E)*, delete the title and functional statement in their entirety, since these activities have been incorporated into the Office of Information Systems Management.

Dated: July 28, 1995.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 95–19874 Filed 8–10–95; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. FR–3778–N–49]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

ADDRESSES: For further information, contact David Pollack, room 7256, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1234; TDD number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 56 FR 23789 (May 24, 1991) and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Judy Breitman, Division of Health Facilities Planning, U.S. Public Health Service, HHS, room 17A–10, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-fee number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 56 FR 23789 (May 24, 1991).

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to David Pollack at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register,** the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: Corps of Engineers: Gary B. Paterson, Chief, Base Realignment and Closure Office, Directorate of Real Estate, 20 Massachusetts Ave., NW, Rm. 4133, Washington, DC 20314–1000; (202) 761–0520; GSA: Ed Guilford, Federal Property Resources Services, GSA, 18th and F Streets NW, Washington, DC 20405; (202) 501–2059; Dept. of Transportation: Ronald D. Keefer, Director, Administrative Services & Property Management, DOT, 400 Seventh St. SW, room 10319, Washington, DC 20590; (202) 366–4246; Dept. of Interior: Lola D. Knight, Property Management Specialist, Dept. of Interior, 1849 C. St. NW, Mailstop 5512–MIB, Washington, DC 20240; (202) 208–4080; (These are not toll-free numbers).

Dated: August 4, 1995.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

Title V, Federal Surplus Property Program, Federal Register Report for 08/11/95

Suitable/Available Properties

Buildings (by State)

California

Bldg. 901
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520001
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 902
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520002
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 903
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520003
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 904
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520004
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 905
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520005
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 906
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520006
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 907
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520007
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 908
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520008
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 909
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520009
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 910
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520010
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 911
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520011
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 912
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520012
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 913
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520013
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 914
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520014
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 915
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520015
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 916
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520016
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 917
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520017
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 918
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520018
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

Bldg. 919
Former Presidio of San Francisco
San Francisco Co: San Francisco CA 94129–
Landholding Agency: Interior
Property Number: 619520019
Status: Surplus
Comment: 2-story wood frame bldgs.; lead paint & asbestos; off-site removal only; incs. office space, warehouse & housing

NPS Residence #723
Rancheria Flat Road
El Portal Co: Mariposa CA 95318–
Landholding Agency: Interior
Property Number: 619520026
Status: Excess
Comment: 2210 sq. ft., one story wooden frame residence, off-site use only

Brown House 07–129
Highway 199
Hiouchi Co: Del Norte CA 95531–
Landholding Agency: Interior
Property Number: 619520030
Status: Excess
Comment: 1 story wood frame residence, off-site removal only

Christ House 07–130
Highway 199
Hiouchi Co: Del Norte CA 95531–
Landholding Agency: Interior
Property Number: 619520031
Status: Excess
Comment: 1269 sq. ft., 1 story wood frame residence, off-site removal only, need repairs

Dunkley House 07–127
Highway 199
Hiouchi Co: Del Norte CA 95531–
Landholding Agency: Interior
Property Number: 619520032
Status: Excess
Comment: 1269 sq. ft., 1 story wood frame residence, need repairs, off-site removal only

Graton House 07–125
Highway 199
Hiouchi Co: Del Norte CA 95531–
Landholding Agency: Interior
Property Number: 619520033
Status: Excess

Comment: 1665 sq. ft., 1 story wood frame residence, need repairs, off-site removal only

Schach House 07–105
Highway 199
Hiouchi Co: Del Norte CA 95531–
Landholding Agency: Interior
Property Number: 619520034
Status: Excess
Comment: 700 sq. ft., 1 story wood frame residence, off-site removal only, need repairs

Young House 07–132
Highway 199
Hiouchi Co: Del Norte CA 95531–
Landholding Agency: Interior
Property Number: 619520035
Status: Excess
Comment: 1442 sq. ft., 1 story wood frame residence, off-site removal only

Colorado

Bldg. 00038
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001–
Landholding Agency: COE—BC
Property Number: 329530007
Status: Unutilized
Base closure
Number of Units: 1
Comment: 846 sq. ft., wood or brick frame, secured area w/alt. access incs. credit union, storage purposes only, bldgs. unutilized until chemical demilitarization is completed in 2004.

Bldg. 00594
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001–
Landholding Agency: COE—BC
Property Number: 329530008
Status: Unutilized
Base closure
Number of Units: 1
Comment: 1000–1400 sq. ft., wood or brick frame, secured area w/alt. access, incs. car wash/maint. fac., storage purposes only, unutil. until chemical demilitarization is completed in 2004

6 Administration Bldgs.
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00153, 00154, 00525, 00542, 00731, 00594
Landholding Agency: COE–BC
Property Number: 329530009
Status: Unutilized
Base closure Number of Units: 6
Comment: 551–46626 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, bldgs. unutilized until chemical demilitarization is completed in 2004

5 Dining Facilities
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00180, 00440, 00556, 00579
Landholding Agency: COE–BC
Property Number: 329530010
Status: Unutilized
Base closure Number of Units: 5
Comment: 727–3557 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, includes lunchrooms & restaurant, unutilized until demilitarization is completed in 2004

16 Support Facilities
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00425, 00427, 00432, 00434, 00558, 00080, 00150, 00164, 00413, 00430, 00494, 00523, 00587, 00032, 00041 & 00042
Landholding Agency: COE–BC
Property Number: 329530011
Status: Unutilized
Base closure Number of Units: 16
Comment: 67–2400 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, incs. cable house, sentry stations, scale houses, unutil. until demilitar. comp.—2004

17 Storage/Shed Facilities
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00542, 00401, 00402, 00408, 00409, 00410, 00407, 00510, 00152, 00162, 00163, 00166–00168, 00157, 00374 & 00503
Landholding Agency: COE–BC
Property Number: 329530012
Status: Unutilized
Base closure Number of Units: 17
Comment: 363–45000 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, incs. liquid props., salv. & surplus storage, unutilized until chemical demil. comp.—2004

20 Storehouses
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00089, 00155, 00131, 00135, 00474, 00560, 00184, 00766, 00771, 00776, 00201, 00203–00209, 00540 & 00938
Landholding Agency: COE–BC
Property Number: 329530013
Status: Unutilized
Base closure Number of Units: 20
Comment: 661–36751 sq. ft., wood or brick frame, secured area w/alt. access, incs. FE storehouses, inflamable materials bldgs, unutilized until chemical demil. comp. in 2004, storage only

19 Maintenance Facs./Shops
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00275, 00323, 00348, 00349, 00373, 00158, 00159, 00590, 00231, 00529, 00532, 00804, 00522, 00941–00943, 00115, 00416 & 00067
Landholding Agency: COE–BC
Property Number: 329530014
Status: Unutilized
Base closure Number of Units: 19
Comment: 30–7294 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, incs. rocket ovhl. facs., dunnage blds, etc., unutilized until chem. demil. comp.—2004

10 Transfer Depots/Range Facs.
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00273, 00296, 00320, 00340, 00365, 00473, 00498, 00946, 01210 & 01220
Landholding Agency: COE–BC
Property Number: 329530015
Status: Unutilized
Base closure Number of Units: 10
Comment: 80–3600 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, blds, are unutilized until chemical demilitarization is completed in 2004

31 Warehouses
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Landholding Agency: COE–BC
Property Number: 329530016
Status: Unutilized
Base closure Number of Units: 31
Comment: 2000–203177 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, incs. gen. purp. & open storage warehouses, unutilized until chem. demil. comp.—2004

38 Ammo Facilities/Shops
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Landholding Agency: COE–BC
Property Number: 329530017
Status: Unutilized
Base closure Number of Units: 38
Comment: 67–14916 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, bldgs. are unutilized until chemical demilitarization is completed in 2004

12 Vehicle Maint. Shops/Facs.
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00567, 00507, 00508, 00575, 00589, 00545, 00546, 00547, 00595, 00594, 00592, & 00074
Landholding Agency: COE–BC
Property Number: 329530018
Status: Unutilized
Base closure Number of Units: 12
Comment: 42–106332 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, incs. gas stat., maint. shops blds. are unutilized until chemical demil. completed in 2004

8 Utility Facilities
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Landholding Agency: COE–BC
Property Number: 329530019
Status: Unutilized
Base closure Number of Units: 8
Comment: 116–17220 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, incs. heating plants, bldgs. unutilized until chemical demilitarization completed in 2004

6 Magazine Facilities
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001-
Location: Includes #00807, 00809, 00816, 00818, 00820 & 00420
Landholding Agency: COE–BC
Property Number: 329530020
Status: Unutilized
Base closure Number of Units: 6
Comment: 69–371 sq. ft., wood or brick frame, secured area w/alt. access, storage purposes only, bldgs. are unutilized until chemical demilitarization is completed in 2004

Former AF Finance Center
3800 York Street
Denver Co: Denver CO 80205-
Landholding Agency: GSA
Property Number: 549310011
Status: Excess
Comment: 293,932 sq. ft., 1-story timber frame with masonry exterior, fair

condition, most recent use—storage, office, rehab
GSA Number: 7–GR–CO–468–D

Massachusetts

17 Single Family Residences
Navy Family Housing, Westover AFB
Chicopee Co: Hampden MA 01022-
Landholding Agency: GSA
Property Number: 549520001
Status: Excess
Comment: Various sq. ft., good condition, utilities systems modification

99 Duplex Residences
Navy Family Housing, Westover AFB
Chicopee Co: Hampden MA 01022-
Landholding Agency: GSA
Property Number: 549520003
Status: Excess
Comment: various sq. ft., good condition, utilities systems modification

20 Fourplex Residences
Navy Family Housing, Westover AFB
Chicopee Co: Hampden MA 01022-
Landholding Agency: GSA
Property Number: 549520004
Status: Excess
Comment: various sq. ft., good condition, utilities systems modification

NPS Tract #250–50
Former Kimpel Property
Sheffield Co: Berkshire MA 01257-
Landholding Agency: Interior
Property Number: 619510004
Status: Excess
Comment: 1724 sq. ft., 2 story wood frame house w/detached garage; off-site removal only

Minnesota

Coast Guard Family Housing
404 East Hamilton Avenue
Baudette Co: Lake of the Woods MN 56623-
Landholding Agency: GSA
Property Number: 549230007
Status: Surplus
Comment: 1333 sq. ft., 1-story frame residence
GSA Number: 2–U–MN–503–E

Coast Guard Family Housing
406 East Hamilton Avenue
Baudette Co: Lake of the Woods MN 56623-
Landholding Agency: GSA
Property Number: 549230008
Status: Surplus
Comment: 1633 sq. ft., 1-story wood frame residence
GSA Number: 2–U–MN–503–E

Coast Guard Family Housing
408 East Hamilton Avenue
Baudette Co: Lake of the Woods MN 56623-
Landholding Agency: GSA
Property Number: 549230009
Status: Surplus
Comment: 1633 sq. ft., 1-story wood frame residence
GSA Number: 2–U–MN–503–E

Coast Guard Family Housing
418 East Hamilton Avenue
Baudette Co: Lake of the Woods MN 56623-
Landholding Agency: GSA
Property Number: 549230010
Status: Surplus
Comment: 1633 sq. ft., 1-story wood frame residence
GSA Number: 2–U–MN–503–E

Nevada

1 Single Family Residence
Tonopah Housing Complex
Tonopah Co: Nye NV 89049-
Landholding Agency: GSA
Property Number: 549430005
Status: Excess
Comment: 1527 sq. ft., 1 story wood residence, 4 bedrooms/2 bathrooms
GSA Number: 9–U–NV–467–C

New Jersey

Sandy Hook Light
Middletown Co: Monmouth NJ 07732-
Location: Adjacent to Gateway National Recreation Area
Landholding Agency: DOT
Property Number: 879340001
Status: Unutilized
Comment: Brick 29′ base diameter lighthouse, historic structure, needs major rehab

New Mexico

Hornkohl Property
Petroglyph National Monument
Albuquerque Co: Bernalillo NM 87120–
Landholding Agency: Interior
Property Number: 619510001
Status: Excess
Comment: 1-story wood frame residence, needs rehab, off-site use only

North Carolina

Portion VA Reservation
Nurses Quarters
Oteen Co: Buncombe NC
Landholding Agency: GSA
Property Number: 549320006
Status: Excess
Comment: 8752 sq. ft., 3-story stucco bldg., presence of asbestos, most recent use—educational facility
GSA Number: 4–GR–NC–481B

Dwelling 1
USCG Coinjock Housing
Coinjock Co: Currituck NC 27923–
Landholding Agency: DOT
Property Number: 879120083
Status: Unutilized
Comment: one story wood residence, periodic flooding in garage and utility room occurs in heavy rainfall

Dwelling 2
USCG Coinjock Housing
Coinjock Co: Currituck NC 27923–
Landholding Agency: DOT
Property Number: 879120084
Status: Unutilized
Comment: one story wood residence, periodic flooding in garage and utility room occurs in heavy rainfall

Dwelling 3
USCG Coinjock Housing
Coinjock Co: Currituck NC 27923–
Landholding Agency: DOT
Property Number: 879120085
Status: Unutilized
Comment: one story wood residence, periodic flooding in garage and utility room occurs in heavy rainfall

Ohio

Zanesville Federal Building
65 North Fifth Street
Zanesville Co: Muskingum OH
Landholding Agency: GSA
Property Number: 549520018
Status: Excess
Comment: 18750 sq. ft., most recent use—office, possible asbestos, eligible for listing on the Natl Register of Historic Places
GSA Number: 2–G–OH–781A

Pennsylvania

NPS Tract #380–51
Appalachian National Scenic Trail
Waynesboro Co: Franklin PA 17268–
Landholding Agency: Interior
Property Number: 619520020
Status: Unutilized
Comment: 982 sq. ft. frame house, off-site use only

Former Coleman House
Appalachian Trail Tract 373–37
Big Flats Co: Cumberland PA 17307–
Location: Ridge Road, Route 1
Landholding Agency: Interior
Property Number: 619530008
Status: Excess
Comment: 1008 sq. ft., 1 story concrete block residence, off-site removal only

Former Raffensperger Cabin
Appalachian Trail Tract 373–39
Ridge Road
Big Flats Co: Cumberland PA 17307–
Landholding Agency: Interior
Property Number: 619530009
Status: Excess
Comment: 380 sq. ft., 1 story wood frame, need repairs, off-site removal only, most recent use—hunting cabin

Tennessee

Knoxville Job Corps Center
621 Dale Avenue
Knoxville Co: Knox TN 37921–
Landholding Agency: GSA
Property Number: 549520005
Status: Excess
Comment: 23,445 sq. ft.; 4 stories, concrete, brick, masonry, steel structure; incs. 115,000 sq. ft. parking lot; most recent use—student housing and Job Corps Center
GSA Number: 4–L–TN–641

Federal Building-Post Office
Liberty and Main Streets
Jacksboro Co: Campbell TN 37757–
Landholding Agency: GSA
Property Number: 549520006
Status: Excess
Comment: 3,967 sq. ft., 2 story brick, steel frame; presence of asbestos; most recent use—office space/storage
GSA Number: 4–G–TN–639

Federal Bldg.—Post Office
Main Street and Maiden Lane
Wartburg TN 37887–
Landholding Agency: GSA
Property Number: 549520008
Status: Excess
Comment: 7,603 sq. ft., 1 story, brick structure; most recent use—post office and office space for federal tenants
GSA Number: 4–G–TN–640

Texas

USDA Subtropical Agricultural Research Center
509 West 4th Street
Weslaco Co: Hidalgo TX 78557–
Landholding Agency: GSA
Property Number: 549520007

Status: Excess
Comment: 8000 sq. ft., 1 story; most recent use—office/lab; potential utilities; needs rehab.
GSA Number: 7–A–TX–1039

Virginia

NPS Tract 422–25
Former White property
County Rd. 602 on Moore Run near 4–H Camp
Front Royal Co: Warren VA 22630–
Landholding Agency: Interior
Property Number: 619440002
Status: Excess
Comment: 864 sq. ft., 2-story frame residence, w/Natl. Appalachian Trails System Act, off-site use only

Former Oliver Shed
Appalachian Trail Tract 420–15
Linden Co: Fauquier VA 22642–
Location: Rural, between routes 55 and 638, southeast of Linden
Landholding Agency: Interior
Property Number: 619530010
Status: Excess
Comment: 800 sq. ft., 1 story wood storing shed, off-site removal only

Housing
Rt. 637—Gwynnville Road
Gwynn Island Co: Mathews VA 23066
Landholding Agency: DOT
Property Number: 879120082
Status: Unutilized
Comment: 929 sq. ft., one story residence

Washington

Construction Office Bldg.
Roosevelt Way
Coulee Dam Co: Okanogan WA 99116–
Landholding Agency: Interior
Property Number: 619410002
Status: Excess
Comment: 7778 sq. ft., 1 story frame structure, off-site removal only, most recent use—offices

Wyoming

Ranger Dwelling #1
205 Spring Street
Cokeville Co: Lincoln WY 83114–
Landholding Agency: GSA
Property Number: 549520015
Status: Excess
Comment: 1652 sq. ft., brick residence
GSA Number: 7–A–WY–535

Old Kelley House
Ranger Dwelling #2, 410 Pine Street
Cokeville Co: Lincoln WY 83114–
Landholding Agency: GSA
Property Number: 549520016
Status: Excess
Comment: 2480 sq. ft., log and wood frame home, needs rehab
GSA Number: 7–A–WY–535–A

Land (by State)

Arizona

Tract No. APO–SRP–RB–5
Mesa Co: Maricopa AZ 85213–
Location: 2000′ south of Thomas Road at Val Vista Drive
Landholding Agency: Interior
Property Number: 619410005
Status: Unutilized
Comment: 0.57 acre; 20 foot strip of land which is 1,026 ft. long

California

Receiver Site
Dixon Relay Station
7514 Radio Station Road
Dixon CA 95620–9653
Location: Approximately .16 miles southeast of Dixon, CA.
Landholding Agency: GSA
Property Number: 549010042
Status: Excess
Comment: 80 acres, 1560 sq. ft. radio receiver bldg. on site, subject to grazing lease, limited utilities.
GSA Number: 9–2–CA–1162–A

Receiver Site
Delano Relay Station
Route 1, Box 1350
Delano Co: Tulare CA 93215–
Location: 5 miles west of Pixley, 17 miles north of Delano.
Landholding Agency: GSA
Property Number: 549010044
Status: Surplus
Comment: 81 acres, 1560 sq. ft. radio receiver bldg. on site, subject to grazing lease, potential utilities, environmental restrictions
GSA Number: 9–2–CA–1308

(P) Camp Elliott
Rosedale Tract
San Diego Co: San Diego CA
Landholding Agency: GSA
Property Number: 549310008
Status: Surplus
Comment: Parcel 1–0.15 acre, Parcel 2–0.17 acre, located in the narrow median strip between Murphy Canyon Rd. and State Highway 15, previously leased by homeless provider
GSA Number: 9–GR(6)–CA–694A

L–4 Reservoir
La Quinta Co: Riverside CA 92253–
Location: Borders Adams St., ¼ mile north of Calle Tampico
Landholding Agency: Interior
Property Number: 619410004
Status: Excess
Comment: 1.69 acres; concrete reservoir; most recent use—water retention

Colorado

Golf Range
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001–
Landholding Agency: COE–BC
Property Number: 32953006
Status: Unutilized
Base closure
Number of Units: 1
Comment: secured area w/alternate access, bldgs. are unutilized until chemical demiliatraization is completed in 2004

619 Ammo Storage Pads
Pueblo Depot Activity
Pueblo CO: Pueblo CO 81001–
Landholding Agency: COE–BC
Property Number: 329530021
Status: Unutilized
Base closure
Number of Units: 619
Comment: 200 sq. yds. each, concrete pads

Florida

Jacksonville Com. Annex
U.S. Highway 17
Orange Park Co: Clay FL 32073–
Landholding Agency: GSA
Property Number: 549520013
Status: Excess
Comment: 5.35 fee acres, bldgs. gutted, road easement
GSA Number: 4–D–FL–780

Georgia

Naval Submarine Base
Kings Bay Co: Camden GA
Landholding Agency: GSA
Property Number: 549520012
Status: Excess
Comment: 20+ acres, elementary school on site/not owned by Fed. Govt. leased to Camden County
GSA Number: 4–N–GA–606B

Nebraska

Farm Site
Mead Co: Saunders NE 68041–
Location ⅛ mi north of the intersection of US Hwy 77 & St Hwy 92
Landholding Agency: GSA
Property Number: 549520017
Status: Excess
Comment: 11.35 acres, periodic flooding, sewage disposal, ''limited access highway''
GSA Number: 7–C–NE–518

Nevada

Freight Yard
Fallon Rail Facility
Fallon Co: Churchill NV 89406–
Landholding Agency: Interior
Property Number: 619440005
Status: Unutilized
Comment: 6.3 acres, subject to a 10-year lease to the City

Ohio

Middleport Public Access Site
Robert C. Byrd Locks & Dam
Middleport Co: Meigs OH 45760–
Landholding Agency: GSA
Property Number: 319230001
Status: Excess
Comment: approximately 17.23 acres including parking lot, flowage easement, right-of-way for city street and utilities
GSA Number: 2–D–OH–793

Puerto Rico

La Hueca—Naval Station
Roosevelt Roads
Vieques PR 00765–
Landholding Agency: GSA
Property Number: 549420006
Status: Excess
Comment: 323 acres, cultural site

Texas

8.83 Acre Tract
Portion, former Fort Wolters
Mineral Wells Co: Parker/Palo Pin TX 76067–
Landholding Agency: GSA
Property Number: 549440004
Status: Excess
Comment: Land w/fomer recreation bldg., bldg. require repairs, potential utilities, parcel contains friable asbestos.
GSA Number: 7–GR–TX–548AA&BB

10.75 Acre Tract
Portion, former Fort Wolters
Mineral Wells Co: Parker/Palo Pin TX 76067–
Landholding Agency: GSA
Property Number: 549440005
Status: Excess
Comment: Land w/former officer's club bldg., bldg. require repairs, potential utilities, parcel contains friable asbestos.

GSA Number: 7–GR–TX–548AA&BB

120.26 Acre Tract
Portion, former Fort Wolters
Mineral Wells Co: Parker/Palo Pin TX 76067–
Landholding Agency: GSA
Property Number: 649440006
Status: Excess
Comment: Unimproved land containing friable asbestos.
GSA Number: 7–GR–TX–548AA&BB

Tracts 909, 954, 958, 967, 970, 971
Whitney Lake Project
Kopprell Co: Bosque TX 76652–
Landholding Agency: GSA
Property Number: 549520009
Status: Excess
Comment: 1.106 acres, maintenance of lake property
GSA Number: 7–D–TX–0505N

Washington

Asotin Quarry-Lower Lock & Dam
West of Upriver Road
Asotin Co: Asotin WA 99402–
Landholding Agency: GSA
Property Number: 549340001
Status: Excess
Comment: 39.42 acres, access easement, most recent use—rock quarry
GSA Number: 9–D–WA–824K

Suitable/Unavailable Properties

Buildings (by State)

Alaska

Ketchikan Ranger House
Ketchikan AK 99901–
Landholding Agency: GSA
Property Number: 549430009
Status: Surplus
Comment: 1832 sq. ft., 2 story residence, needs rehab, on National Register of Historic Places
GSA Number: 9–A–AK–0746

California

Suppiger Residence
Point Reyes National Seashore
Point Reyes Co: Marin CA 94956–
Landholding Agency: GSA
Property Number: 549410003
Status: Excess
Comment: 850 sq. ft., 2 story frame structure, need repairs, off-site removal only, narrow access road, removal restrictions
GSA Number: 9–I–CA–958B

VA Triangular Parcel
1401 Sepulveda Blvd.
Los Angeles Co: Los Angeles CA
Landholding Agency: GSA
Property Number: 549510003
Status: Surplus
Comment: 2904 sq. ft., 1-story bldg. on 2.13 acres, fair condition, possible asbestos
GSA Number: 9–G–CA–514K

Kansas

U.S. Post Office & Courthouse
812 North 7th Street
Kansas City Co: Wyandotte KS 66101–
Landholding Agency: GSA
Property Number: 549420003
Status: Excess
Comment: 52257 sq. ft., 4-story plus basement, presence of asbestos and lead based paint, most recent use—offices
GSA Number: 7–G–KS–0514

Kentucky

Federal Building
4th & Main Streets
Danville Co: Boyle KY 40422–
Landholding Agency: GSA
Property Number: 549430015
Status: Excess
Coment: 4890 sq. ft., 3-story, stone-concrete foundation, presence of asbestos, first floor occupied by US Court of Appeals Judge & staff until expiration of his tenure
GSA Number: 4–G–KY–604

Maine

9 Capehart Family Houses
Charleston Family Housing Annex, Union St.
Bangor Co: Penobscot ME
Landholding Agency: GSA
Property Number: 189310052
Status: Surplus
Comment: 2916–7097 sq. ft., 1–2 story wood, 3-duplexes, 24-fourplexes totaling 114 units with garages
GSA Number: 2–D–ME–526G

Mount Desert Rock Light
U.S. Coast Guard
Southwest Harbor Co: Hancock ME 04679–
Landholding Agency: DOT
Property Number: 879240023
Status: Unutilized
Comment: 1600 sq. ft., 2-story wood frame, dwelling, needs rehab, limited utilities, limited access, property is subject to severe storms

Little River Light
U.S. Coast Guard
Cutler Co: Washington ME
Landholding Agency: DOT
Property Number: 879240026
Status: Unutilized
Comment: 1100 sq. ft., 2-story wood frame dwelling, well is contaminated, limited utilities

Burnt Island Light
U.S. Coast Guard
Southport Co: Lincoln ME 04576–
Landholding Agency: DOT
Property Number: 879240027
Status: Unutilized
Comment: 750 sq. ft., 2-story wood frame dwelling

Massachusetts

Lowell Federal Building
50 Kearny Square
Lowell Co: Middlesex MA 01854–
Landholding Agency: GSA
Property Number: 549320003
Status: Excess
Comment: 40,283 sq. ft., 3-story concrete and steel bldg., most recent use—storage/office and medical clinic
GSA Number: 2–G–MA–778

Keepers Dwelling
Cape Ann Light, Thachers Island
U.S. Coast Guard
Rockport Co: Essex MA 01966–
Landholding Agency: DOT
Property Number: 879240024
Status: Unutilized
Comment: 1000 sq. ft., 2-story brick dwelling, large wave action with severe ocean storms

Assistant Keepers Dwelling
Cape Ann Light, Thachers Island
U.S. Coast Guard
Rockport Co: Essex MA 01966–
Landholding Agency: DOT
Property Number: 879240025
Status: Unutilized
Comment: 1100 sq. ft., 2-story wood frame dwelling, large wave action with severe ocean storms

Michigan

Detroit Job Corps Center
10401 E. Jefferson & 1438 Garland;
1265 St. Clair
Detroit Co: Wayne MI 42128–
Landholding Agency: GSA
Property Number: 549510002
Status: Surplus
Comment: Main bldg. is 80,590 sq. ft., 5-story, adjacent parking lot, 2nd bldg. on St. Clair Ave. is 5140 sq. ft., presence of asbestos in main bldg., to be vacated 8/95
GSA Number: 2–L–MI–757

Minnesota

Army Reserve Center
301 Lexington Ave. South
New Prague Co: LeSueur MN 56071–
Landholding Agency: GSA
Property Number: 549330003
Status: Surplus
Comment: 4316 sq. ft. brick veneer and concrete block office and training bldg. and a 1170 sq. ft. maintenance shop on 3.82 acres of land leased by the city
GSA Number: 2–D–MN–558

Missouri

Federal Office Building
911 Walnut Street
Kansas City Co: Jackson MO 64106–
Landholding Agency: GSA
Property Number: 549510005
Status: Excess
Comment: 210,098 sq. ft., concrete/brick structure, 50% occupied until 6/95, does not meet handicap reqs., most recent use—offices
GSA Number: 7–G–MO–0626

Nebraska

Bldg. 20, Portion of VA Center
600 South 70th Street
Lincoln Co: Lancaster NE 68510–
Landholding Agency: GSA
Property Number: 549430003
Status: Excess
Comment: 3428 sq. ft., 2 story, needs major rehab, presence of asbestos, ornamental concrete block structure
GSA Number: 7–GR–NE–427C

Nevada

17 Single Family Residences
Tonopah Housing Complex
Tonopah Co: Nye NV 89049–
Landholding Agency: GSA
Property Number: 549430004
Status: Excess
Comment: 1192 to 1378 sq. ft., 1 story wood residences, 3 bedrooms/1 bathroom, (4 of these residences are unavailable for homeless asst. use due to a compelling Federal need)
GSA Number: 9–U–NV–467–C

Bldg. 111
Tonopah Housing Complex
Tonopah Co: Nye NV 89049–
Landholding Agency: GSA
Property Number: 549430006

Status: Excess
Comment: 2507 sq. ft., most recent use—office
GSA Number: 9–U–NV–467–D

Bldg. 112
Tonopah Housing Complex
Tonopah Co: Nye NV 89049–
Landholding Agency: GSA
Property Number: 549430007
Status: Excess
Comment: 1920 sq. ft., most recent use—storage
GSA Number: 9–U–NV–467–D

Bldg. 120
Tonopah Housing Complex
Tonopah Co: Nye NV 89049–
Landholding Agency: GSA
Property Number: 549430008
Status: Excess
Comment: 1440 sq. ft., most recent use—motor pool
GSA Number: 9–U–NV–467–D

New Mexico

Socorro Field Division Office
2401 State Road 1
Socorro NM 87801–0678
Landholding Agency: GSA
Property Number: 549510004
Status: Surplus
Comment: 8056 sq. ft., 1 story wood and metal frame, most recent use—offices/shop/storage, fair condition, off-site removal only
GSA Number: 7–I–NM–0564

Mobile Home, GQ
Gran Quivira Ruins
Mountainair Co: Socorro NM 87036–
Landholding Agency: Interior
Property Number: 619430003
Status: Excess
Comment: 938 sq. ft.; wood frame/wood siding mobile home; off-site removal only

North Carolina

Federal Bldg.—Post Office
226 Carthage Street
Sanford Co: Lee NC 27330–
Landholding Agency: GSA
Property Number: 549440013
Status: Excess
Comment: 5195 sq. ft., 2 story brick frame, water damage in basement, existing lease for 88% of building, most recent use—office/storage
GSA Number: 4–G–NC–713

Pennsylvania

Storage & Maint. Facility
1200 Airport Road
Hopewell Co: Beaver PA 15001–
Landholding Agency: GSA
Property Number: 549330004
Status: Excess
Comment: 44157 sq. ft., 1-story concrete block bldg. (inadequate heating) and 19 acres of land, easements for pipelines and public utilities
GSA Number: 4–L–PA–766

Texas

Bldg. 2
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014815
Status: Unutilized
Comment: 94606 sq. ft., 1 story wood, masonry, and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 4
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014816
Status: Excess
Comment: 1350 sq. ft.; 1 story structured clay title and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 17
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014817
Status: Excess
Comment: 68 sq. ft.; wood and metal frame; subject to sewer pipeline easement; needs rehab; most recent use—guard house.
GSA Number: 7–D–TX–879A

Bldg. 29
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014818
Status: Excess
Comment: 5028 sq. ft.; 1 story wood, masonry and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 30
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014819
Status: Excess
Comment: 5323 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 18
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014820
Status: Excess
Comment: 9560 sq. ft.; 1 story wood, masonry and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 6
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014821
Status: Excess
Comment: 1258 sq. ft.; 1 story structured clay tile and metal frame; subject to pipeline easement; needs rehab.
GSA Number: 7–TX–879A

Bldg. 7
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014822
Status: Excess
Comment: 508 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 8
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014824
Status: Excess
Comment: 171 sq. ft.; 2 story concrete block and brick; subject to sewer pipeline easement; needs rehab; most recent use—watch tower.
GSA Number: 7–D–TX–879A

Bldg. 16
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014825
Status: Excess
Comment: 17263 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 19
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014826
Status: Excess
Comment: 25399 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 31
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014827
Status: Excess
Comment: 1392 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 9
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014828
Status: Excess
Comment: 244 sq. ft.; 1 story wood, hollow tile and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 25
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014829
Status: Excess
Comment: 1320 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab; most recent use—fire house.
GSA Number: 7–D–TX–879A

Bldg. 10
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014830
Status: Excess
Comment: 354 sq. ft.; 2 story concrete block and brick; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–897A

Bldg. 26
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA

Property Number: 219014831
Status: Excess
Comment: 3510 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 21
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014832
Status: Excess
Comment: 65 sq. ft.; wood and metal frame; subject to sewer pipeline easement; needs rehab; most recent use—guard house.
GSA Number: 7–D–TX–879A

Bldg. 22
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014833
Status: Excess
Comment: 50581 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Bldg. 27
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014834
Status: Excess
Comment: 228 sq. ft.; 2 story wood and metal frame; subject to sewer pipeline easement; needs rehab; most recent use—control tower.
GSA Number: 7–D–TX–879A

Bldg. 32
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014835
Status: Excess
Comment: 19546 sq. ft.; 1 story wood and metal frame; subject to sewer pipeline easement; needs rehab.
GSA Number: 7–D–TX–879A

Del Rio Federal Building
Main at Broadway
Del Rio Co: Val Verde TX 78840–
Landholding Agency: GSA
Property Number: 549310001
Status: Excess
Comment: 15600 sq. ft.; 3 story plus basement, masonry frame, most recent use—offices and courthouse.
GSA Number: 7–G–TX–1034

19 Buildings and Land
Subtropical Agricultural Research Worksite
Brownsville Co: Cameron TX 78520–
Landholding Agency: GSA
Property Number: 549440007
Status: Excess
Comment: 25,000 sq. ft. structures, 1 story, pres. of asbestos, most recent use—housing, 18.76 acres which includes 16 acres of vacant land
GSA Number: 7–A–TX–0451G

Brownsville Urban System
(Grantee)
700 South Iowa Avenue
Brownsville Co: Cameron TX 78520–
Landholding Agency: DOT
Property Number: 879010003
Status: Unutilized
Comment: 3500 sq. ft., 1 story concrete block, (2nd floor of Admin. Bldg.) on 10750 sq. ft. land, contains underground diesel fuel tanks

West Virginia

Point Pleasant Depot
State Route 35
Point Pleasant Co: Mason WV
Landholding Agency: GSA
Property Number: 549430013
Status: Excess
Comment: 2400 sq. ft. masonry storage bldg., 936 sq. ft. garage, on 275 acres of land
GSA Number: WV0015PP

Land (by State)

Alaska

Nome Site
Lot 10, Block 67
E. Fifth Avenue
Nome Co: Nome AK 99762–
Landholding Agency: GSA
Property Number: 549510007
Status: Excess
Comment: 17000 sq. ft., trailer site, no known uitility hook up
GSA Number: 9–A–AK–619E

Arizona

Land—640 acres
Ave. B—County 23 St.
Yuma Co: Yuma AZ 85364–
Landholding Agency: Interior
Property Number: 619340001
Status: Unutilized
Comment: desert land, currently no water available, possible lease restrictions

Tract No. APO–SRP–JL–4
West of 91st Ave. & South of Indian School Rd Co: Maricopa AZ
Landholding Agency: Interior
Property Number: 619340002
Status: Unutilized
Comment: 26 foot strip of land 800 feet long, possible easement restrictions

Quartermaster Depot
4th Avenue and Colorado River
Yuma Co: Yuma AZ 85364–
Landholding Agency: Interior
Property Number: 619420001
Status: Unutilized
Comment: Less than 1 acre, dirt and shrubbery along the river, lease restrictions, historical site

California

Receiver Site
Delano Relay Station
Route 1, Box 1350
Delano Co: Tulare CA 93215–
Location: 5 miles west of Pixley, 17 miles north of Delano.
Landholding Agency: GSA
Property Number: 549010044
Status: Excess
Comment: 81 acres, 1560 sq. ft. radio receiver bldg. on site, subject to grazing lease, potential utilities, environmental restrictions
GSA Number: 9–2–CA–1308

Folsom South Canal
SW corner of Whiterock Rd. & Folsom S Canal
Rancho Cordova Co: Sacramento CA 95670–
Landholding Agency: Interior
Property Number: 619310002
Status: Excess
Comment: 1.52 acres, perpetual easement over .25 acre, surrounding land use is commercial

Oklahoma

Parcel No. 43
Fort Gibson Lake
Section 11
Co: Mayes OK 74434
Landholding Agency: GSA
Property Number: 319011371
Status: Surplus
Comment: 60.09 acres; potential utilities; portion subject to grazing lease and flowage easements.
GSA Number: 7–D–OK–0442E–0006

Parcel No. 49
Fort Gibson Lake
Section 15
Co: Mayes OK 74434
Landholding Agency: GSA
Property Number: 319011377
Status: Surplus
Comment: 26.94 acres; potential utilities; portion subject to grazing lease and flowage easements.
GSA Number: 7–D–OK–0442E–0007

Washington

Former Stadium Homes site
1701 28th Avenue, South
Seattle Co: King WA 98144–
Landholding Agency: GSA
Property Number: 549410005
Status: Excess
Comment: 1.46 acres; most recent use—highway equipment storage; potential for city utility services; land slopes
GSA Number: 9–GR(1)–WA–543

Sandpoint Control Tower
Near 7600 Sandpoint Way, NE
Seattle Co: King WA 98115–
Landholding Agency: GSA
Property Number: 549440003
Status: Excess
Comment: 11.3 acres, w/deteriorated bldg. and parking lot
GSA Number: 9–C–WA–1069

Suitable/To Be Excessed

Buildings (by State)

Massachusetts

Cuttyhunk Boathouse
South Shore of Cuttyhunk Pond
Gosnold Co: Dukes MA 02713–
Landholding Agency: DOT
Property Number: 879310001
Status: Unutilized
Comment: 2700 sq. ft., wood frame, one story, needs rehab, limited utilities, off-site use only

Nauset Beach Light
Nauset Beach Co: Barnstable MA
Landholding Agency: DOT
Property Number: 879420001
Status: Unutilized
Comment: 48 foot tower, cylindrical cast iron, most recent use—aid to navigation

Plymouth Light
Co: Plymouth MA
Landholding Agency: DOT
Property Number: 879420003
Status: Unutilized

Comment: 250 sq. ft. tower, and 2096 sq. ft. dwelling, wood frame, most recent use—aid to navigation/housing

Light Tower, Highland Light
Near Rt. 6, 9 miles south of Race Point
North Truro Co: Barnstable MA 02652–
Landholding Agency: DOT
Property Number: 879430005
Status: Excess
Comment: 66 ft. tower, 14′9″ diameter, brick structure, scheduled to be vacated 9/94

Keepers Dwelling
Highland Light
Near Rt. 6, 9 miles south of Race Point
North Truro Co: Barnstable MA 02652–
Landholding Agency: DOT
Property Number: 879430006
Status: Excess
Comment: 1160 sq. ft., 2-story wood frame, attached to light tower, scheduled to be vacated 9/94

Duplex Housing Unit
Highland Light
Near Rt. 6, 9 miles south of Race Point
North Truro Co: Barnstable MA 02652–
Landholding Agency: DOT
Property Number: 879430007
Status: Excess
Comment: 2 living units, 930 sq. ft. each, 1-story each, located on eroding ocean bluff, scheduled to be vacated 9/94

Oregon

Yaquina Head Lighthouse
860 Lighthouse Drive
Newport Co: Lincoln OR 97365–
Landholding Agency: DOT
Property Number: 879430003
Status: Underutilized
Comment: 300 sq. ft. tower and needs repair, 4.52 acres lighthouse area, historic property

Washington

Quarters No. 1204
604 S. Maple
Warden Co: Grant WA 98857–
Landholding Agency: Interior
Property Number: 619330001
Status: Excess
Comment: 850 sq. ft., one story frame residence, asbestos siding

Quarters No. 1208
608 S. Maple
Warden Co: Grant WA 98857–
Landholding Agency: Interior
Property Number: 619330002
Status: Excess
Comment: 709 sq. ft., one story frame residence, asbestos siding

Quarters No. 1301
3 SE and N Warden Road
Warden Co: Grant WA 98857–
Landholding Agency: Interior
Property Number: 619330003
Status: Excess
Comment: 709 sq. ft., one story frame residence on 4.9 acres, asbestos siding

Land (by State)

California

Tehama Colusa Canal
Portion of Unit No. T–2
Red Bluff Co: Tehama CA 96080–
Landholding Agency: Interior
Property Number: 619510007
Status: Excess
Comment: 4.02 acres, sloped banks, legal access would have to be conveyed to new owner, most recent use—spoil material

Michigan

U.S. Coast Guard—Air Station
Traverse City Co: Grand Traverse MI 49684–
Landholding Agency: DOT
Property Number: 879120099
Status: Underutilized
Comment: 21.7 acres, most recent use—helo landings

Unsuitable Properties

Buildings (by State)

Alabama

Dwelling A
USCG Mobile Pt. Station
Ft. Morgan
Gulfshores Co: Baldwin AL 36542–
Landholding Agency: DOT
Property Number: 879120001
Status: Excess
Reason: Floodway

Dwelling B
USCG Mobile Pt. Station
Ft. Morgan
Gulfshores Co: Baldwin AL 36542–
Landholding Agency: DOT
Property Number: 879120002
Status: Excess
Reason: Floodway

Oil House
USCG Mobile Pt. Station
Ft. Morgan
Gulfshores Co: Baldwin AL 36542–
Landholding Agency: DOT
Property Number: 879120003
Status: Excess
Reason: Floodway

Garage
USCG Mobile Pt. Station
Ft. Morgan
Gulfshores Co: Baldwin AL 36542–
Landholding Agency: DOT
Property Number: 879120004
Status: Excess
Reason: Floodway

Shop Building
USCG Mobile Pt. Station
Ft. Morgan
Gulfshores Co: Baldwin AL 36542–
Landholding Agency: DOT
Property Number: 879120005
Status: Excess
Reason: Floodway

Alaska

USCG MSD Office (2 buildings)
2958 Tongass Avenue
Ketchikan Co: Ketchikan AK 99901–
Landholding Agency: GSA
Property Number: 879130004
Status: Excess
Reason: Extensive deterioration

Bldg. 28
USCG Support Center
Kodiak Co: Kodiak Island AK 99619–5000
Landholding Agency: DOT
Property Number: 879210126
Status: Excess
Reason: Within airport runway clear zone; Secured Area

Bldg. 24
USCG Support Center
Kodiak Co: Kodiak Island AK 99619–5000
Landholding Agency: DOT
Property Number: 879210127
Status: Excess
Reason: Within airport runway clear zone; Secured Area; Within 2000 ft. of flammable or explosive material

Bldg. 19
USCG Support Center
Kodiak Co: Kodiak Island AK 99619–5000
Landholding Agency: DOT
Property Number: 879210128
Status: Excess
Reason: Within airport runway clear zone; Secured Area; Other
Comment: Extensive deterioration

Bldg. 94
USCG Support Center
Kodiak Co: Kodiak Island AK 99619–5000
Landholding Agency: DOT
Property Number: 879210129
Status: Excess
Reason: Secured Area; Other
Comment: Extensive deterioration

Bldg. 18
USCG Support Center
Kodiak Co: Kodiak Island AK 99619–5000
Landholding Agency: DOT
Property Number: 879210132
Status: Excess
Reason: Secured Area; Within airport runway clear zone
GSA Number: U–ALAS–655A

Bldg. A512
USCG Support Center
Kodiak Co: Kodiak Island AK 99619–5000
Landholding Agency: DOT
Property Number: 879210133
Status: Excess
Reason: Secured Area; Within airport runway clear zone; Within 2000 ft. of flammable or explosive material

Bldg. R1, Holiday Beach
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310014
Status: Unutilized
Reason: Secured Area

Bldg. S–3
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310015
Status: Unutilized
Reason: Secured Area

Bldg. S–16
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310016
Status: Unutilized
Reason: Secured Area

Bldg. 82
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310017
Status: Unutilized
Reason: Secured Area

Bldg. 86
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014

Landholding Agency: DOT
Property Number: 879310018
Status: Unutilized
Reason: Secured Area

Bldg. 98
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310019
Status: Unutilized
Reason: Secured Area

Bldg. 524A
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310020
Status: Unutilized
Reason: Within airport runway clear zone Secured Area

Bldg. 624
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310021
Status: Unutilized
Reason: Within airport runway clear zone Secured Area

Housing Ketchikan (Naushon UPH
3615 Baranof Avenue
Ketchikan Co: Ketchikan AK 99801–
Landholding Agency: DOT
Property Number: 879320005
Status: Unutilized
Reason: Extensive deterioration

Old Petersburg Moorings
Cannery Wharf
Petersburg AK 99833–
Landholding Agency: DOT
Property Number: 879330002
Status: Unutilized
Reason: Extensive deterioration

Arkansas

Silver Hill Cabin
Buffalo National River
St. Joe Co: Newton AR 72775–
Landholding Agency: Interior
Property Number: 619440003
Status: Unutilized
Reason: Extensive deterioration

Paul Ray/Barbara Still House
Hwy. 268
Yellville Co: Marion AR 72687–
Landholding Agency: Interior
Property Number: 619440006
Status: Unutilized
Reason: Extensive deterioration

Hagerty Residence
102 Shore Drive
Hot Springs Co: Garland AR 71901–
Landholding Agency: Interior
Property Number: 619530002
Status: Excess
Reason: Extensive deterioration

Meyers Residence
101 Granger Drive
Hot Springs Co: Garland AR 71901–
Landholding Agency: Interior
Property Number: 619530003
Status: Excess
Reason: Extensive deterioration

Bednar Residence
106 Clinton Street
Hot Springs Co: Garland AR 71901–
Landholding Agency: Interior
Property Number: 619530004
Status: Excess
Reason: Extensive deterioration

Disheroon Residence
100 Akin Street
Hot Springs Co: Garland AR 71901–
Landholding Agency: Interior
Property Number: 619530005
Status: Excess
Reason: Extensive deterioration

Swain Residence
200 Earhart Street
Hot Springs Co: Garland AR 71901–
Landholding Agency: Interior
Property Number: 619530006
Status: Excess
Reason: Extensive deterioration

Scott Residence
207 Congress Street
Hot Springs Co: Garland AR 71901–
Landholding Agency: Interior
Property Number: 619530007
Status: Excess
Reason: Extensive deterioration

California

Former Naval Research Bldg.
Pasadena Co: Los Angeles CA 91106–
Landholding Agency: GSA
Property Number: 549430001
Status: Excess
Reason: Extensive deterioration
GSA Number: 9–N–CA–1304A

NW Seal Rock & Lighthouse
St. George Reef Co: Del Norte CA
Landholding Agency: GSA
Property Number: 549430012
Status: Excess
Reason: Other
Comment: Inaccessible
GSA Number: 9–U–CA–556B

Naval Indust. Rsve. Ord. Plant
Pomona Co: Los Angeles CA 91769–2426
Landholding Agency: GSA
Property Number: 549520019
Status. Excess
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: 9–N–CA–734B

Bldg. 4147, Downey House
Tract 01–40
Wawona Co: Mariposa CA 95389–
Landholding Agency: Interior
Property Number: 619520024
Status. Unutilized
Reason: Extensive deterioration

Yosemite Village Gas Station/Photo Center
Yosemite Co: Mariposa CA 95389–
Landholding Agency: Interior
Property Number: 619520025
Status. Unutilized
Reason: Extensive deterioration

Dixon Residence 08–102
Oceanview Terrace
Klamatch Co: Del Norte CA 95548–
Landholding Agency: Interior
Property Number: 619520027
Status. Unutilized
Reason: Extensive deterioration

Waterson Residence 08–107
Oceanview Terrace
Klamatch Co: Del Norte CA 95531–
Landholding Agency: Interior
Property Number: 619520036
Status. Unutilized
Reason: Extensive deterioration

10 Bldg.
USCG Station Humboldt Bay
Samoa Co: Humboldt CA 95564–9999
Landholding Agency: DOT
Property Number: 879440027
Status. Excess
Reason: Extensive deterioration
Comment: Land to be relinquished to BLM (Public Domain Land)

Colorado

Waste Treatment Facilities
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001–
Landholding Agency: COE–BC
Property Number: 329530001
Status. Unutilized
Base closure Number of Units: 1
Reason: Other
Comment: Waste treatment facility

2 Powder Storage Magazines
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001–
Landholding Agency: COE–BC
Property Number: 329530002
Status. Unutilized
Base closure Number of Units: 2
Reason: Within 2000 ft. of flammable or explosive material

3 Buildings
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001–
Location: Includes 00533, 00534 & 00536
Landholding Agency: COE–BC
Property Number: 329530003
Status. Unutilized
Base closure Number of Units: 3
Reason: Other
Comment: Sewage pump stations

6 Buildings
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001–
Location: Includes 00170, 00186, 00187, 00562, 00566 & 00596
Landholding Agency: COE–BC
Property Number: 329530004
Status. Unutilized
Base closure Number of Units: 6
Reason: Other
Comment: Detached latrines

618 Igloo Storage Facilities
Pueblo Depot Activity
Pueblo Co: Pueblo CO 81001–
Landholding Agency: COE–BC
Property Number: 329530005
Status. Unutilized
Base closure Number of Units: 1
Reason: Within 2000 ft. of flammable or explosive material

Alemeda Facility
350 S. Santa Fe Drive
Denver Co: Denver CO 80223–
Landholding Agency: DOT
Property Number: 879010014
Status. Unutilized
Reason: Other environmental
Comment: Contamination

Connecticut

Falkner Island Light
U.S. Coast Guard
Guilford Co: New Haven CT 06512–
Landholding Agency: DOT
Property Number: 879240031

Status. Unutilized
Reason: Floodway

Florida

Bldg. #3, Recreation Cottage
USCG Station
Marathon Co: Monroe FL 33050–
Landholding Agency: DOT
Property Number: 879210008
Status: Unutilized
Reason: Secured Area, Floodway

Bldg. 103, Trumbo Point
Key West Co: Monroe FL 33040–
Landholding Agency: DOT
Property Number: 879230001
Status: Unutilized
Reason: Floodway, Secured Area

Exchange Building
St. Petersburg Co: Pinellas FL 33701–
Landholding Agency: DOT
Property Number: 879410004
Status: Unutilized
Reason: Floodway

9988 Keepers Quarters A
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440009
Status: Underutilized
Reason: Secured Area, Floodway

9989 Keepers Quarters B
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440010
Status: Underutilized
Reason: Secured Area, Floodway

9990 Bldg.
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440011
Status: Underutilized
Reason: Secured Area, Floodway

9991 Plant Bldg.
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440012
Status: Underutilized
Reason: Secured Area, Floodway

9992 Shop Bldg.
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440013
Status: Underutilized
Reason: Secured Area, Floodway

9993 Admin. Bldg.
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440014
Status: Underutilized
Reason: Secured Area, Floodway

9994 Water Pump Bldg.
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440015
Status: Underutilized
Reason: Secured Area, Floodway

Storage Bldg.
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440016
Status: Underutilized
Reason: Secured Area, Floodway

9999 Storage Bldg.
Cape San Blas
Port St. Joe Co: Gulf FL
Landholding Agency: DOT
Property Number: 879440017
Status: Underutilized
Reason: Secured Area, Floodway

3 Bldgs. and Land
Peanut Island Station
Riveria Beach Co: Palm Beach FL 33419–0909
Landholding Agency: DOT
Property Number: 879510009
Status: Unutilized
Reason: Secured Area, Floodway

Illinois

Calumet Harbor Station
U.S. Coast Guard
Chicago Co: Cook IL
Landholding Agency: DOT
Property Number: 879310005
Status: Excess
Reason: Secured Area

Maine

Supply Bldg., Coast Guard
Southwest Harbor
Southwest Harbor Co: Hancock ME 04679–5000
Landholding Agency: DOT
Property Number: 879240005
Status: Unutilized
Reason: Floodway

Base Exchange, Coast Guard
Southwest Harbor
Southwest Harbor Co: Hancock ME 04679–5000
Landholding Agency: DOT
Property Number: 879240006
Status: Unutilized
Reason: Floodway

Engineering Shop, Coast Guard
Southwest Harbor
Southwest Harbor Co: Hancock ME 04679–5000
Landholding Agency: DOT
Property Number: 879240007
Status: Unutilized
Reason: Floodway

Storage Bldg., Coast Guard
Southwest Harbor
Southwest Harbor Co: Hancock ME 04679–5000
Landholding Agency: DOT
Property Number: 879240008
Status: Unutilized
Reason: Floodway

Squirrel Point Light
U.S. Coast Guard
Phippsburg Co: Sayadahoc ME 04530–
Landholding Agency: DOT
Property Number: 879240032
Status: Unutilized
Reason: Floodway

Keepers Dwelling
Heron Neck Light, U.S. Coast Guard
Vinalhaven Co: Knox ME 04841–
Landholding Agency: DOT
Property Number: 879240035
Status: Unutilized
Reason: Extensive deterioration

Fort Popham Light
Phippsburg Co: Sagadahoc ME 04562–
Landholding Agency: DOT
Property Number: 879320024
Status: Unutilized
Reason: Extensive deterioration

Nash Island Light
U.S. Coast Guard
Addison Co: Washington ME 04606–
Landholding Agency: DOT
Property Number: 879420005
Status: Unutilized
Reason: Other
Comment: Inaccessible

Bldg.—South Portland Base
U.S. Coast Guard
S. Portland Co: Cumberland ME 04106–
Landholding Agency: DOT
Property Number: 879420006
Status: Unutilized
Reason: Secured Area

Garage—Boothbay Harbor Stat.
Boothbay Harbor Co: ME 04538–
Landholding Agency: DOT
Property Number: 879430001
Status: Unutilized
Reason: Secured Area

Massachusetts

Trailers, Former Kimpel Prop.
South Egremont
Sheffield Co: Berkshire MA 01257–
Landholding Agency: Interior
Property Number: 619510003
Status: Excess
Reason: Extensive deterioration

Bldg. 4, USCG Support Center
Commercial Street
Boston Co: Suffolk MA 02203–
Landholding Agency: DOT
Property Number: 879240001
Status: Underutilized
Reason: Secured Area

Eastern Point Light
U.S. Coast Guard
Goucester Co: Essex MA 01930–
Landholding Agency: DOT
Property Number: 879240029
Status: Unutilized
Reason: Floodway Secured Area

Storage Shed
Highland Light
N. Truro Co: Barnstable MA 02652–
DeSoto Johnson
Landholding Agency: DOT
Property Number: 87940004
Status: Unutilized
Reason: Extensive deterioration

Michigan

Bldg. 402, U.S. Air Station
Traverse City Co: Grand Traverse MI 49684–3586
Landholding Agency: DOT
Property Number: 879220001
Status: Unutilized
Reason: Extensive deterioration

Minnesota

Naval Weapons Industrial
Reserve Plant
1902 West Minnehaha
St. Paul Co: Ramsey MN
Landholding Agency: GSA

Property Number: 549410004
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: 2–N–MN–559

Mississippi

Natchez Moorings
82 L.E. Berry Road
Natchez Co: Adams MS 39121-
Landholding Agency: DOT
Property Number: 879340002
Status: Unutilized
Reason: Extensive deterioration

Montana

Sioux Pass Radio Relay Tower
17 Miles South of Culbertson Co: Richland MT 57212-
Landholding Agency: GSA
Property Number: 549320012
Status: Excess
Reason: Other
Comment: No public access
GSA Number: 7–F–MT–594

Barn/Garage
316 N. 26th Street
Billings Co: Yellowstone MT
Landholding Agency: Interior
Property Number: 619520022
Status: Excess
Reason: Extensive deterioration

Nevada

Residence
237 Southeast Street
Fallon Co: Churchill NV 89406-
Landholding Agency: Interior
Property Number: 619430013
Status: Unutilized
Reason: Extensive deterioration

Storage Shed
Fallon Rail Facility
Fallon Co: Churchill NV 89406-
Landholding Agency: Interior
Property Number: 619440004
Status: Unutilized
Reason: Extensive deterioration

New Jersey

Piers and Wharf
Station Sandy Hook
Highlands Co: Monmouth NJ 07732–5000
Landholding Agency: DOT
Property Number: 879240009
Status: Unutilized
Reason: Extensive deterioration; Secured Area

Chapel Hill Front Range Light Tower
Middletown Co: Monmouth NJ 07748-
Landholding Agency: DOT
Property Number: 879440002
Status: Unutilized
Reason: Other
Comment: Skeletal tower

New Mexico

Tract 102–34 (Gravette Resid.)
Lava Tubes District
Grants Co: Cibola NM 87020-
Landholding Agency: Interior
Property Number: 619510005
Status: Unutilized
Reason: Extensive deterioration

Tract 102–37 (Abeita)
Grants Co: Cibola NM 87020-
Landholding Agency: Interior
Property Number: 619510006
Status: Excess
Reason: Extensive deterioration

New York

Naval Indus. Rsv. Ordance Pl.
121 Lincoln Avenue
Rochester Co: Monroe NY 14611-
Landholding Agency: GSA
Property Number: 549430011
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: TENT–2–N–NY–592

2 Buildings
Ant Saugerties
Saugerties Co: Ulster NY 12477-
Landholding Agency: DOT
Property Number: 879230005
Status: Unutilized
Reason: Extensive deterioration

Bldg. 605, USCG Station
Fort Totten
New York Co: Queens NY 11359-
Landholding Agency: DOT
Property Number: 879240010
Status: Excess
Reason: Secured Area

Bldg. 606, USCG Station
Fort Totten
New York Co: Queens NY 11359-
Landholding Agency: DOT
Property Number: 879240011
Status: Excess
Reason: Secured Area

Bldg. 607, USCG Station
Fort Totten
New York Co: Queens NY 11359-
Landholding Agency: DOT
Property Number: 879240012
Status: Excess
Reason: Secured Area

Bldg. 606, Fort Totten
New York Co: Queens NY 11359-
Landholding Agency: DOT
Property Number: 879240020
Status: Unutilized
Reason: Secured Area

Bldg. 607, Fort Totten
New York Co: Queens NY 11359-
Landholding Agency: DOT
Property Number: 879240021
Status: Unutilized
Reason: Secured Area; Other
Comment: Extensive deterioration

Bldg. 605, Fort Totten
New York Co: Queens NY 11359-
Landholding Agency: DOT
Property Number: 879240022
Status: Unutilized
Reason: Secured Area; Other
Comment: Extensive deterioration

Eatons Neck Station
U.S. Coast Guard
Huntington Co: Suffolk NY 11743-
Landholding Agency: DOT
Property Number: 879310003
Status: Unutilized
Reason: Extensive deterioration; Secured Area

Bldg. 517, USCG Support Center
Governors Island Co: Manhattan NY 10004-
Landholding Agency: DOT
Property Number: 879320025
Status: Unutilized
Reason: Secured Area

Bldg. 138
U.S. Coast Guard Support Center
Governors Island Co: Manhattan NY 10004-
Landholding Agency: DOT
Property Number: 879410003
Status: Unutilized
Reason: Secured Area

Point AuRoche Light
Beekmantown Co: Clinton NY 12901-
Landholding Agency: GSA
Property Number: 879420002
Status: Excess
Reason: Floodway; Extensive deterioration
GSA Number: 2–4–NY–817

Bldg. 830
U.S. Coast Guard
Governors Island Co: Manhattan NY 10004-
Landholding Agency: DOT
Property Number: 879420004
Status: Unutilized
Reason: Secured Area

Rochester Harbor Light
Greece Township Co: Monroe NY
Landholding Agency: DOT
Property Number: 879430008
Status: Excess
Reason: Secured Area; Extensive deterioration

North Carolina

Group Cape Hatteras
Boiler Plant
Buxton Co: Dare NC 27902–0604
Landholding Agency: DOT
Property Number: 879240018
Status: Unutilized
Reason: Secured Area

Group Cape Hatteras
Bowling Alley
Buxton Co: Dare NC 27902–0604
Landholding Agency: DOT
Property Number: 879240019
Status: Unutilized
Reason: Secured Area

Bldg. 21, Fuel Farm
U.S. Coast Guard Air Station
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320010
Status: Unutilized
Reason: Floodway; Secured Area

Bldg. 22, Fuel Farm
U.S. Coast Guard Air Station
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320011
Status: Unutilized
Reason: Floodway; Secured Area

Bldg. 25, Fuel Farm
U.S. Coast Guard Air Station
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320012
Status: Unutilized
Reason: Floodway; Secured Area

Bldg. 27, Fuel Farm
U.S. Coast Guard Air Station
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320013

Status: Unutilized
Reason: Floodway; Secured Area

Bldg. 32, Fuel Farm
U.S. Coast Guard Air Station
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320014
Status: Unutilized
Reason: Floodway Secured Area

Bldg. 67, USCG Support Center
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320016
Status: Unutilized
Reason: Secured Area

Bldg. 69, USCG Support Center
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320017
Status: Unutilized
Reason: Secured Area

Bldg. 71, USCG Support Center
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320018
Status: Unutilized
Reason: Secured Area

Bldg. 73, USCG Support Center
Elizabeth City Co: Pasquotank NC 27909–5006
Landholding Agency: DOT
Property Number: 879320019
Status: Unutilized
Reason: Secured Area

Bldg. 54
Group Cape Hatteras
Buston Co: Dare NC 27902–0604
Landholding Agency: DOT
Property Number: 879340004
Status: Unutilized
Reason: Secured Area

Bldg. 83
Group Cape Hatteras
Buxton Co: Dare NC 27902–0604
Landholding Agency: DOT
Property Number: 879340005
Status: Unutilized
Reason: Secured Area

Water Tanks
Group Cape Hatteras
Buxton Co: Dare NC 27902–0604
Landholding Agency: DOT
Property Number: 879340006
Status: Unutilized
Reason: Secured Area

USCG Gentian (WLB 290)
Fort Macon State Park
Atlantic Beach Co: Carteret NC 27601–
Landholding Agency: DOT
Property Number: 879420007
Status: Excess
Reason: Secured Area

Pennsylvania

NPS Tract #362–09 (6 Bldgs)
Former Lehmer Farm
Marysville Co: Perry PA 17053–
Location: Off Route 850
Landholding Agency: Interior
Property Number: 619520023
Status: Excess
Reason: Extensive deterioration

Puerto Rico

NAFA Warehouse
U.S. Coast Guard Air Station Borinquen
Aquadilla PR 00604–
Landholding Agency: DOT
Property Number: 879310011
Status: Unutilized
Reason: Secured Area

Storage Equipment Bldg.
U.S. Coast Guard Air Station Borinquen
Aquadilla PR 00604–
Landholding Agency: DOT
Property Number: 879330001
Status: Unutilized
Reason: Secured Area

Bldg. 115
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510001
Status: Unutilized
Reason: Secured Area

Bldg. 117
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510002
Status: Unutilized
Reason: Secured Area

Bldg. 118
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510003
Status: Unutilized
Reason: Secured Area

Bldg. 119
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510004
Status: Unutilized
Reason: Secured Area

Bldg. 120
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510005
Status: Unutilized
Reason: Secured Area

Bldg. 122
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510006
Status: Unutilized
Reason: Secured Area

Bldg. 128
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510007
Status: Unutilized
Reason: Secured Area

Bldg. 129
U.S. Coast Guard Base
San Juan PR 00902–2029
Landholding Agency: DOT
Property Number: 879510008
Status: Unutilized
Reason: Secured Area

Rhode Island

Station Point Judith Pier
Narranganset Co: Washington RI 02882–
Landholding Agency: DOT
Property Number: 879310002
Status: Unutilized
Reason: Extensive deterioration

Texas

Bldg. 14
Saginaw Army Aircraft Plant
Saginaw Co: Tarrant TX 76070–
Landholding Agency: GSA
Property Number: 219014823
Status: Excess
Reason: Other Comment: Pump house
GSA Number: 7–D–TX–879A

Old Exchange Bldg.
U.S. Coast Guard
Galveston Co: Galveston TX 77553–3001
Landholding Agency: DOT
Property Number: 879310012
Status: Unutilized
Reason: Secured Area

Vermont

Depot Street
Downtown at the Waterfront
Burlington Co: Chittenden VT 05401–5226
Landholding Agency: DOT
Property Number: 879220003
Status: Excess
Reason: Floodway

Virginia

Chandler House 272 & 272A
220 Zweybrucken Road
Yorktown Co: York VA 23690–
Landholding Agency: Interior
Property Number: 619520028
Status: Unutilized
Reason: Extensive deterioration

Jenkins House, Bldg. JH
218 Zweybrucken Road
Yorktown Co: York VA 23690–
Landholding Agency: Interior
Property Number: 619520029
Status: Unutilized
Reason: Extensive deterioration

Bldg. 052 & Tennis Court
USCG Reserve Training Center
Yorktown Co: York VA 23690–
Landholding Agency: DOT
Property Number: 879230004
Status: Excess
Reason: Secured Area

Damage Control Bldg.
Coast Guard, Group Eastern Shores
Chincoteague Co: Accomack VA 23361–510
Landholding Agency: DOT
Property Number: 879240013
Status: Unutilized
Reason: Secured Area

Admin. Bldg.
Coast Guard, Group Eastern Shores
Chincoteague Co: Accomack VA 23361–510
Landholding Agency: DOT
Property Number: 879240014
Status: Unutilized
Reason: Secured Area

Storage Bldg.
Coast Guard, Group Eastern Shores
Chincoteague Co: Accomack, VA 23361–510
Landholding Agency: DOT
Property Number: 879240015
Status: Unutilized

Reason: Secured Area

Little Creek Station
Navamphib Base, West Annex, U.S. Coast Guard
Norfolk Co: Princess Anne VA 23520–
Landholding Agency: DOT
Property Number: 879310004
Status: Unutilized
Reason: Secured Area

Washington

Bldg. 875
Portion, Ft. Vancouver Barracks
E. 10th & Cabell Road, I–95 North
Vancouver WA
Landholding Agency: GSA
Property Number: 549430002
Status: Excess
Reason: Extensive deterioration
GSA Number: 9–D–WA–500L

Cabins 896 & 897
Olympic National Park
Port Angeles Co: Clallam WA 98362–
Landholding Agency: Interior
Property Number: 619510002
Status: Unutilized
Reason: Extensive deterioration

Perrigo House, Lean To & Shed
LK Quinalt Rgr. Station, Olympic Nat'l Park
Amanda Park Co: Grays Harbor WA 98526–
Landholding Agency: Interior
Property Number: 619520021
Status: Unutilized
Reason: Extensive deterioration

Land (by State)

Alaska

Russian Creek Aggregate Site
USCG Support Center Kodiak
Kodiak Co: Kodiak AK 99619–
Landholding Agency: DOT
Property Number: 879440025
Status: Excess
Reason: Floodway

Sargent Creek Aggregate Site
USCG Support Center Kodiak
Kodiak Co: Kodiak AK 99619–
Landholding Agency: DOT
Property Number: 879440026
Status: Excess
Reason: Floodway

Arizona

Santa Fe Pacific Pipelines
Avenue 7E North from Hwy. 95
Yuma Co: Yuma AZ 85364–
Landholding Agency: Interior
Property Number: 619420003
Status: Unutilized
Reason: Secured Area

Ed Bull Land
Northeast corner of Price & Galveston
Chandler Co: Maricopa AZ 85224–
Landholding Agency: Interior
Property Number: 619530011
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material

California

Central Valley Project
San Luis Drain
Tracy Co: San Joaquin CA 95376–
Landholding Agency: GSA
Property Number: 549230003
Status: Excess
Reason: Other
Comment: Landlocked
GSA Number: 9–I–CA–1325

Parcel B
Santa Rosa Co: Sonoma CA
Landholding Agency: GSA
Property Number: 549310016
Status: Excess
Reason: Other
Comment: Sewage Treatment Plant
GSA Number: 9–G–CA–580C

Portion of Lot 7
Former State of California Land/Stockpile
Yreka Co: Siskiyou CA
Landholding Agency: GSA
Property Number: 549330006
Status: Excess
Reason: Other
Comment: Inaccessible
GSA Number: 9–G–CA–956A

L–5 Pumping Station
LaQuinta Co: Riverside CA 92253–
Landholding Agency: Interior
Property Number: 619420002
Status: Unutilized
Reason: Secured Area; Other
Comment: Pumping Station

Florida

Land—approx. 220 acres
Cape San Blas
Port St. Joe Co: Gulf, FL
Landholding Agency: DOT
Property Number: 879440018
Status: Underutilized
Reason: Secured Area, Floodway

Michigan

Middle Marker Facility
Yipsilanti Co: Washtenaw, MI 48198
Location: 549 ft. north of intersection of Coolidge and Bradley Ave. on East side of street
Landholding Agency: DOT
Property Number: 879120006
Status: Unutilized
Reason: Within airport runway clear zone

Mississippi

Land—Grenada Lake Dam & Reservoir Project
Co: Yalobusha, MS
Location: 5 miles southeast of Coffeeville, MS on State Highway 330
Landholding Agency: GSA
Property Number: 549520011
Status: Excess
Reason: Floodway
GSA Number: 4–D–MS–548

Montana

Sherryl Tap Point Site
3 miles south of Drummond, MT
Co: Granite, MT
Landholding Agency: GSA
Property Number: 549240006
Status: Excess
Reason: Other
Comment: Inaccessible
GSA Number: 7–B–MT–0598

Puerto Rico

Flamenco Point
Culebra Island, PR
Landholding Agency: GSA
Property Number: 549530003
Status: Excess
Reason: Other
Comment: No Public Access
GSA Number: 1–N–PR–482

119.3 acres
Culebra Island, PR 00775-
Landholding Agency: Interior
Property Number: 619210001
Status: Excess
Reason: Floodway

South Carolina

Land—2.66 acres
Port Royal Co: Beaufort, SC 29902–6148
Landholding Agency: GSA
Property Number: 549240009
Status: Excess
Reason: Floodway
GSA Number: 4–N–SC–0489A

Texas

Tract J–936
Portion of Whitney Lake Proj.
Bosque Co: Bosque, TX
Location: Off F. M. Highway 56 within the community of Kopperl.
Landholding Agency: GSA
Property Number: 319110032
Status: Excess
Reason: Other
Comment: No public access
GSA Number: 7–D–TX–0505M

Eagle Pass Auxiliary Airfield
10 mi. NW of Eagle Pass
Co: Maverick, TX 78853-
Landholding Agency: GSA
Property Number: 549520001
Status: Excess
Reason: Within airport runway clear zone

[FR Doc. 95–19782 Filed 8–10–95; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–964–1410–00–P]

Alaska; Alaska Native Claims Selection; Notice for Publication

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that decisions to issue conveyance under the provisions of Secs. 14(e) and 22(j) of the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1601, 1613(e), and 1621(j) will be issued to Doyon, Limited.

Serial No.	Approximate land description	Acreage
F–21904–35 .	Secs. 3 to 8, T. 4 N., R. 26 W., Fairbanks Meridian, Alaska.	2,154
F–21905–48 .	Secs. 1 to 36, T. 5 N., R. 26 W., Fairbanks Meridian, Alaska.	22,524

Serial No.	Approximate land description	Acreage
F–21904–38 .	Secs. 1, 2, 11, and 12, T. 4 N., R. 27 W., Fairbanks Meridian, Alaska.	1,815
F–21903–87 .	Secs. 35 and 36, T. 3 S., R. 28 E., Kateel River Meridian, Alaska.	140

A notice of the decisions will be published once a week, for four (4) consecutive weeks, in the Fairbanks Daily News-Miner. Copies of the decisions may be obtained by contacting the Alaska State Office of the Bureau of Land Management, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599 ((907) 271–5960).

Any party claiming a property interest which is adversely affected by the decisions, an agency of the Federal government, or regional corporation, shall have until September 11, 1995 to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management at the address identified above, where the requirements for filing an appeal may be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E, shall be deemed to have waived their rights.

Elizabeth Sherwood,

Land Law Examiner, Branch of Northern Adjudication.

[FR Doc. 95–19914 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–JA–P

Cowhead/Massacre Management Framework Plan; California

AGENCY: Surprise Resource Area Office, Bureau of Land Management, Interior.

ACTION: Notice of intent—proposed amendment of Cowhead/Massacre Management Framework Plan.

SUMMARY: Pursuant to 43 CFR 1601.3 and 40 CFR 1501.7, notice is hereby given that the Surprise Resource Area, Cedarville, California of the Susanville District, Bureau of Land Management, Susanville, California, will consider an amendment to the Cowhead/Massacre Management Framework Plan (MFP) adopted in 1983. This amendment will consider domestic sheep grazing and reintroduction of California bighorn sheep on an area known as the Massacre Mountain grazing allotment.

The Cowhead/Massacre MFP has several decisions related to domestic sheep grazing and bighorn reintroduction in the Massacre Mountain Allotment. These decisions allocated adjacent portions of the allotment to existing cattle and domestic sheep operations and for the future reintroduction of California bighorn sheep. A Habitat Management Plan for a portion of the allotment was completed by the Bureau in cooperation of the Nevada Division of Wildlife in 1984 and provided for the reintroduction of California bighorn sheep into an area known as High Rock Canyon. Since the Cowhead/Massacre MFP was adopted in 1983, the general consensus among wildlife biologists and veterinarians working with domestic and bighorn sheep disease issues is that direct contact between the two types of sheep should be avoided to prevent transmission of diseases. The current Bureau of Land Management policy regarding domestic and bighorn sheep calls for a nine mile buffer between the two species.

Early in 1995, the grazing privileges associated with domestic sheep use of the Massacre Mountain Allotment were relinquished by the permittee to the Bureau of Land Management. The Nevada Division of Wildlife has requested permission to reintroduce bighorn sheep into the allotment during the winter of 1995–1996. The Reno Chapter of Nevada Bighorns Unlimited has requested that the Cowhead/Massacre be amended to prevent future licensing of domestic sheep grazing within the allotment to ensure that no direct contact between reintroduced bighorn and domestic sheep occurs in the future.

At least two alternatives will be considered in an Environmental Assessment: (1) Amend the Cowhead/Massacre MFP to only allow for cattle use on the Massacre Mountain Allotment. (2) Do not amend the MFP (No Action). Other alternatives may be developed as a result of comments received through the scoping process. An interdisciplinary team consisting of specialists in wildlife biology and rangeland management will consider the environmental issues of livestock/bighorn interactions and the appropriate class of livestock for the allotment in the analysis.

Dates: The preparation of the Environmental Assessment will be completed by September 1995 and the amendment, including public and Nevada Governor's review would be complete by November 1995.

Public Participation: Opportunities for public input and comments will be solicited through the media, a mailing, and personal contacts.

For Further Information Contact: Susan Stokke, Area Manager, Surprise Resource Area, Bureau of Land Management, P.O. Box 460, Cedarville, California 96104, Telephone (916) 279–6101.

Susan T. Stokke,

Area Manager.

[FR Doc. 95–19847 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–40–M

[NM–930–1310–01; NMNM 90538]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Public Law 97–451, a petition for reinstatement of Oil and Gas Lease NMNM 90538, Lea County, New Mexico, was timely filed and was accompanied by all required rentals and royalties accruing from March 1, 1995, the date of termination. No valid lease has been issued affecting the land. The lessee has agreed to new lease terms for rentals and royalties at rates of $10.00 per acre, or a fraction thereof, and 16⅔ percent, respectively. Payment of a $500.00 administrative fee has been made. Having met all the requirements for reinstatement of the lease as set in Section 31 (d) and (e) of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 188 (d) and (e)), the Bureau of Land Management is proposing to reinstate the lease effective March 1, 1995, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above, and the reimbursement for cost of publication of this Notice.

FOR FURTHER INFORMATION CONTACT: Gloria S. Baca, BLM, New Mexico State Office, (505) 438–7566.

Dated: August 3, 1995.

Glorida S. Baca,

Land Law Examiner.

[FR Doc. 95–19849 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–FB–M

[NM–930–1310–01; NMNM 90906]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Public Law 97–451, a petition for

reinstatement of Oil and Gas Lease NMNM 90906, Lea County, New Mexico, was timely filed and was accompanied by all required rentals and royalties accruing from June 1, 1995, the date of termination. No valid lease has been issued affecting the land. The lessee has agreed to new lease terms for rentals and royalties at rates of $10.00 per acre, or fraction thereof, and 16⅔ percent, respectively. Payment of a $500.00 administrative fee has been made. Having met all the requirements for reinstatement of the lease as set in Section 31(d) and (e) of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 188(d) and (e)), the Bureau of Land Management is proposing to reinstate the lease effective June 1, 1995, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above, and the reimbursement for cost of publication of this Notice.

FOR FURTHER INFORMATION CONTACT: Gloria S. Baca, BLM, New Mexico State Office, (505) 438–7566.

Dated: August 3, 1995.

Gloria S. Baca,

Land Law Examiner.

[FR Doc. 95–19850 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–FB–M

[NM–930–1310–01; NMNM 93230]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Public Law 97–451, a petition for reinstatement of Oil and Gas Lease NMNM 93230, Lea County, New Mexico, was timely filed and was accompanied by all required rentals and royalties accruing from June 1, 1995, the date of termination. No valid lease has been issued affecting the land. The lessee has agreed to new lease terms for rentals and royalties at rates of $10.00 per acre, or fraction thereof, and 16⅔ percent, respectively. Payment of a $500.00 administrative fee has been made. Having met all the requirements for reinstatement of the lease as set in Section 31 (d) and (e) of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 188 (d) and (e)), the Bureau of Land Management is proposing to reinstate the lease effective June 1, 1995, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above, and the reimbursement for cost of publication of this Notice.

FOR FURTHER INFORMATION CONTACT: Gloria S. Baca, BLM, New Mexico State Office, (505) 438–7566.

Dated: August 3, 1995.

Gloria S. Baca,

Land Law Examiner.

[FR Doc. 95–19851 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–FB–M

[NM–930–1310–01; NMNM 90920]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Public Law 97–451, a petition for reinstatement of Oil and Gas Lease NMNM 90920, Lea County, New Mexico, was timely filed and was accompanied by all required rentals and royalties accruing from June 1, 1995, the date of termination. No valid lease has been issued affecting the land. The lessee has agreed to new lease terms for rentals and royalties at rates of $10.00 per acre, or fraction thereof, and 16⅔ percent, respectively. Payment of a $500.00 administrative fee has been made. Having met all the requirements for reinstatement of the lease as set in Section 31 (d) and (e) of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 188(d) and (e)), the Bureau of Land Management is proposing to reinstate the lease effective June 1, 1995, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above, and the reimbursement for cost of publication of this Notice.

FOR FURTHER INFORMATION CONTACT: Gloria S. Baca, BLM, New Mexico State Office, (505) 438–7566.

Dated: August 3, 1995.

Gloria S. Baca,

Land Law Examiner.

[FR Doc. 95–19852 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–FB–M

[NM–930–1310–01; NMNM 92767]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Public Law 97–451, a petition for reinstatement of Oil and Gas Lease NMNM 92767, Eddy County, New Mexico, was timely filed and was accompanied by all required rentals and royalties accruing from March 1, 1995, the date of termination. No valid lease has been issued affecting the land. The lessee has agreed to new lease terms for rentals and royalties at rates of $10.00 per acre, or fraction thereof, and 16⅔ percent, respectively. Payment of a $500.00 administrative fee has been made. Having met all the requirements for reinstatement of the lease as set in Section 31 (d) and (e) of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 188 (d) and (e)), the Bureau of Land Management is proposing to reinstate the lease effective March 1, 1995, subject to the original terms and conditions of the lease and the increased rental and royalty rates cites above, and the reimbursement for cost of publication of this Notice.

FOR FURTHER INFORMATION CONTACT: Gloria S. Baca, BLM, New Mexico State Office, (505) 438–7566.

Dated: August 3, 1995.

Gloria S. Baca,

Land Law Examiner.

[FR Doc. 95–19853 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–FB–M

[NM–930–1310–01; NMNM 92773]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the provisions of Public Law 97–451, a petition for reinstatement of Oil and Gas Lease NMNM 92773, Lea County, New Mexico, was timely filed and was accompanied by all required rentals and royalties accruing from March 1, 1995, the date of termination. No valid lease has been issued affecting the land. The lessee has agreed to new lease terms for rentals and royalties at rates of $10.00 per acre, or fraction thereof, and 16⅔ percent, respectively. Payment of a $500.00 administrative fee has been made. Having met all the requirements for reinstatement of the lease as set in Section 31(d) and (e) of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 188(d) and (e)), the Bureau of Land Management is proposing to reinstate the lease effective March 1, 1995, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited

above, and the reimbursement for cost of publication of this Notice.

FOR FURTHER INFORMATION CONTACT: Gloria S. Baca, BLM, New Mexico State Office, (505) 438–7566.

Dated: August 3, 1995.

Gloria S. Baca,

Land Law Examiner.

[FR Doc. 95–19848 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–FB–M

Fish and Wildlife Service

Availability of Draft Recovery Plan for Nineteen Florida Scrub and High Pineland Plants for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability and public comment period.

SUMMARY: The Fish and Wildlife Service (Service) announces the availability for public review of a draft recovery plan for nineteen plants from dry habitats in central Florida (Florida scrub and high pineland vegetation). This plan is a revision and expansion of a recovery plan, published in 1990, that covered eleven of these plant species. The Service solicits review and comment from the public on this draft plan.

DATES: Comments on the draft recovery plan must be received on or before October 10, 1995, to receive consideration by the Service.

ADDRESSES: Persons wishing to review the draft recovery plan may obtain a copy by contacting the Field Supervisor, Jacksonville Field Office, U.S. Fish and Wildlife Service, 6620 Southpoint Drive, South, Suite 310, Jacksonville, Florida 32216 (Telephone: 904–232–2580, FAX 904–232–2404) or Assistant Regional Director, Ecological Services, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Atlanta, Georgia, 30345 (Telephone: 404–679–7086). Written comments and materials regarding the plan should be addressed to the Field Supervisor, at the Jacksonville, Florida address. Comments and materials received are available on request for public inspection, by appointment, during normal business hours also at the Jacksonville, Florida address.

FOR FURTHER INFORMATION CONTACT: David L. Martin at the Jacksonville, Florida address.

SUPPLEMENTARY INFORMATION:

Background

Restoring endangered or threatened plants and animals to the point where they are secure self-sustaining members of their ecosystems is a primary goal of the Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the listed specieis native to the United States. Recovery plans describe actions considered necessary for conservation of the species, establish criteria for the recovery levels for downlisting or delisting species, and estimate time and cost for implementing the recovery measures needed.

The Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 *et seq.*) requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act, as amended in 1988, requires that public notice, and an opportunity for public review and comment be provided during recovery plan development. The Service will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will take these comments into account in the course of implementing approved recovery plans.

The nineteen species covered by this recovery plan inhabit dry upland vegetation, either Florida scrub with shrubby evergreen oaks and sand pines, or high pineland with longleaf pine, deciduous oaks (either turkey oak or bluejack oak) and abundant wiregrass. The plants were added to the Federal List of Endangered (E) and Threatened (T) Plants as follows: Chionanthus pygamaeus (pygmy fringe tree) (E), Eryngium cuneifolium (a snakeroot) (E), Hypericum cumulicola (Highlands scrub hypericum) (E), Paronychia chartacea (papery whitlow-wort) (T), Polygonella basiramia (a wireweed) (E), Prunus geniculata (scrub plum) (E), and Warea carteri (Carter's mustard) (E) on January 21, 1987 (52 FR 2227). Lupinus aridorum (scrub lupine) (E) on April 7, 1987 (52 FR 11172). Bonamia grandiflora (Florida bonamia) (T) on November 2, 1987 (52 FR 42068). Liatris ohlingerae (scrub blazing star) and Ziziphus celata (Florida ziziphus) (E) on July 27, 1989, (54 FR 31190). Cladonia perforata (Florida perforate cladonia, a lichen) (E), Clitoria fragrans (pigeon-wings) (T), Crotalaria avonensis (Avon Park harebells) (E), Eriogonum longifolium var. gnaphalifolium (scrub buckwheat) (T), Nolina brittoniana (scrub beargrass) (E), Polygala lewtonii (Lewton's polygala) (E), Polygonella myriophylla (sandlace) (E) on April 27, 1993 (58 FR 25746). Conradina brevifolia (short-leaved rosemary) (E) on July 12, 1993 (58 FR 37432).

The nineteen species became threatened because most of their habitat was destroyed for agricultural purposes or urban development, and because some remaining habitat was degraded due to lack of appropriate prescribed fire. The recovery plan contains six basic elements: 1. Protect habitat through purchase and other means (including the Habitat Conservation Plan process for threatened animals in the Florida scrub habitat); 2. Manage protected habitats; 3. Conserve germ plasm and establish new populations of Ziziphus celata and (if possible) Lupinus aridorum; 5. Assess progress and plan post-recovery monitoring.

The 1990 edition of this recovery plan emphasized the need for land acquisition to protect these plants. At the time, the State and private organizations had already made significant acquisitions, and more have been accomplished since then (including initial land purchase for the Lake Wales Ridge National Wildlife Refuge). These land purchases, accompanied by the other elements of the recovery plan, are likely to assure the full recovery or at least the downlisting of the large majority of the nineteen plants.

Public Comments Solicited

The Service solicits written comments on the recovery plan. All comments received by the date specified above will be considered prior to the approval of the plans.

Authority

The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: August 4, 1995.

David J. Wesley,

Field Supervisor.

[FR Doc. 95–19846 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–55–M

Endangered and Threatened Species Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application.

The following applicant has 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.*).

PRT–805269

Applicant: Dr. Daniel A. Soluk, Illinois Natural History Survey, Champaign, Illinois.

The applicant requests a permit to take (collect, live-capture, and handle) Hine's Emerald Dragonflies (*Somatochlora hineana*) in Cook, DuPage, and Will Counties, Illinois, for biological research studies aimed at enhancement of propagation or survival of the species.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Division of Endangered Species, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with Dr. Soluk's application are available for review 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, Division of Endangered Species, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056. Telephone: (612/725–3536, x 250); FAX: (612/725–3526).

Dated: August 4, 1995.

John A. Blankenship,

Assistant Regional Director, Ecological Services, Region 3, Fish and Wildlife Service, Fort Snelling, Minnesota.

[FR Doc. 95–19920 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–55–M

Minerals Management Service

Request for Comments on the Draft Proposed 5-Year Outer Continental Shelf (OCS) Oil and Gas Leasing Program for 1997–2002

SUMMARY: Comments are requested on the Draft Proposed 5-year OCS Oil and Gas Leasing Program for 1997–2002. This is the first proposal for a new program to succeed the current program that expires in July 1997.

Section 18 of the OCS Lands Act (43 USC 1344) specifies a multi-step process of consultation and analysis that must be completed before the Secretary of the Interior may approve a new 5-year program. The required steps following this notice include the development of a proposed program, a proposed final program, and Secretarial approval. Pursuant to the National Environmental Policy Act, the Minerals Management Service (MMS) also will prepare an Environmental Impact Statement (EIS) for the new 5-year program.

DATES: Please submit comments and information to MMS on or before October 10, 1995.

ADDRESSES: Respondents should mail comments and information to: 5-Year Program project Director, Minerals Management Service (MS–4430), Room 1324, 381 Elden Street, Herndon, Virginia 22070. The MMS will accept hand deliveries at 1849 C Street, NW, Room 4230, Washington, DC. Envelopes or packages should be marked ''Comments on the Draft proposed 5-Year OCS Oil and Gas Leasing Program for 1997–2002.'' When submitting any privileged or proprietary information to be treated as confidential, respondents should mark the envelope, ''Contains Confidential Information.''

FOR FURTHER INFORMATION CONTACT: Carol Hartgen, 5-Year Program Project Director, or Tim Redding, Program Decision Document Project Manager, at (703) 787–1216. To order copies of the new Draft Proposed Program decision document and maps or documents describing the current 5-year program for 1992–1997, telephone (703) 787–1216.

SUPPLEMENTARY INFORMATION: The MMS requests comments from States, local governments, Native groups, tribes, the oil and gas industry, Federal Agencies, environmental and other interest organizations, and all other interested parties to assist in the preparation of a 5-year OCS oil and gas leasing program for 1997–2002 and applicable EIS.

Background

Management of the Nation's offshore oil and gas resources is governed by the OCS Lands Act, which specifies the conditions under which the Secretary of the Interior grants rights to explore for, develop, and produce those resources. The Secretary has assigned the responsibility for implementing the requirements of the OCS Lands Act to the MMS.

Section 18 of the Act requires the Secretary to prepare an oil and gas leasing program that indicates a 5-year schedule of lease sales that he determines will best meet the Nation's energy needs. Section 18 requires that the 5-year program be prepared in a manner consistent with four main principles: (1) Consideration of economic, social, and environmental values and the potential impact on marine, coastal, and human environments; (2) consideration of diverse environmental, geographical, and equitable regional factors; (3) a proper balance among potential for environmental damage, discovery of oil and gas, and adverse impact on the coastal zone; and (4) assurance of receiving fair market value. There is no set equation for the weight to be accorded each principle and factor. It is within the Secretary's discretion after taking these matters into consideration to determine how best to proceed.

In addition to the requirements of section 18, the following policy objectives endorsed by the President and the Secretary have been considered in developing the Draft Proposed Program: consensus-based decisionmaking, science-based decisionmaking, and the use of natural gas as an environmentally preferred fuel.

On November 16, 1994, the MMS published a **Federal Register** Notice requesting comments on the preparation of a new 5-year program for 1997–2002. Over 2300 comments were received from affected State and local governments, Alaska Native organizations and communities, federal agencies, environmental and other interest organizations, the oil and gas industry, and the general public. Those comments have been considered in developing the Draft Proposed Program.

Moving From Conflict to Consensus

Preparation of the 5-year Draft proposed Program for 1997–2002 recognizes the need not only to incorporate and consider analyses that were updated from the 1992–1997 program but also to engage in dialogue with the parties that would be most affected by the program. In its 1993 report, Moving beyond Conflict to Consensus, the Subcommittee on OCS Legislation of the OCS Policy Committee, an independent body that advises the Secretary of the Interior, recommended that the Secretary, where local constituents were willing, use regional task forces representing OCS program stakeholders to focus on reaching consensus on OCS lease sales. The OCS Policy Committee also recognized that ''overall, the prevailing controversies and the measures used to deal with them have seriously diminished the effectiveness of the federal OCS oil and gas program in helping to meet the Nation's energy needs.'' This program embraces the advice provided by the OCS Policy Committee and reflects the beginning of a long-term movement from conflict to consensus in the OCS program.

The OCS Policy Committee established an Alaska Regional Stakeholders Task Force consisting of diverse Alaskan constituencies which was a first attempt to reach consensus on recommending to the Secretary the appropriate planning areas to be

proposed for evaluation in an OCS 5-year program. The OCS Policy Committee approved the continued existence of the task force to advise the Secretary throughout the remainder of the 5-year program.

The Draft Proposed Program provides for environmentally responsible oil and gas leasing in selected prospective areas of the OCS where it appears there is sufficient industry interest, where the laws and policies of adjacent States and localities are not a significant impediment to OCS program activity, and where there is agreement among interested and affected parties that further evaluation of leasing is reasonable. The program provides a framework for resolving concerns relating to new leasing and development of existing leases on a basis supported by sound science. In addition, to help assure that the new program and future leasing decisions are based on good science, the Director of the MMS has asked the OCS Policy and Scientific Committees to form a subcommittee to provide an independent review and evaluation of specific information needs for areas where controversy has led to executive and/or legislative restrictions on leasing.

National Energy Needs

Analysis in the Proposed Final Program for 1992–1997 (April 1992) showed the economic dangers associated with the Nation's dependence on imported petroleum and how OCS production had helped reduce the need for even greater volumes of imported petroleum.

The growing need for imported petroleum remains a serious concern. In its December 1994 report to the President, The Effect of Imports of Crude Oil and Refined Petroleum Products on the National Security, the Department of Commerce concluded that petroleum imports threaten to impair U.S. national security.

Increasing imports will make the Nation more vulnerable to supply disruptions and increase the Nation's balance of payments deficit. Environmentally responsible development of OCS oil and gas resources will have to play a role in any effort to slow or reverse the increase in imported energy.

The decisions on the new 5-year program will have a long-term effect on the contribution of OCS resources to meeting the Nation's energy needs and improving its trade balance. Most production resulting from lease sales held under the new 5-year program is likely to begin over the first decade of the next century and continue for another 25 years.

Maps 1 and 2 contain the areas proposed for leasing consideration in the new program. Table A is a summary of the proposed schedule of lease sales for the new program. Individual planning area maps are included in the Draft Proposed Program decision document.

TABLE A.—PROPOSED LEASE SALE SCHEDULE

Region and planning area	Year	Proposed activity
Alaska:		
Beaufort Sea	1998	Small sale, focusing on nearshore blocks in center of program area (Map 1).
	2000	Sale in program area (Map 1).
Cook Inlet/Shelikof Strait	1999	Sale in program area (Map 1).
Gulf of Alaska	2001	Sale in program area (Map 1).
Chukchi Sea/Hope Basin	2002	Combined sale in program area (Map 1).
Gulf of Mexico:		
Western Gulf of Mexico	Annual	Sale in program area (Map 2).
Central Gulf of Mexico	Annual	Sale in program area (Map 2).
Eastern Gulf of Mexico	2001	Sale in program area (Map 2) (offshore Alabama, 100 miles off Florida).

Draft Proposed Program Decision

Alaska Region

The Draft Proposed Program for 1997–2002 includes lease offerings in 5 of the 15 Alaska OCS planning areas—Beaufort Sea, Cook Inlet/Shelikof Strait, Gulf of Alaska, Chukchi Sea, and Hope Basin. The lease offerings do not encompass the entire planning areas, rather they are focused on specific areas within the planning areas. These planning areas were recommended for further evaluation by the Alaska Regional Stakeholders Task Force, established by the OSC Policy Committee in November 1994 to make recommendations on the Alaska component of this 5-year program. The Task Force consists of representatives of Federal and State agencies, local governments and community organizations, Native/subsistence and development communities, oil and gas and commercial fishing industries, and environmental interests. Task Force members met in Alaska as a group and conducted meetings in selected communities before preparing a report to the Secretary recommending areas to be considered in the new 5-year program.

The Draft Proposed Program for 1997–2002 proposes no leasing for the remaining 10 Alaska OCS planning areas. St. George Basin has relatively low net social value and low industry interest, and consensus among interested parties including the Alaska Regional Stakeholders Task Force was that this area should be excluded from the new program. Norton Basin, Navarin Basin, St. Matthew-Hall, North Aleutian Basin, Aleutian Basin, Bowers Basin, Aleutian Arc, Shumagin, and Kodiak were excluded from the current 5-year program based on low net social value, low industry interest, and other section 18 considerations. No new information supports including these areas for leasing consideration in the new program, and the Alaska Regional Stakeholders Task Force did not recommend that they be evaluated further.

Gulf of Mexico

Annual area wide sales for the Central and Western Gulf of Mexico Planning Areas are proposed to continue to provide industry and others with the flexibility and the reliable schedule so important to long-term planning. The proposed Eastern Gulf of Mexico lease sale would cover blocks offshore Alabama and in the deep-water areas along the boundary of the Central Gulf of Mexico Planning Area. It recognizes the high potential for the development of natural gas in the areas of current development offshore Alabama and the potential for deepwater development along the Central Gulf of Mexico and Eastern Gulf of Mexico Planning Areas' boundary line. It is also consistent with Florida's continued opposition to activity within 100 miles of its coast and Alabama's desire to share in the benefits

of new OCS leasing and development. The MMS will concentrate its efforts on resolving disputes relating to those existing leases in the Eastern Gulf of Mexico offshore Florida rather than exacerbate an already contentious situation with additional leasing.

Pacific Region

There are no proposed lease sales offshore the west coast. There are outstanding scientific information needs that have not been fulfilled.

The MMS will continue working with interested and affected parties to resolve issues concerning existing leases in the Southern California Planning Area. In previous comments and in response to the November 1994 **Federal Register** Notice soliciting comments on the development of a new 5-year program, the State of California has opposed any leasing off its coast. Local government policies and ordinances have reflected this opposition as well. The MMS Pacific Regional Office and officials from Santa Barbara, Ventura, and San Luis Obispo counties in Southern California and several State agencies have formed a Tri-County Forum to address issues related to exploration and development on existing leases. Because of the cooperative nature of this forum to date in resolving oil and gas issues, two of the local counties indicated they would not oppose limited leasing off their coasts provided that several conditions such as impact assistance and an enhanced local role in OCS leasing decisions were met. However, there are still several issues to resolve for the future development of significant oil reserves under existing leases. Rather than propose additional acreage for leasing consideration, the MMS will continue working with interested and affected parties on issues concerning the existing leases.

Atlantic Region

There are no proposed lease sales. The MMS will continue working with interested and affected parties to resolve issues concerning existing leases in the Mid- and South Atlantic Planning Areas. In keeping with the Administration's goal of encouraging the use of natural gas, the MMS examined gas-prone areas off the coast of North Carolina and another off the coast of New Jersey. The areas offshore North Carolina are currently leased and are subject to litigation relating to application of the Coastal Zone Management Act and the Outer Banks Protection Act. No new leasing is proposed in these areas at this time, but the MMS will continue to pursue resolving disputes related to the existing leases outside of litigation. The area offshore New Jersey has been leased in the past. A significant natural gas discovery was made in the 1970's. Given the recent dormancy in this area, rather than proposing leasing during the 5-year program, the MMS will begin preliminary discussions with constituents in the area.

No leasing is proposed in the North Atlantic and Straits of Florida Planning Areas. No new information supports including these areas for leasing in the new program.

Configuration of Planning Areas

The Draft Proposed Program decision moves the boundary between the Beaufort Sea and Chukchi Sea Planning Areas to more accurately conform those areas with the bodies of water after which they were named. In addition, Official Protraction Diagrams were created and planning area boundaries revised to be consistent with the current projection of the U.S. Exclusive Economic Zone as depicted on official maps prepared by the National Oceanic and Atmospheric Administration. Whole and partial Official Protraction Diagrams have been added to the Beaufort Sea; Aleutian Arc; Washington-Oregon; Northern, Central, and Southern California; and South Atlantic Planning Areas; none of the additions would be considered for leasing. The Official Protraction Diagrams beyond the OCS and Exclusive Economic Zone in the Gulf of Alaska have been deleted.

Assurance of Fair Market Value

The basic minimum bid level would be set at $25 per acre, subject to sale-by-sale reconsideration, and the current two-phased bid adequacy process is retained. As announced in the Call for Comment published in the **Federal Register** on April 20, 1995, both of these measures are under separate review to ensure that fair market value is obtained through the MMS's leasing policies. Relevant comments received in response to that Notice will be considered in developing the fair market value provisions of the new 5-year program. The existing measures will be maintained until the separate review is complete. The results of the analysis will be addressed in formulating the proposed program.

Information Requested

We request all interested and affected parties to comment on the size, timing, and location of leasing and the procedures for assuring fair market value that are proposed in the Draft Proposed Program for 1997–2002. Information provided by commenters should relate to the principles and factors of section 18, and suggestions for revising the Draft Proposed Program should include rationale corresponding to those considerations and to the policy objectives identified by the MMS, as discussed in the background presented above. Respondents who submitted information in response to the April 20, 1995, Call for Comment discussed above may wish to reference that information, as appropriate, rather than repeating it in their comments on the Draft Proposed Program. We also invite comments and suggestions on how to proceed with the section 18 analysis for the next draft of the new program, the Proposed Program.

As the scoping process continues for the programmatic EIS that will be prepared, we again request comments on significant environmental issues attendant to OCS leasing and development and on alternative options for size, timing, and location of sales that should be evaluated.

Respondents who wish to provide illustrated information pertaining to the size and location of lease sales can obtain larger OCS block-specific maps by calling (703) 787–1216.

Section 18(g) authorizes confidential treatment of privileged or proprietary information that is submitted. In order to protect the confidentiality of such information respondents should include it as an attachment to other comments submitted and mark it appropriately. On request the MMS will treat such information as confidential from the time of its receipt until 5 years after approval of the new leasing program, subject to the standards of the Freedom of Information Act. The MMS will not treat as confidential any aggregate summaries of such information, the names of respondents, and comments not containing such information.

Next Steps in the Process

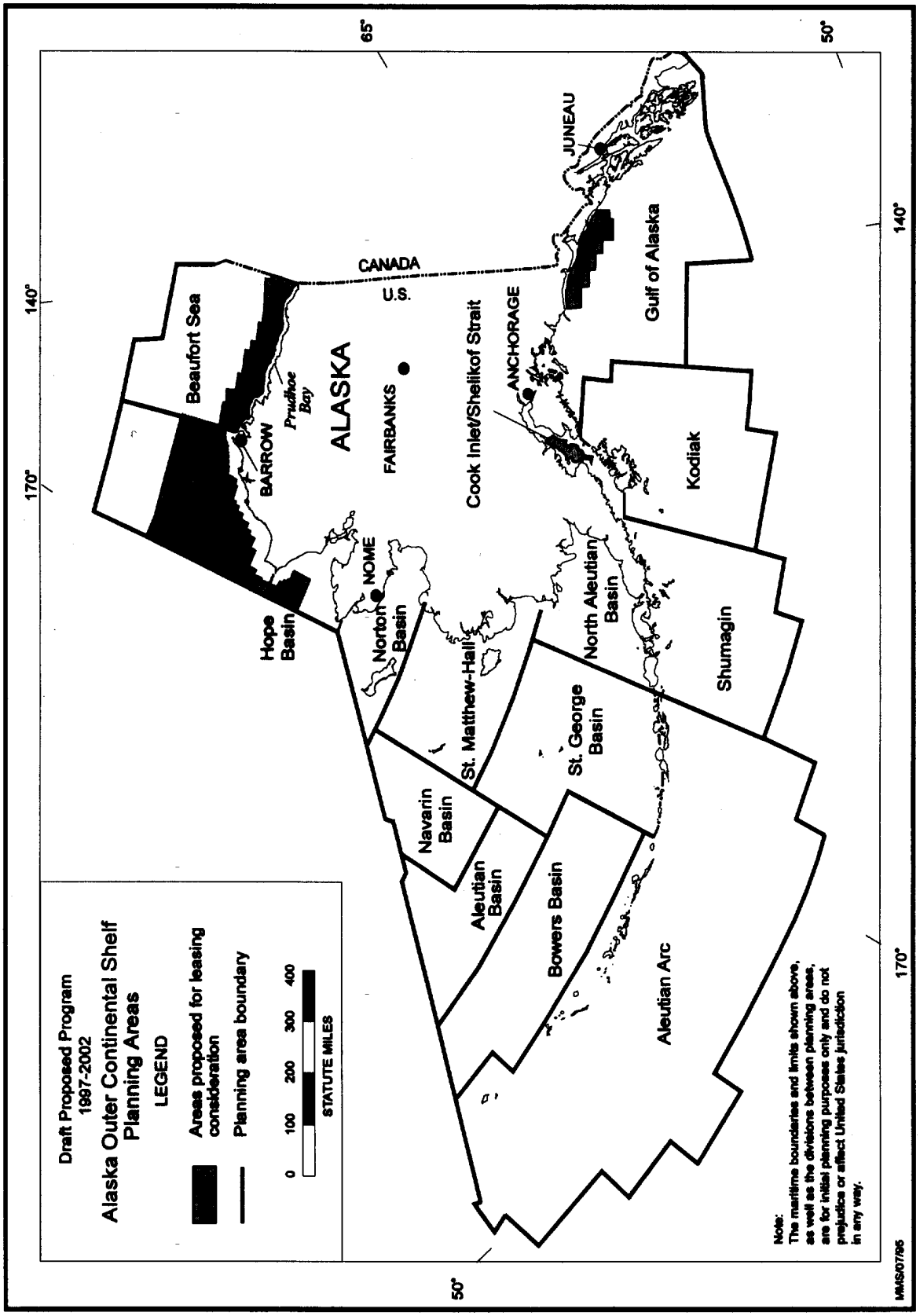
The Proposed Program and draft EIS are scheduled to be issued in January 1996 followed by a 90-day comment period. The Proposed Final Program and final EIS are scheduled to be issued in August 1996. The Secretary may approve the new 5-year program 60 days later.

Dated: August 7, 1995.

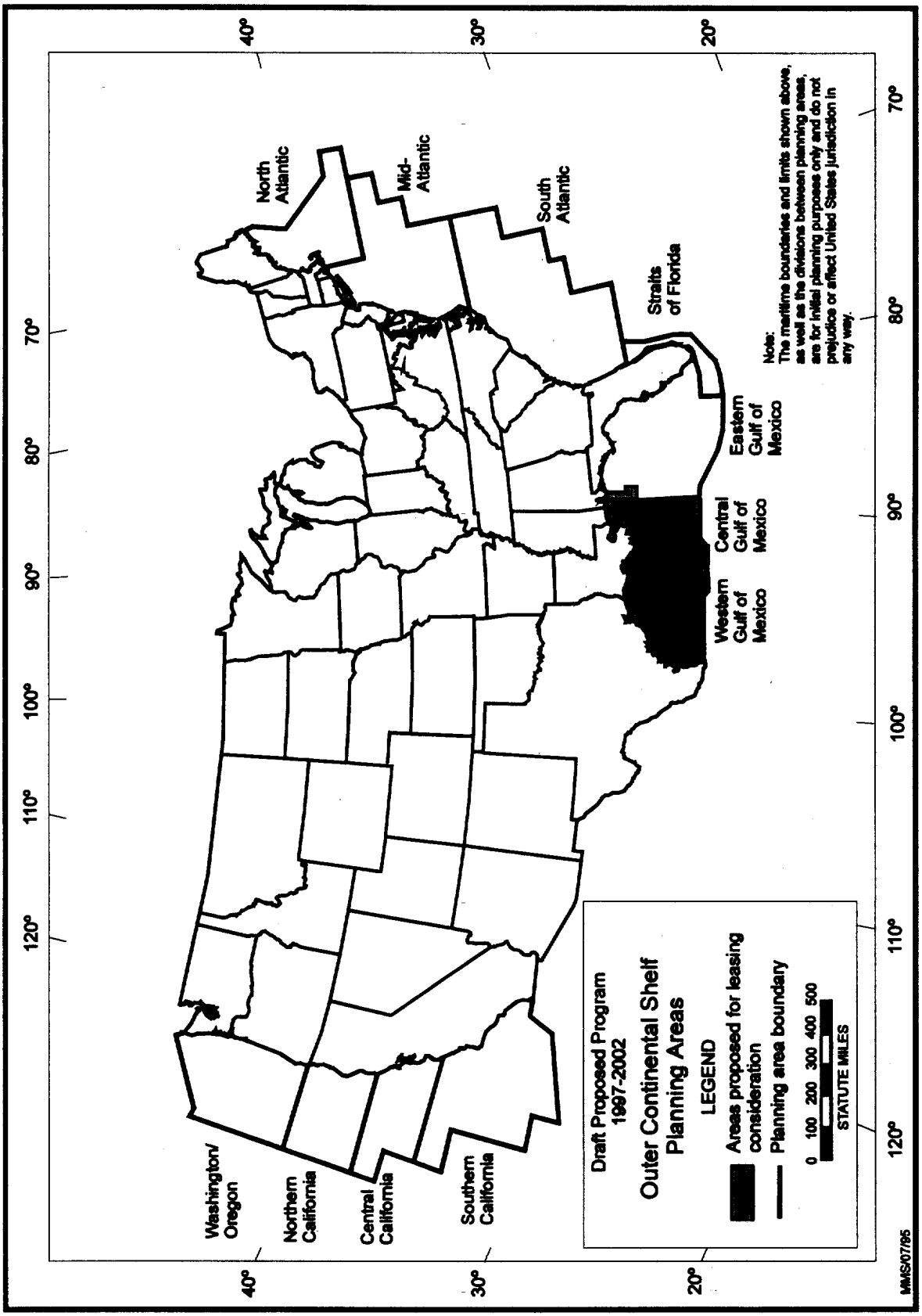
Cynthia Quarterman,

Director, Minerals Management Service.

BILLING CODE 4310–MR–M


Draft Proposed Program
1997-2002
Alaska Outer Continental Shelf
Planning Areas
LEGEND
Areas proposed for leasing consideration
Planning area boundary
0 100 200 300 400
STATUTE MILES
Note:
The maritime boundaries and limits shown above, as well as the divisions between planning areas, are for initial planning purposes only and do not prejudice or affect United States jurisdiction in any way.
MMS/07/95
Beaufort Sea
Hope Basin
Norton Basin
Navarin Basin
St. Matthew-Hall
Aleutian Basin
Bowers Basin
St. George Basin
North Aleutian Basin
Aleutian Arc
Shumagin
Kodiak
Gulf of Alaska
Cook Inlet/Shelikof Strait
ALASKA
CANADA
U.S.
BARROW
Prudhoe Bay
NOME
FAIRBANKS
ANCHORAGE
JUNEAU
65°
50°
140°
170°

Map 1. Alaska



Map 2. Lower 48 States

[FR Doc. 95–19828 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–MR–C

Outer Continental Shelf; Western Gulf of Mexico; Notice of Leasing Systems, Sale 155

Section 8(a)(8) (43 U.S.C. 1337(a)(8)) of the Outer Continental Shelf Lands Act (OCSLA) requires that, at least 30 days before any lease sale, a Notice be submitted to the Congress and published in the **Federal Register**:

1. Identifying the bidding systems to be used and the reasons for such use; and

2. Designating the tracts to be offered under each bidding system and the reasons for such designation.

This Notice is published pursuant to these requirements.

1. *Bidding systems to be used.* In the Outer Continental Shelf (OCS) Sale 155, blocks will be offered under the following two bidding systems as authorized by section 8(a)(1) (43 U.S.C. 1337(a)(1)): (a) Bonus bidding with a fixed 16⅔-percent royalty on all unleased blocks in less than 400 meters of water; and (b) bonus bidding with a fixed 12½-percent royalty on all remaining unleased blocks.

a. *Bonus Bidding with a 16⅔-Percent Royalty.* This system is authorized by section (8)(a)(1)(A) of the OCSLA. This system has been used extensively since the passage of the OCSLA in 1953 and imposes greater risks on the lessee than systems with higher contingency payments but may yield more rewards if a commercial field is discovered. The relatively high front-end bonus payments may encourage rapid exploration.

b. *Bonus Bidding with a 12½-Percent Royalty.* This system is authorized by section (8)(a)(1)(A) of the OCSLA. It has been chosen for certain deeper water blocks proposed for the Western Gulf of Mexico (Sale 155) because these blocks are expected to require substantially higher exploration, development, and production costs, as well as longer times before initial production, in comparison to shallow-water blocks. Department of the Interior analyses indicate that the minimum economically developable discovery on a block in such high-cost areas under a 12½-percent royalty system would be less than for the same blocks under a 16⅔-percent royalty system.

As a result, more blocks may be explored and developed. In addition, the lower royalty rate system is expected to encourage more rapid production and higher economic profits. It is not anticipated, however, that the larger cash bonus bid associated with a lower royalty rate will significantly reduce competition, since the higher costs for exploration and development are the primary constraints to competition.

2. *Designation of Blocks.* The selection of blocks to be offered under the two systems was based on the following factors:

a. Lease terms on adjacent, previously leased blocks were considered to enhance orderly development of each field.

b. Blocks in deep water were selected for the 12½-percent royalty system based on the favorable performance of this system in these high-cost areas as evidenced in our analyses.

The specific blocks to be offered under each system are shown on the ''Stipulations, Lease Terms, and Bidding Systems Map'' for Western Gulf of Mexico Lease Sale 155. This map is available from the Public Information Unit, Minerals Management Service, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394.

Cynthia Quarterman,

Director, Minerals Management Service.

Approved: August 4, 1995.

Bob Armstrong,

Assistant Secretary, Land and Minerals Management.

[FR Doc. 95–19826 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–MR–P

Outer Continental Shelf, Western Gulf of Mexico, Oil and Gas Lease Sale 155

AGENCY: Minerals Management Service.

ACTION: Final notice of sale.

1. *Authority.* This Notice is published pursuant to the Outer Continental Shelf (OCS) Lands Act (43 U.S.C. 1331–1356, (1988)), and the regulations issued thereunder (30 CFR Part 256).

2. *Filing of Bids.* Sealed bids will be received by the Regional Director (RD), Gulf of Mexico Region, Minerals Management Service (MMS), 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394. Bids may be delivered in person to that address during normal business hours (8 a.m. to 4 p.m., Central Standard Time (c.s.t.)) until the Bid Submission Deadline at 10 a.m. Tuesday, September 12, 1995. Hereinafter, all times cited in this Notice refer to c.s.t. unless otherwise stated. Bids will not be accepted the day of Bid Opening, Wednesday, September 13, 1995. Bids received by the RD later than the time and date specified above will be returned unopened to the bidders. Bids may not be modified or withdrawn unless written modification or written withdrawal request is received by the RD prior to 10 a.m. Tuesday, September 12, 1995. Bid Opening Time will be 9 a.m., Wednesday, September 13, 1995, at the downtown Hilton Hotel (Poydras Street at the Mississippi River) New Orleans, Louisiana. All bids must be submitted and will be considered in accordance with applicable regulations, including 30 CFR Part 256. The list of restricted joint bidders which applies to this sale appeared in the **Federal Register** at 60 FR 14777, published on March 20, 1995.

3. *Method of Bidding.* (a) *Submission of Bids.* A separate signed bid in a sealed envelope labeled ''Sealed Bid for Oil and Gas Lease Sale 155, not to be opened until 9 a.m., c.s.t., Wednesday, September 13, 1995'' must be submitted for each block bid upon. The sealed envelope and the bid should contain the following information: The company name, Gulf of Mexico Company Number (GOM Company Number), area number and/or name (abbreviations acceptable), and the block number of the block bid upon. In addition, the total amount bid must be in whole dollar amounts.

Bidders must submit with each bid one-fifth of the cash bonus, in cash or by cashier's check, bank draft, or certified check, payable to the order of the U.S. Department of the Interior—Minerals Management Service. For identification purposes, the following information must appear on the check or draft: Company name, GOM Company Number, and the area and block bid on (abbreviation acceptable). No bid for less than all of the unleased portions of a block will be considered.

All documents must be executed in conformance with signatory authorizations on file in the Gulf of Mexico regional office. Partnerships also need to submit or have on file a list of signatories authorized to bind the partnership. Bidders submitting joint bids must state on the bid form the proportionate interest of each participating bidder, in percent to a maximum of five decimal places, e.g., 33.33333 percent. Other documents may be required of bidders under 30 CFR 256.46. Bidders are warned against violation of 18 U.S.C. 1860 prohibiting unlawful combination or intimidation of bidders.

(b) *Submission of Statement Regarding Certain Geophysical Data.* Each company submitting a bid, or participating as a joint bidder in such a bid, shall submit, prior to the Bid Submission Deadline specified in paragraph 2 of this Notice, a statement or statements identifying any processed or reprocessed pre and post stack depth migrated geophysical data in their possession or control pertaining to each and every block on which they are participating as a bidder. The existence,

extent, and type of such data must be clearly identified. In addition, the statement shall certify that no such data is in their possession for any other blocks on which they participate as a bidder. The statement shall be submitted in an envelope separate from those containing bids and shall be clearly marked; an example of a preferred format for the statement and the envelope is included in the document titled ''Trial Procedures for Access to Certain Geophysical Data in the Gulf of Mexico.'' Only one statement per bidder is required for each sale, but more than one may be submitted if desired, provided that all tracts bid on by that company are covered in the one or more statements.

Paragraph 14(j), *Information to Lessees,* contains additional information pertaining to this requirement.

4. *Bidding, Yearly Rental, and Royalty Systems.* The following bidding, yearly rental, and royalty systems apply to this sale:

(a) *Bidding Systems.* All bids submitted at this sale must provide for a cash bonus in the amount of $25.00 or more per acre or fraction thereof.

(b) *Yearly Rental.* All leases awarded will provide for a yearly rental payment of $5 per acre or fraction thereof.

(c) *Royalty Systems.* All leases will provide for a minimum royalty of $5 per acre or fraction thereof. The following royalty systems will be used in this sale.

(1) *Leases with a 12½-Percent Royalty.* This royalty rate applies to blocks in water depths of 400 meters or greater; this area is shown on the Stipulations, Lease Terms, and Bidding Systems map applicable to this Notice (see paragraph 13). Leases issued on the blocks offered in this area will have a fixed royalty rate of 12½ percent.

(2) *Leases with a 16⅔-Percent Royalty.* This royalty rate applies to blocks in water depths of less than 400 meters (see aforementioned map). Leases issued on the blocks offered in this area will have a fixed royalty rate of 16⅔ percent.

5. *Equal Opportunity.* The certification required by 41 CFR 60–1.7(b) and Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, on the Compliance Report Certification Form, Form MMS–2033 (June 1985), and the Affirmative Action Representation Form, Form MMS–2032 (June 1985) must be on file in the Gulf of Mexico regional office prior to lease award (see paragraph 14(e)).

6. *Bid Opening.* Bid opening will begin at the bid opening time stated in paragraph 2. The opening of the bids is for the sole purpose of publicly announcing bids received, and no bids will be accepted or rejected at that time. If the Department is prohibited for any reason from opening any bid before midnight on the day of bid opening, that bid will be returned unopened to the bidder as soon thereafter as possible.

7. *Deposit of Payment.* Any cash, cashier's checks, certified checks, or bank drafts submitted with a bid may be deposited by the Government in an interest-bearing account in the U.S. Treasury during the period the bids are being considered. Such a deposit does not constitute and shall not be construed as acceptance of any bid on behalf of the United States.

8. *Withdrawal of Blocks.* The United States reserves the right to withdraw any block from this sale prior to issuance of a written acceptance of a bid for the block.

9. *Acceptance, Rejection, or Return of Bids.* The United States reserves the right to reject any and all bids. In any case, no bid will be accepted, and no lease for any block will be awarded to any bidder, unless:

(a) the bidder has complied with all requirements of this Notice and applicable regulations;

(b) the bid is the highest valid bid; and

(c) the amount of the bid has been determined to be adequate by the authorized officer.

No bonus bid will be considered for acceptance unless it provides for a cash bonus in the amount of $25.00 or more per acre or fraction thereof. Any bid submitted which does not conform to the requirements of this Notice, the OCS Lands Act, as amended, and other applicable regulations may be returned to the person submitting that bid by the RD and not considered for acceptance.

10. *Successful Bidders.* Each person who has submitted a bid accepted by the authorized officer will be required to execute copies of the lease, pay the balance of the cash bonus bid along with the first year's annual rental for each lease issued, by electronic funds transfer in accordance with the requirements of 30 CFR 218.155, and satisfy the bonding requirements of 30 CFR 256, Subpart I, as amended. See **Federal Register** at 58 FR 45255, published August 27, 1993.

11. *Leasing Maps and Official Protraction Diagrams.* Blocks offered for lease may be located on the following Leasing Maps or Official Protraction Diagrams which may be purchased from the Gulf of Mexico regional office (see paragraph 14(a)):

(a) Outer Continental Shelf Leasing Maps—Texas, Nos. 1 through 8. This is a set of 16 maps which sells for $18.00.

(b) Outer Continental Shelf Official Protraction Diagrams. These diagrams sell for $2.00 each.

NG 14–3 Corpus Christi (rev. 01/27/76)
NG 14–6 Port Isabel (rev. 01/15/92)
NG 15–1 East Breaks (rev. 01/27/76)
NG 15–2 Garden Banks (rev. 10/19/81)
NG 15–4 Alaminos Canyon (rev. 04/27/89)
NG 15–5 Keathley Canyon (rev. 04/27/89)
NG 15–8 (No Name) (rev. 04/27/89)

12. *Description of the Areas Offered for Bids.* (a) Acreages of blocks are shown on Leasing Maps and Official Protraction Diagrams. Some of these blocks, however, may be partially leased, or transected by administrative lines such as the Federal/State jurisdictional line. Information on the unleased portions of such blocks, including the exact acreage, is included in the following document available from the Gulf of Mexico regional office; this document is also included in the Final Notice of Sale package sent by this office:

Western Gulf of Mexico Lease Sale 155—Final. Unleased Split Blocks and Unleased Acreage of Blocks with Aliquots and Irregular Portions Under Lease.

(b) *Blocks which have recently become available for leasing:* Attention is drawn to the following update list which is included as a matter of convenience for interested parties. This update list reflects blocks which have become available since the publication of the Preliminary Final Notice of Sale 155. Any questions on this may be directed to Ms. Patricia Bryars, phone (504) 736–2763.

Update List: Matagorda Island Area block 602; Brazos Area blocks 501 and 506; Galveston Area blocks 332, 383, 392, and 393; High Island Area, East Addition, South Extension block A–341; and Garden Banks Area blocks 166, 208, 210, 211, 252, 299, 342, and 381.

(c) *Blocks not available for leasing:* The areas offered for leasing include all those blocks shown on the OCS Leasing Maps and Official Protraction Diagrams listed in paragraph 11 (a) and (b), except for those blocks or partial blocks already under lease and those blocks or partial blocks listed in (1), (2), and (3) below. A list of Western Gulf of Mexico blocks currently under active lease is included at the end of this Notice.

(1) *Flower Garden Banks area:* No bids will be accepted on the following blocks at the Flower Garden Banks National Marine Sanctuary: High Island Area, East Addition, South Extension, blocks A–375 and A–398.

(2) *Navy Mine Warfare Training area:* No bids will be accepted on the

following blocks located off Corpus Christi which have been identified by the Navy as needed for testing equipment and training mine warfare personnel: Mustang Island Area blocks 793, 799, and 816.

(3) *Blocks not available for leasing due to appeals:* The lease status of the following blocks are currently under appeal and therefore these blocks are unavailable for leasing in this sale: Galveston Area, South Addition, block A–125; and Brazos Area block 578.

13. *Lease Terms and Stipulations.*

(a) Leases resulting from this sale will have initial terms as shown on the Stipulations, Lease Terms, and Bidding Systems Map applicable to this Notice and will be on Form MMS–2005 (March 1986). Copies of the map and lease form are available from the Gulf of Mexico regional office (see paragraph 14(a)).

(b) The applicability of the stipulations which follow is as shown on the map described in paragraph 13(a) and as supplemented by references in this Notice.

Stipulation No. 1—Topographic Features

(This stipulation will be included in leases located in the areas so indicated in the Biological Stipulation Map Package associated with this Notice and which is available from the Gulf of Mexico regional office (see paragraph 14(a))

The banks that cause this stipulation to be applied to blocks of the Western Gulf are:

Bank name	No activity zone defined by isobath (meters)
Shelf Edge Banks:	
West Flower Garden Bank [1].	100 (defined by ¼ ¼ ¼ system)
East Flower Garden Bank [1].	100 (defined by ¼ ¼ ¼ system)
MacNeil Bank	82
29 Fathom Bank	64
Rankin Bank	85
Geyer Bank	85
Elvers Bank	85
Bright Bank [2]	85
McGrail Bank [2]	85
Rezak Bank [2]	85
Sidner Bank [2]	85
Parker Bank [2]	85
Stetson Bank	62
Appelbaum Bank	85
Low Relief Banks [3]:	
Mysterious Bank	74, 76, 78, 80, 84
Coffee Lump	Various
Blackfish Ridge	70
Big Dunn Bar	65
Small Dunn Bar	65
32 Fathom Bank	52
Claypile Bank [4]	50
South Texas Banks [5]:	
Dream Bank	78, 82
Southern Bank	80
Hospital Bank	70
North Hospital Bank	68
Aransas Bank	70
South Baker Bank	70
Baker Bank	70

[1] Flower Garden Banks—In paragraph (c) a ''4–Mile Zone'' rather than a ''1–Mile Zone'' applies.

[2] Central Gulf of Mexico bank with a portion of its ''1–Mile Zone'' and/or ''3–Mile Zone'' in the Western Gulf of Mexico.

[3] Low Relief Banks—Only paragraph (a) applies.

[4] Claypile Bank—Paragraphs (a) and (b) apply. In paragraph (b) monitoring of the effluent to determine the effect on the biota of Claypile Bank shall be required rather than shunting.

[5] South Texas Banks—Only paragraphs (a) and (b) apply.

(a) No activity including structures, drilling rigs, pipelines, or anchoring will be allowed within the listed isobath (''No Activity Zone'' as shown in the aforementioned Biological Stipulation Map Package) of the banks as listed above.

(b) Operations within the area shown as ''1,000–Meter Zone'' in the aforementioned Biological Stipulation Map Package shall be restricted by shunting all drill cuttings and drilling fluids to the bottom through a downpipe that terminates an appropriate distance, but no more than 10 meters, from the bottom.

(c) Operations within the area shown as ''1–Mile Zone'' in the aforementioned Biological Stipulation Map Package shall be restricted by shunting all drill cuttings and drilling fluids to the bottom through a downpipe that terminates an appropriate distance, but no more than 10 meters, from the bottom. (Where there is a ''1–Mile Zone'' designated, the ''1,000–Meter Zone'' in paragraph (b) is not designated.)

(d) Operations within the area shown as ''3–Mile Zone'' in the aforementioned Biological Stipulation Map Package shall be restricted by shunting all drill cuttings and drilling fluids from development operations to the bottom through a downpipe that terminates an appropriate distance, but no more than 10 meters, from the bottom.

Stipulation No. 2—Military Areas

(This stipulation will be included in leases located within the Warning Areas as shown on the map described in paragraph 13(a))

(a) Hold and Save Harmless

Whether compensation for such damage or injury might be due under a theory of strict or absolute liability or otherwise, the lessee assumes all risks of damage or injury to persons or property, which occur in, on, or above the Outer Continental Shelf (OCS), to any persons or to any property of any person or persons who are agents, employees, or invitees of the lessee, its agents, independent contractors, or subcontractors doing business with the lessee in connection with any activities being performed by the lessee in, on, or above the OCS, if such injury or damage to such person or property occurs by reason of the activities of any agency of the United States Government, its contractors or subcontractors, or any of its officers, agents or employees, being conducted as a part of, or in connection with, the programs and activities of the command headquarters listed in the following table.

Notwithstanding any limitation of the lessee's liability in Section 14 of the lease, the lessee assumes this risk whether such injury or damage is caused in whole or in part by any act or omission, regardless of negligence or fault, of the United States, its contractors or subcontractors, or any of its officers, agents, or employees. The lessee further agrees to indemnify and save harmless the United States against all claims for loss, damage, or injury sustained by the lessee, or to indemnify and save harmless the United States against all claims for loss, damage, or injury sustained by the agents, employees, or invitees of the lessee, its agents, or any independent contractors or subcontractors doing business with the lessee in connection with the programs and activities of the aforementioned military installation, whether the same be caused in whole or in part by the negligence or fault of the United States, its contractors, or subcontractors, or any of its officers, agents, or employees and whether such claims might be sustained under a theory of strict or absolute liability or otherwise.

(b) Electromagnetic Emissions

The lessee agrees to control its own electromagnetic emissions and those of its agents, employees, invitees, independent contractors or subcontractors emanating from individual designated defense warning areas in accordance with requirements specified by the commander of the command headquarters listed in the following table to the degree necessary to prevent damage to, or unacceptable interference with, Department of Defense flight, testing, or operational activities, conducted within individual designated warning areas. Necessary

monitoring control, and coordination with the lessee, its agents, employees, invitees, independent contractors or subcontractors, will be effected by the commander of the appropriate onshore military installation conducting operations in the particular warning area; provided, however, that control of such electromagnetic emissions shall in no instance prohibit all manner of electromagnetic communication during any period of time between a lessee, its agents, employees, invitees, independent contractors or subcontractors and onshore facilities.

(c) Operational

The lessee, when operating or causing to be operated on its behalf, boat, ship, or aircraft traffic into the individual designated warning areas shall enter into an agreement with the commander of the individual command headquarters listed in the following list, upon utilizing an individual designated warning area prior to commencing such traffic. Such an agreement will provide for positive control of boats, ships, and aircraft operating into the warning areas at all times.

W–228—Chief, Naval Air Training, Naval Air Station, Office No. 206, Corpus Christi, Texas 78419–5100, Telephone: (512) 939–3862/3902

W–602—Headquarters ACC/DOSR, Detachment 1, Operations Headquarters, U.S. Strategic Air Command, Offutt AFB, Nebraska 68113–5550, Telephone: (402) 294–2334

Stipulation No. 3—Operations in the Naval Mine Warfare Area

(This stipulation will apply to leases located in Mustang Island Area, East Addition, blocks 732, 733, and 734)

(a) The placement, location, and planned periods of operation of surface structures on this lease during the exploration stage are subject to approval by the Regional Director (RD), Minerals Management Service Gulf of Mexico Region, after the review of the operator's Exploration Plan (EP). Prior to approval of the EP, the RD will consult with the Commander, Mine Warfare Command, in order to determine the EP's compatibility with scheduled military operations. No permanent structures nor debris of any kind shall be allowed in the area covered by this lease during exploration operations.

(b) To the extent possible, sub-seafloor development operations for resources subsurface to this area should originate outside the area covered by this lease. Any above-seafloor development operations within the area covered by this lease must be compatible with scheduled military operations as determined by the Commander, Mine Warfare Command. The lessee will consult with and coordinate plans for above-seafloor development activities (including abandonment) with the Commander, Mine Warfare Command. The Development Operations Coordination Document (DOCD) must contain the locations of any permanent structures, fixed platforms, pipelines, or anchors planned to be constructed or placed in the area covered by this lease as part of such development operations. The DOCD must also contain the written comments of the Commander, Mine Warfare Command on the proposed activities. Prior to the approval of the DOCD, the RD will consult with the Commander in order to determine the DOCD's compatibility with scheduled military operations.

For more information, consultation, and coordination, the lessee must contact: Commander, Mine Warfare Command, 325 Fifth Street, SE., Corpus Christi, Texas 78419–5032, Phone: (512) 939–4895.

14. *Information to Lessees.* (a) *Supplemental Documents.* For copies of the various documents identified as available from the Gulf of Mexico regional office, prospective bidders should contact the Public Information Unit, Minerals Management Service, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394, either in writing or by telephone at (800) 200–GULF or (504) 736–2519. For additional information, contact the Regional Supervisor for Leasing and Environment at that address or by telephone at (504) 736–2759.

(b) *Navigation Safety.* Operations on some of the blocks offered for lease may be restricted by designation of fairways, precautionary zones, anchorages, safety zones, or traffic separation schemes established by the U.S. Coast Guard pursuant to the Ports and Waterways Safety Act (33 U.S.C. 1221 et seq.), as amended.

U.S. Army Corps of Engineers (COE) permits are required for construction of any artificial islands, installations, and other devices permanently or temporarily attached to the seabed located on the OCS in accordance with section 4(e) of the OCS Lands Act, as amended.

For additional information, prospective bidders should contact Lt. Commander Ken Parris, Assistant Marine Port Safety Officer, 8th Coast Guard District, Hale Boggs Federal Building, New Orleans, Louisiana 70130, (504) 589–6901. For COE information, prospective bidders should contact Mr. Dolan Dunn, Chief Evaluation Section, Regulatory Branch, Post Office Box 1229, Galveston, Texas 77553, (409) 766–3935.

(c) *Offshore Pipelines.* Bidders are advised that the Department of the Interior and the Department of Transportation have entered into a Memorandum of Understanding, dated May 6, 1976, concerning the design, installation, operation, and maintenance of offshore pipelines. Bidders should consult both Departments for regulations applicable to offshore pipelines.

(d) *8–Year Leases.* Bidders are advised that any lease issued for a term of 8 years will be cancelled after 5 years, following notice pursuant to the OCS Lands Act, as amended, if within the initial 5-year period of the lease, the drilling of an exploratory well has not been initiated; or if initiated, the well has not been drilled in conformance with the approved exploration plan criteria; or if there is not a suspension of operations in effect. Bidders are referred to 30 CFR 256.37 and the MMS Gulf of Mexico OCS Region Letter to Lessees of February 13, 1995.

(e) *Affirmative Action.* Revision of Department of Labor regulations on affirmative action requirements for Government contractors (including lessees) has been deferred, pending review of those regulations (see **Federal Register** of August 25, 1981, at 46 FR 42865 and 42968). Should changes become effective at any time before the issuance of leases resulting from this sale, section 18 of the lease form (Form MMS–2005, March 1986), would be deleted from leases resulting from this sale. In addition, existing stocks of the affirmative action forms described in paragraph 5 of this Notice contain language that would be superseded by the revised regulations at 41 CFR 60–1.5(a)(1) and 60–1.7(a)(1). Submission of Form MMS–2032 (June 1985) and Form MMS–2033 (June 1985) will not invalidate an otherwise acceptable bid, and the revised regulations' requirements will be deemed to be part of the existing affirmative action forms.

(f) *Ordnance Disposal Areas.* Bidders are cautioned as to the existence of two inactive ordnance disposal areas in the Corpus Christi and East Breaks areas, shown on the map described in paragraph 13(a). These areas were used to dispose of ordnance of unknown composition and quantity. These areas have not been used since about 1970. Water depths in the Corpus Christi area range from approximately 600 to 900 meters. Water depths in the East Breaks area range from approximately 300 to

700 meters. Bottom sediments in both areas are generally soft, consisting of silty clays. Exploration and development activities in these areas require precautions commensurate with the potential hazards.

(g) *Archaeological Resources.* Bidders are advised that a Final Rule regarding archaeological resources was published in the **Federal Register** on October 21, 1994 (59 FR 53091), granting specific authority to each MMS Regional Director to require archaeological surveys and reports (under 30 CFR 250, 256, 260, and 281) and the submission of these reports to the Regional Director prior to exploration, development and production, or installation of lease-term or right-of-way pipelines. MMS Notice to Lessees (NTL) 91–02 (Outer Continental Shelf Archaeological Resources Requirements for the Gulf of Mexico OCS Region) published in the **Federal Register** on December 20, 1991 (50 FR 66076) effective February 17, 1992, specifies survey methodology, linespacing, and archaeological report writing requirements for lessees and operators in the Gulf of Mexico Region.

Two additional documents are available from the MMS Gulf of Mexico Region Public Information Office (see paragraph 14(a)):

''List of Lease Blocks Within the High-Probability Area for Historic Period Shipwrecks on the OCS'' dated January 30, 1995. This list supersedes the list promulgated by the MMS Letter to Lessees (LTL) of November 30, 1990.

''List of Lease Blocks Within the High-Probability Area for Prehistoric Archaeological Resources on the OCS'' dated January 30, 1995.

Implementation of this Final Rule and NTL 91–02 obviates the need for the Protection of Archaeological Resources Stipulation required for previous issues.

(h) *Proposed Rigs to Reefs.* Bidders are advised that there are OCS artificial reef sites and planning sites for the Gulf of Mexico. These are generally located in water depths of less than 200 meters. While all existing and proposed sites require a permit from the U.S. Army Corps of Engineers, this ''Rigs to Reefs'' program is implemented through State sponsorship through the following State Coordinators:

Alabama Mr. Walter M. Tatum, (334) 968–7578

Louisiana Mr. Rick Kasprzak, (504) 765–2375

Mississippi Mr. Mike Buchanan, (601) 385–5860

Texas Ms. Jan Coulbertson, (713) 474–2811

For more information, on artificial reef sites, prospective bidders should contact the above listed State Artificial Reef Coordinators for their areas of interest.

(i) *Proposed Lightering Zones.* Bidders are advised that the U.S. Coast Guard has proposed designating certain areas of the Gulf of Mexico (60 FR 1958 of January 5, 1995), as lightering zones for the purpose of permitting single hull vessels to off-load oil within the U.S. Exclusive Economic Zone. Such designation may have implications for oil and gas operations in the areas. Additional information may be obtained from Lieutenant Commander Stephen Kantz, Project Manager, Oil Pollution Act (OPA 90) Staff, at (202) 267–6740.

(j) *Statement Regarding Certain Geophysical Data.* Pursuant to Sections 18 and 26 of the OCS Lands Act, as amended, and the regulations issued thereunder, MMS has a right of access to certain geophysical data and information obtained or developed as a result of operations on the OCS. MMS is sensitive to the concerns expressed by industry regarding the confidentiality of individual company work products and client lists and the potential burden of responding to a myriad of requests from MMS pertaining to the existence and availability of these types of reprocessed geophysical data. To resolve the concerns of both industry and MMS with respect to such cases, MMS has worked with industry to develop the requirements contained within paragraph 3(b) *Method of Bidding* above. These requirements are being imposed on a trial basis to determine their effectiveness and are subject to modification in future sales.

The details of this requirement are specified in the document ''Trial Procedures for Access to Certain Geophysical Data in the Gulf of Mexico,'' which is provided in the Sale Notice package and which is available upon request from the MMS Gulf of Mexico Region Public Information Office (see paragraph 14(a)). In brief, these requirements include:

1. In the period for ninety (90) days after the sale, bidders will allow MMS to inspect such data within seven (7) days of a written request from MMS, and upon further written request will transmit to MMS, within ten (10) working days, such data. After this ninety day period, a response time of thirty (30) days following an MMS written request will be considered adequate.

2. Successful bidders must retain such data for three (3) years after the sale, and unsuccessful bidders must retain such data for six (6) months after the sale, for possible acquisition by MMS.

For the six (6) month period after the sale, based on a review of the allowable cost of data reproduction to MMS for three-dimensional and two-dimensional data sets, the company providing the reprocessed data will be reimbursed at a rate of $480 per block or part thereof for three-dimensional data and $2 per line mile for two-dimensional data. Afterwards, reimbursement will be subject to the terms and conditions of 30 CFR 251.13(a).

All geophysical data and information obtained and reviewed by MMS pursuant to these procedures shall be held in the strictest confidence and treated as proprietary in accordance with the applicable terms of 30 CFR 251.14.

For additional information, contact the MMS Gulf of Mexico Regional Office of Resource Evaluation at (504) 736–2720.

(k) *Information about Indicated Hydrocarbons.* Bidders are advised that MMS makes available, about 3 months prior to a lease sale, a list of unleased tracts having well bores with indicated hydrocarbons. Basic information relating to production, well bores, and pay range for each tract is included in the list. The list is available from the Public Information Unit, Minerals Management Service, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394; telephone (800) 200–GULF or (504) 736–2519.

(l) *Minimizing Oil and Gas Structures Near the Flower Garden Banks.* Bidders are reminded of Notice to Lessees and Operators (NTL) 85–8, ''Minimizing Oil and Gas Structures in the Gulf of Mexico,'' dated November 26, 1985. Section II of the NTL sets forth the MMS' policy with regard to the minimization of structures for drilling, development, and production on OCS leases. The policy requires that such structures including lease-term pipelines be placed in a manner that causes minimum interference with other significant uses of the OCS. Please be advised that the MMS will strictly adhere to this policy when reviewing Exploration Plans and Development Operations Coordination Documents which propose the use or installation of such structures within the ''Four-Mile Zone'' and adjacent areas surrounding

the Flower Garden Banks National Marine Sanctuary.

Cynthia Quarterman,

Director, Minerals Management Service.

Approved: August 4, 1995.

Bob Armstrong,

Assistant Secretary, Land and Minerals Management.

Western Gulf of Mexico Leased Lands

June 21, 1995

Descriptions of blocks listed represent all Federal acreage leased unless otherwise noted.

South Padre Island

1030, 1040, 1052, 1059, 1060, 1063, 1064, 1069, 1073, 1111, 1112, 1122, 1125, 1134, 1151, 1166

North Padre Island

897, 908, 956, 957, 967, 968, 969, 976, 989

North Padre Island, East Addition

892, 911, 913, 970, 974, 975, 990, 993, 995, 996, 1011, 1014, 1018, A–6, A–8, A–10, A–12, A–23, A–27, A–28, A–38, A–42, A–43, A–45, A–46, A–48, A–55, A–59, A–64, A–69, A–70, A–72, A–75, A–76, A–86, A–87

Mustang Island

737, 738, 739, 740, 742, 743, 752, 754, 756, 757, 758, 759, 762, 763, 767, 779, 780, 781, 782, 783, 784, 785, 786, 787, 789, 791, 801, 803, 804, 805, 806, 807, 810, 812, 813, 814, 824, 826, 828, 829, 831, 833, 838, 842, 843, 846, 847, 848, 851, 855, 858, 859, 868, 873, 875, 876, 879, A–1, A–2, A–5, A–6, A–7, A–10, A–11, A–12, A–14, A–15, A–16, A–17, A–19, A–20, A–22, A–26, A–27, A–31, A–32, A–33, A–38

Mustang Island, East Addition

733, 735, 736, A–51, A–52, A–53, A–57, A–58, A–61, A–65, A–85, A–86, A–95, A–96, A–97, A–110, A–111, A–112, A–121, A–122, A–124, A–152, A–153

Matagorda Island

487, 518, 519, 520, 526, 527, 528, 529, 555, 556, 557, 564, 565, 566, 568, 569, 586, 587, 588, 589, 591, 592, 604, 605, 606, 616, 617, 618, 619, 620, 622, 623, 624, 631, 632, 633, 634 (Seaward of 8(g) Line), 635, 636, 637, 638, 639, 650, 651, 652, 653, 654, 656, 657, 658, 663, 664, 665, 667, 668, 669, 670, 671, 672, 673, 674, 676, 678, 679, 680, 681, 682, 683, 685, 686, 687, 688, 689, 696, 697, 699, 700, 701, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, A–4, A–5, A–7, A–8

Brazos

341, 342, 364, 365, 375, 376, 377, 378, 396, 397, 398, 399, 411, 412, 413, 415, 416, 417, 431, 432, 434, 435 (Seaward of 8(g) Line), 436, 437, 439, 450, 451, 452 (E½), 453, 454, 455, 456, 457, 458, 459, 466, 468, 469, 470, 471, 473, 474, 475, 476, 477, 488, 490, 491, 493, 494, 495, 496, 498, 502, 504, 507, 509, 514, 515, 517, 531, 532, 536, 537, 538, 539, 541, 542, 543, 544, 545, 546, 549, 550, 552, 570, 572, 575, 577, 579, 580, 581, 585, 611, 612, 613, 614, 615, A–1, A–2, A–3, A–6, A–7, A–8, A–9, A–10, A–17, A–19, A–20, A–21, A–22, A–23, A–24, A–25, A–31, A–37, A–38, A–39, A–42, A–43

Brazos, South Addition

A–46, A–47, A–48, A–51, A–52, A–53, A–61, A–62, A–65, A–66, A–69, A–70, A–71, A–75, A–76, A–77, A–84, A–85, A–101, A–102, A–104, A–105, A–106, A–131, A–132, A–133

Galveston

144, 152, 180, 182, 189, 190, 191, 192, 209, 210, 211, 212, 213, 222, 223, 227, 237, 238, 239, 240, 241, 242, 244, 252, 255, 256, 257, 258, 265, 266, 267, 268, 270, 271, 272, 273, 274, 281, 283, 285, 286, 288, 289, 290, 294, 295 (S½NE¼NE¼; NW¼NE¼; W½SW¼NE¼; NE¼SW¼NE¼; N½SE¼NE¼; W½; W½NW¼SE¼; S½SE¼), 296 (NE¼; NE¼NE¼NW¼; S½NE¼NW¼; SE¼NW¼; S½SW¼NW¼; N½SW¼; NE¼SW¼SW¼; N½SE¼SW¼; N½SE¼; N½SW¼SE¼; SE¼SE¼), 297, 298, 299, 300, 301, 302, 303, 312, 313, 314, 315, 316, 317, 319, 320, 321, 322, 323, 324, 325, 327, 328, 329, 330, 333, 334, 343, 344, 346, 347, 348, 349, 350, 353, 357, 358, 359, 360, 362, 363, 380, 385, 386, 390, 391, 394, 395, 418, 420, 421, 428, 429, 465, A–2, A–3, A–10, A–15, A–16, A–18, A–20, A–21, A–24, A–34, A–35, A–39, A–40, A–41, A–42, A–49, A–50, A–86, A–96, A–101, A–105, A–110, A–111

Galveston, South Addition

A–122, A–142, A–143, A–144, A–145, A–188, A–192, A–194, A–213, A–215, A–218, A–248

High Island

19, 21, 22, 34, 36, 47, 52, 53, 66, 69, 71, 72, 73, 86, 90, 92, 93, 95, 105, 109, 110, 111, 115, 116, 117, 131, 134, 135 (N½; N½S½; SW¼SW¼; W½SE¼SW¼; NE¼SE¼SW¼; N½S½SE¼), 136 (E½; E½NE¼SW¼; S½SE¼SW¼), 137, 138 (N½), 139, 140, 141, 142, 143, 153, 154, 155 (W½), 156, 158, 159, 160, 161 (NW¼NE¼NW¼; S½NE¼NW¼; W½NW¼; SE¼NW¼; NE¼NE¼SW¼; W½NE¼SW¼; NW¼SW¼; NW¼SW¼SW¼), 162, 163, 164, 165, 169, 170, 176, 177, 179, 193, 194, 195, 196, 197, 199, 200, 201, 202, 205, 206, 207, 208, 228, 229, 230, 231, 232, 234, 235, 236, 261, 262, 263, A–2, A–3, A–4, A–5, A–6, A–9, A–10, A–12, A–16, A–18, A–19, A–20, A–21, A–22, A–23, A–24, A–25, A–26, A–36, A–37, A–42, A–44, A–45, A–46, A–52, A–53, A–60, A–61, A–62, A–63, A–64, A–68, A–73, A–77, A–78, A–83, A–87, A–100, A–125, A–127, A–128, A–129, A–130, A–133

High Island, South Addition

A–417, A–421, A–422, A–438, A–441, A–442, A–443, A–444, A–446, A–447, A–448, A–451, A–462, A–465, A–466, A–467, A–468, A–469, A–471, A–472, A–474, A–475, A–477, A–479, A–486, A–488, A–489, A–490, A–491, A–493, A–494, A–496, A–497, A–498, A–499, A–500, A–501, A–510, A–511, A–512, A–513, A–515, A–517, A–518, A–519, A–520, A–521, A–523, A–528, A–530, A–531, A–532, A–535, A–536, A–537, A–538, A–539, A–540, A–544, A–545, A–546, A–547, A–548, A–549, A–550, A–551, A–552, A–553, A–555, A–556, A–557, A–560, A–561, A–562, A–563, A–564, A–568, A–570, A–571, A–572, A–573, A–574, A–576, A–577, A–582, A–583, A–586, A–587, A–588, A–589, A–590, A–591, A–595, A–596

High Island, East Addition

38, 39, 45, 46, 74, 75, 76, 85, 118, 119, 120, 128, 129, 130, 166, 167, A–168, A–169, A–170, A–171, A–172, A–173, A–174, A–175, A–176, A–177, A–180, A–187, A–192, A–200, A–201, A–217, A–218, A–224, A–231, A–243, A–245, A–246, A–247, A–250, A–253, A–257, A–258, A–259

High Island, East Addition, South Extension

A–260, A–261, A–262, A–263, A–266, A–269, A–270, A–271, A–272, A–273, A–276, A–279, A–280, A–281, A–282, A–283, A–285, A–286, A–287, A–288, A–291, A–292, A–300, A–301, A–302, A–303, A–305, A–309, A–310, A–312, A–313, A–314, A–315, A–316, A–317, A–323, A–325, A–326, A–327, A–330, A–331, A–332, A–334, A–335, A–339, A–340, A–342, A–343, A–345, A–346, A–347, A–348, A–349, A–350, A–351, A–352, A–355, A–356, A–359, A–360, A–362, A–365, A–368, A–369, A–370, A–371, A–372, A–373, A–376, A–378, A–379, A–380, A–382, A–384, A–385, A–386, A–389, A–391, A–392, A–393, A–395, A–396, A–397, A–402, A–403

Sabine Pass

17, 18, 40

East Breaks

109, 110, 112, 117, 122, 154, 156, 157, 158, 159, 160, 161, 165, 167, 168, 169, 173, 197, 209, 212, 213, 237, 238, 256,

294, 295, 296, 303, 305, 329, 330, 342, 343, 344, 345, 346, 386, 388, 389, 390, 402, 403, 430, 431, 473, 474, 475, 506, 507, 518, 520, 562, 563, 564, 565, 566, 593, 598, 599, 602, 604, 605, 607, 608, 609, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 653, 654, 683, 684, 685, 686, 688, 689, 690, 691, 692, 728, 729, 732, 739, 740, 741, 783, 784, 785, 901, 902, 904, 943, 944, 945, 946, 947, 948, 949, 987, 988, 989, 990, 991, 992, 994

Garden Banks

21, 22, 26, 28, 29, 65, 66, 70, 71, 72, 73, 75, 76, 83, 84, 85, 102, 103, 115, 117, 119, 120, 127, 128, 134, 135, 136, 140, 141, 142, 147, 158, 159, 161, 162, 164, 165, 171, 172, 180, 184, 186, 189, 190, 191, 192, 201, 202, 203, 209, 212, 213, 215, 216, 217, 224, 225, 235, 236, 237, 240, 248, 254, 255, 257, 258, 259, 260, 261, 265, 269, 278, 279, 280, 281, 282, 287, 290, 291, 298, 300, 302, 304, 319, 322, 323, 343, 344, 345, 371, 379, 382, 386, 387, 388, 389, 405, 406, 416, 419, 420, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 463, 464, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 498, 499, 506, 507, 508, 512, 513, 514, 515, 516, 517, 520, 535, 543, 544, 550, 554, 555, 556, 557, 558, 559, 562, 563, 598, 599, 600, 601, 602, 603, 607, 608, 612, 639, 644, 645, 646, 653, 656, 683, 694, 697, 727, 738, 739, 740, 741, 754, 767, 768, 769, 772, 782, 783, 784, 785, 803, 804, 806, 812, 826, 833, 848, 849, 850, 877, 885, 902, 903, 919, 920, 921, 929, 930, 938, 939, 940, 947, 963, 964, 974, 975

Port Isabel

39, 40, 81, 82, 125, 126, 130, 131, 174, 175, 216, 218, 393, 436, 437, 438, 481, 482, 483, 519, 520, 524, 525, 526, 527, 563, 564, 568, 569, 570, 571, 572, 610, 611, 613, 653, 654, 655, 656, 657, 696, 697, 698, 700, 701, 740, 741

Alaminos Canyon

20, 21, 22, 23, 24, 25, 26, 65, 192, 236, 237, 261, 280, 305, 336, 337, 380, 398, 441, 442, 485, 489, 490, 491, 529, 533, 534, 556, 557, 558, 599, 600, 601, 602, 644, 645, 646, 647, 648, 687, 691, 719, 720, 726, 730, 731, 734, 735, 736, 763, 764, 766, 767, 770, 774, 775, 780, 781, 810, 811, 813, 814, 818, 827, 854, 856, 857, 900, 901, 903, 904, 947, 951, 954

Keathley Canyon

6, 7, 133, 134, 156, 157, 158, 159, 177, 178, 179, 199, 201, 202, 221, 243, 245, 246, 324, 583, 584

[FR Doc. 95–19827 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–MR-P

National Park Service

Notice of Inventory Completion for Native American Human Remains in the Possession of Knife River Indian Villages National Historic Site, National Park Service, Stanton, ND

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003(d), of the completion of the inventory of human remains in the possession of the National Park Service at Knife River Indian Villages National Historic Site, Stanton, ND.

A detailed inventory and assessment of these remains has been made by the staff of Knife River Indian Villages National Historic Site in consultation with representatives of the Three Affiliated Tribes of North Dakota.

The human remains represent at least nine individuals from nine sites recovered within the Knife River Indian Villages National Historic Site during excavations conducted by the University of North Dakota during 1976–1981. No associated funerary objects were identified. Five bone fragments representing one individual were recovered from Hidatsa Site (32ME10). Two partial human teeth representing one individual were recovered from Sakakawea Site (32ME11). One bone fragment representing 1 individual was recovered from Scovill site (32ME409). Two bone fragments representing one individual were recovered from Long Ridge Cemetery Site (32ME479). Three bone fragments, 1 tooth fragment, and 1 molar tooth representing one individual were recovered from Soni Site (32ME492). One bone fragment representing one individual was recovered from Ramble Site (32ME496). Two concentrations of bone fragments and 1 tooth representing one individual were recovered from Small Site (32ME498). Three bone fragments, two teeth fragments, and one molar tooth representing one individual were recovered from Sakakawea Cemetery Site (32ME493). Four bone fragments and one tooth surface representing one individual were recovered from Buchfink Burial Area (32ME411). No known individuals were identified.

Each of these nine sites has been identified as being within the Hidatsa's traditional occupation area based on cultural continuities, historic written records, and consultation with the Three Affiliated Tribes. Based on the above mentioned information, officials of the National Park Service have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity which can be reasonably traced between the Native American human remains and the Three Affiliated Tribes of North Dakota.

This notice has been sent to officials of the Three Affiliated Tribes. Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Chas Cartwright, Superintendent, Knife River Indian Villages National Historic Site, PO Box 9, Stanton, ND 58571, telephone—(701)745–3309, before September 11, 1995. Repatriation of the human remains the Three Affiliated Tribes of North Dakota will begin after that date if no additional claimants come forward.

Dated: August 7, 1995

Francis P. McManamon

Departmental Consulting Archeologist

Chief, Archeological Assistance Division

[FR Doc. 95–19927 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–70–F

Notice of Intent to Repatriate Cultural Items in the Possession of Knife River Indian Villages National Historic Site, National Park Service, Stanton, ND

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given under the Native American Graves Protection and Repatriation Act of 1990 of the intent to repatriate cultural items in the possession of the Knife River Indian Villages National Historic Site which meet the definition of ''sacred object'' and ''unassociated funerary object'' under section 2 of the Act.

Four pipe fragments were recovered from surface collection or excavation within the Knife River Indian Villages National Historic Site. One wide-mouthed, grey/brown clay pipe bowl fragment (Accession #KNRI–00040, Catalog #KNRI–72) was collected from the ground surface by a ranger in the park during the 1980s. One half of an orange clay pipe (Accession #KNRI–00072, Catalog #KNRI–120) was collected from the ground surface by a ranger from the Big Hidatsa Site (32ME12) during the 1980s. One small yellowish-white, undecorated kaolin pipe stem fragment (Accession #KNRI–00085, Catalog #KNRI–575) excavated at the Sakakawea Site (32ME11) by the University of North Dakota in 1976/1977. One clay pipe bowl (Accession

#KNRI–00085, Catalog #KNRI–802) excavated at the Sakakawea Site (32ME11) by the University of North Dakota in 1976/1977. Representatives of the Three Affiliated Tribes identified Knife River Indian Villages National Historic Site—including Big Hidatsa Site, and Sakakawea Site—as part of the Hidatsa's traditional occupation area. Representatives of the Three Affiliated Tribes identified these four pipe fragments as objects that, as a part of the death rite or ceremony of a culture, are reasonably believed to have been placed with individual human remains either at the time of death or later.

Based on the above mentioned information, officials of the National Park Service have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity which can be reasonably traced between the four pipe fragments and the Three Affiliated Tribes of North Dakota. Officials of the National Park Service have also determined that the four pipe fragments are objects that, as a part of the death rite or ceremony of a culture, are reasonably believed to have been placed with individual human remains either at the time of death or later, where the remains are not in the possession or control of the Federal agency or museum pursuant to 25 U.S.C. 3001 (3)(B).

Eleven objects were donated to the Knife River Indian Villages National Historic Site by the Robinson family in 1991. George Robinson ran a mercantile store in Cole Harbor, ND (near the Fort Berthold reservation) from the 1880's through the early 1900's. Much of Mr. Robinson's business was conducted with members of the Three Affiliated Tribes, especially Arikara people. The cultural items were received in trade for food and supplies by Mr. Robinson during this time. These eleven objects include: one small wooden pipe (Accession #KNRI–00164, Catalog #KNRI–2133); one catlinite pipe with a ''T'' bowl squared at one end to cylindrical then tapered at the other end and one wooden taylor stem (Accession #KNRI–00164, Catalog #KNRI–2150 a and b); one catlinite pipe with a ''T'' style bowl squared at one end to cylindrical then tapered at the other end and one wooden stem with beading, ribbons, and painted surfaces (Accession #KNRI–00164, Catalog #KNRI–2151 a and b); one red catlinite pipe with an ''elbow'' style bowl (Accession #KNRI–00164, Catalog #KNRI–2156); one red catlinite toy pipe with a ''T'' style bowl and one wooden stem with plaited quillwork and feathers (Accession #KNRI–00164, Catalog #KNRI–2161 a and b); one red catlinite pipe with a ''T'' style bowl cylindrical at one end to tapered then hexagonal at the other end and one wooden taylor stem (Accession #KNRI–00164, Catalog #KNRI–2163 a and b); one hide bag with beadwork, quillwork, and fringe (Accession #KNRI–00164, Catalog #KNRI–2168); one hide bag with beadwork, quillwork, and fringe (Accession #KNRI–00164, Catalog #KNRI–2180); one rectangular hide bag with drawstring top and fringe (Accession #KNRI–00164, Catalog #KNRI–2133); one brown wooden dance stick with light horsehair and yellow and purple ribbons (Accession #KNRI–00164, Catalog #KNRI–2117); and one brown wooden dance stick with 2 horn tips and black, white, and green horsehair (Accession #KNRI–00164, Catalog #KNRI–2118).

Representatives of the Three Affiliated Tribes identified these eleven objects as coming from the traditional occupation area of the Hidatsa, Mandan, and Arikara. Representatives of the Three Affiliated Tribes identified these eleven objects as ceremonial objects which are needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present day adherents.

Based on the above mentioned information, officials of the National Park Service have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity which can be reasonably traced between the cultural items and the Three Affiliated Tribes. Officials of the National Park Service have also determined that the eleven objects are ceremonial objects which are needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present day adherents pursuant to 25 U.S.C. 3001 (3)(C).

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the cultural items should contact Chas Cartwright, Superintendent, Knife River Indian Villages National Historic Site, P.O Box 9, Stanton, ND 58571, telephone: (701) 745–3309, before September 11, 1995. Repatriation of the cultural objects to the Three Affiliated Tribes of North Dakota will begin after that date if no additional claimants come forward.

Dated: August 7, 1995

Francis P. McManamon

Departmental Consulting Archeologist

Chief, Archeological Assistance Division

[FR Doc. 95–19928 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–70–F

Bureau of Reclamation

Central Valley Project Improvement Act, Criteria for Evaluating Water Conservation Plans

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of draft decision of evaluation of water conservation plans.

SUMMARY: To meet the requirements of the Central Valley Project Improvement Act (CVPIA), the Bureau of Reclamation (Reclamation) developed and published the Criteria for Evaluating Water Conservation Plans (Criteria) dated April 30, 1993. These Criteria were developed based on information provided during public scoping and public review sessions held throughout Reclamation's Mid-Pacific (MP) Region. Reclamation uses these Criteria to evaluate the adequacy of all water conservation plans developed by project contractors in the MP Region, including those required by the Reclamation Reform Act of 1982. The Criteria were developed and the plans evaluated for the purpose of promoting the most efficient water use reasonably achievable by all MP Region's contractors. Reclamation made a commitment (stated within the Criteria) to publish a notice of its draft determination on the adequacy of each contractor's water conservation plan in the **Federal Register** and to allow the public a minimum of 30 days to comment on its preliminary determinations. This program is on-going; an updated list will be published to recognize districts as plans are revised to meet the Criteria.

DATES: All public comments must be received by Reclamation by September 11, 1995.

ADDRESSES: Please mail comments to the address provided below.

FOR FURTHER INFORMATION CONTACT: Debra Goodman, Bureau of Reclamation, 2800 Cottage Way, MP–402, Sacramento, CA 95825. To be placed on a mailing list for any subsequent information, please write Debra Goodman or telephone at (916) 979–2397.

SUPPLEMENTARY INFORMATION: Under provisions of Section 3405(e) of the CVPIA (Title 34 of Public Law 102–575), ''The Secretary (of the Interior) shall establish and administer an office on Central Valley Project water conservation best management practices that shall * * * develop criteria for evaluating the adequacy of all water conservation plans developed by project contractors, including those plans

required by section 210 of the Reclamation Reform Act of 1982.'' Also, according to section 3405(e)(1), these criteria will be developed ''* * * with the purpose of promoting the highest level of water use efficiency reasonably achievable by project contractors using best available cost-effective technology and best management practices.''

The MP Criteria states that all parties (districts) that contract with Reclamation for water supplies (municipal and industrial contracts greater than 2,000 acre feet and agricultural contracts over 2,000 irrigable acres) will prepare water conservation plans which will be evaluated by Reclamation based on the following required information detailed in the steps listed below to develop, implement, monitor and update their water conservation plans. The steps are:

1. Coordinate with other agencies and the public.
2. Describe the district.
3. Inventory water resources.
4. Review the past water conservation plan and activities.
5. Identify best management practices to be implemented.
6. Develop schedules, budgets and projected results.
7. Review, evaluate, and adopt the water conservation plan.
8. Implement, monitor and update the water conservation plan.

The MP contractors listed below have developed water conservation plans which Reclamation has evaluated and preliminarily determined meet the requirements of the Criteria.

- Banta Carbona Irrigation District
- Carpinteria County Water District
- Central San Joaquin Water Conservation District
- Glide Water District
- Kanawha Water District
- Madera Irrigation District
- Mercy Springs Water District
- Montecito Water District
- Santa Barbara County Water Agency
- Shafter Wasco Irrigation District

Public comment on Reclamation's preliminary (i.e., draft) determinations at this time is invited. Copies of the plans listed above will be available for review at Reclamation's MP Regional Office and MP's area offices. If you wish to review a copy of the plans, please contact Ms. Goodman to find the office nearest you.

Dated: August 3, 1995.

Dan M. Fults,

Assistant Regional Director.

[FR Doc. 95–19918 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–94–M

Competitive Sale of Federal Land

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of realty action.

SUMMARY: The following described land has been identified for disposal under the Act of February 2, 1911 (36 Stat. 895, 43 U.S.C. Section 374), at no less than the appraised fair market value. The Bureau of Reclamation (Reclamation) will accept bids on the lands described below and will reject any bids for less than the appraised value.

DATES: Comments must be submitted on or before September 25, 1995.

Sealed bids will be accepted if received before 10 a.m., Pacific Daylight-Saving Time on October 19, 1995, at which time the sealed bids will be opened.

ADDRESSES: Interested parties may submit comments to the Regional Director, Mid-Pacific Regional Office, Bureau of Reclamation, 2800 Cottage Way, Sacramento, CA 95825-1898.

Sealed bids will be accepted at the Bureau of Reclamation, Lahontan Basin Area Office, 705 N. Plaza Street, Room 338, Carson City, Nevada 89701-4015. The sealed bid sale will be held at the Lahontan Basin Area Office.

FOR FURTHER INFORMATION CONTACT: Rochelle Ames, Realty Specialist, Lahontan Basin Area Office, 705 N. Plaza Street, Carson City, Nevada 89701–4015, telephone number (702) 884–8354.

SUPPLEMENTARY INFORMATION: A tract of land in the Southwest Quarter (SW¼) of Section 30, Township Nineteen 19 North, Range 29 East, Mount Diablo Base and Meridian, and County of Churchill, State of Nevada, containing an area of 6.353 acres, more or less. The street address of the property is 380 North Taylor Street, Fallon, Nevada 89406.

The tract will be subject to easements or rights-of-way existing or of record in favor of the public as to third parties.

The tract will be offered for sale through the competitive bidding process. The tract will be sold to the highest qualified bidder at no less than the appraised price of $290,600.00. Sealed bids will be accepted at the Lahontan Basin Area Office, if received before 10 a.m., Pacific Daylight-Saving Time on October 19, 1995. Reclamation may accept or reject any offers, or withdraw any land or interest in land for sale, if, in the opinion of the Authorized Officer, consummation of the sale would not be fully consistent with the Act of February 2, 1911 (36 Stat. 895, 43 U.S.C. Section 374), or other applicable laws. To promote full and free competition, a certificate of independent price determination must accompany each sealed bid included in the bid package. This can be obtained from the Lahontan Basin Area Office.

The tract is within the County of Churchill, State of Nevada. The tract has potential for various industrial or commercial uses. Current land use is for a rail freight loading facility and storage area. The sale is consistent with Reclamation land-use planning. It was decided that the public interest would best be served by offering this land for sale.

Resource clearances consistent with the National Environmental Policy Act requirements have been completed and approved. A Categorical Exclusion checklist has been completed and approved, and is available for public review at the Reclamation's, Lahontan Basin Area Office.

The quitclaim deed issued for the tract sold will be subject to any rights-of-way of record, any public road and utility easements identified by Churchill County, Nevada, if applicable, and a 10-year lease to the City of Fallon, Nevada, expiring January 31, 2000.

Any adverse comments will be evaluated by the Regional Director who may vacate or modify this Realty Action and issue a final determination. In the absence of any action by the Regional Director, this Realty Action will become the final determination of the Department of the Interior.

Dated: July 18, 1995.

Franklin E. Dimick,

Acting Regional Director.

[FR Doc. 95–19919 Filed 8–10–95; 8:45 am]

BILLING CODE 4310–94–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–722]

Honey from the People's Republic of China

AGENCY: United States International Trade Commission.

ACTION: Suspension of investigation and cancellation of hearing.

SUMMARY: On August 3, 1995, the Department of Commerce (Commerce) notified the United States International Trade Commission (Commission) of the suspension of its antidumping investigation on honey from the People's Republic of China (China). The basis for the suspension is an agreement between Commerce and the Government

of China for the purpose of encouraging free and fair trade in honey, establishing more normal market relations, and preventing the suppression or undercutting of price levels of the domestic product. Pursuant to the agreement, the Government of China will restrict the volume and prices of direct or indirect exports to the United States of honey products from all Chinese producers/exporters, subject to the terms in the agreement. Accordingly, the Commission gives notice of the suspension of its antidumping investigation involving imports from China of honey, provided for in heading 0409 and subheadings 1702.90.54, 1702.90.58, 2106.90.68, 2106.90.72, 2106.90.89, and 2106.90.91 of the Harmonized Tariff Schedule of the United States. The Commission also gives notice of the cancellation of the hearing scheduled in connection with this investigation.

EFFECTIVE DATE: August 2, 1995.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained 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. Information can also be obtained by calling the Office of Investigations' remote bulletin board system for personal computers at 202–205–1895 (N,8,1).

Authority: This investigation is being suspended under authority of § 734(f)(1)(B) of the Tariff Act of 1930. This notice is published pursuant to section 207.40 of the Commission's rules (19 CFR 207.40).

Issued: August 8, 1995.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 95–19855 Filed 8–10–95; 8:45 am]

BILLING CODE 7020–02–P

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32547]

The Kansas City Southern Railway Co.—Construction and Operation Exemption—To Exxon Corporation's Plastics Plant near Baton Rouge and Baker, LA

The Kansas City Southern Railway Company (KCS) has petitioned the Interstate Commerce Commission (Commission) for authority to construct and operate a 0.31 mile rail line near Baton Rouge and Baker, Louisiana. The Commission's Section of Environmental Analysis (SEA) has prepared an Environmental Assessment (EA). Based on the information provided and the environmental analysis conducted to date, this EA concludes that this proposal should not significantly affect the quality of the human environment if the recommended mitigation measures set forth in the EA are implemented. Accordingly, SEA preliminarily recommends that the Commission impose on any decision approving the proposed construction and operation conditions requiring Kansas City Southern Railway Company to implement the mitigation contained in the EA. The EA will be served on all parties of record as well as all appropriate Federal, state and local officials and will be made available to the public upon request. SEA will consider all comments received in response to the EA in making its final environmental recommendations to the Commission. The Commission will then consider SEA's final recommendations and the environmental record in making its final decision in this proceeding.

Comments (an original and 10 copies) and any questions regarding this Environmental Assessment should be filed with the Commission's Section of Environmental Analysis, Office of Economic and Environmental Analysis, Room 3219, Interstate Commerce Commission, Washington, D.C. 20423, to the attention of Michael Dalton (202) 927–6202. Requests for copies of the EA should also be directed to Mr. Dalton.

Date made available to the public: August 11, 1995.

Comment due date: September 11, 1995.

By the Commission, Elaine K. Kaiser, Chief, Section of Environmental Analysis, Office of Economic and Environmental Analysis.

Vernon A. Williams,

Secretary.

[FR Doc. 95–19912 Filed 8–10–95; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF LABOR

Employment Standards Administration

Wage and Hour Division; Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29

CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, N.W., Room S–3014, Washington, D.C. 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Connecticut
CT950001 (Feb. 10, 1995)
CT950003 (Feb. 10, 1995)
CT950004 (Feb. 10, 1995)
New York
NY950002 (Feb. 10, 1995)
NY950003 (Feb. 10, 1995)
NY950004 (Feb. 10, 1995)
NY950007 (Feb. 10, 1995)
NY950008 (Feb. 10, 1995)
NY950013 (Feb. 10, 1995)
NY950017 (Feb. 10, 1995)
NY950018 (Feb. 10, 1995)
NY950026 (Feb. 10, 1995)
NY950031 (Feb. 10, 1995)
NY950033 (Feb. 10, 1995)
NY950038 (Feb. 10, 1995)
NY950040 (Feb. 10, 1995)
NY950042 (Feb. 10, 1995)
NY950048 (Feb. 10, 1995)
NY950049 (Feb. 10, 1995)
NY950051 (Feb. 10, 1995)
NY950074 (Feb. 17, 1995)
NY950076 (Feb. 17, 1995)
Vermont
VT950002 (Feb. 10, 1995)

Volume II

Pennsylvania
PA950001 (Feb. 10, 1995)
PA950002 (Feb. 10, 1995)
PA950003 (Feb. 10, 1995)
PA950005 (Feb. 10, 1995)
PA950011 (Feb. 10, 1995)
PA950013 (Feb. 10, 1995)
PA950017 (Feb. 10, 1995)
PA950018 (Feb. 10, 1995)
PA950024 (Feb. 10, 1995)
PA950027 (Feb. 10, 1995)
PA950032 (Feb. 10, 1995)
PA950052 (Feb. 10, 1995)
PA950062 (Feb. 10, 1995)
PA950063 (Feb. 10, 1995)

Volume III

Kentucky
KY950001 (Feb. 10, 1995)
KY950002 (Feb. 10, 1995)
KY950003 (Feb. 10, 1995)
KY950004 (Feb. 10, 1995)
KY950007 (Feb. 10, 1995)
KY950025 (Feb. 10, 1995)
KY950026 (Feb. 10, 1995)
KY950027 (Feb. 10, 1995)
KY950028 (Feb. 10, 1995)
KY950029 (Feb. 10, 1995)
KY950035 (Feb. 10, 1995)

Volume IV

Indiana
IN950002 (Feb. 10, 1995)
IN950004 (Feb. 10, 1995)
IN950005 (Feb. 10, 1995)
IN950006 (Feb. 10, 1995)
IN950017 (Feb. 10, 1995)
IN950018 (Feb. 10, 1995)
Minnesota
MN950007 (Feb. 10, 1995)
MN950008 (Feb. 10, 1995)
MN950015 (Feb. 10, 1995)
MN950027 (Feb. 10, 1995)
MN950031 (Feb. 10, 1995)
MN950035 (Feb. 10, 1995)
MN950039 (Feb. 10, 1995)
MN950059 (Feb. 10, 1995)
MN950061 (Feb. 10, 1995)
Wisconsin
WI950004 (Feb. 10, 1995)
WI950009 (Feb. 10, 1995)
WI950024 (Feb. 10, 1995)

Volume V

Arkansas
AR950001 (Feb. 10, 1995)
AR950008 (Feb. 10, 1995)
Kansas
KS950012 (Feb. 10, 1995)
Missouri
MO950002 (Feb. 10, 1995)
MO950004 (Feb. 10, 1995)
MO950005 (Feb. 10, 1995)
MO950012 (Feb. 10, 1995)
MO950014 (Feb. 10, 1995)
MO950015 (Feb. 10, 1995)
MO950018 (Feb. 10, 1995)
MO950020 (Feb. 10, 1995)
MO950039 (Feb. 10, 1995)
MO950041 (Feb. 10, 1995)
MO950042 (Feb. 10, 1995)
MO950051 (Feb. 10, 1995)
MO950052 (Feb. 10, 1995)
MO950056 (Feb. 10, 1995)
MO950060 (Feb. 10, 1995)
MO950062 (Feb. 10, 1995)
MO950063 (Feb. 10, 1995)
MO950065 (Feb. 10, 1995)
MO950066 (Feb. 10, 1995)
MO950067 (Feb. 10, 1995)
MO950068 (Feb. 10, 1995)
MO950069 (Feb. 10, 1995)
MO950074 (Feb. 10, 1995)
MO950075 (Feb. 10, 1995)
MO950076 (Feb. 10, 1995)
MO950077 (Feb. 10, 1995)
MO950078 (Feb. 10, 1995)
Nebraska
NE950002 (Feb. 10, 1995)
NE950060 (Feb. 10, 1995)
Texas
TX950003 (Feb. 10, 1995)
TX950005 (Feb. 10, 1995)
TX950007 (Feb. 10, 1995)
TX950018 (Feb. 10, 1995)
TX950069 (Feb. 10, 1995)
TX950096 (Feb. 10, 1995)

Volume VI

Alaska
AK950001 (Feb. 10, 1995)
AK950002 (Feb. 10, 1995)
AK950003 (Feb. 10, 1995)
AK950005 (Feb. 10, 1995)
Oregon
OR950001 (Feb. 10, 1995)
Washington
WA950001 (Feb. 10, 1995)
WA950002 (Feb. 10, 1995)
WA950003 (Feb. 10, 1995)
WA950007 (Feb. 10, 1995)
WA950008 (Feb. 10, 1995)
WA950025 (Feb. 10, 1995)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at (703) 487–4630.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which

includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, DC this 4th day of August 1995.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 95–19692 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–27–M

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 21, 1995.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than August 21, 1995.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 31st day of July, 1995.

Russell Kile,

Acting Program Manager, Office of Trade Adjustment Assistance.

Appendix

PETITIONS INSTITUTED ON 07/31/95

TA–W	Subject firm (petitioners)	Location	Date of petition	Product(s)
31,286	Blairsville Machine (Wkrs)	Blairsville, PA	07/14/95	Military Tank Track pins.
31,287	Garan, Inc. Lambert Mills (Wkrs)	Lambert, MS	07/13/95	Acrylic Apparel.
31,288	General Motors Corp (Wkrs)	Somerset, NJ	06/30/95	Office Workers—Extended Warranty.
31,289	Graham Energy Services (Comp)	Covington, LA	07/20/95	Oil & Gas Exploration, Production.
31,290	Kerotest Mfg Corp (Wkrs)	Pittsburgh, PA	07/17/95	Steel Valves.
31,291	Lucas AUL, Hazelton Div (IUE)	Hazleton, PA	07/14/95	Communication Equipment.
31,292	McBriar Cap Co (Comp)	Waycross, GA	07/17/95	Caps (Headwear Apparel).
31,293	Movie Star of Purvis (Comp)	Purvis, MS	07/14/95	Ladies' Lingerie.
31,294	Newline Manufacturer (ILGWU)	So. Hackensack, NJ	06/15/95	Women's Coats.
31,295	Portac, Inc of Tacoma (Wkrs)	Beaver, WA	07/17/95	Softwood Dimensional Lumber.
31,296	Portac, Inc of Tacoma (Wkrs)	Forks, WA	07/17/95	Softwood Dimensional Lumber.
31,297	Richfield Knitwear Co (Comp)	Brooklyn, NY	07/15/95	Infants & Children's Playwear.
31,298	Karabelas Collection Ltd (Wkrs)	New York City, NY	07/19/95	Fur Coats.
31,299	P and M Tile, Inc. (Co.)	Mt. Gilead, NC	07/21/95	Ceramic Floor Tiles.
31,300	Omega News & Advertising (Wkrs)	El Paso, TX	07/08/95	Newspaper Advertising.
31,301	Electrio Wires (Wkrs)	EL Paso, TX	07/17/95	Automobile Wire Components.

[FR Doc. 95–19880 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–30–M

Footwear Management Company, TA–W–30,545 Nocona Boot Company, Nocona, Texas TA–W–30,545A Tony Lama Division, El Paso, Texas A/K/A Justin Management Company, El Paso, Texas TA–W–30,545B Justin Boot Company, Fort Worth, Texas TA–W–30,545C Justin Boot Company, Cassville, Missouri TA–W–30,545D Justin Boot Company, Sarcoxie, Missouri TA–W–30,545E Justin Boot Company, Carthage, Missouri and TA–W–30,545F Nocona Boot Outlet, Operating in Various Locations Within the State of Texas; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 26, 1995, applicable to all workers at the Nocona Boot Company, Nocona, Texas who were engaged in the production of leather boots. The notice was published in the **Federal Register** on February 14, 1995 (60 FR 8415).

The certification has been amended several times to include other operating facilities of Nocona Boot and other divisions of the Footwear Management Company.

New information received from the company shows that workers of Nocona Boot Outlets operating in various locations within the State of Texas have been adversely affected by increased imports. Accordingly, the Department is again amending the certification to properly reflect this matter.

The amended notice applicable to TA–W–30,545 is hereby issued as follows:

''All workers of Footwear Management Company in the following divisions: Tony Lama Division, El Paso, Texas, a/k/a Justin Management Company, El Paso, Texas; Justin Boot Company, Forth Worth, Texas; Cassville, Missouri; Sarcoxie, Missouri; and Carthage, Missouri; Nocona Boot Company in Nocona, Texas and Nocona Boot Outlet operating in various locations within the State of Texas who became totally or partially separated from employment on or after November 29, 1993 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, DC this 3rd day of August 1995.

Arlene O'Connor,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–19878 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–30,875, TA–W–30,875A]

Val Mode Lingerie, Incorporated; Bridgeton, New Jersey and New York, New York; Amended Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Notice of Certification Regarding Eligibility to Apply for Worker Adjustment Assistance on April 14, 1995, applicable to all workers of Val Mode Lingerie, Incorporated, Bridgeton, New Jersey. The notice was published in the **Federal Register** on April 27, 1995 (60 FR 20764).

New information received from the State Agency shows that worker separations have occurred at the New York, New York location of Val Mode Lingerie, Incorporated.

It is the Department's intent to provide coverage to all workers of Val Mode Lingerie, Incorporated, adversely affected by increased imports. Accordingly, the Department is amending the certification to properly reflect this matter.

The amended notice applicable to TA–W–30,875 is hereby issued as follows:

''All workers of Val Mode Lingerie, Bridgeton, New Jersey and New York, New York engaged in employment related to the production of ladies' sleepwear who became totally or partially separated from employment on or after March 17, 1994 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, DC this 2nd day of August 1995.

Arlene O'Connor,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–19884 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–30–M

Job Training Partnership Act, Title III, Demonstration Program: Specialized/Targeted Dislocated Worker Services Project

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of change in date.

SUMMARY: All prospective applicants are hereby notified that the closing date for receipt of applications for SGA/DAA 95–006, published in the **Federal Register** dated June 20, 1995, 60 FR 32171, shall be Monday, August 28, 1995, and any dates referenced in previous **Federal Register** Notices are deleted in their entirety.

FOR FURTHER INFORMATION CONTACT: Mr. Willie E. Harris, Division of Acquisition and Assistance, Telephone: (202) 219–7300 (this is not a toll-free number).

Signed at Washington, DC this 7th day of August, 1995.

Janice E. Perry,

Grant Officer, Division of Acquisition and Assistance.

[FR Doc. 95–19875 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–30–M

Footwear Management Company, NAFTA–00252 Tony Lama Division, El Paso, Texas A/K/A Justin Management Company, El Paso, Texas NAFTA–00252A Justin Boot Company, Fort Worth, Texas, NAFTA–00252B Justin Boot Company, Cassville, Missouri NAFTA–00252C Nocona Boot Company, Nocona, Texas NAFTA–00252D Justin Boot Company, Sarcoxie, Missouri NAFTA–00252E Justin Boot Company, Carthage, Missouri and NAFTA–00252F Nocona Boot Outlet, Operating in Various Locations Within the State of Texas; Amended Certification Regarding Eligibility to Apply for NAFTA Transitional Adjustment Assistance

In accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2273), the Department of Labor issued a Notice of Certification for NAFTA Transitional Adjustment Assistance on November 14, 1994, applicable to all workers at the subject firm. The notice was published in the **Federal Register** on December 9, 1994 (59 FR 68324).

The certification has been amended several times to include other operating facilities of Footwear Management Company.

New information received from the company shows that workers of Nocona Boot Outlets operating in various locations within the State of Texas have been adversely affected by increased imports. Accordingly, the Department is again amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Footwear Management Company adversely affected by increased imports.

The amended notice applicable to NAFTA–00252 is hereby issued as follows:

''All workers of Footwear Management Company in the following divisions: Tony Lama Division, El Paso, Texas a/k/a Justin Management Company, El Paso, Texas; Justin Boot Company, Fort Worth, Texas; Cassville, Missouri; Sarcoxie, Missouri; and Carthage, Missouri; Nocona Boot Company in Nocona, Texas and Nocona Boot Outlet operating in various locations within the State of Texas who became totally or partially separated from employment on or after December 8, 1993 are eligible to apply for NAFTA–TAA Section 250 of the Trade Act of 1974.''

Signed at Washington, DC this 3rd day of August 1995.

Arlene O'Connor,

Acting Program Manager, Policy, and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–19879 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–30–M

[NAFTA—00425]

Val Mode Lingerie, Incorporated Bridgeton, New Jersey and New York, New York NAFTA—00425A; Amended Certification Regarding Eligibility to Apply for NAFTA Transitional Adjustment Assistance

In accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act of 1974, as amended (19 USC 2273), the Department of Labor issued a Notice of Certification of Eligibility to Apply for NAFTA Transitional Adjustment Assistance on May 9, 1995, applicable to all workers at the subject firm. The amended notice was published in the **Federal Register** on May 17, 1995 (60 FR 26460).

New information received from the State Agency shows that worker separations have occurred at the New York, New York location of Val Mode Lingerie, Inc.

It is the Department's intent to provide coverage to all workers of Val

Mode Lingerie, Inc., adversely affected by increased imports. Accordingly, the Department is amending the certification to properly reflect this matter.

The amended notice applicable to NAFTA–00425 is hereby issued as follows:

All workers of workers of Val Mode Lingerie, Inc., Bridgeton, New Jersey (NAFTA–00425) and New York, New York (NAFTA–00425A), who became totally or partially separated from employment on or after March 29, 1994, are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed at Washington, DC this 2nd day of August 1995.

Arlene O'Connor,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–19881 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–30–M

[NAFTA–00392]

General Mills Inc., CFTO-South Chicago Plant, Chicago, Illinois; Negative Determination on Reconsideration

On June 20, 1995, the Department issued an Affirmative Determination Regarding Application for Reconsideration for workers and former workers of the subject firm. This notice was published in the **Federal Register** on June 29, 1995 (60 FR 33849).

The petitioner submitted additional documents and claims that imports of cereal from Mexico impacted sales of the subject firm.

The Department's denial was based on the fact that the increased import criteria (3) and (4) were not met. There was no shift of production from the subject plant to Mexico or Canada, and General Mills did not import breakfast cereal from Mexico or Canada. The Department's survey of General Mills major customers revealed that customers importing ready-to-eat breakfast cereals from Mexico or Canada relied on imports for a very minor portion of their total needs. Most respondents did not import ready-to-eat breakfast cereal from Mexico or Canada.

Findings on reconsideration show that U.S. imports of cereals from Mexico and Canada declined in 1994 compared to 1993, but increased during the 12 month period of April 1994–March 1995 compared to April 1993–March 1994. However, aggregate U.S. imports of cereal from Mexico and Canada are negligible (less than one percent) when compared to General Mills sales and production.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for transitional adjustment assistance to workers and former workers of General Mills Incorporated, CFTO-South Chicago Plant, in Chicago, Illinois.

Signed at Washington, DC, this 2nd day of August 1995.

Arlene O'Connor,

Acting Program Manager, Policy and Reemployment Services, Office of Trade Adjustment Assistance.

[FR Doc. 95–19882 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–30–M

U.S. National Administrative Office, North American Agreement on Labor Cooperation, National Advisory Committee; Appointment of Members

Notice is hereby given that appointments have been made to fill the vacancies on the National Advisory Committee (NAC).

The following twelve (12) individuals have been appointed to the Committee at this time:

Representing Labor

Mr. Steve Beckman, International Economist, United Auto Workers, Washington, DC;
Mr. Ron Blackwell, Assistant to the President, Amalgamated Clothing and Textile Workers Union, New York;
Mr. Morton Bahr, President, Communications Workers of America, Washington, DC;
Mr. John S. Gaal, Assistant Administrator, St. Louis Carpenters Joint Apprenticeship Program, United Brotherhood of Carpenters and Joiners of America, Missouri;

Representing Business

Mr. Frank P. Doyle, Executive Vice President, General Electric Company, Connecticut;
Mr. Abraham Katz, President, U.S. Council for International Business, New York;
Ms. Carroll E. Bostic, Director, Human Resources, Eastman Kodak Co., Washington, DC;
Mr. Edward A. Brill, Partner, Law Firm; Proskauer, Rose, Goetz, and Mendelsohn, New York;

Representing Academics

Ms. Maria L. Ontiveros, Associate Professor of Law, Golden Gate University, School of Law, California;
Ms. Margaret E. Montoya, Assistant Professor of Law, The University of New Mexico, School of Law, New Mexico;

Representing the Public at Large

Dr. Edward Williams, Professor, the University of Arizona, Arizona;
Ms. Marley S. Weiss, Associate Professor of Law, University of Maryland, School of Law, Maryland;

The Chairperson selected from the membership by the Secretary of Labor was Marley S. Weiss.

The NAC was established under article 17 of the North American Agreement on Labor Cooperation (NAALC) to advise on implementation and further elaboration of the Agreement.

DATES: These appointments will expire at the end of two years, subject to the Committee's being rechartered.

FOR ADDITIONAL INFORMATION CONTACT: Irasema Garza, Secretary, National Administrative Office (NAO), Bureau of International Labor Affairs (ILAB), Department of Labor, 200 Constitution Avenue, NW., Room C–4327, Washington, DC 20210. Telephone 202–501–6653 (this is not a toll free number).

Signed at Washington, DC, this 4th day of August 1995.

Robert B. Reich,

Secretary, Department of Labor.

[FR Doc. 95–19877 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–23–M

Pension and Welfare Benefits Administration

[Application No. D–09940, et al.]

Proposed Exemptions; Morgan Stanley & Co. Incorporated (MS&Co) and Morgan Stanley Trust Company (MSTC)

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

Unless otherwise stated in the Notice of Proposed Exemption, all interested persons are invited to submit written comments, and with respect to exemptions involving the fiduciary prohibitions of section 406(b) of the Act, requests for hearing within 45 days from the date of publication of this **Federal Register** Notice. Comments and request

for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N–5649, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5507, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Morgan Stanley & Co. Incorporated (MS&Co) and Morgan Stanley Trust Company (MSTC) Located in New York, New York

[Application No. D–09940]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a)(1)(A) through (D) and 406(b)(1) and (2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the lending of securities to Morgan Stanley & Co., Incorporated (MS&Co) and to any other U.S. registered broker-dealers affiliated with Morgan Stanley Trust Company (the Affiliated Broker-Dealer, collectively, the MS Group) by employee benefit plans for which Morgan Stanley Trust Company (MSTC) acts as directed trustee or custodian and securities lending agent and to the receipt of compensation by MSTC in connection with these transactions, provided that the following conditions are met:

1. Neither MS&Co nor MSTC has discretionary authority or control over a client-plan's assets involved in the transaction or renders investment advice (within the meaning of 29 CFR 2510.3–21(c)) with respect to those assets;

2. Any arrangement for MSTC to lend plan securities to the MS Group will be approved in advance by a plan fiduciary who is independent of MSTC and the MS Group;

3. A client-plan may terminate the arrangement at any time without penalty on five business days notice;

4. The client-plans will receive collateral consisting of cash, securities issued or guaranteed by the U.S. government or its agencies or instrumentalities, bank letters of credit or other collateral permitted under PTE 81–6, from the MS Group by physical delivery, book entry in a securities depository, wire transfer or similar means by the close of business on or before the day the loaned securities are delivered to the MS Group;

5. The market value of the collateral will initially equal at least 102 percent of the market value of the loaned securities and, if the market value of the collateral falls below 100 percent, the MS Group will deliver additional collateral on the following day such that the market value of the collateral will again equal 102 percent;

6. All procedures regarding the securities lending activities will at a minimum conform to the applicable provisions of Prohibited Transaction Exemptions (PTEs) 81–6 and 82–63;

7. MS&Co will indemnify each lending client-plan against any losses incurred by such plan in connection with the lending of securities to the MS Group;

8. The client-plan will receive the equivalent of all distributions made to holders of the borrowed securities during the term of the loan, including, but not limited to, cash dividends, interest payments, shares of stock as a result of stock splits and rights to purchase additional securities, or other distributions;

9. Only plans with total assets having an aggregate market value of at least $50 million will be permitted to lend securities to the MS Group;

10. With regard to the ''exclusive borrowing'' agreement (as described below), MS&Co will directly negotiate the agreement with a plan fiduciary who is independent of the MS Group and MSTC, and such agreement may be terminated by either party to the agreement at any time; and

11. Prior to any plan's approval of the lending of its securities to the MS Group, a copy of this exemption, if granted, (and the notice of pendency) will be provided to the plan.

Summary of Facts and Representations

1. MS&Co, a wholly owned subsidiary of Morgan Stanley Group Inc., is an investment services firm which is a member of the New York Stock Exchange and other principal securities exchanges in the United States and a member of the National Association of Securities Dealers. MS&Co is one of the largest investment firms in the United States. As of January 31, 1994, MS&Co's parent, Morgan Stanley Group Inc., had consolidated capital of over $9.8 billion.

2. MS&Co and its Affiliated Broker-Dealers (collectively, the MS Group), acting as principal, borrows securities from institutions and either utilizes such securities to satisfy its own needs or re-lends these securities to brokerage firms and other entities which need a particular security for a certain period of time. Borrowers often need securities to satisfy deliveries in cases of short sales or where a broker fails to receive securities it is required to deliver. The MS Group, which borrows and lends

securities equal in value to approximately $37 billion on an average daily basis, is among the largest institutional securities borrowers and lenders in the United States. In making such loans, the MS Group carefully reviews the credit worthiness of its counterparties.

3. MSTC is a wholly owned subsidiary of Morgan Stanley Group Inc. and an affiliate of MS&Co. MSTC is organized as a trust company in New York and provides a variety of services to its clients, including services as custodian and clearing agent and in the future may provide services as trustee.

4. An institutional investor, such as a pension fund, lends securities in its portfolio to a broker-dealer or bank in order to earn a fee in addition to any interest, dividends or other distributions paid on those securities. The lender generally requires that the security loans be fully collateralized, and the collateral usually is in the form of cash or high quality liquid securities such as U.S. Government or Federal Agency obligations or certain bank letters of credit. When cash is the collateral, the lender generally invests the cash and rebates a portion of the earnings on the collateral to the borrower. The ''fee'' received by the lender would then be the difference between the earnings on the collateral and the amount of rebate paid to the borrower. When a loan of securities is collateralized with Government or Federal Agency securities or bank letters of credit, a fee is paid directly by the borrower to the lender. Institutional investors often utilize the services of an agent in the performance of their securities lending transactions. The lending agent is paid a fee for its services which may be calculated as a percentage of the income earned by the investor from its securities lending activity. The applicants believe that the essential functions which define a securities lending agent are the identification of appropriate borrowers of securities and the negotiation of the terms of a loan to the borrowers. There are services ancillary to securities lending which include monitoring the level of collateral and the value of the loaned securities and investing the collateral in some instances.

5. MSTC and MS&Co request an exemption for the lending of securities owned by certain pension plans (client-plans) for which MSTC will serve as directed trustee or custodian to the MS Group, following disclosure of MSTC's affiliation with the MS Group, under either of the two arrangements described as Plan A and Plan B and for the receipt of compensation in connection with such transactions. However, because MSTC under the proposed arrangements will have discretion with respect to whether there is a loan of plan securities to the MS Group, the lending of securities to the MS Group by plans may be outside the scope of relief provided by PTE 81–6 [1] and PTE 82–63.[2]

6. When a loan is collateralized with cash, MSTC, at the plan's direction, will either transfer such cash collateral to the client-plan or its designated agent for investment or shall invest the cash in short-term securities or interest-bearing accounts and, in either case, will rebate a portion of the earnings on such collateral to the MS Group on behalf of the client-plan. The MS Group will pay a fee to the client-plan based on the value of the loaned securities where the collateral consists of obligations other than cash. Under Plan A and, in some instances, under Plan B (see paragraph 27 regarding the types of lending services which may be provided to plans by MSTC under Plan B), the client-plan will pay a fee to MSTC for providing lending services to the plan which will reduce the income earned by the client-plan from the lending of securities to the MS Group. The client-plan and MSTC will agree in advance to this fee which will represent a percentage of the income the client-plan earns from its lending activities. Several safeguards, described more fully below, are incorporated in the application in order to ensure the protection of the client-plan assets involved in the transactions. In addition, the applicants represent that each of the two arrangements incorporates the relevant conditions contained in PTE 81–6 and PTE 82–63.

7. *Plan A.* A fiduciary of a client-plan who is independent of MSTC and The MS Group will sign a securities lending authorization (the Authorization) before the client-plan may participate in MSTC's securities lending program. This Authorization describes the operation of the lending program and allows MSTC to lend securities held by the client-plan to securities brokers, including the MS Group, as selected by MSTC. The Authorization also sets forth, in an attachment, the basis and rate for MSTC's compensation from the client-plan for the performance of securities lending services.

8. The independent fiduciary also must sign an Affiliated Broker-Dealer Lending Authorization before MSTC may include security loans to the MS Group in the lending activities of the client-plan. The Affiliated Broker-Dealer Lending Authorization will specify, in an attached exhibit, the method of determining the daily securities lending rates (fees and rebates), the minimum lending fees payable by the MS Group and the maximum rebate rate payable to the MS Group. A client-plan may terminate both the Authorization and the Affiliated Broker-Dealer Lending Authorization at any time.

9. MSTC, as securities lending agent, will negotiate a Customer Securities Loan Agreement (Basic Loan Agreement) with the MS Group on behalf of its client-plans. An independent fiduciary of the client-plan will approve the form of the agreement before that fiduciary executes the Affiliated Broker-Dealer Lending Authorization. The Basic Loan Agreement will specify, among other things, the right of the client-plan to terminate a loan at any time (subject to the customary notification period) and the client-plan's rights in the event of any default by the MS Group. The agreement will explain the basis for compensation to the client-plan for lending securities to the MS Group under each category of collateral. The agreement will also contain a requirement that the MS Group must pay all transfer fees and transfer taxes related to the security loans.

10. Before entering into the Basic Loan Agreement, the MS Group will furnish its most recent publicly available audited and unaudited financial statements to MSTC, who, in turn, will provide such statements to a client-plan before the plan is asked to approve the terms of the Basic Loan Agreement. The Basic Loan Agreement will contain a requirement that the MS Group must give prompt notice at the time of a loan of any material adverse changes in its financial condition since the date of the most recently furnished financial statements. If any such changes have taken place, MSTC will request that an independent fiduciary of the client-plan approve the loan in view of the changed financial condition.

[1] PTE 81–6 (46 FR 7527, January 23, 1981, as amended at 52 FR 18754, May 19, 1987) provides an exemption under certain conditions from section 406(a)(1) (A) through (D) of ERISA and the corresponding provisions of section 4975(c) of the Code for the lending of securities that are assets of an employee benefit plan to certain broker dealers or banks which are parties in interest.

[2] PTE 82–63 (47 FR 14804, April 6, 1982) provides an exemption under specified conditions from section 406(b)(1) of ERISA and section 4975(c)(1)(E) of the Code for the payment of compensation to a plan fiduciary for services rendered in connection with loans of plan assets that are securities. PTE 82–63 permits the payment of compensation to a plan fiduciary for the provision of securities lending services only if the loan of securities itself is not prohibited under section 406(a) of ERISA.

11. The client-plan and MSTC will agree to the fee MSTC will receive for its services as lending agent prior to the commencement of any lending activity. The agreement by MSTC to provide securities lending services to a client-plan will be in writing and subject to the prior written approval of a fiduciary of the client-plan who is independent of the MS Group and MSTC.[3] The Basic Loan Agreement will allow termination by the client-plan without penalty to the plan within five business days of written notice. Before entering into an agreement, MSTC will provide the client-plan with any reasonably available information which it believes is necessary for the plan to make a determination whether to enter into or renew the agreement and such other information as the plan may request.

12. Each time a client-plan loans securities to the MS Group pursuant to the Basic Loan Agreement, the MS Group will execute a designation letter specifying the material terms of the loan, including the securities to be loaned, the required level of collateral, the fee or rebate payable, and any special delivery instructions. The terms of each loan will be at least as favorable to the client-plan as those of a comparable arm's-length transaction between unrelated parties.

13. MSTC will credit to the account of the client-plan all interest, dividends and the like received on the loaned securities during the loan period, including distributions and rights of any kind. The Basic Loan Agreement will provide that the client-plan may terminate any loan at any time. Upon a termination, the MS Group will return the loaned securities to the client-plan within five business days of written notification. If the MS Group fails to return the securities within the designated time, the client-plan has certain rights that it may exercise under the Basic Loan Agreement.

14. MSTC will establish each day separate written schedules of lending fees and rebate rates to assure uniformity of treatment among borrowing brokers and to limit the discretion MSTC would have in negotiating securities loans to the MS Group. Loans to all borrowers of a given security on that day will be made at rates or lending fees on the relevant daily schedules or at rates or lending fees which may be more advantageous to the client-plans. In no case will loans be made to the MS Group at rates or lending fees less advantageous to the client-plan than those on the schedule. The daily schedule of rebate rates will be based on the current value of the clients' reinvestment vehicles and on market conditions, as reflected by demand for securities by borrowers other than the MS Group. As with rebate rates, the daily schedule of lending fees will also be based on market conditions, as reflected by demand for securities by borrowers other than the MS Group, and will generally track the rebate rates with respect to the same security or class of securities.

15. MSTC will adopt maximum daily rebate rates for cash collateral payable to the MS Group on behalf of a lending plan. Separate maximum daily rebate rates will be established with respect to loans of designated classes of securities such as U.S. government securities, U.S. equities and corporate bonds, international fixed income securities and international equities. With respect to each designated class of securities, the maximum rebate rate will be the lower of (i) the 7 day LIBOR rate, minus a stated percentage of such LIBOR rate and (ii) the client's actual reinvestment rate for the relevant cash collateral, minus a stated percentage of such reinvestment rate, as pre-approved by the independent fiduciary. Thus, when cash is used as collateral, the daily rebate rate will always be lower than the rate of return to the client-plans from authorized investments for cash collateral by such stated percentage as shall be pre-approved by the independent fiduciary. MSTC will submit the formula for determining the maximum daily rebate rates to an independent fiduciary of the client-plan for approval before lending any securities to the MS Group on behalf of the plan.

16. MSTC will also adopt minimum daily lending fees for non-cash collateral payable by the MS Group to MSTC on behalf of a plan. Separate minimum daily lending fees will be established with respect to loans of designated classes of securities, such as U.S. government securities, U.S. equities and corporate bonds, international fixed income securities and international equities. With respect to each designated class of securities, the minimum lending fee will be stated as a percentage of the principal value of the loaned securities. MSTC will submit such minimum daily lending fees to an independent fiduciary to the client-plan for approval before initially lending any securities to the MS Group on behalf of the plan.

17. For collateral other than cash, the lending fees charged the previous day are reviewed by MSTC for competitiveness. Based on the demand of the marketplace, this daily fee tends to remain constant and, with respect to domestic securities and international debt securities, is currently at least one tenth of one percent of the principal value of the loaned securities. With respect to international equity securities, the daily fee is currently one fifth of one percent of the principal value of the loaned securities. Because 50 percent or more of securities loans by client-plans will be to unrelated brokers or dealers,[4] the competitiveness of MSTC's fee schedule will be continuously tested in the marketplace. Accordingly, loans to the MS Group should result in a competitive rate of income to the lending client-plan.

18. Should MSTC recognize prior to the end of a business day that, with respect to new and/or existing loans, it must change the rebate rate or lending fee formula in the best interest of client-plans, it may do so (i) with respect to borrowers other than the MS Group, at the end of such business day, and (ii) with respect to the MS Group, upon MSTC's receipt of a written approval of the client-plan's independent fiduciary.[5]

MSTC may propose a change in the lending fee or rebate rate determination, as applicable, with respect to an outstanding loan by delivering written notice of the effective date and the new determination pursuant to which a lending fee or rebate rate, as the case may be, may be determined at least five business days before the date of the proposed change. In the event that the client-plan does not consent to such change by not providing MSTC acknowledgement of its consent in writing by such means that will ensure receipt by MSTC prior to 10:00 a.m. New York time, on the effective date of the change, then MSTC will not make such change. The applicants represent that allowing MSTC to request a modification to the lending fee or the rebate rate formula with respect to an existing loan to the MS Group when market conditions change will be beneficial to the client-plans. According to the applicants, in the absence of the ability to make such modification, the MS Group may be forced by market conditions to terminate the loan and seek better terms elsewhere. Such termination may then force the client-

[3] This closely parallels conditions c and d of PTE 82–63 which require that the payment of compensation to a ''lending fiduciary'' is made under a written instrument and is subject to prior written authorization of an independent ''authorizing fiduciary''.

[4] This 50 percent requirement applies regardless of the type of collateral used to secure the loan.

[5] MSTC represents that it will not initiate any modification in such rates or fees which would be detrimental to the client-plans.

plan to seek new borrowers for its securities who, in light of the changed market conditions, are likely to negotiate for the lending fee or rebate rate which the MS Group would have received or paid had MSTC had the written authority from the independent fiduciary to decrease the lending fee or increase the rebate rate.

19. While MSTC will normally loan securities to requesting borrowers on a first come, first served basis, as a means of assuring uniformity of treatment among borrowing brokers, it should be recognized that in some cases it may not be possible to adhere to a first come, first served allocation. This can occur, for example, in instances where (a) the credit limit established for a ''first in line'' borrower by the client-plan has already been satisfied; (b) the ''first in line'' borrower is not approved as a borrower by the particular client-plan whose securities are sought to be borrowed; or (c) the ''first in line'' borrower cannot be ascertained, as an operational matter, because several borrowers spoke to differed MSTC representatives at or about the same time with respect to the same security. In situation (a) and (b), loans would normally be effected with the ''second in line'' borrower. In situation (c), securities would be allocated equitably among all eligible borrowers.

20. MS&Co will indemnify each lending client-plan against any losses due directly to the lending of such plan's securities to the MS Group. Accordingly, MS&Co will assure the client-plan that the rate of return on each loan will at a minimum equal the transactional cost to the plan of lending securities to The MS Group. The applicants contend that, as a result of this indemnity, the rate of return earned by client-plans from lending to the MS Group will, in total, exceed the return from lending securities to other brokers.

21. By the close of business on the day the loaned securities are delivered to the MS Group, MSTC will receive from the MS Group non-cash collateral by physical delivery or book entry in a securities depository, or, cash collateral by wire transfer or book entry. At the discretion of the client-plan, cash collateral may be managed either by the plan, by its designated agent or by MSTC. If a client-plan chooses to manage its cash collateral, MSTC will promptly forward the cash collateral to the client-plan. The non-cash collateral will consist of securities issued or guaranteed by the U.S. Government or its agencies or irrevocable bank letters of credit (issued by a person other than MS&Co or its affiliates) or other collateral permitted under PTE 81–6 or any successor. The market value of the collateral on the day the loan settles will be at least 102 percent of the market value of the loaned securities. The Basic Loan Agreement will give the client-plan a continuing security interest in and a lien on the collateral. MSTC will monitor the level of the collateral daily. If the market value of the collateral falls below 100 percent of that of the loaned securities, MSTC will require the MS Group to deliver by the close of business the next day sufficient additional collateral to bring the level back to at least 102 percent.

22. A client-plan that loans securities to the MS Group will receive a weekly report with which to monitor lending activity, rates on loans to the MS Group compared with loans to other brokers, and the level of collateral on the loans. The weekly report will show, on a daily basis, the market value of all outstanding security loans to the MS Group and to other borrowers as compared to the total collateral held for both categories of loans.

23. The weekly report will state the daily fees where collateral other than cash is utilized and will specify the details used to establish the daily rebate payable to all brokers where cash is used as collateral. The weekly report also will state, on a daily basis, the rates at which securities are loaned to the MS Group compared with those at which securities are loaned to other brokers. This statement will give an independent fiduciary information which can be compared to that contained in the daily rate schedule.

24. MSTC will send a monthly transaction report to each client-plan participating in the lending program. The monthly report will provide a list of all security loans outstanding and closed for a specified period. The report will identify for each open loan position, the securities involved, the value of the security for collateralization purposes, the current value of the collateral, the rate at which the security is loaned, and the number of days the security has been on loan.

25. Only client-plans with assets having an aggregate market value of at least $50 million will be permitted to lend securities to the MS Group. The applicants maintain that this restriction is intended to assure that any lending to the MS Group will be monitored by an independent fiduciary of above average experience and sophistication in matters of this kind.

26. MSTC will record on audio tape all telephone traffic between its securities lending department and all borrowers, including the MS Group. The telephone tapes will be retained for a period of at least six months. This recording procedure will enable client-plans and the Department to review MSTC's adherence to its policy of lending securities to the first interested borrower at rates or lending fees on the daily schedule, or at rates or lending fees which are more advantageous to the client-plans.

27. *Plan B.* MS&Co will directly negotiate ''exclusive borrowing'' agreements with fiduciaries of plans, including plans for which MSTC serves as custodian or in the future may serve as directed trustee, where such fiduciary is independent of the MS Group and MSTC. Under such an agreement, the MS Group will have exclusive access for a specified period of time to borrow certain securities of the plan pursuant to certain conditions. MSTC will not participate in the negotiation of the agreement. The involvement of MSTC, if any, will be limited to such activities as holding securities available for lending, handling the movement of borrowed securities and collateral and investing or depositing any cash collateral and supplying the plans with certain reports. The applicants represent that, under the exclusive borrowing agreement, neither the MS Group nor MSTC will perform for client-plans the functions which constitute the essential functions of a securities lending agent.

28. Upon delivery of loaned securities to the MS Group, MSTC, or another custodian, on behalf of a client-plan, will receive from the MS Group, the same day by wire transfer or book entry cash collateral or, by physical delivery or book entry in a securities depository, collateral consisting of securities issued or guaranteed by the U.S. Government or its agencies, irrevocable bank letters of credit, or other non-cash collateral permitted under PTE 81–6. The market value of the collateral on the day the loan settles will be at least 102 percent of the market value of the loaned securities. MSTC or such other custodian will monitor the level of the collateral daily and, if its market value falls below 100 percent, the MS Group will deliver sufficient additional collateral on the following day such that the market value of all collateral will equal at least 102 percent of the market value of the loaned securities. The MS Group or, in the case of some client plans, MSTC, will provide a weekly report to the plan showing, on a daily basis, the aggregate market value of all outstanding security loans to the MS Group and the aggregate market value of the collateral.

29. Before entering into an exclusive borrowing agreement, the MS Group will furnish to the plan the most recent

publicly available audited and unaudited statements of its financial condition. Further, the agreement will contain a representation by the MS Group, as provided in section 18(c)(ii) of the Securities Lending Agreement, that as of each time it borrows securities, there have been no material adverse changes in its financial condition. All the procedures under the agreement will, at a minimum, conform to the applicable provisions of PTE 81–6 and PTE 82–63.

30. In exchange for the exclusive right to borrow certain securities from a client-plan, the MS Group will pay the plan either a flat fee, or a minimum flat fee plus a percentage (negotiated at the time the exclusive borrowing agreement is entered into) of the total balance outstanding of borrowed securities, or a percentage of the total balance outstanding without any flat fee. In light of this fee arrangement, all earnings generated by cash collateral will be returned to the MS Group. The client-plan will receive credit for all interest dividends or other distributions on any borrowed securities.

31. The exclusive borrowing agreement may be terminated by either party to the agreement at any time. MS&Co will agree that upon termination it will deliver any borrowed securities back to the client-plan within five business days of written notice of termination. If the MS Group fails to return the securities or the equivalent thereof, the client-plan will have certain rights under the agreement to realize upon the collateral. Pursuant to the terms of the agreement, the MS Group will indemnify the plan against any losses due to its use of the borrowed securities equal to the difference between the replacement cost of the securities and the market value of the collateral on the date a loan is declared to be in default.

32. With regard to those plans for which MSTC provides custodial, clearing and/or reporting functions relative to securities loans, MSTC and a plan fiduciary independent of MSTC and the MS Group will agree in advance and in writing to any fee that MSTC is to receive for such services. Such fees, if any, would be fixed fees (e.g., MSTC might negotiate to receive a fixed percentage of the value of the assets with respect to which it performs these services or to receive a stated dollar amount) and any such fee would be in addition to any fee MSTC has negotiated to receive from any such client-plan for standard custodial or other services unrelated to the securities lending activity. The arrangement to have MSTC provide such functions relative to securities loans to the MS Group will be terminable by the client-plan within five business days of receipt of written notice without penalty to the plan except for the return to the MS Group of part of any flat fee paid by the MS Group to the plan, if the client-plan has also terminated its exclusive borrowing agreement with the MS Group. Before entering into an agreement with a plan to provide such functions relative to securities loans to the MS Group, MSTC will furnish to the plan any publicly available information which it believes is necessary for the plan to determine whether to enter into or renew the agreement.

33. In summary, the applicants represent that the described transactions satisfy the statutory criteria of section 408(a) of the Act because: (a) Plan A requires approval of the form of a basic loan agreement and the execution of the Affiliated Broker-Dealer Lending Authorization by a plan fiduciary independent of the MS Group and MSTC before a client-plan lends any securities to the MS Group, while under Plan B, The MS&Co will directly negotiate exclusive borrowing agreements with a client-plan; (b) the lending arrangements will permit the client-plans to benefit from the MS Group's substantial market position as securities lenders and will enable the plans to earn additional income from the loaned securities while still receiving dividends, interest and other distributions on those securities; (c) the client-plan will receive sufficient information concerning the MS Group's financial condition before the plan lends any securities to the MS Group; (d) the collateral on each loan to the MS Group initially will be at least 102 percent of the market value of the loaned securities, which is in excess of the 100 percent collateral required under PTE 81–6, and will be monitored daily by MSTC; (e) the client-plans will receive a weekly report and monthly report, so that an independent fiduciary of the client-plans also may monitor loan activity, fees, the level of the collateral and loan return/yield; (f) MSTC will have no discretionary authority or control over the plan's acquisition or disposition of securities available for loan; (g) the terms of each loan will be at least as favorable to the plans as those of a comparable arm's-length transaction between unrelated parties; and (h) all the procedures under the proposed transactions will, at a minimum, conform to the applicable provisions of PTE 81–6 and PTE 82–63.

FOR FURTHER INFORMATION CONTACT: Virginia J. Miller of the Department, telephone (202) 219–8971. (This is not a toll-free number.)

Central Freight Lines Employees Profit Sharing and Retirement Plan (the Plan) Located in Waco, TX

[Application No. D–09994]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) shall not apply to the proposed cash sale by the Plan of certain unimproved real property (the Property) to Central Freight Lines, Inc. (the Employer), a party in interest with respect to the Plan.

This proposed exemption is conditioned upon the following requirements: (1) All terms and conditions of the sale are at least as favorable to the Plan as those obtainable in an arm's length transaction with an unrelated party; (2) the sale is a one-time transaction for cash; (3) the Plan is not required to pay any real estate commissions or fees in connection with the proposed transaction; and (4) the Plan receives a sales price for the Property which is not less than the greater of (a) the fair market value of the Property as determined by a qualified, independent appraiser, or (b) the net acquisition cost of the Property.

Summary of Facts and Representations

1. The Plan is a defined contribution plan with 3,149 participants and net assets available for benefits of approximately $103,639,097 as of December 31, 1994. The trustee of the Plan and decisionmaker with respect to Plan investments is A.G. Edwards Trust Company of St. Louis, Missouri.

2. The Employer, which maintains its general offices in Waco, Texas, is a trucking company that is involved in the transportation and delivery of freight throughout the midwestern and southwestern United States. The Employer is a wholly-owned subsidiary of Roadway Services, Inc. (Roadway), a publicly-owned trucking company which maintains its corporate offices in Akron, Ohio.

3. Prior to 1989, the Plan, through two separate purchases, acquired a 38.810 acre tract of undeveloped land for a total purchase price of $1,495,352. The

Property is located on the northwest side of Spur 482 (Storey Lane) and approximately 1,500 feet northeast of State Highway 114 in the City of Irving, Dallas County, Texas. The Property adjoins the Employer's Dallas freight terminal.

The Plan acquired the Property for investment purposes from unrelated parties. On July 12, 1976, the Plan purchased 36.464 acres of land (Tract A) from the University of Dallas. The Plan paid a purchase price of $1,284,009 for Tract A and closing costs of $697. Thus, the total acquisition price paid by the Plan for Tract A was $1,284,706.

On August 1, 1980, the Plan purchased 1.928 acres of adjoining land (Tract B) from Jack H. Beachum. The Plan paid a purchase price for Tract B of $210,624 plus closing costs of $22. Thus, the total acquisition price paid by the Plan for Tract B was $210,646.[6]

4. On December 30, 1983, the Plan sold the Property to FrittsSesler Investments, Inc. (FrittsSesler), a real estate investment company and an unrelated party, for $4,226,418. The terms of the sale provided for a cash downpayment of $845,284 with the balance to be paid over 10 years. The unpaid portion of the purchase price was evidenced by a promissory note in the amount of $3,381,134. The note carried interest at 11 percent interest per annum and provided for interest only payments for the first 5 years and payments of principal and interest for the last 5 years of the loan. The note was secured by a deed of trust on the Property.

From the date of closing until January 1987, the Plan received $845,284 in principal and $1,115,774 in interest on the note. In 1987, FrittsSesler defaulted on the note. The note was then accelerated and the Property was posted for foreclosure. In January 1988, the Property was deeded back to the Plan by a Deed in Lieu of Foreclosure. At the time of the foreclosure, an appraisal completed of the Property on January 13, 1988 by Messrs. Scott D. Evans, Associate Appraiser, and Mr. Ronald W. Potts, MAI, SRPA, independent appraisers affiliated with Cushman & Wakefield of Texas, Inc., located in Dallas, Texas, placed the fair market value of the Property at $4,280,000.

5. It is represented that the Property has never been used by or leased to parties in interest since its initial acquisition and reacquisition by the Plan. It is also represented that the Plan has incurred certain costs totaling $512,598 in connection with its reacquisition of the Property. These costs represent expenses of $58,942 that are associated with the Plan's acceptance of the Deed in Lieu of Foreclosure; $90 for closing costs; and $453,566 for real estate taxes.

6. Since repossessing the Property, the Plan has continually advertised it for sale. However, due to the depressed real estate market in the State of Texas and because of changes in growth patterns of the Dallas-Fort Worth area, no interest has been expressed in purchasing the Property. In addition, the Property has generated no income to the Plan and has declined in value. Therefore, the Employer requests an administrative exemption from the Department in order that it may purchase the Property from Plan. The proposed sales price for the Property will represent not less than the greater of the (a) fair market value of the Property as determined by a qualified, independent appraiser or (b) $46,892 representing the net acquisition cost of the Property.[7]

7. The Employer has obtained an independent appraisal of the Property from Bill C. Dotson, MAI and Richard S. Neely, Associate Appraiser, independent appraisers affiliated with the Alliance Appraisal Group, Inc. of Dallas, Texas. In an appraisal report dated January 16, 1995, Messrs. Dotson and Neely have placed the fair market value of the Property at $1,270,000 as of January 3, 1995.

In an addendum to the appraisal report dated July 13, 1995, Mr. Dotson states that he has re-analyzed the initial valuation of the Property to determine whether there is any assemblage value due to the proximity of the Property to other real property owned by the Employer. In making this determination, Mr. Dotson represents that he has considered (a) the Employer's existing facility which he believes is in no need for further expansion, (b) larger tracts of commercial land in the vicinity of the Property for which he can ascertain no significant assemblage value and (c) the valuation adage that ''Property is worth more to the adjacent owner than to a third party.'' He notes that for the adage to be true, there has to be a proven demand for the property for there to be assemblage value. In his opinion, the Employer has not shown a demand factor over and above common market forces.

Mr. Dotson asserts that the subject Property is a stand alone tract which can be utilized for a number of purposes. In his view, the Property is not co-dependent on any other tracts of land for frontage, access or visibility. Thus, Mr. Dotson concludes that the Property has no assemblage or premium value by reason of its proximity to other existing real property that is owned by the Employer.

8. Because the fair market value of the Property is greater than its net acquisition cost, the Plan will sell the Property to the Employer for $1,270,000. The Employer will pay the consideration to the Plan in cash. In addition, the Plan will not be required to pay any real estate fees or commissions in connection with the proposed sale.

9. In summary, it is represented that the proposed transaction will satisfy the statutory criteria for an exemption under section 408(a) of the Act because: (a) All terms and conditions of the sale will be at least as favorable to the Plan as those obtainable in an arm's length transaction with an unrelated party; (b) the sale will be a one-time transaction for cash; (c) the Plan will not be required to pay any real estate commissions or fees in connection with the proposed sale; and (d) the Plan will receive a sales price for the Property which is not less than the greater of (i) the fair market value of the Property as determined by a qualified, independent appraiser, or (ii) the net acquisition cost of the Property.

Notice to Interested Persons

Notice of the proposed exemption will be given to all interested persons within 5 days of the date of publication of the notice of pendency in the **Federal Register**. Notice will be posted at the Employer's work sites. Such notice will include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment. Comments with respect to the notice of proposed exemption are due within 35 days after the date of publication of this proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady of the Department,

[6] The Department notes, that the dimensions of Tract A and Tract B, if aggregated, equal 38.392 acres instead of 38.810 acres. In attempting to explain this discrepancy, the applicant has advised that the subject Property does consist of 38.810 acres of land based on a survey of the Tracts. The applicant attributes the size references and legal descriptions of Tract A and Tract B to ''old field notes.'' When the Property was subsequently surveyed, the applicant states that either the dimensions of the Tracts, individually, or when taken together, were larger than originally thought.

[7] The $46,892 net acquisition cost of the Property is determined as follows: $2,007,950 [representing the total acquisition price plus certain costs incurred by the Plan since its reacquisition of the Property (i.e., $1,495,352+$512,598)] minus $1,961,058 [representing the total revenues received by the Plan for the Property (i.e., $845,284+$1,115,774)].

telephone (202) 219–8881. (This is not a toll-free number.)

Donald D. Busker Individual Retirement Account (the IRA) Located in Detroit Lakes, Minnesota

[Application No. D–10005]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed cash sale of two parcels of unimproved real property (the Properties) by the IRA to Donald D. Busker, a disqualified person with respect to the IRA [8] provided the following conditions are met:

(a) The sale is a one-time transaction for cash;

(b) The terms and conditions of the sale are at least as favorable to the IRA as those obtainable in an arm's-length transaction with an unrelated party;

(c) The IRA receives the fair market value of the Properties as established at the time of the sale by an independent qualified appraiser; and

(d) The IRA is not required to pay any commissions, costs or other expenses in connection with the sale.

Summary of Facts and Representations

1. The IRA is an individual retirement account, as described under section 408(a) of the Code, which was established by Donald D. Busker (Mr. Busker). As of June 14, 1995, the IRA had assets valued at $362,470. The trustee of the IRA is the First Trust Company of North Dakota, N.A.

2. The applicants states that a portion of the IRA's existing assets, including the Properties, were obtained from a rollover of assets received by Mr. Busker in 1990 from distributions to which he was entitled as a participant in the Country Equities Inc. Retirement Plan (the CER Plan). The applicant states further that the CER Plan had received such assets from prior rollovers made to Mr. Busker from the Donald D. Busker and Associates Pension Trust (the Busker Pension Plan), which had been terminated in January 1982.

The Properties consist of two parcels of unimproved real property.

The first parcel (Property I) is located in Shell Lake Township in Becker County, east of Detroit Lakes, Minnesota. Property I consists of approximately eighty acres of unimproved wooded lowland in a fairly remote part of Becker County. The applicant states that access to Property I is available by easement over county land to the south.

The second parcel (Property II) is located near Frazee, Minnesota, on Murphy and Silver Lakes in Gorman Township, Otter Tail County. Property II currently consists of approximately 144 acres of unimproved land, part of which is zoned for agricultural conservation and part of which is zoned for potential development as a recreational area. In this regard, the applicant states that approximately 53 acres on Property II are part of the Conservation Reserve Program (CRP), a U.S. Government subsidy program for farmland that is not being used for agricultural purposes. In addition, part of the remaining acres which comprise Property II are located adjacent to Murphy Lake and are available for recreational uses. However, the applicant states that only about 3000 feet of this part of Property II is useable and that the remaining parts of Property II adjacent to the lakes are not currently capable of development because the land is excessively low and wet.

Mr. Busker represents that he does not own any land which is adjacent to either of the Properties and that the Properties have not been leased to or used by any disqualified person.

3. The Properties were originally acquired as a real estate investment by the Busker Pension Plan. The applicant states that the Properties were acquired from unrelated parties in two separate cash transactions. Specifically, Property I was acquired by the Busker Pension Plan in 1978 for $4,250. Property II was acquired in 1978 as part of a larger parcel of real estate, which included a residential house and other improvements, for a total of $98,500 (the Original Property II). Portions of the Original Property II were subsequently platted for development and, along with the house, sold by the Busker Pension Plan to unrelated parties. However, Mr. Busker has not been able to sell the remaining portions of the Original Property II, currently owned by the IRA (i.e. Property II as described above). The applicant states that parts of Property II have also been platted for possible sale as separate parcels. The applicant states further that the IRA has received approximately $2992 in CRP subsidy payments as a result of its ownership of the acres on Property II which are subject to the CRP subsidy program.

4. Roger K. Tinjum, an accredited rural appraiser associated with Tinjum Appraisal Company, located in Detroit Lakes, Minnesota, appraised the Properties in December 1993 and updated his appraisal in June 1995. Mr. Tinjum states that he is a qualified real estate appraiser with over thirty years of experience and is familiar with the Properties and other similar properties located in the area. In addition, Mr. Tinjum represents that both he and his firm are independent of, and unrelated to, Mr. Busker.

Mr. Tinjum's appraisal of the Properties relied primarily on the market approach, with an analysis of recent sales of similar properties in the area, to establish the fair market value of the Properties. Mr. Tinjum states that his analysis took into consideration the potential of the Properties for further development. In this regard, Mr. Tinjum represents that the highest and best use for the Properties would be recreational use. Based on this analysis, Mr. Tinjum concluded that the fair market values of Property I and Property II were $20,000 and $72,000, respectively, as of December 10, 1993.

By letter dated June 15, 1995, Mr. Tinjum states that the present fair market value of the Properties has not changed since December 10, 1993.

The applicant states that Mr. Tinjum will update his appraisal of the Properties at the time of the proposed transaction to establish their fair market value. Such appraisal will take into consideration any recent sales of comparable properties in the area since the date of Mr. Tinjum's last appraisal.

5. The applicant requests an exemption for the proposed sale of the Properties by the IRA to Mr. Busker. As noted above, the IRA would receive cash in exchange for the Properties in an amount equal to the fair market value of the Properties, as determined by an independent, qualified appraiser at the time of the transaction.

The applicant represents that the proposed transaction would be in the best interests of the IRA because it would allow the IRA to dispose of the Properties, which at the present time are illiquid investments which have not been appreciating in value, and reinvest the sale proceeds in more liquid investments which would offer greater returns. The applicant states that the terms and conditions of the sale would be at least as favorable to the IRA as the terms and condition which the IRA could obtain in an arm's-length transaction with an unrelated party. The applicant states further that the IRA

[8] Pursuant to 29 CFR 2510.3–2(d), there is no jurisdiction with respect to the IRA under Title I of the Act. However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

would not pay any commissions or other expenses in connection with the transaction.

6. In summary, the applicant represents that the proposed transaction satisfies the statutory criteria of section 4975(c)(2) of the Code because: (a) The terms and conditions of the sale would be at least as favorable to the IRA as those obtainable in an arm's-length transaction with an unrelated party; (b) the sale would be a one-time cash transaction which would allow the IRA to dispose of illiquid assets which have not been appreciating in value; (c) the IRA would receive the fair market value of the Property, as established at the time of the sale by an independent, qualified appraiser; (d) the IRA would not be required to pay any commissions, costs or other expenses in connection with the sale; and (e) Mr. Busker has determined that the proposed sale of the Properties would be in the best interests of the IRA.

NOTICE TO INTERESTED PERSONS: Because Mr. Busker is the only participant in the IRA, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and requests for a hearing are due thirty (30) days after publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mr. E. F. Williams of the Department, telephone (202) 219–8194. (This is not a toll-free number.)

Profit Sharing Plan for Employees of Athens Disposal Co., Ranco Leasing, Covina Disposal Co., and South Pasadena Disposal Co. (the Plan), Located in City of Industry, California

[Application No. D–10029]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of sections 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the cash sale on March 24, 1994, for $300,000 (the Sale) of 7,500 shares (the Shares) of common stock issued by Garfield Bank (the Bank), chartered in California and located in Montebello, California, by the Plan to Athens Disposal Co., Inc., a party in interest with respect to the Plan; provided that (1) the Plan experienced no loss nor incurred any expense from the Sale; and (2) the Plan received as consideration from the Sale an amount that was no less than the fair market value of the Shares on the date of the Sale.

EFFECTIVE DATE: If this proposed exemption is granted, the effective date of the exemption will be March 24, 1994.

Summary of Facts and Representations

1. There are three closely-held corporations that currently sponsor the Plan (the Employers) that are all incorporated in California and are wholly owned by various members of the Arakelian family. One of the three corporations that make up the Employers is the Athens Disposal Co., Inc. (the Applicant), incorporated on July 1, 1958, which is headquartered in City of Industry, California and is engaged in the business of municipal solid waste collection and disposal. The second of the Employers is the South Pasadena Disposal Co., Inc. (South Pasadena), incorporated September 5, 1992, which provides the same services as the Applicant for the City of Pasadena, California. The third member of the Employers is the Ranco Leasing Co., Inc. (Ranco), incorporated November 21, 1981, which owns rubbish collection vehicles that it leases to the Applicant and to South Pasadena and provides fleet maintenance services for the leased vehicles.[9]

2. The Plan is a profit sharing plan that maintains individual accounts for its 254 participants and beneficiaries with net assets of $4,975,373, as of June 30, 1994. The Plan is intended to satisfy the qualification requirements of section 401(a) of the Code. The named fiduciary of the Plan is a committee (the Committee) currently consisting of two individuals, Messrs. Ron Arakelian and Ron Arakelian, Jr., who are controlling shareholders as well as officers and directors of the Applicant. The Committee is appointed by the Board of Directors of the Applicant and charged with the responsibility to administer the Plan, which includes among other things directing investments of Plan assets and appointing legal counsel, accountants, plan administrator, and trustees.

The Committee has employed and delegated responsibility for administering the accounting and recordkeeping services for the Plan to Page Services Corporation, a California corporation, located in Los Angeles, California. Messrs. Ron Arakelian and Ron Arakelian, Jr. also serve the Plan as the trustees (the Trustees) of its assets.

3. During the Plan's fiscal year ended June 30, 1985, the Applicant conveyed the 7,500 Shares to the Plan as its $300,000 funding contribution for the fiscal year.[10] The Shares, originally purchased by the applicant over a 10 year period at a price of $40 per share, were determined to have a fair market value of $40 per share on the date that they were contributed to the Plan.

While the Plan continued to hold the Shares the Bank began experiencing a poor financial performance resulting in net losses from operations for the years ended December 31, 1993 and 1994. The poor financial performance of the Bank was also manifested by limited dividend payments of the Bank to the holders of the Shares. The only dividend payments made to the Plan totalled $1,875 for each of the years 1992 and 1993.

The Applicant represents that the Bank became the subject of examinations during 1993 by both the Federal Reserve Bank (the FRB) and the Superintendent of Banks for the State of California (the State). The State completed its examination by September 24, 1993, whereas, the FRB took an additional year to complete its examination on September 24, 1994. In preliminary letters in 1993 from both the FRB and the State, the Bank was notified, among other things, that it was in an unsafe and unsound condition with a continuing deterioration in asset quality, an inadequate loan loss reserve, and a decline in capital and liquidity. The FRB concluded that the continued deterioration in asset quality threatened the already marginal capital position of the Bank and negatively impacted on its future earnings prospects. The Applicant further represents that the FRB reclassified the Bank as significantly undercapitalized for purposes of federal regulations which resulted in restrictions (a) on the ability of the Bank to pay dividends and management fees; (b) on the growth of its total assets; and (c) on its ability to expand through acquisitions, branching, or new lines of business. According to the Applicant the State also issued an order to the Bank that its capital is considered to be impaired as of September 30, 1994, which subjects the

[9] Covina Disposal Co., Inc., incorporated in California on October 3, 1985, a wholly-owned subsidiary of the Applicant, had been another sponsor of the Plan, but was liquidated on June 30, 1990, and had its assets and liabilities distributed to the Applicant with its participants in the Plan absorbed by the Applicant.

[10] The Applicant represents that the contribution of the Shares was not a prohibited transaction under the Act. The Department expresses no opinion as to whether the contribution was a prohibited transaction.

Shares to assessment under certain circumstances and potential forfeiture.

The common stock of the Bank was appraised on January 21, 1994, and February 11, 1994, by an independent appraiser, Mr. Glenn Garlick, Principal of Houlihan Valuation Appraisers located in Costa Mesa, California. When making the appraisals Mr. Garlick understood that the Applicant intended to purchase the Shares from the Plan at the greater of either $40 per share or the fair market value based upon an independent appraisal. In the February 11, 1994, appraisal, Mr. Garlick concluded that without consideration of the intent of the applicant to purchase the Shares, the fair market value of the Shares is not greater than $27 per share.

The Applicant further represents that another indication of the continued decline in the fair market value of the Shares was manifested in the private placement offering of Units in March 1995 by the Bank to individual subscribers for $10 per Unit. Each Unit consists of one share of common stock of the Bank plus one five-year warrant convertible into one share common stock for the additional consideration of $10.

4. In order to eliminate the ever increasing risk associated with the continued investment in the Shares by the Plan and to permit the Plan to distribute or otherwise invest the original value of the assets in the Plan, the Applicant on March 24, 1994, made a $300,000 cash purchase of the Shares from the Plan. The Plan incurred no expenses or commissions from the Sale. Furthermore, the Applicant represents that the Plan was able to invest the proceeds from the Sale into more liquid and income producing investments; such as, U.S. Treasury Bills, money market accounts, and publicly traded common stock.

The Applicant represents that the Plan's elimination of the risks inherent in the continued investment in the Shares by the Sale to the Applicant was in the best interests of the Plan and its participants and beneficiaries, and also served to protect the rights of the participants and beneficiaries. The Trustees of the Plan made these determinations based on their knowledge that the Bank was subject to the FRB and State examinations and resulting enforcement actions described above that presented significant risks to the Plan if it continued to hold the Shares. In addition, the Trustees were motivated to act because the Shares were providing little or no income for the Plan, plus there was little or no likelihood that there would be income received in the foreseen future by the Plan.

5. In summary, the applicant represents that the transaction satisfies the criteria for an exemption under section 408(a) of the Act because (a) the Plan received from the Applicant in a one-time transaction cash in an amount that was no less than the fair market value of the Shares on the date of the Sale; (b) the transaction enabled the Plan and its participants and beneficiaries to avoid the continuing risks associated with holding the Shares; (c) the Plan incurred no loss or expense from the Sale; (d) the Trustees have determined that the transaction was in the best interests of the Plan and its participants and beneficiaries and was protective of their rights under the Plan.

FOR FURTHER INFORMATION CONTACT: Mr. C. E. Beaver of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

Banc One Capital Corporation (Banc One) Located in Columbus, OH

[Application No. D–10046]

Proposed Exemption

Section I. Transactions

A. Effective June 2, 1995, the restrictions of sections 406(a) and 407(a) of the Act and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1) (A) through (D) of the Code shall not apply to the following transactions involving trusts and certificates evidencing interests therein:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and an employee benefit plan when the sponsor, servicer, trustee or insurer of a trust, the underwriter of the certificates representing an interest in the trust, or an obligor is a party in interest with respect to such plan;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates; and

(3) The continued holding of certificates acquired by a plan pursuant to Subsection I.A. (1) or (2).

Notwithstanding the foregoing, Section I.A. does not provide an exemption from the restrictions of sections 406(a)(1)(E), 406(a)(2) and 407 for the acquisition or holding of a certificate on behalf of an Excluded Plan by any person who has discretionary authority or renders investment advice with respect to the assets of that Excluded Plan.[11]

B. Effective June 2, 1995, the restrictions of sections 406(b)(1) and 406(b)(2) of the Act and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1)(E) of the Code shall not apply to:

(1) The direct or indirect sale, exchange or transfer of certificates in the initial issuance of certificates between the sponsor or underwriter and a plan when the person who has discretionary authority or renders investment advice with respect to the investment of plan assets in the certificates is (a) an obligor with respect to 5 percent or less of the fair market value of obligations or receivables contained in the trust, or (b) an affiliate of a person described in (a); if:

(i) The plan is not an Excluded Plan;

(ii) Solely in the case of an acquisition of certificates in connection with the initial issuance of the certificates, at least 50 percent of each class of certificates in which plans have invested is acquired by persons independent of the members of the Restricted Group and at least 50 percent of the aggregate interest in the trust is acquired by persons independent of the Restricted Group;

(iii) A plan's investment in each class of certificates does not exceed 25 percent of all of the certificates of that class outstanding at the time of the acquisition; and

(iv) Immediately after the acquisition of the certificates, no more than 25 percent of the assets of a plan with respect to which the person has discretionary authority or renders investment advice are invested in certificates representing an interest in a trust containing assets sold or serviced by the same entity.[12] For purposes of this paragraph B.(1)(iv) only, an entity will not be considered to service assets contained in a trust if it is merely a subservicer of that trust;

(2) The direct or indirect acquisition or disposition of certificates by a plan in the secondary market for such certificates, provided that the conditions

[11] Section I.A. provides no relief from sections 406(a)(1)(E), 406(a)(2) and 407 for any person rendering investment advice to an Excluded Plan within the meaning of section 3(21)(a)(ii) and regulation 29 CFR 2510.3–21(c).

[12] For purposes of this exemption, each plan participating in a commingled fund (such as a bank collective trust fund or insurance company pooled separate account) shall be considered to own the same proportionate undivided interest in each asset of the commingled fund as its proportionate interest in the total assets of the commingled fund as calculated on the most recent preceding valuation date of the fund.

set forth in paragraphs B.(1) (i), (iii) and (iv) are met; and

(3) The continued holding of certificates acquired by a plan pursuant to Subsection I.B. (1) or (2).

C. Effective June 2, 1995, the restrictions of sections 406(a), 406(b) and 407(a) of the Act, and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c) of the Code, shall not apply to transactions in connection with the servicing, management and operation of a trust, provided:

(1) Such transactions are carried out in accordance with the terms of a binding pooling and servicing arrangement; and

(2) The pooling and servicing agreement is provided to or described in all material respects in the prospectus or private placement memorandum provided to investing plans before they purchase certificates issued by the trust.[13]

Notwithstanding the foregoing, Section I.C. does not provide an exemption from the restrictions of section 406(b) of the Act or from the taxes imposed by reason of section 4975(c) of the Code for the receipt of a fee by a servicer of the trust from a person other than the trustee or sponsor, unless such fee constitutes a ''qualified administrative fee'' as defined in Section III.S.

D. Effective June 2, 1995, the restrictions of sections 406(a) and 407(a) of the Act, and the taxes imposed by sections 4975 (a) and (b) of the Code by reason of sections 4975(c)(1) (A) through (D) of the Code, shall not apply to any transactions to which those restrictions or taxes would otherwise apply merely because a person is deemed to be a party in interest or disqualified person (including a fiduciary) with respect to a plan by virtue of providing services to the plan (or by virtue of having a relationship to such service provider described in section 3(14) (F), (G), (H) or (I) of the Act or section 4975(e)(2) (F), (G), (H) or (I) of the Code), solely because of the plan's ownership of certificates.

Section II. General Conditions

A. The relief provided under Section I is available only if the following conditions are met:

(1) The acquisition of certificates by a plan is on terms (including the certificate price) that are at least as favorable to the plan as they would be in an arm's length transaction with an unrelated party;

(2) The rights and interests evidenced by the certificates are not subordinated to the rights and interests evidenced by other certificates of the same trust;

(3) The certificates acquired by the plan have received a rating at the time of such acquisition that is in one of the three highest generic rating categories from either Standard & Poor's Corporation (S&P's), Moody's Investors Service, Inc. (Moody's), Duff & Phelps Inc. (D&P) or Fitch Investors Service, Inc. (Fitch);

(4) The trustee is not an affiliate of any member of the Restricted Group. However, the trustee shall not be considered to be an affiliate of a servicer solely because the trustee has succeeded to the rights and responsibilities of the servicer pursuant to the terms of a pooling and servicing agreement providing for such succession upon the occurrence of one or more events of default by the servicer;

(5) The sum of all payments made to and retained by the underwriters in connection with the distribution or placement of certificates represents not more than reasonable compensation for underwriting or placing the certificates; the sum of all payments made to and retained by the sponsor pursuant to the assignment of obligations (or interests therein) to the trust represents not more than the fair market value of such obligations (or interests); and the sum of all payments made to and retained by the servicer represents not more than reasonable compensation for the servicer's services under the pooling and servicing agreement and reimbursement of the servicer's reasonable expenses in connection therewith; and

(6) The plan investing in such certificates is an ''accredited investor'' as defined in Rule 501(a)(1) of Regulation D of the Securities and Exchange Commission under the Securities Act of 1933.

B. Neither any underwriter, sponsor, trustee, servicer, insurer, nor any obligor, unless it or any of its affiliates has discretionary authority or renders investment advice with respect to the plan assets used by a plan to acquire certificates, shall be denied the relief provided under Section I, if the provision of Subsection II.A.(6) above is not satisfied with respect to acquisition or holding by a plan of such certificates, provided that (1) such condition is disclosed in the prospectus or private placement memorandum; and (2) in the case of a private placement of certificates, the trustee obtains a representation from each initial purchaser which is a plan that it is in compliance with such condition, and obtains a covenant from each initial purchaser to the effect that, so long as such initial purchaser (or any transferee of such initial purchaser's certificates) is required to obtain from its transferee a representation regarding compliance with the Securities Act of 1933, any such transferees will be required to make a written representation regarding compliance with the condition set forth in Subsection II.A.(6) above.

Section III. Definitions

For purposes of this exemption:

A. ''Certificate'' means:

(1) A certificate—

(a) that represents a beneficial ownership interest in the assets of a trust; and

(b) that entitles the holder to pass-through payments of principal, interest, and/or other payments made with respect to the assets of such trust; or

(2) A certificate denominated as a debt instrument—

(a) that represents an interest in a Real Estate Mortgage Investment Conduit (REMIC) within the meaning of section 860D(a) of the Internal Revenue Code of 1986; and

(b) that is issued by and is an obligation of a trust; with respect to certificates defined in (1) and (2) above for which Banc One or any of its affiliates is either (i) the sole underwriter or the manager or co-manager of the underwriting syndicate, or (ii) a selling or placement agent.

For purposes of this exemption, references to ''certificates representing an interest in a trust'' include certificates denominated as debt which are issued by a trust.

B. ''Trust'' means an investment pool, the corpus of which is held in trust and consists solely of:

(1) Either—

(a) secured consumer receivables that bear interest or are purchased at a discount (including, but not limited to, home equity loans and obligations secured by shares issued by a cooperative housing association);

(b) secured credit instruments that bear interest or are purchased at a discount in transactions by or between business entities (including, but not limited to, qualified equipment notes secured by leases, as defined in Section III.T);

(c) obligations that bear interest or are purchased at a discount and which are secured by single-family residential,

[13] In the case of a private placement memorandum, such memorandum must contain substantially the same information that would be disclosed in a prospectus if the offering of the certificates were made in a registered public offering under the Securities Act of 1933. In the Department's view, the private placement memorandum must contain sufficient information to permit plan fiduciaries to make informed investment decisions.

multi-family residential and commercial real property (including obligations secured by leasehold interests on commercial real property);

(d) obligations that bear interest or are purchased at a discount and which are secured by motor vehicles or equipment, or qualified motor vehicle leases (as defined in Section III.U);

(e) ''guaranteed governmental mortgage pool certificates,'' as defined in 29 CFR 2510.3–101(i)(2);

(f) fractional undivided interests in any of the obligations described in clauses (a)–(e) of this Section B.(1);

(2) Property which had secured any of the obligations described in Subsection B.(1);

(3) Undistributed cash or temporary investments made therewith maturing no later than the next date on which distributions are to be made to certificateholders; and

(4) Rights of the trustee under the pooling and servicing agreement, and rights under any insurance policies, third-party guarantees, contracts of suretyship and other credit support arrangements with respect to any obligations described in Subsection B.(1).

Notwithstanding the foregoing, the term ''trust'' does not include any investment pool unless: (i) The investment pool consists only of assets of the type which have been included in other investment pools, (ii) certificates evidencing interests in such other investment pools have been rated in one of the three highest generic rating categories by S&P's, Moody's, D&P, or Fitch for at least one year prior to the plan's acquisition of certificates pursuant to this exemption, and (iii) certificates evidencing interests in such other investment pools have been purchased by investors other than plans for at least one year prior to the plan's acquisition of certificates pursuant to this exemption.

C. ''Underwriter'' means:

(1) Banc One;

(2) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with Banc One; or

(3) Any member of an underwriting syndicate or selling group of which Banc One or a person described in (2) is a manager or co-manager with respect to the certificates.

D. ''Sponsor'' means the entity that organizes a trust by depositing obligations therein in exchange for certificates.

E. ''Master Servicer'' means the entity that is a party to the pooling and servicing agreement relating to trust assets and is fully responsible for servicing, directly or through subservicers, the assets of the trust.

F. ''Subservicer'' means an entity which, under the supervision of and on behalf of the master servicer, services loans contained in the trust, but is not a party to the pooling and servicing agreement.

G. ''Servicer'' means any entity which services loans contained in the trust, including the master servicer and any subservicer.

H. ''Trustee'' means the trustee of the trust, and in the case of certificates which are denominated as debt instruments, also means the trustee of the indenture trust.

I. ''Insurer'' means the insurer or guarantor of, or provider of other credit support for, a trust. Notwithstanding the foregoing, a person is not an insurer solely because it holds securities representing an interest in a trust which are of a class subordinated to certificates representing an interest in the same trust.

J. ''Obligor'' means any person, other than the insurer, that is obligated to make payments with respect to any obligation or receivable included in the trust. Where a trust contains qualified motor vehicle leases or qualified equipment notes secured by leases, ''obligor'' shall also include any owner of property subject to any lease included in the trust, or subject to any lease securing an obligation included in the trust.

K. ''Excluded Plan'' means any plan with respect to which any member of the Restricted Group is a ''plan sponsor'' within the meaning of section 3(16)(B) of the Act.

L. ''Restricted Group'' with respect to a class of certificates means:

(1) Each underwriter;

(2) Each insurer;

(3) The sponsor;

(4) The trustee;

(5) Each servicer;

(6) Any obligor with respect to obligations or receivables included in the trust constituting more than 5 percent of the aggregate unamortized principal balance of the assets in the trust, determined on the date of the initial issuance of certificates by the trust; or

(7) Any affiliate of a person described in (1)–(6) above.

M. ''Affiliate'' of another person includes:

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with such other person;

(2) Any officer, director, partner, employee, relative (as defined in section 3(15) of the Act), a brother, a sister, or a spouse of a brother or sister of such other person; and

(3) Any corporation or partnership of which such other person is an officer, director or partner.

N. ''Control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

O. A person will be ''independent'' of another person only if:

(1) Such person is not an affiliate of that other person; and

(2) The other person, or an affiliate thereof, is not a fiduciary who has investment management authority or renders investment advice with respect to any assets of such person.

P. ''Sale'' includes the entrance into a forward delivery commitment (as defined in section Q below), provided:

(1) The terms of the forward delivery commitment (including any fee paid to the investing plan) are no less favorable to the plan than they would be in an arm's length transaction with an unrelated party;

(2) The prospectus or private placement memorandum is provided to an investing plan prior to the time the plan enters into the forward delivery commitment; and

(3) At the time of the delivery, all conditions of this exemption applicable to sales are met.

Q. ''Forward delivery commitment'' means a contract for the purchase or sale of one or more certificates to be delivered at an agreed future settlement date. The term includes both mandatory contracts (which contemplate obligatory delivery and acceptance of the certificates) and optional contracts (which give one party the right but not the obligation to deliver certificates to, or demand delivery of certificates from, the other party).

R. ''Reasonable compensation'' has the same meaning as that term is defined in 29 CFR 2550.408c–2.

S. ''Qualified Administrative Fee'' means a fee which meets the following criteria:

(1) The fee is triggered by an act or failure to act by the obligor other than the normal timely payment of amounts owing in respect of the obligations;

(2) The servicer may not charge the fee absent the act or failure to act referred to in (1);

(3) The ability to charge the fee, the circumstances in which the fee may be charged, and an explanation of how the fee is calculated are set forth in the pooling and servicing agreement; and

(4) The amount paid to investors in the trust will not be reduced by the amount of any such fee waived by the servicer.

T. ''Qualified Equipment Note Secured By A Lease'' means an equipment note:

(1) Which is secured by equipment which is leased;

(2) Which is secured by the obligation of the lessee to pay rent under the equipment lease; and

(3) With respect to which the trust's security interest in the equipment is at least as protective of the rights of the trust as the trust would have if the equipment note were secured only by the equipment and not the lease.

U. ''Qualified Motor Vehicle Lease'' means a lease of a motor vehicle where:

(1) The trust holds a security interest in the lease;

(2) The trust holds a security interest in the leased motor vehicle; and

(3) The trust's security interest in the leased motor vehicle is at least as protective of the trust's rights as the trust would receive under a motor vehicle installment loan contract.

V. ''Pooling and Servicing Agreement'' means the agreement or agreements among a sponsor, a servicer and the trustee establishing a trust. In the case of certificates which are denominated as debt instruments, ''Pooling and Servicing Agreement'' also includes the indenture entered into by the trustee of the trust issuing such certificates and the indenture trustee.

W. ''Banc One'' means Banc One Capital Corporation, an Ohio corporation, and its affiliates.

The Department notes that this proposed exemption is included within the meaning of the term ''Underwriter Exemption'' as it is defined in Section V(h) of Prohibited Transaction Exemption (PTE) 95–60 (60 FR 35925, July 12, 1995), the Class Exemption for Certain Transactions Involving Insurance Company General Accounts, at 35932.

EFFECTIVE DATE: If granted, this proposed exemption will be effective for transactions occurring on or after June 2, 1995.

Summary of Facts and Representations

1. Banc One, formerly Meuse, Rinker, Chapman, Endres and Brooks, is the wholly owned, separately capitalized investment banking subsidiary of Banc One Corporation, a Columbus, Ohio-based holding company which had assets of $88.9 billion as of December 31, 1994 and operates 69 affiliate banks with 1,418 offices in 12 states. Banc One Corporation also owns and operates subsidiaries that engage in data processing, trust, brokerage, investment management, equipment leasing, mortgage banking, consumer finance and insurance.

Banc One was established in 1981 and it maintains its principal place of business in Columbus, Ohio. Banc One has branch operations located in Dallas, Milwaukee, Chicago, Indianapolis, Los Angeles, Phoenix, Louisville and Washington, D.C. As a member of the National Association of Securities Dealers, Banc One maintains a fixed income securities brokerage for the initial placement and remarketing of offerings originated by the firm as well as other issues traded in the secondary market. As of December 31, 1994, Banc One had total assets of $437,336,000.

Since 1988, Banc One has been securitizing assets ranging from mobile home loans to development lots. Its professional staff has a combined experience of working as an underwriter and financial advisor. Banc One's investment bankers have extensive experience in creating taxable and tax-exempt obligations having a wide range of structural characteristics as well as security arrangements.

Banc One represents that it has the legal authority to underwrite asset-backed securities. In an order dated July 16, 1990, the Federal Reserve Board granted Banc One the power to underwrite and deal in mortgage-backed securities and other asset-backed securities. This order is subject to the condition that Banc One does not derive more than 10 percent of its total gross revenues from such activities. In addition, Banc One's affiliates have the power to sell interests in their own assets in the form of asset-backed securities.

Trust Assets

2. Banc One seeks exemptive relief to permit plans to invest in pass-through certificates representing undivided interests in the following categories of trusts: (1) Single and multi-family residential or commercial mortgage investment trusts; [14] (2) motor vehicle receivable investment trusts; (3) consumer or commercial receivables investment trusts; and (4) guaranteed governmental mortgage pool certificate investment trusts.[15]

3. Commercial mortgage investment trusts may include mortgages on ground leases of real property. Commercial mortgages are frequently secured by ground leases on the underlying property, rather than by fee simple interests. The separation of the fee simple interest and the ground lease interest is generally done for tax reasons. Properly structured, the pledge of the ground lease to secure a mortgage provides a lender with the same level of security as would be provided by a pledge of the related fee simple interest. The terms of the ground leases pledged to secure leasehold mortgages will in all cases be at least ten years longer than the term of such mortgages.[16]

Trust Structure

4. Each trust is established under a pooling and servicing agreement between a sponsor, a servicer and a trustee. The sponsor or servicer of a trust selects assets to be included in the trust. These assets are receivables which may have been originated, in the ordinary course of business, by a sponsor or servicer of the trust, an affiliate of the sponsor or servicer, or by an unrelated lender and subsequently acquired by the trust sponsor or servicer.

On or prior to the closing date, the sponsor acquires legal title to all assets selected for the trust, establishes the trust and designates an independent entity as trustee. On the closing date, the sponsor conveys to the trust legal title to the assets and the trustee issues certificates representing fractional undivided interests in the trust assets. Banc One, or one or more broker-dealers (which may include Banc One), acts as underwriter or placement agent with respect to the sale of the certificates. All of the public offerings of certificates presently contemplated have been or are to be underwritten by Banc One on a firm commitment basis. In addition, Banc One anticipates privately placing certificates on both a firm commitment

[14] The Department notes that PTE 83–1 (48 FR 895, January 7, 1983), a class exemption for mortgage pool investment trusts, would generally apply to trusts containing single-family residential mortgages, provided that the applicable conditions of PTE 83–1 are met. Banc One and its affiliates request relief for single-family residential mortgages in this exemption because it would prefer one exemption for all trusts of similar structure. However, Banc One has stated that it may still avail itself of the exemptive relief provided by PTE 83–1.

[15] Guaranteed governmental mortgage pool certificates are mortgage-backed securities with respect to which interest and principal payable is guaranteed by the Government National Mortgage Association, the Federal Home Loan Mortgage Corporation, or the Federal National Mortgage Association. The Department's regulation relating to the definition of plan assets (29 CFR 2510.3–101(i)) provides that where a plan acquires a guaranteed governmental mortgage pool certificate, the plan's assets include the certificate and all of its rights with respect to such certificate under applicable law, but do not, solely by reason of the plan's holding of such certificate, include any of the mortgages underlying such certificate. The applicant is requesting exemptive relief for trusts containing guaranteed governmental mortgage pool certificates because the certificates in the trusts may be plan assets.

[16] Trust assets may also include obligations that are secured by leasehold interests on residential real property. See PTE 90–32 involving Prudential-Bache Securities, Inc. (55 FR 23147, June 6, 1990 at 23150).

and an agency basis. Banc One may also act as the lead underwriter for a syndicate of securities underwriters.

Certificateholders are entitled to receive monthly, quarterly or semi-annual installments of principal and/or interest or lease payments due on the receivables, adjusted, in the case of payments of interest, to a specified rate—the pass-through rate—which may be fixed or variable.

5. Some of the certificates will be multi-class certificates. Banc One requests exemptive relief for two types of multi-class certificates: ''strip'' certificates and ''fast-pay/ slow-pay'' certificates. Strip certificates are a type of security in which the stream of interest payments on receivables is split from the flow of principal payments and separate classes of certificates are established, each representing rights to disproportionate payments of principal and interest.[17]

''Fast-pay/slow-pay'' certificates involve the issuance of classes of certificates having different stated maturities or the same maturities with different payment schedules. Interest and/or principal payments received on the underlying receivables are distributed first to the class of certificates having the earliest stated maturity of principal, and/or earlier payment schedule, and only when that class of certificates have been paid in full (or has received a specified amount) will distributions be made with respect to the second class of certificates. Distributions on certificates having later stated maturities will proceed in like manner until all the certificateholders have been paid in full. The only difference between this multi-class pass-through arrangement and a single-class pass-through arrangement is the order in which distributions are made to certificateholders. In each case, certificateholders will have a beneficial ownership interest in the underlying assets. In neither case will the rights of a plan purchasing a certificate be subordinated to the rights of another certificateholder in the event of default on any of the underlying obligations. In particular, if the amount available for distribution to certificateholders is less than the amount required to be so distributed, all senior certificateholders then entitled to receive distributions will share in the amount distributed on a *pro rata* basis.[18]

6. For tax reasons, the trust must be maintained as an essentially passive entity. Therefore, both the sponsor's discretion and the servicer's discretion with respect to assets included in a trust are severely limited. Pooling and servicing agreements provide for the substitution of receivables by the sponsor only in the event of defects in documentation discovered within a short time after the issuance of trust certificates (within 120 days, except in the case of obligations having an original term of 30 years, in which case the period will not exceed two years). Any receivable so substituted is required to have characteristics substantially similar to the replaced receivable and will be at least as creditworthy as the replaced receivable.

In some cases, the affected receivable would be repurchased, with the purchase price applied as a payment on the affected receivable and passed through to certificateholders.

Parties to Transactions

7. The originator of a receivable is the entity that initially lends money to a borrower (obligor), such as a home owner or automobile purchaser, or leases property to the lessee. The originator may either retain a receivable in its portfolio or sell it to a purchaser, such as a trust sponsor.

Originators of receivables included in the trusts will be entities that originate receivables in the ordinary course of their business, including finance companies for whom such origination constitutes the bulk of their operations, financial institutions for whom such origination constitutes a substantial part of their operations, and any kind of manufacturer, merchant, or service enterprise for whom such origination is an incidental part of its operations. Each trust may contain assets of one or more originators. The originator of the receivables may also function as the trust sponsor or servicer.

8. The sponsor of a trust will be one of three entities: (i) a special-purpose corporation unaffiliated with the servicer, (ii) a special-purpose or other corporation affiliated with the servicer, or (iii) the servicer itself. Where the sponsor is not also the servicer, the sponsor's role will generally be limited to acquiring the receivables to be included in the trust, establishing the trust, designating the trustee and assigning the receivables to the trust.

9. The trustee of a trust is the legal owner of the obligations in the trust. The trustee is also a party to or beneficiary of all the documents and instruments deposited in the trust, and as such, is responsible for enforcing all the rights created thereby in favor of certificateholders.

The trustee will be an independent entity, and therefore, will be unrelated to Banc One, the trust sponsor or the servicer. Banc One represents that the trustee will be a substantial financial institution or trust company experienced in trust activities. The trustee receives a fee for its services which will be paid by the servicer, sponsor or the trust as specified in the pooling and servicing agreement. The method of compensating the trustee will be specified in the pooling and servicing agreement and disclosed in the prospectus or private placement memorandum relating to the offering of the certificates.

10. The servicer of a trust administers the receivables on behalf of the certificateholders. The servicer's functions typically involve, among other things, notifying borrowers of amounts due on receivables, maintaining records of payments received on receivables and instituting foreclosure or similar proceedings in the event of default. In cases where a pool of receivables has been purchased from a number of different originators and deposited in a trust, it is common for the receivables to be ''subserviced'' by their respective originators and for a single entity to ''master service'' the pool of receivables on behalf of the owners of the related series of certificates. Where this arrangement is adopted, a receivable continues to be serviced from the perspective of the borrower by the local subservicer, while the investor's perspective is that the entire pool of receivables is serviced by a single, central master servicer who collects payments from the local subservicers and passes them through to certificateholders.

Receivables of the type suitable for inclusion in a trust invariably are serviced with the assistance of a computer. After the sale, the servicer keeps the sold receivables on the computer system in order to continue monitoring the accounts. Although the records relating to sold receivables are kept in the same master file as receivables retained by the originator, the sold receivables are flagged as

[17] It is the Department's understanding that where a plan invests in REMIC ''residual'' interest certificates to which this exemption applies, some of the income received by the plan as a result of such investment may be considered unrelated business taxable income to the plan, which is subject to income tax under the Code. The Department emphasizes that the prudence requirement of section 404(a)(l)(B) of the Act would require plan fiduciaries to carefully consider this and other tax consequences prior to causing plan assets to be invested in certificates pursuant to this exemption.

[18] If a trust issues subordinated certificates, holders of such subordinated certificates may not share in the amount distributed on a *pro rata* basis with the senior certificateholders. The Department notes that the exemption does not provide relief for plan investment in such subordinated certificates.

having been sold. To protect the investor's interest, the servicer ordinarily covenants that this ''sold flag'' will be included in all records relating to the sold receivables, including the master file, archives, tape extracts and printouts.

The sold flags are invisible to the obligor and do not affect the manner in which the servicer performs the billing, posting and collection procedures relating to the sold receivables. However, the servicer uses the sold flag to identify the receivables for the purposes of reporting all activity on those receivables after their sale to the investors.

Depending on the type of receivable and the details of the servicer's computer system, in some cases, the servicer's internal reports can be adapted for investor reporting with little or no modification. In other cases, the servicer may have to perform special calculations to fulfill the investor reporting responsibilities. These calculations can be performed on the servicer's main computer or on a small computer with data supplied by the main system. In all cases, the numbers produced for the investor are reconciled to the servicer's books and reviewed by public accountants.

The underwriter will be a registered broker-dealer that acts as underwriter or placement agent with respect to the sale of the certificates. Public offerings of certificates are generally made on a firm commitment basis. Private placements of certificates may be made on a firm commitment or agency basis. It is anticipated that the lead or co-managing underwriter will make a market in certificates offered to the public.

In some cases, the originator and servicer of receivables to be included in a trust and the sponsor of the trust (though they themselves may be related) will be unrelated to Banc One. However, affiliates of Banc One may originate or service receivables included in a trust or they may sponsor a trust.

Certificate Price, Pass-Through Rate and Fees

11. In some cases, the sponsor will obtain the receivables from various originators pursuant to existing contracts with such originators under which the sponsor continually buys receivables. In other cases, the sponsor will purchase the receivables at fair market value from the originator or the finance company pursuant to a purchase and sale agreement related to the specific offering of certificates. In other cases, the sponsor will originate the receivables, itself.

As compensation for the receivables transferred to the trust, the sponsor receives cash or certificates representing the entire beneficial interest in the trust. The sponsor sells some or all of these certificates for cash to investors or securities underwriters.

12. The price of the certificates, both in the initial offering and in the secondary market, is affected by market forces, including investor demand, the pass-through interest rate on the certificates in relation to the rate payable on investments of similar types and quality, expectations as to the effect on yield resulting from prepayment of underlying receivables and expectations as to the likelihood of timely payment.

The pass-through rate for certificates is equal to the interest rate on receivables included in the trust minus a specified servicing fee.[19] This rate is generally determined by the same market forces that determine the price of a certificate. The price of a certificate and its pass-through, or coupon rate, together determine the yield to investors. If an investor purchases a certificate at less than par, that discount augments the stated pass-through rate; conversely, a certificate purchased at a premium yields less than the stated coupon.

13. As compensation for performing its servicing duties, the servicer (who may also be the sponsor or an affiliate thereof, and receive fees for acting as sponsor) will retain the difference between payments received on the receivables in the trust and payments payable (at the pass-through rate) to certificateholders, except that in some cases, a portion of the payments on receivables may be paid to a third party, such as a fee paid to a provider of credit support. The servicer may receive additional compensation by having the use of the amounts paid on the receivables between the time they are received by the servicer and the time they are due to the trust (which time is set forth in the pooling and servicing agreement). Typically, the servicer will be required to pay the administrative expenses of servicing the trust, including, in some cases, the trustee's fee, out of its servicing compensation.

The servicer is also compensated to the extent it may provide credit enhancement to the trust or otherwise arrange to obtain credit support from another party. This ''credit support fee'' may be aggregated with other servicing fees, and is either paid in a lump sum at the time the trust is established, or on the receivables in excess of the pass-through rate.

14. The servicer may be entitled to retain certain administrative fees paid by a third party, usually the obligor. These administrative fees fall into three categories: (a) Prepayment fees; (b) late payment and payment extension fees; and (c) expenses, fees and charges associated with foreclosure or repossession or other conversion of a secured position into cash proceeds upon default of an obligation.

Compensation payable to the servicer will be set forth or referred to in the pooling and servicing agreement and described in reasonable detail in the prospectus or private placement memorandum relating to the certificates.

15. Payments on receivables may be made by obligors to the servicer at various times during the period preceding any date on which pass-through payments to the trust are due. In some cases, the pooling and servicing agreement may permit the servicer to place these payments in non-interest bearing accounts in itself or to commingle such payments with its own funds prior to the distribution dates. In these cases, the servicer would be entitled to the benefit derived from the use of the funds between the date of payment on a receivable and the pass-through date. Commingled payments may not be protected from the creditors of the servicer in the event of the servicer's bankruptcy or receivership. In those instances when payments on receivables are held in non-interest bearing accounts or are commingled with the servicer's own funds, the servicer is required to deposit these payments by a date specified in the pooling and servicing agreement into an account from which the trustee makes payments to certificateholders.

16. The underwriter will receive a fee in connection with the securities underwriting or private placement of certificates. In a firm commitment underwriting, this fee would normally consist of the difference between what the underwriter receives for the certificates that it distributes and what it pays the sponsor for those certificates. In a private placement, the fee normally takes the form of an agency commission paid by the sponsor. In a best efforts underwriting in which the underwriter would sell certificates in a public offering on an agency basis, the underwriter would receive an agency commission rather than a fee based on the difference between the price at which the certificates are sold to the public and what it pays the sponsor. In some private placements, the

[19] The pass-through rate on certificates representing interests in trusts holding leases is determined by breaking down lease payments into ''principal'' and ''interest'' components based on an implicit interest rate.

underwriter may buy certificates as principal, in which case, its compensation would be the difference between what it receives for the certificates that it sells and what it pays the sponsor for these certificates.

Purchase of Receivables by the Servicer

17. As the principal amount of the receivables in a trust is reduced by payments, the cost of administering the trust generally increases, making the servicing of the trust prohibitively expensive at some point. Consequently, the pooling and servicing agreement generally provides that the servicer may purchase the receivables remaining in the trust when the aggregate unpaid balance payable on the receivables is reduced to a specified percentage (usually 5 to 10 percent) of the initial aggregate unpaid balance.

The repurchase price for such an option is set at a level such that the certificateholders will receive the full amount on all of the receivables held by the trust plus the full amount of property, if any, that has been acquired by the trust through collections on or liquidations of the receivables.

Certificate Ratings

18. The certificates will have received one of the three highest ratings available from either S&P's, Moody's, D&P or Fitch. Insurance or other credit support (such as overcollateralization, surety bonds, letters of credit or guarantees) will be obtained by the trust sponsor to the extent necessary for the certificates to attain the desired rating. The amount of this credit support is set by the rating agencies at a level that is a multiple of the worst historical net credit loss experience for the type of obligations included in the issuing trust.

Provision of Credit Support

19. In some cases, the master servicer or an affiliate of the master servicer may provide credit support to the trust (i.e., act as an insurer). In these cases, the master servicer, in its capacity as servicer, will first advance funds to the full extent that it determines that such advances will be recoverable (a) out of late payments by the obligors, (b) from the credit support provider (which may be itself), or, (c) in the case of a trust that issues subordinated certificates, from amounts otherwise distributable to holders of subordinated certificates, and the master servicer will advance such funds in a timely manner. In some transactions, the master servicer may not be obligated to advance funds, but instead, would be called upon to provide funds to cover defaulted payments to the full extent of its obligations as insurer. Moreover, a master servicer typically can recover advances either from the provider of credit support from the future payment stream. When the servicer is the provider of the credit support and provides its own funds to cover defaulted payments, it will do so either on the initiative of the trustee, or on its own initiative on behalf of the trustee, but in either event it will provide such funds to cover payments to the full extent of its obligations under the credit support mechanism.

If the master servicer fails to advance funds, fails to call upon the credit support mechanism to provide funds to cover defaulted payments or otherwise fails in its duties, the trustee would be required and would be able to enforce the certificateholders' rights, as both a party to the pooling and servicing agreement and the owner of the trust estate, including rights under the credit support mechanism. Therefore, the trustee, who is independent of the servicer, will have the ultimate right to enforce the credit support arrangement.

When a master servicer advances funds, the amount so advanced is recoverable by the servicer out of future payments on receivables held by the trust to the extent not covered by credit support. However, where the master servicer provides credit support to the trust, there are protections in place to guard against a delay in calling upon the credit support to take advantage of the fact that the credit support declines proportionally with the decrease in the principal amount of the obligations in the trust as payments on receivables are passed through to investors. These safeguards include:

(a) There is often a disincentive to postponing credit losses because the sooner repossession or foreclosure activities are commenced, the more value that can be realized on the security for the obligation;

(b) The master servicer has servicing guidelines which include a general policy as to the allowable delinquency period after which an obligation ordinarily will be deemed uncollectible. The pooling and servicing agreement will require the master servicer to follow its normal servicing guidelines and will set forth the master servicer's general policy as to the period of time after which delinquent obligations ordinarily will be considered uncollectible;

(c) As frequently as payments are due on the receivables included in the trust (monthly, quarterly or semi-annually, as set forth in the pooling and servicing agreement), the master servicer is required to report to the independent trustee the amount of all past-due payments and the amount of all servicer advances, along with other current information as to collections on the receivables and draws upon the credit support. Further, the master servicer is required to deliver to the trustee annually a certificate of an executive officer of the master servicer stating that a review of the servicing activities has been made under such officer's supervision, and either stating that the master servicer has fulfilled all of its obligations under the pooling and servicing agreement or, if the master servicer has defaulted under any of its obligations, specifying any such default. The master servicer's reports are reviewed at least annually by independent accountants to ensure that the master servicer is following its normal servicing standards and that the master servicer's reports conform to the master servicer's internal accounting records. The results of the independent accountants' review are delivered to the trustee; and

(d) The credit support has a ''floor'' dollar amount that protects investors against the possibility that a large number of credit losses might occur towards the end of the life of the trust, whether due to servicer advances or any other cause. Once the floor amount has been reached, the master servicer lacks an incentive to postpone the recognition of credit losses because the credit support amount becomes a fixed dollar amount, subject to reduction only for actual draws. From the time that the floor amount is effective until the end of the life of the trust, there are no proportionate reductions in the credit support amount caused by reductions in the pool principal balance. Indeed, since the floor is a fixed dollar amount, the amount of credit support ordinarily increases as a percentage of the pool principal balance during the period that the floor is in effect.

Disclosure

20. In connection with the original issuance of certificates, the prospectus or private placement memorandum will be furnished to investing plans. The prospectus or private placement memorandum will contain information material to a fiduciary's decision to invest in the certificates, including:

(a) Information concerning the payment terms of the certificates, the rating of the certificates, and any material risk factors with respect to the certificates;

(b) A description of the trust as a legal entity and a description of how the trust was formed by the seller/servicer or other sponsor of the transaction;

(c) Identification of the independent trustee for the trust;

(d) A description of the receivables contained in the trust, including the types of receivables, the diversification of the receivables, their principal terms and their material legal aspects;

(e) A description of the sponsor and servicer;

(f) A description of the pooling and servicing agreement, including a description of the seller's principal representations and warranties as to the trust assets and the trustee's remedy for any breach thereof; a description of the procedures for collection of payments on receivables and for making distributions to investors, and a description of the accounts into which such payments are deposited and from which such distributions are made; identification of the servicing compensation and any fees for credit enhancement that are deducted from payments on receivables before distributions are made to investors; a description of periodic statements provided to the trustee, and provided to or made available to investors by the trustee; and a description of the events that constitute events of default under the pooling and servicing contract and a description of the trustee's and the investors' remedies incident thereto;

(g) A description of the credit support;

(h) A general discussion of the principal federal income tax consequences of the purchase, ownership and disposition of the pass-through securities by a typical investor;

(i) A description of the underwriters' plan for distributing the pass-through securities to investors; and

(j) Information about the scope and nature of the secondary market, if any, for the certificates.

21. Reports indicating the amount of payments of principal and interest are provided to certificateholders at least as frequently as distributions are made to certificateholders. Certificateholders will also be provided with periodic information statements setting forth material information concerning the underlying assets, including, where applicable, information as to the amount and number of delinquent and defaulted loans or receivables.

22. In the case of a trust that offers and sells certificates in a registered public offering, the trustee, the servicer or the sponsor will file such periodic reports as may be required to be filed under the Securities Exchange Act of 1934. Although some trusts that offer certificates in a public offering will file quarterly reports on Form 10–Q and Annual Reports on Form 10–K, many trusts obtain, by application to the Securities and Exchange Commission, a complete exemption from the requirement to file quarterly reports on Form 10–Q and a modification of the disclosure requirements for annual reports on Form 10–K. If such an exemption is obtained, these trusts normally would continue to have the obligation to file current reports on Form 8–K to report material developments concerning the trust and the certificates. While the Securities and Exchange Commission's interpretation of the periodic reporting requirements is subject to change, periodic reports concerning a trust will be filed to the extent required under the Securities Exchange Act of 1934.

23. At or about the time distributions are made to certificateholders, a report will be delivered to the trustee as to the status of the trust and its assets, including underlying obligations. Such report will typically contain information regarding the trust's assets, payments received or collected by the servicer, the amount of prepayments, delinquencies, servicer advances, defaults and foreclosures, the amount of any payments made pursuant to any credit support, and the amount of compensation payable to the servicer. Such report also will be delivered to or made available to the rating agency or agencies that have rated the trust's certificates.

In addition, promptly after each distribution date, certificateholders will receive a statement prepared by the trustee summarizing information regarding the trust and its assets. Such statement will include information regarding the trust and its assets, including underlying receivables. Such statement will typically contain information regarding payments and prepayments, delinquencies, the remaining amount of the guaranty or other credit support and a breakdown of payments between principal and interest.

Forward Delivery Commitments

24. To date, Banc One has not entered into any forward delivery commitments in connection with the offering of pass-through certificates. However, Banc One may contemplate entering into such commitments. The utility of forward delivery commitments has been recognized with respect to the offering of similar certificates backed by pools of residential mortgages. As such, Banc One may find it desirable in the future to enter into such commitments for the purchase of certificates.

Secondary Market Transactions

25. It is Banc One's normal policy to attempt to make a market for securities for which it is lead or co-managing underwriter. Banc One anticipates that it will make a market in certificates.

Retroactive Relief

26. Banc One represents that it has not engaged in transactions related to mortgage-backed and asset-backed securities based on the assumption that retroactive relief would be granted prior to the date of this application. However, Banc One requests the exemptive relief granted to be retroactive to June 2, 1995, the date of this application, and would like to rely on such retroactive relief for transactions entered into prior to the date exemptive relief may be granted.

Summary

27. In summary, Banc One represents that the transactions for which exemptive relief is requested satisfy the statutory criteria of section 408(a) of the Act due to the following:

(a) The trusts contain ''fixed pools'' of assets. There is little discretion on the part of the trust sponsor to substitute receivables contained in the trust once the trust has been formed;

(b) Certificates in which plans invest will have been rated in one of the three highest rating categories by S&P's, Moody's, D&P or Fitch. Credit support will be obtained to the extent necessary to attain the desired rating;

(c) All transactions for which Banc One seeks exemptive relief will be governed by the pooling and servicing agreement, which is made available to plan fiduciaries for their review prior to the plan's investment in certificates;

(d) Exemptive relief from sections 406(b) and 407 for sales to plans is substantially limited; and

(e) Banc One anticipates that it will make a secondary market in certificates.

Discussion of Proposed Exemption

I. Differences Between Proposed Exemption and Class Exemption PTE 83–1

The exemptive relief proposed herein is similar to that provided in PTE 81–7 (46 FR 7520, January 23, 1981), Class Exemption for Certain Transactions Involving Mortgage Pool Investment Trusts, amended and restated as PTE 83–1 (48 FR 895, January 7, 1983).

PTE 83–1 applies to mortgage pool investment trusts consisting of interest-bearing obligations secured by first or second mortgages or deeds of trust on single-family residential property. The exemption provides relief from sections 406(a) and 407 for the sale, exchange or

transfer in the initial issuance of mortgage pool certificates between the trust sponsor and a plan, when the sponsor, trustee or insurer of the trust is a party-in-interest with respect to the plan, and the continued holding of such certificates, provided that the conditions set forth in the exemption are met. PTE 83–1 also provides exemptive relief from section 406 (b)(1) and (b)(2) of the Act for the above-described transactions when the sponsor, trustee or insurer of the trust is a fiduciary with respect to the plan assets invested in such certificates, provided that additional conditions set forth in the exemption are met. In particular, section 406(b) relief is conditioned upon the approval of the transaction by an independent fiduciary. Moreover, the total value of certificates purchased by a plan must not exceed 25 percent of the amount of the issue, and at least 50 percent of the aggregate amount of the issue must be acquired by persons independent of the trust sponsor, trustee or insurer. Finally, PTE 83–1 provides conditional exemptive relief from section 406(a) and (b) of the Act for transactions in connection with the servicing and operation of the mortgage trust.

Under PTE 83–1, exemptive relief for the above transactions is conditioned upon the sponsor and the trustee of the mortgage trust maintaining a system for insuring or otherwise protecting the pooled mortgage loans and the property securing such loans, and for indemnifying certificateholders against reductions in pass-through payments due to defaults in loan payments or property damage. This system must provide such protection and indemnification up to an amount not less than the greater of one percent of the aggregate principal balance of all trust mortgages or the principal balance of the largest mortgage.

The exemptive relief proposed herein differs from that provided by PTE 83–1 in the following major respects: (a) The proposed exemption provides individual exemptive relief rather than class relief; (b) the proposed exemption covers transactions involving trusts containing a broader range of assets than single-family residential mortgages; (c) instead of requiring a system for insuring the pooled receivables, the proposed exemption conditions relief upon the certificates having received one of the three highest ratings available from S&P's, Moody's, D&P or Fitch (insurance or other credit support would be obtained only to the extent necessary for the certificates to attain the desired rating); and (d) the proposed exemption provides more limited section 406(b) and section 407 relief for sales transactions.

II. Ratings of Certificates

After consideration of the representations of the applicant and information provided by S&P's, Moody's, D&P and Fitch, the Department has decided to condition exemptive relief upon the certificates having attained a rating in one of the three highest generic rating categories from S&P's, Moody's, D&P or Fitch. The Department believes that the rating condition will permit the applicant flexibility in structuring trusts containing a variety of mortgages and other receivables while ensuring that the interests of plans investing in certificates are protected. The Department also believes that the ratings are indicative of the relative safety of investments in trusts containing secured receivables. The Department is conditioning the proposed exemptive relief upon each particular type of asset-backed security having been rated in one of the three highest rating categories for at least one year and having been sold to investors other than plans for at least one year.[20]

III. Limited Section 406(b) and Section 407(a) Relief for Sales

Banc One represents that in some cases a trust sponsor, trustee, servicer, insurer, and obligor with respect to receivables contained in a trust, or an underwriter of certificates may be a pre-existing party in interest with respect to an investing plan.[21] In these cases, a direct or indirect sale of certificates by that party in interest to the plan would be a prohibited sale or exchange of property under section 406(a)(1)(A) of the Act.[22] Likewise, issues are raised under section 406(a)(1)(D) of the Act where a plan fiduciary causes a plan to purchase certificates where trust funds will be used to benefit a party in interest.

Additionally, Banc One represents that a trust sponsor, servicer, trustee, insurer, and obligor with respect to receivables contained in a trust, or an underwriter of certificates representing an interest in a trust may be a fiduciary with respect to an investing plan. Banc One represents that the exercise of fiduciary authority by any of these parties to cause the plan to invest in certificates representing an interest in the trust would violate section 406(b)(1), and in some cases section 406(b)(2), of the Act.

Moreover, Banc One represents that to the extent there is a plan asset ''look through'' to the underlying assets of a trust, the investment in certificates by a plan covering employees of an obligor under receivables contained in a trust may be prohibited by sections 406(a) and 407(a) of the Act.

After consideration of the issues involved, the Department has determined to provide the limited sections 406(b) and 407(a) relief as specified in the proposed exemption.

Notice to Interested Persons

The applicant represents that because those potentially interested participants and beneficiaries cannot all be identified, the only practical means of notifying such participants and beneficiaries of this proposed exemption is by the publication of this notice in the **Federal Register**. Comments and requests for a hearing must be received by the Department not later than 30 days from the date of publication of this notice of proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other

[20] In referring to different ''types'' of asset-backed securities, the Department means certificates representing interests in trusts containing different ''types'' of receivables, such as single family residential mortgages, multi-family residential mortgages, commercial mortgages, home equity loans, auto loan receivables, installment obligations for consumer durables secured by purchase money security interests, etc. The Department intends this condition to require that certificates in which a plan invests are of the type that have been rated (in one of the three highest generic rating categories by S&P's, D&P, Fitch or Moody's) and purchased by investors other than plans for at least one year prior to the plan's investment pursuant to the proposed exemption. In this regard, the Department does not intend to require that the particular assets contained in a trust must have been ''seasoned'' (e.g., originated at least one year prior to the plan's investment in the trust).

[21] In this regard, we note that the exemptive relief proposed herein is limited to certificates with respect to which Banc One or any of its affiliates is either (a) the sole underwriter or manager or co-manager of the underwriting syndicate, or (b) a selling or placement agent.

[22] The applicant represents that where a trust sponsor is an affiliate of Banc One, sales to plans by the sponsor may be exempt under PTE 75–1, Part II (relating to purchases and sales of securities by broker-dealers and their affiliates), if Banc One is not a fiduciary with respect to plan assets to be invested in certificates.

provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete and accurately describe all material terms of the transaction which is the subject of the exemption. In the case of continuing exemption transactions, if any of the material facts or representations described in the application change after the exemption is granted, the exemption will cease to apply as of the date of such change. In the event of any such change, application for a new exemption may be made to the Department.

Signed at Washington, DC, this 7th day of August, 1995.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 95–19871 Filed 8–10–95; 8:45 am]

BILLING CODE 4510–29–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–26351]

Filings Under the Public Utility Holding Company Act of 1935, as amended (''Act'')

August 4, 1995.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by August 28, 1995, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

The Columbia Gas System, Inc. (70–8659)

The Columbia Gas System, Inc. (''Columbia''), 20 Montchanin Road, Wilmington, Delaware 19807, a registered holding company, has filed an application-declaration under sections 6(a), 7, 9(a) and 10 of the Act.

Columbia seeks authority to enter into interest rate hedge transactions to limit its exposure to a potential rise in long-term interest rates from now until the interest rates on its long-term debt are fixed upon its emergence from bankruptcy. Columbia's interest rate exposure is due to a projected fixed rate debt issuance of approximately $2.1 billion to fund Columbia's proposed plan or reorganization (''Columbia Plan''). An application by Columbia to issue this debt was filed on May 7, 1995 (File No. 70–8627) and is currently pending.

Among other things, the Columbia Plan contemplates the issuance of up to $2.1 billion in debentures (the ''New Indenture Securities'') to be issued under a new form of indenture on the date the Columbia Plan becomes effective (the ''Effective Date''), currently anticipated to be December 31, 1995. The New Indenture Securities are to be issued in seven series, each series bearing a maturity that will range from approximately 5 to thirty years. The principal amount of each series will be substantially the same as that of each other series; provided, however, that no series other than series A will have an initial principal amount that is more than 150% of that of any other series. The rate of interest to be borne by the New Indenture Securities of each series will be determined prior to the Effective Date based on market rates for securities of similar maturities and debt rating and in accordance with the pricing methodology set forth in the Columbia Plan.

Recent declines in long-term interest rates permit Columbia to lock in historically attractive interest rates on its New Indenture Securities. To take advantage of these rates, Columbia requests authorization to enter into certain interest rate hedging transactions prior to the issuance of the New Indenture Securities. These transactions include any or all of the following: (i) A sale of exchange-traded U.S. Treasury futures contracts, a forward sale of U.S. Treasury securities and/or a forward interest rate swap, (ii) the purchase of put options on U.S. Treasury securities (each a ''Put Options Purchase''), (iii) a Put Options Purchase in combination with the sale of call options on U.S. Treasury securities, or (iv) some combination of the above. These transactions may be executed on the Chicago Board of Trade (''CBOT'') with brokers through the opening of futures and/or options positions traded on the CBOT, the opening of over-the-counter positions with one or more counterparties or a combination of the two.

In a sale of exchange-traded U.S. Treasury futures contracts or in a forward sale of U.S. Treasury securities, Columbia would ''lock-in'' the U.S. Treasury security component of the New Indenture Securities at the then current Treasury forward yield by selling U.S. Treasury futures and/or by selling spot U.S. Treasury securities forward. Columbia would then reverse its short positions on or around the Effective Date by purchasing the U.S. Treasury futures contracts and/or U.S. Treasury securities previously sold.

In a forward swap, Columbia would agree to enter into a fixed-to-floating rate swap for a period equal to the maturity of the series of New Indenture Securities being hedged, as of a future settlement date. The future settlement date will be on or around the Effective Date. In the swap agreement, Columbia would contract to pay a fixed rate and received floating-rate payments. On or about the Effective Date, Columbia would unwind the swap by entering into a floating-to-fixed rate swap for a notional amount equal to that of the swap being unwound.

Any gains resulting from interest rate rises in closing the forward sale or sale of Treasury futures or in unwinding the swap would be offset ratably over the life of the New Indenture Securities being hedged by the higher financing cost of such securities. Any losses resulting from interest rate drops in closing such hedging transactions would be offset ratably over the life of the New Indenture Securities being hedged by the lower financing cost of such securities.

Using a Put Options Purchase strategy, Columbia would buy the right, but not the obligation, to sell U.S. Treasury securities forward at a predetermined price or yield. A Put Options Purchase would protect Columbia from a rise in U.S. Treasury rates and would permit Columbia to benefit from a decline in U.S. Treasury rates. To purchase this right, Columbia would be required to pay an up-front option premium.

Columbia additionally requests approval to sell call options on U.S. Treasury securities to earn premiums that would offset the cost of a Put Options Purchase. Columbia would buy the right to sell U.S. Treasury securities forward at a predetermined price and yield (through a put option purchase), and would sell the right to buy the same U.S. Treasury securities forward at a higher predetermined price and lower yield. The premiums paid for the put options would be paid for by the premiums received on the call options that are sold.

Alabama Power Company (70–8661)

Alabama Power Company (''Alabama''), 600 North 18th Street, Birmingham, Alabama 35291, an electric utility subsidiary of The Southern Company, a registered holding company, has filed an application-declaration pursuant to sections 6(a), 7, 9(a) and 10 of the Act and rule 54 thereunder.

Alabama entered into Installment Sale Agreements and supplements thereto (''Agreements'') with the Industrial Development Boards of various cities within the State of Alabama (''Boards'') to finance and refinance certain pollution control facilities at Alabama's plants located in or near such cities (''Projects''). Pursuant to the Agreements, the Boards purchased the then existing portions of the Projects, undertook to complete their construction and to sell the completed Projects to Alabama for a purchase price payable in semi-annual installments over a term of years.

Each Board issued its Series A pollution control revenue bonds (''Original Bonds''), and, in certain cases, subsequent series of pollution control revenue bonds (''Additional Bonds'') pursuant to various trust indentures and supplements thereto (''Indentures''), in various amounts, then estimated to be sufficient to cover the cost of construction of the Projects. To secure its obligations under the Agreements, Alabama granted to certain Boards a security interest in the Board's Project subordinate to the lien of the Indenture dated as of January 1, 1942, between Alabama and Chemical Bank, as Trustee, as supplemented and amended (''First Mortgage Indenture''). In other instances, Alabama issued and pledged bonds under the First Mortgage Indenture (''Mortgage'') (''Collateral First Mortgage Bonds'') as security for its obligations under the Agreements. Each Board assigned all its right, title and interest in the Agreement, including either the Collateral First Mortgage Bonds or the subordinate security interest, to the trustee under the Indenture (''Revenue Bond Trustee'') as security for the pollution control revenue bonds, including the Original Bonds and Additional Bonds to be issued under such Indenture.

The proceeds of the sale of the Original Bonds and the Additional Bonds were deposited by the Board with the Revenue Bond Trustee. The proceeds have been applied to payment of the cost of construction of the Projects. The total cost of construction of one or more of the Projects may exceed the proceeds of the Original Bonds and the Additional Bonds. Additionally, it may be necessary or appropriate to refund one of more series of such bonds.

Consequently, Alabama proposes to request that the appropriate Board or Boards issue up to an aggregate of $500 million principal amount of revenue bonds (''New Bonds'') through December 31, 2000. Upon issuance of the New Bonds, Alabama and the Board will execute and deliver to the Revenue Bond Trustee, as required by the Indenture, a supplement to the Agreement (''Supplemental Agreement'') providing for: (1) Any required revision to assure that the semi-annual purchase price payments will be sufficient (together with other moneys held by the Revenue Bond Trustee under the Indenture for that purpose) to pay the principal of, premium (if any), and interest on the New Bonds as they become due and payable; and (2) the payment of all expenses and costs incurred or to be incurred by virtue of the issuance of the new Bonds. The Board and the Revenue Bond Trustee will enter into a supplement (''Supplement'') to the Indenture providing for the New Bonds. The Supplement will provide for redemption provisions for the New Bonds comparable to those provided for the Original Bonds and the Additional Bonds.

It is proposed that the New Bonds will mature not more than 40 years from the first day of the month in which they are initially issued. The New Bonds may be entitled to the benefit of serial maturities and/or a mandatory redemption sinking fund calculated to retire a portion of the New Bonds prior to maturity.

The effective cost to Alabama of any series of the New Bonds will not exceed the yield on U.S. Treasury securities having a maturity comparable to that of such series of New Bonds. Such effective cost will reflect the applicable interest rate or rates and any underwriters' discount or commission.

The premium (if any) payable upon the redemption of any New Bonds at the option of Alabama will not exceed the greater of: (1) 5% of the principal amount of the New Bonds so to be redeemed; or (2) a percentage of such principal amount equal to the rate of interest per annum borne by the New Bonds.

The Supplement may give the holders of the related New Bonds the right, during such time, if any, as such New Bonds bear interest at a fluctuating rate, to require Alabama to purchase such New Bonds from time to time, and arrangements may be made for the remarketing of any such New Bonds through a remarketing agent. Alabama also may be required to purchase the New Bonds, or the New Bonds may be subject to mandatory redemption, at any time if the interest thereon is determined to be subject to federal income tax. Also, in the event of taxability, interest on the New Bonds may be effectively converted to a higher variable or fixed rate, and Alabama also may be required to indemnify the bondholders against any other additions

to interest, penalties, and additions to tax.

Alternatively, Alabama may enter into a new Agreement with the appropriate Board, and such Board may enter into a new Indenture with the appropriate Revenue Bond Trustee pursuant to which the New Bonds will be issued. In such event, the Agreement and the Indenture will contain provisions described, below.

In order to obtain the benefit of ratings for the New Bonds equivalent to the rating of Alabama's first mortgage bonds outstanding under the Mortgage, Alabama may determine to secure its obligations under the Agreements by delivering to the Revenue Bond Trustee, to be held as collateral, a series of Collateral First Mortgage Bonds in principal amount either: (1) Equal to the principal amount of the New bonds; or (2) equal to the sum of the principal amount of the New Bonds plus interest payments thereon for a specified period. The Collateral First Mortgage Bonds will be issued under an indenture supplemental to the Mortgage (''Supplemental Indenture'') to be dated as of the first day of the month in which the Collateral First Mortgage Bonds are to be issued and delivered, will mature on the maturity date of the New Bonds and will be nontransferable by the Revenue Bond Trustee. The Collateral First Mortgage Bonds in: (1) Above, would bear interest at a rate or rates equal to the interest rate or rates to be borne by the related New Bonds; and (2) above, would be non-interest bearing.

The Supplemental Indenture will provide, however, that the obligation of Alabama to make payments with respect to the Collateral First Mortgage Bonds will be satisfied to the extent that payments are made under the Agreement sufficient to meet the payments when due in respect of the related New Bonds. The Supplemental Indenture will provide that, upon acceleration by the Revenue Bond Trustee of the principal amount of all related outstanding New Bonds under the Indenture, the Revenue Bond Trustee may demand the mandatory redemption of the related Collateral First Mortgage Bonds then held by it as collateral at a redemption price equal to the principal amount thereof plus accrued interest, if any, to the date fixed for redemption. The Supplemental Indenture may also provide that, upon the optional redemption of the New Bonds, in whole or in part, at any time after they have been outstanding for a specified period, a related principal amount of the Collateral First Mortgage Bonds will be redeemed at the redemption price of the New Bonds.

In the case of interest bearing Collateral First Mortgage Bonds, because interest accrues in respect to the Collateral First Mortgage Bonds until satisfied by payments under the Agreement, ''annual interest charges'' in respect of such Collateral First Mortgage Bonds will be included in computing the ''interest earnings requirement'' of the Mortgage which restricts the amount of first mortgage bonds which may be issued and sold to the public in relation to Alabama's net earnings. In the case of non-interest bearing Collateral First Mortgage Bonds, since no interest would accrue in respect of such Collateral First Mortgage Bonds, the ''interest earnings requirement'' would be unaffected.

The Indenture will provide that, upon deposit with the Revenue Bond Trustee of funds sufficient to pay or redeem all or any part of the related New Bonds, or open direction to the Revenue Bonds Trustee by Alabama to apply available funds for that purpose, or upon delivery of such outstanding New Bonds to the Revenue Bond Trustee by or for the account of Alabama, the Revenue Bond Trustee will be obligated to deliver to Alabama the Collateral First Mortgage Bonds then held as collateral in an aggregate principal amount as they relate to the aggregate principal amount of the New Bonds for the payment or redemption of which the funds have been deposited or applied or which shall have been so delivered.

Alabama may determine to secure its obligations under any Agreement by causing an irrevocable letter of credit (''Letter of Credit'') of a bank (''Bank'') to be delivered to the Trustee. The Letter of Credit would be an irrevocable obligation of the Bank to pay to the Trustee, upon request, up to an amount necessary in order to pay principal of and premium (if any) and certain accrued interest on the related New Bonds when due. Any Letter of Credit issued as security for the payment of New Bonds will be issued pursuant to a Reimbursement Agreement between Alabama and the financial institution issuing such Letter of Credit.

Pursuant to the Reimbursement Agreement, Alabama will agree to pay or cause to be paid to the financial institution, on each date that any amount is drawn under such institution's Letter of Credit, an amount equal to the amount of such drawing, whether by cash or by means of a borrowing from such institution pursuant to the Reimbursement Agreement. Any such borrowing may have a term of up to 10 years and will bear interest at the lending institution's prevailing rate offered to corporate borrowers of similar quality which will not exceed the prime rate or: (1) The London Interbank Offered Rate plus up to ⅜ of 1%; (2) the lending institution's certificate of deposit rate plus up to ½ of 1%; or (3) a rate not to exceed the prime rate, to be established by agreement with the lending institution prior to the borrowing. Such delivery of the Letter of Credit to the Trustee would obtain for the related New Bonds the benefit of a rating equivalent to the credit rating of the Bank.

As an alternative to, or in conjunction with, securing its obligations under any Agreement as described above, and in order to obtain a ''AAA'' rating for the related New Bonds by one or more nationally recognized securities rating agencies, Alabama may cause an insurance company to issue a policy of insurance guaranteeing the payment when due of the principal of and interest on such New Bonds. The insurance policy would extend for the term of the related New Bonds and would be non-cancelable by the insurance company for any reason. Alabama's payment in respect of said insurance policy could be in various forms, including a non-refundable, one-time insurance premium paid at the time the policy is issued, and/or an additional interest percentage to be paid to the issuer in correlation with regular interest payments. In addition, Alabama may be obligated to make payments of certain specified amounts into separate escrow funds and to increase the amounts on deposit in such funds under certain circumstances. The amount in each escrow fund would be payable to the insurance company as indemnity for any amounts paid pursuant to the related insurance policy in respect of principal of or interest on the related New Bonds.

It is contemplated that any New Bonds will be sold by the Board pursuant to arrangements with a purchaser or purchasers to be selected. In accordance with the laws of the State of Alabama, the interest rate to be borne by any series of New Bonds will be fixed by the Board and will be either a fixed rate, which fixed rate may be convertible to a rate which will fluctuate in accordance with a specified prime or base rate or rates or be determined through auction or remarketing procedures, or a fluctuating rate, which fluctuating rate may be convertible to a fixed rate. Bond counsel will issue an opinion that interest on the New Bonds will generally be exempt from federal income taxation. Alabama has been advised that the annual interest rates on obligations, the interest on which is tax exempt, recently have

been and can be expected at the time of issue of any series of New Bonds to be approximately one to three percentage points lower that the rates on obligations of like tenor and comparable quality, interest on which is fully subject to federal income tax.

Alabama also proposes that it may enter into arrangements providing for the delayed or future delivery of New Bonds to one or more purchasers, placement agents or underwriters. The obligations of the purchasers, placement agents or underwriters to purchase New Bonds under any such arrangements may be secured by U.S. Treasury securities, letters of credit or other collateral.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–19838 Filed 8–10–95; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. 1C–21269; 811–7057]

Trademark Funds; Notice of Application

August 4, 1995.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the ''Act'').

APPLICANT: Trademark Funds.

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 May 8, 1995 and amended on July 26, 1995.

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 August 29, 1995, and should be accompanied by proof of service on 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 5th Street, N.W., Washington, D.C. 20549. Applicant, Federated Investors Tower, Pittsburgh Pennsylvania 15222–3779.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Staff Attorney, at (202) 942–0574, or Robert A. Robertson, 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 at the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is an open-end management investment company organized as a Massachusetts business trust. On November 25, 1992, applicant registered under the Act as an investment company and filed a registration statement under the Securities Act of 1933. The registration statement was declared effective on February 8, 1993, and applicant's initial public offering commenced promptly thereafter. Applicant's series include: Trademark Equity Fund, Trademark Kentucky Municipal Bond Fund, Trademark Short-Intermediate Government Fund and Trademark Government Income Fund.

2. On August 15, 1994, the investment adviser to the Trademark Funds, Liberty National Bank and Trust Company of Kentucky, was acquired indirectly by Banc One Corporation. At a meeting held on October 7, 1994, applicant's trustees, including the independent trustees, unanimously approved an agreement and plan of reorganization (the ''Plan''). Under the Plan, Trademark Equity Fund, Trademark Kentucky Municipal Bond Fund, Trademark Short-Intermediate Government Fund and Trademark Government Income Fund would be acquired by The One Group Large Company Growth Fund, The One Group Kentucky Municipal Bond Fund, The One Group Intermediate Bond Fund and The One Group Government Bond Fund, respectively. Proxy materials were filed with the SEC and were distributed to applicant's shareholders on or about December 12, 1994. At a special meeting held on January 12, 1995, applicant's shareholders approved the Plan.

3. At the end of the business day on January 19, 1995, the specified One Group investment companies acquired all of the assets of the corresponding Trademark series in exchange for One Group shares, which then were distributed pro rata by the Trademark series to their shareholders in complete liquidation and termination of the Trademark series. As a result, each shareholder of the Trademark series received a number of full and fractional shares equal in value at the date of exchange to the value of the net assets of the Trademark series transferred to the corresponding One Group investment companies attributable to the shareholder.

4. All fees and expenses, including accounting expenses, portfolio transfer taxes or other similar expenses incurred in connection with the reorganization will be paid by the fund directly incurring such fees and expenses, except that the costs of proxy materials and proxy solicitation, including legal expenses, will be borne by Banc One Corporation.

5. Applicant has no assets or liabilities and is not a party to any litigation or administrative proceeding. At the time of the application, applicant had no securityholders.

6. Applicant is neither engaged in, nor does it propose to engage in, any business activities other than those necessary for the winding-up of its affairs. Applicant intends to file all documents required to terminate its existence as a Massachusetts business trust.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–19839 Filed 8–10–95; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–36050; File No. SR–DTC–95–10]

Self-Regulatory Organizations; The Depository Trust Company; Order Approving a Proposed Rule Change Implementing the Advice of Confirm Correction/Cancellation Feature and Modifying the Authorization/Exception Processing Feature of the Institutional Delivery System

August 2, 1995.

On April 27, 1995, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–DTC–95–10) under Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] to implement the Advice of Confirm Correction/Cancellation feature and modify the Authorization/Exception Processing feature of the Institutional Delivery system (''ID''). Notice of the proposal was published in the **Federal Register**

[1] 15 U.S.C. 78(b)(1) (1988).

on June 1, 1995.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

In a previous filing with the Commission, DTC described several enhancements to the ID System that it planned to implement, including the Advice of Confirm Correction/Cancellation feature and the modification of Authorization/Exception processing.[3] These are the subject of this approval order.

The Advice of Confirm Correction/Cancellation feature is one of three electronic mail features described in the Enhanced ID filing.[4] The Advice of Confirm Correction/Cancellation feature enables an institution or its agent which has received a confirmation through the ID system to notify the broker-dealer of the reason(s) why the institution disagrees with the confirmation. This communication from the institution, which is sometimes called a ''DK'' (*i.e.*, don't know) of the trade, enables the broker-dealer to take steps to resolve the discrepancy between its records of the trade and the institution's records. The Advice of Confirm Correction/Cancellation also was described in another DTC filing as a feature which will enable a prime broker to DK a trade when it receives an ID confirmation from an executing broker.[5]

The proposal also modifies Authorization/Exception processing by increasing the number of trades which can be processed and by extending the period during which the process can be used.[6] Prior to the modification, only ID trades which were schedules to settle on the third day following the trade date (''T+3'') or later could be authorized or excepted from settlement through an instruction submitted or excepted from settlement through an instruction submitted on settlement date minus one (''S–1''). The modification allows authorization or exception of trades settling on T+1 and later through an instruction submitted on any of the twenty-three business days from S–1 through S+21.

II. Discussion

Sections 17A(b)(3)(A) and (F) of the Act[7] require that a clearing agency be organized and its rules be designed to facilitate and promote the prompt and accurate clearance and settlement of securities transactions. The Commission believes that DTC's proposal is consistent with Section 17A of the Act[8] because the proposal should promote efficiencies in the clearance and settlement of securities transactions by increasing the number of trades eligible and by expanding the timeframe for Authorization/Exception processing. The proposal also should promote efficiencies by improving communications among the parties to institutional trades by making the Advice of Confirm Correction/Cancellation feature more interactive and automated. These changes should help DTC participants settle trades in a three-day settlement cycle.[9]

III. Conclusion

The Commission finds that DTC's proposal is consistent with the requirements of the Act and particularly with Section 17A and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–DTC–95–10) be, and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–19837 Filed 8–10–95; 8:45 am]

BILLING CODE 8010–01–M

[2] Securities Exchange Act Release No. 35758 (May 24, 1995), 60 FR 28636.

[3] Securities Exchange Act Release No. 33466 (January 1994), 59 FR 3139 [File No. SR–DTC–93–07] (order approving proposed rule change relating to the enhanced ID system) (''Enhanced ID Filing'').

[4] The other two electronic mail features (*i.e.*, Notice of Order Execution and Institution Instructions) were previously approved by the Commission. For a complete description of these features, refer to Securities Exchange Act Release No. 34199 (June 10, 1994), 59 FR 31660 [File No. SR–DTC–94–04] (order granting accelerated approval of a proposed rule change to implement the interactive capabilities and the electronic mail features of the enhanced ID system).

[5] Securities Exchange Act Release No. 34779 (October 3, 1994), 59 FR 34779 [File No. SR–DTC–94–13] (order granting accelerated approval on a temporary basis through May 31, 1995, of a proposed rule change implementing the prime broker option in the ID system).

More recently, DTC filed a proposed rule change modifying features of the prime broker option in the ID system. For a complete description of that filing, refer to Securities Exchange Act Release No. 35971 (July 14, 1995), 60 FR 37696 [File No. SR–DTC–95–11] (notice of filing and immediate effectiveness of proposed rule change relating to modifications to the prime broker option in the Institutional Delivery System).

[6] The Authorization/Exception function affords participants twenty-three business days to authorize for or except from automated settlement any eligible, affirmed next day funds settlement (''NDFS'') or same-day funds settlement (''SDFS'') trade in an interactive environment.

[7] 15 U.S.C. 78q–1(b)(3)(A) and (F) (1988).

[8] 15 U.S.C. 78q–1 (1988).

[9] On October 6, 1993, the Commission adopted Rule 15c6–1 under the Act, which establishes three business days after the trade date instead of five business days as the standard settlement timeframe for most broker-dealer transactions. The rule became effective June 7, 1995. Securities Exchange Act Release Nos. 33023 (October 6, 1993), 58 FR 52891 (release adopting Rule 15c6–1); 34952 (November 9, 1994), 59 FR 59137 (release changing the effective date of the three day settlement cycle).

[10] 17 CFR 200.30–3(a)(12) (1994).

[Release No. 34–36062; International Series Release No. 835 File No. SR–Phlx–95–42]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc., to List and Trade 3D Foreign Currency Options on the Japanese Yen

August 4, 1995.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 14, 1995, 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 Exchange. The Exchange subsequently filed Amendment No. 1 to the proposed rule change on July 7, 1995.[3] 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 proposes to list and trade cash settled foreign currency options on the Japanese Yen. The text of the proposed rule change is available at the Office of the Secretary, the Exchange, and at the Commission.

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 Exchange included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Phlx submitted Amendment No. 1 to the Commission to make certain technical corrections to the proposal. See Letter from Michele Weisbaum, Associate General Counsel, Phlx, to John Ayanian, Attorney, Office of Market Supervision (''OMS''), Division of Market Regulation (''Market Regulation''), Commission, dated July 7, 1995.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to list and trade Dollar Denominated Delivery (''3D'') foreign currency options (''FCOs'') on the Japanese Yen. In March 1994, the Commission approved the listing and trading of 3D FCOs on the German Mark.[4] 3D FCOs are cash-settled, European-style options issued by the Options Clearing Corporation (''OCC'') that allow holders to receive U.S. dollars representing the difference between the current foreign exchange spot price[5] and the exercise price of the option. Specifically, upon exercise of an in-the-money 3D FCO structured as a call, the holder will receive, from OCC, U.S. dollars representing the difference between the exercise strike price and the closing settlement value of the 3D FCO contract multiplied by the number of units of currency covered by the contract. For a 3D FCO structured as a put, the holder will receive U.S. dollars representing the excess of the exercise price over the closing settlement value of the 3D FCO contract multiplied by the number of units of foreign currency covered by the contract.

Unlike other Phlx-traded FCOs, 3D FCOs which are in-the-money by any amount on the expiration date will be exercised automatically by OCC. 3D FCOs which are out-of-the-money at expiration will expire worthless.

German 3D FCOs were originally listed with one-week and two-week expirations to provide a hedging vehicle to sophisticated retail customers, portfolio managers and multi-national corporations which needed to hedge their short term foreign currency exposure and also to banks which needed to hedge the risks associated with trading in the forward and cash markets. Recently, the Exchange received approval from the Commission to list German 3D FCO contracts with longer term expirations up to twelve months[6] due to the interest expressed by the users of the product who did not wish to establish foreign bank credit lines or worry about the potential of exchanging currency at exercise and assignment.

The Exchange is now proposing to list and trade 3D FCOs on the Japanese yen (U.S. dollar/Japanese yen). The contract size will be 6,250,000 yen, the same as physically settled Japanese yen contract. Pursuant to Phlx Rule 1012(a)(ii), the contracts will be listed with expirations at one week and two weeks and one, two, three, six and nine months (twelve month options will not be listed at this time). The options will be on the March, June, September, December cycle and no month end or long term expirations will be listed. The expiration date for the consecutive and cycle month options will be the Monday preceding the third Wednesday of each month. The Exchange expects that the symbols for these options will be as follows:

XJA	first Monday of month expiration
XJB	second Monday of month expiration
XJC	third Monday of month expiration
XJD	fourth Monday of month expiration
XJE	fifth Monday of month expiration
XJS	settlement symbol

The 1, 2, 3, 6, and 9 month options will be listed with the symbol XJB or XJC depending on whether expiration will be the second or third Monday of that month and will carry that symbol to expiration. For example, a Sept 1995 option which would expire on Monday Sept. 18, would listed as an XJC Sept 85 call whereas the Nov 1995 option which would expire on Monday, Nov. 13, would be listed as an XJB Nov 85 call.

Similar to the 3D German mark contracts, the Exchange proposes that a series of 3D Japanese yen options will trade during normal trading hours for foreign currency options, specifically, 2:30 a.m. to 2:30 p.m. E.T. Monday through Friday. The expiring FCO contract will cease trading at 10:30 a.m. and expire at 11:59 p.m. on its expiration Monday, unless such Monday is an Exchange holiday or an Exchange designated bank holiday, when, under Phlx Rule 1000(b)(21), ''Expiration date,'' as amended, the 3D FCO will expire at 11:59 p.m. on the preceding business date.

Accordingly, on Exchange holidays and Exchange designated bank holidays, the expiring 3D FCOs will cease trading at 10:30 a.m. on the preceding business day. In addition, when Monday is an exchange holiday, a new two-week contract will be listed on the following Tuesday at 2:30 a.m. E.T. as opposed to the normal Monday morning listing.

The closing settlement value, which will be disseminated through the Options Price Reporting Authority (''OPRA''), will be determined by a designated agent(s) of the Exchange under Phlx Rule 1057, ''Cash/Spot Foreign Currency Option Closing Settlement Value.'' Pursuant to Phlx Rule 1057, at 10 a.m. (E.T.), on every expiration date for 3D FCOs, the market information vendor(s), acting as the Exchange's designated agent will collect a bid and offer quotation for the current Japanese yen spot price from the quotations submitted by at least 15 interbank foreign exchange participants, which the designated agent will select randomly from a list of at least 25 active interbank foreign exchange market participants.[7] After discarding the five highest offers and five lowest bids, the designated agent will arithmetically average the remaining ten bids and ten offers to arrive at a closing settlement value. This value will be calculated and sent to the Phlx every 30 seconds until 10:30 a.m. when the designated agent will determine the final settlement value. At that time, the settlement value will be automatically entered into the Phlx's systems, and then the Phlx disseminates it to OPRA and the OCC for entry into the OCC clearing systems.

The position limits and exercise limits for the 3D yen will be the same as the position and exercise limit for the physically settled Japanese yen contracts pursuant to Phlx Rule 1001[8] and Rule 1002 and positions in the 3D yen will be aggregated with positions in the physically settled Japanese yen contracts. The Phlx proposes to initially list exercise strike prices for each expiration around the current spot price and new strikes may be added during the life of the option in accordance with Phlx Rule 1012 at half-cent intervals for the 3 near term month and at one cent intervals for the six and nine month options.

The 3D Japanese yen options will trade in accordance with the rules governing all Phlx FCOs, including sales practice rules and floor trading rules. For example, Phlx Rule 1014, ''Obligations and Restrictions Applicable to Specialists and Registered

[4] See Securities Exchange Act Release No. 33732 (March 8, 1995), 59 FR 12023 (March 15, 1994).

[5] The ''spot price'' with respect to an option contract on a foreign currency option contract means the price for the sale of one foreign currency for another, quoted by various commercial banks in the interbank foreign exchange market for the sale of a single unit of such foreign currency for immediate delivery (which generally means delivery within two business days following the date on which the terms of such sale are agreed upon). See Phlx Rule 1000(b)(16).

[6] See Securities Exchange Act Release No. 35756 (May 24, 1995), 60 FR 28638 (June 1, 1995).

[7] The Phlx will select the list of interbank market participants by evaluating the number of times each contributor supplies Japanese yen spot quotes to the market information vendor(s) on Monday mornings between 10 a.m. and 10:30 a.m. The pool of quote contributors will be reviewed monthly based on these criteria and substitutions will be made, if necessary. If at any time an interbank market participant ceases to distribute JY spot quotes or is no longer in the business of making JY markets, that entity will be replaced.

[8] Position and exercise limits on the Japanese yen are 100,000 contracts on either side of the market, however, the Phlx has recently proposed to raise this limit to 200,000 contracts. This proposal is currently under review at the Commission. See Securities Exchange Act Release No. 35688 (May 8, 1995), 60 FR 26062 (May 16, 1995).

Options Traders'' provides that bid/ask differentials for 3D FCOs shall be determined by reference to the underlying foreign currency. Further, 3D Japanese yen options will not be subject to customized trading pursuant to Phlx Rule 1069.

The 3D Japanese yen will have the same customer margin requirements as are provided for the existing Japanese yen FCOs pursuant to Phlx Rule 722, ''Margin Accounts.'' Specifically, for any put or call on 3D options which are issued, guaranteed or carried ''short'' in a customer's account, the required margin shall be 100% of the options premium plus 4% of the value of the underlying contract less any out-of-the-money amount, with an adjustment for out-of-the money options to be not less than 100% of the options premium plus ¾% of the underlying contract margin within five days following the date on which a customer enters into a 3D FCO position and within two days if the option has two weeks or less to expiration.

The Exchange believes that the proposed rule change is consistent with Section 6 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, as well as to protect investors and the public interest by providing foreign currency option users who do not necessarily need to exchange currency at settlement with an alternative cash settled foreign currency option with corresponding expirations.

(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.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were solicited or 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 date of 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 such 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. Person 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 Phlx. All submissions should refer to SR–Phlx–95–42 and should be submitted by September 1, 1995.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 95–19931 Filed 8–10–95; 8:45 am]

BILLING CODE 8010–01–M

[9] 17 CFR 220.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

1994–95 Advisory Council on Social Security; Meeting

AGENCY: Social Security Administration.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces a meeting of the 1994–95 Advisory Council on Social Security (the Council).

DATES: Thursday, August 31, 1995, 9 a.m. to 5 p.m. and Friday, September 1, 1995, 9 a.m. to 3 p.m.

ADDRESSES: The Embassy Row Hotel, 2015 Massachusetts Avenue, NW, Washington, DC 20036, (202) 265–1600.

FOR FURTHER INFORMATION CONTACT: By mail—Dan Wartonick, 1994–95 Advisory Council on Social Security, Suite 705, 1825 Connecticut Avenue, NW, Washington, DC 20009; By telephone—(202) 482–7117; By telefax—(202) 482–7123.

SUPPLEMENTARY INFORMATION:

I. Purpose

Under section 706 of the Social Security Act (the Act), the Secretary of Health and Human Services (the Secretary) appoints the Council every 4 years. The Council examines issues affecting the Social Security Old-Age, Survivors, and Disability Insurance (OASDI) programs, as well as the Medicare program and impacts on the Medicaid program, which were created under the Act.

In addition, the Secretary has asked the Council specifically to address the following:

- Social Security financing issues, including developing recommendations for improving the long-range financial status of the OASDI programs;
- General program issues such as the relative equity and adequacy of Social Security benefits for persons at various income levels, in various family situations, and various age cohorts, taking into account such factors as the increased labor force participation of women, lower marriage rates, increased likelihood of divorce, and higher poverty rates of aged women.

In addressing these topics, the Secretary suggested that the Council may wish to analyze the relative roles of the public and private sectors in providing retirement income, how policies in both sectors affect retirement decisions and the economic status of the elderly, and how the disability insurance program provisions and the availability of health insurance and health care costs affect such matters.

The Council is composed of 12 members in addition to the chairman: Robert Ball, Joan Bok, Ann Combs, Edith Fierst, Gloria Johnson, Thomas Jones, George Kourpias, Sylvester Schieber, Gerald Shea, Marc Twinney, Fidel Vargas, and Carolyn Weaver. The chairman is Edward Gramlich.

The Council met previously on June 24–25, 1994 (59 FR 30367), July 29, (59 FR 35942), September 29–30 (59 FR 47146), October 21–22 (59 FR 51451), November 18–19 (59 FR 55272), January 27, 1995 (60 FR 3416), February 10–11 (60 FR 5433), March 8–9 (60 FR 10091), March 10–11 (60 FR 10090), April 21–22 (60 FR 18419), May 19–20 (60 FR 24961), June 2–3 (60 FR 27372) July 27–28 (60 FR 35097).

II. Agenda

The following topics will be presented and discussed:

* Previously developed plans that would revise the OASDI program along different lines (including the possible use of relatively small individual accounts on a voluntary or mandatory basis);

* Plans to restructure Social Security that would involve the use of larger notional and/or funded individual accounts, including a discussion of transition issues and options;

* Changes affecting voluntary private pensions and individual retirement saving, including recent initiatives of the Departments of Treasury and Labor, the concept of indexed bonds, and proposals of the Committee for Economic Development.

* As time permits, various OASDI program issues, such as the structure of family benefits.

The meeting is open to the public to the extent that space is available. Interpreter services for persons with hearing impairments will be provided. A transcript of the meeting will be available to the public on an at-cost-of duplication basis. The transcript can be ordered from the Executive Director of the Council.

(Catalog of Federal Domestic Assistance Program Nos. 93.802, Social Security-Disability Insurance; 93.803, Social Security-Retirement Insurance; 93.805, Social Security-Survivors Insurance)

Dated: August 4, 1995.

David C. Lindeman,

Executive Director, 1994–95 Advisory Council on Social Security.

[FR Doc. 95–19910 Filed 8–10–95; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements

AGENCY: Department of Transportation (DOT), Office of the Secretary.

ACTION: Notice.

SUMMARY: This notice lists those forms, reports, and recordkeeping requirements imposed upon the public which were transmitted by the Department of Transportation to the Office of Management and Budget (OMB) for its approval in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 USC Chapter 35).

DATES: August 4, 1995.

ADDRESSES: Written comments on the DOT information collection requests should be forwarded, as quickly as possible, to Edward Clarke, Office of Management and Budget, New Executive Office Building, Room 10202, Washington, DC 20503. If you anticipate submitting substantive comments, but find that more than 10 days from the date of publication are needed to prepare them, please notify the OMB official of your intent immediately.

FOR FURTHER INFORMATION CONTACT: Copies of the DOT information collection requests submitted to OMB may be obtained from Susan Pickrel or Gemma deGuzman, Information Resource Management (IRM) Strategies Division, M–32, Office of the Secretary of Transportation, 400 Seventh Street SW., Washington, DC 20590, (202) 366–4735.

SUPPLEMENTARY INFORMATION: Section 3507 of Title 44 of the United States Code, as adopted by the Paperwork Reduction Act of 1980, requires that agencies prepare a notice for publication in the **Federal Register**, listing those information collection requests submitted to OMB for approval or renewal under that Act. OMB reviews and approves agency submissions in accordance with criteria set forth in that Act. In carrying out its responsibilities, OMB also considers public comments on the proposed forms and the reporting and recordkeeping requirements. OMB approval of an information collection requirement must be renewed at least once every three years.

Items Submitted to OMB for Review

The following information collection requests were submitted to OMB on August 4, 1995:

DOT No: 4091.

OMB No: 2115–0597.

Administration: United States Coast Guard.

Title: State Access to the Oil Spill Liability Trust Fund for Removal Costs under the Oil Pollution Act of 1990.

Need for Information: 33 USC 2712 provides Coast Guard the authority to promulgate regulations detailing the manner in which to obligate the Oil Spill Liability Trust Fund.

Proposed Use of Information: This information will be used by the Coast Guard s National Pollution Fund Center to determine whether expenditures submitted by the State to the Fund are compensable and to ensure that the correct amount of funding of costs is made from the Fund.

Frequency: On occasion.

Burden Estimate: 6,792 hours.

Respondents: State Governments.

Form(s): None.

Average Burden Hours Per Response: 1.5 hours reporting.

DOT No: 4092.

OMB No: 2125–New.

Administration: Federal Highway Administration.

Title: Indian Reservation Roads Program Administration Survey.

Need for Information: 23 USC 204(f) provides the authority for the Federal Highway Administration (FHWA) and the Bureau of Indian Affairs (BIA) to jointly administer the Indian Reservation Roads Program. The Government Performance and Results Act requires the establishment of performance measures consistent with the overall program goals and outcomes.

Proposed Use of Information: This information will be used by the FHWA and the BIA to improve the administration of the Indian Reservation Roads Program.

Frequency: Annual.

Burden Estimate: 272 hours.

Respondents: State, Local or Tribal Government.

Form(s): None.

Average Burden Hours Per Response: 30 minutes.

DOT No: 4093.

OMB No: 2127–0046.

Administration: National Highway Traffic Safety Administration (NHTSA).

Title: 49 CFR part 552, Petitions for Rulemaking, Defect, and Noncompliance Orders.

Need for Information: 49 USC 30162 specifies that any ''interested person may file a petition with the Secretary of Transportation requesting the Secretary to begin a proceeding'' to prescribe a motor vehicle safety standard under 49 USC Chapter 301 or to decide whether to issue an order under 49 USC 30118(b). To implement these statutory provisions, NHTSA promulgated part 552 according to the informal rulemaking provisions of the Administrative Procedure Act (5 USC 553 et seq.) This regulation allows the agency to ensure that the petitions filed under section 30162 are both properly substantiated and efficiently processed.

Proposed Use of Information: This information will be used by NHTSA to identify and respond on a timely basis to petitions for rulemaking or defect or noncompliance determination and to inform the public of the procedures following in response to such petitions.

Frequency: On occasion.

Burden Estimate: 100 hours.

Respondents: Individuals, businesses, or small businesses.

Form(s): None.

Average Burden Hours Per Response: 1 hour.

DOT No: 4094.
OMB No: 2132–0047.
Administration: National Highway Traffic Safety Administration.
Title: 49 CFR part 580, Odometer Disclosure Statement.
Need for Information: The Motor Vehicle Information and Cost Savings Act, as amended by 15 USC 1988, and implementing regulations, 49 CFR Part 580, require each transferor of a motor vehicle to provide the transferee a written disclosure of the vehicle s mileage.
Proposed Use of Information: This information will be used by motor vehicle transferors and lessors to determine the mileage and value of the vehicles.
Frequency: On occasion.
Burden Estimate: 2,586,160 hours.
Respondents: Individuals and businesses.
Form(s): None.
Average Burden Hours Per Response: .004 hours.

DOT No: 4095.
OMB No: 2120–0564
Administration: Federal Aviation Administration.
Title: Unescorted Access Privilege—Parts 107 and 108 of the Federal Aviation Regulation.
Need for Information: Section 105 of Public Law 101–604, the Aviation Security Improvement Act of 1990, directs the FAA Administrator to promulgate regulations that subject individuals with unescorted access to U.S. or foreign air carrier aircraft, or to secured areas of U.S. airports served by air carriers, to access investigations, including such criminal history records checks as the Administrator determines necessary to ensure air transportation security.
Proposed Use of Information: This information will be used by airport operators and air carriers to maintain evidence of compliance with investigative requirements for all affected individuals. The Federal Aviation Administration will review the records to ensure that individuals with unescorted access to the Security Identification Display Area have been subject to the access investigation requirements and a determination has been made permitting such authority.
Frequency: As needed.
Burden Estimate: 36,720 annually.
Respondents: Air carriers and airports.
Form(s): None.
Average Burden Hours Per Response: 10 minutes per individual recordkeeping.

DOT No: 4096.
OMB No: 2120–0508.
Administration: Federal Aviation Administration.
Title: Fuel Venting and Exhaust Emission Requirements for Turbine Engine Powered Airplanes.
Need for Information: As required by FAR 45, this is a labeling requirement to put the data of manufacture and compliance status on the identification plate and is intended to minimize the effort required to determine whether a turbojet engine may legally be installed and operate on an aircraft in the United States.
Proposed Use of Information: This information will be used by the Federal Aviation Administration inspectors, purchasers, owners and operators periodically, during the course of the year, to confirm that the engines meet U.S. Environmental Protection Agency pollution requirements in lieu of searching through extensive paper records.
Frequency: As required.
Burden Estimate: 100 hours annually.
Respondents: Manufacturers of aviation engines.
Form(s): None.
Average Burden Hours Per Response: 5 minutes or less per response.

DOT No: 4097
OMB No: 2120–0040
Administration: Federal Aviation Administration.
Title: Aviation Maintenance Technician Schools.
Need for Information: 49 USC 44707 authorizes the Administrator of the Federal Aviation Administration to examine and rate the air agencies.
Proposed Use of Information: This information will be used by the Federal Aviation Administration to rate aviation maintenance technician schools to maintain a standardized level of proficiency.
Frequency: As required.
Burden Estimate: 78,461 hours annually.
Respondents: Aviation Maintenance Technician School Operators.
Form(s): FAA Form 8310–6.
Average Burden Hours Per Response: 40 hours per applicant.

DOT No: 4098.
OMB No: 2120–0034.
Administration: Federal Aviation Administration.
Title: Application for Airman Medical Certificate or Airman Medical and Student Pilot Certificate.
Need for Information: 49 USC 40113, 44701, 44510, 44702, 44703, 44709, 45303, and 80111 authorizes the collection of this information. Airman medical certification program is implemented by Title 14, Code of Federal Regulations parts 61 and 67.
Proposed Use of Information: This information will be used by the Federal Aviation Administration to perform the duties associated with the class of airman medical certificate sought.
Frequency: As required.
Burden Estimate: 859,069 hours.
Respondents: Airmen.
Form(s): FAA Forms 8500–7, 8500–8, 8500–14, 8500–20.
Average Burden Hours Per Response: FAA Form 8500–7 = 15 minutes, FAA Form 8500–8 = 2 hours, FAA Form 8500–14 = 15 minutes, FAA Form 8500–20 = 11 minutes.

DOT No: 4099.
OMB No: 2127–0003.
Administration: National Highway Traffic Safety Administration.
Title: Highway Safety Program Cost Summary HS Form 217.
Need for Information: The Surface Transportation and Uniform Relocation Assistance Act of 1987 Section 206(d) authorizes the Secretary to begin a rulemaking process to determine those programs most effective in reducing accidents, injuries, and deaths.
Proposed Use of Information: The information will be used by the National Highway Traffic Safety Administration to determine whether the States have demonstrated compliance with the statutory requirements for the State and Community Highway Safety Grant Program.
Frequency: Annually.
Burden Estimate: 31,601 hours.
Respondents: States.
Form(s): HS–217.
Average Burden Hours Per Response: 3 hours.

DOT No: 4100
OMB No: 2137–0047
Administration: Research and Special Programs Administration.
Title: Transportation of Hazardous Liquids by Pipeline: Recordkeeping and Accident Reporting.
Need for Information: 49 USC 60117 authorizes the Secretary of Transportation to require hazardous liquid pipeline operators to prepare and maintain written records and reports and to make them available to the Secretary of Transportation upon request.
Proposed Use of Information: This information will be used by the Research and Special Programs Administration to evaluate the compliance of operators of hazardous liquid pipelines with the pipeline safety requirements.
Frequency: On occasion.
Burden Estimate: 49,219 hours.

Respondents: pipeline operators.

Form(s): DOT 7000–1.

Average Burden Hours Per Response: 12 minutes.

DOT No: 4101

OMB No: 2137–0578.

Administration: Research and Special Programs Administration.

Title: Reporting Safety-Related Conditions on Gas, Hazardous Liquid, and Carbon Pipelines and Liquefied Natural Gas Facilities.

Need for Information: 49 USC 60102 requires each operator of a pipeline facility (except master meter) to submit to DOT a written report on any safety-related condition that causes or has caused a significant change or restriction in the operation of a pipeline facility or a condition that is a hazard to life, property or the environment.

Proposed Use of Information: This information will be used by the Research and Special Programs Administration to monitor the corrective actions proposed by operators in order to prevent the occurrence of an incident or accident.

Frequency: On occasion.

Burden Estimate: 342 hours.

Respondents: Gas, Hazardous Liquid, Carbon Dioxide, and Liquefied Natural Gas Operators.

Form(s): None.

Average Burden Hours Per Response: 6 hours.

DOT No: 4102

OMB No: 2115–New.

Administration: U.S. Coast Guard.

Title: Operational Measures for Existing Tank Vessels 5,000 Gross Tons or Greater without Double Hulls.

Need for Information: Title 46 USC 3703A mandates that regulations be established to provided improved protection from oil spills in waters subject to the jurisdiction of the United States due to collisions and groundings.

Proposed Use of Information: Coast Guard inspectors will use this information to determine if a vessel is in compliance with the regulations or in case of a casualty, whether failure to meet these proposed regulations contributed to the casualty.

Frequency: Annually.

Burden Estimate: 76,908 hours.

Respondents: Master, owner or operator of tank vessels.

Form(s): None.

Average Burden Hours Per Response: 55 hours reporting; 37 hours recordkeeping.

Issued in Washington, DC, on August 4, 1995.

Ray Reynaldo,

Computer Specialist, Information Resource Management (IRM) Strategies Division.

[FR Doc. 95–19895 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–62–P

Federal Aviation Administration

Noise Exposure Map Notice; Receipt of Noise Compatibility Program and Request for Review Westover Metropolitan Airport/Air Reserve Base Chicopee, Massachusetts

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure map for Westover Metropolitan Airport/Air Reserve Base, as submitted by the Westover Metropolitan Development Corporation under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) and 14 CFR part 150, is in compliance with applicable requirements. The FAA also announces that it is reviewing a proposed noise compatibility program that was submitted for Westover Metropolitan Airport/Air Reserve Base under Part 150 in conjunction with the noise exposure map, and that this program will be approved or disapproved on or before January 27, 1996.

EFFECTIVE DATE: The effective date of the FAA's determination on the noise exposure map and of the start of its review of the associated noise compatibility program is July 31, 1995. The public comment period ends on September 29, 1995.

FOR FURTHER INFORMATION CONTACT: John C. Silva, Federal Aviation Administration, New England Region, Airports Division, ANE–600, 12 New England Executive Park, Burlington, Massachusetts 01803.

Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure map submitted for Westover Metropolitan Airport/Air Reserve Base is in compliance with applicable requirements of part 150, effective July 31, 1995. Further, FAA is reviewing a proposed noise compatibility program for that airport which will be approved or disapproved on or before January 27, 1996. This notice also announces the availability of this program for public review and comment.

Under section 103 of Title I of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as ''the Act''), an airport operator may submit to the FAA a noise exposure map which meets applicable regulations and which depicts noncompatible land uses as of the date of submission of such map, a description of projected aircraft operations, and the ways in which such operations will affect such map. The Act requires such map to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted a noise exposure map that is found by FAA to be in compliance with the requirements of Federal Aviation Regulation (FAR) part 150, promulgated pursuant to Title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken, or proposes, for the introduction of additional noncompatible uses.

The Westover Metropolitan Development Corporation submitted to the FAA on January 26, 1994, a noise exposure map, descriptions, and other documentation which were produced during the Airport Noise Compatibility Planning (part 150) study at Westover Metropolitan Airport/Air Reserve Base from October 1990 to June 1995. It was requested that the FAA review this material as the noise exposure map, as described in section 103(a)(1) of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 104(b) of the Act.

The FAA has completed its review of the noise exposure map and related descriptions submitted by Westover Metropolitan Airport/Air Reserve Base. The specific maps under consideration were Figures 10.1, '' Westover Metropolitan Airport/ARB Existing Case Ldn Contours'' and 10.3, '' Westover Metropolitan Airport/ARB Forecast Case Ldn Contours'', along with the supporting documentation in '' Westover Metropolitan Airport/Air Reserve Base; FAR part 150 Documentation; Noise Exposure Map''. The FAA has determined that the maps for Westover Metropolitan Airport/Air Reserve Basevelopment Corporation are in compliance with applicable requirements. This determination is effective on July 31, 1995.

FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the

procedures contained in appendix A of FAR part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure map to resolve questions concerning, for example, which properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under part 150 or through FAA's review of a noise exposure map. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted the map, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport operator, under § 150.21 or FAR part 150, that the statutorily required consultation has been accomplished.

The FAA has formally received the noise compatibility program for Westover Metropolitan Airport/Air Reserve Base, also effective on July 31, 1995. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before January 27, 1996. The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, § 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure map, the FAA's evaluation of the map, and the proposed noise compatibility program are available for examination at the following locations:

Westover Metropolitan Airport, 3911 Pendleton Avenue, Chicopee, Massachusetts 01022

Federal Aviation Administration, New England Region, Airports Division, ANE–600, 12 New England Executive Park, Burlington, Massachusetts 01803.

Questions may be directed to the individual named above under the heading: **FOR FURTHER INFORMATION CONTACT**.

Issued in Burlington, Massachusetts on July 31, 1995.

Vincent A. Scarano,

Manager, Airports Division, New England Region.

[FR Doc. 95–19908 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–13–M

Notice of Passenger Facility Charge (PC) Approvals and Disapprovals

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Monthly notice of PFC approvals and disapprovals. In July 1995, there were six applications approved. Additionally, four approved amendments to previously approved applications are listed.

SUMMARY: The FAA publishes a monthly notice, as appropriate, of PFC approvals and disapprovals under the provisions of 49 U.S.C. 40117 (Pub. L. 103–272) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158). This notice is published pursuant to paragraph d of § 158.29.

PFC Applications Approved

Public Agency: City of Chicago, Department of Aviation, Chicago, Illinois.

Application Number: 95–03–C–00–MDW.

Application Type: Impose and use PFC revenue.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $11,916,250.

Charge Effective Date: August 1, 1998.

Estimated Charge Expiration Date: March 1, 2000.

Class of Air Carriers not Required to Collect PFC's: Air taxi operators.

Determination: Approved. Based on information contained in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Midway Airport.

Brief Description of Projects Approved for Use: Runway 13L/31R rehabilitation, Landside pavement replacement.

Brief Description of Projects Approved for Collection and Use: Midway terminal development planning/design, Airfield lighting control panel, Land acquisition, parcels 50, 57, 64, 65, 66, 68, 70, and 71, Update Part 150, Demonstration home soundproofing.

Brief Description of Project Approved for Collection: Runway 4R/22L reconstruction.

Brief Description of Disapproved Project: Runway arrestment system.

Determination: Disapproved. The FAA has determined the runway arrestment system project is ineligible for Airport Improvement Program (AIP) funding as per FAA Order 5100.38A, paragraph 521(a). The proposed development is not consistent with FAA design and engineering standards. Accordingly, the FAA has determined that this project does not meet the requirements of § 158.15(b)(1).

Decision Date: July 5, 1995.

FOR FURTHER INFORMATION CONTACT: Louis H. Yates, Chicago Airports District Office, (708) 294–7335.

Public Agency: City of Syracuse, New York.

Application Number: 95–01–C–00–SYR.

Application Type: Impose and use PFC revenue.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $9,699,050.

Charge Effective Date: October 1, 1995.

Estimated Charge Expiration Date: October 1, 1998.

Class of Air Carriers Not Required to Collect PFC's: Air taxi/commercial operators filing FAA Form 1800–31.

Determination: Approved. Based on information submitted in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Syracuse Hancock International Airport.

Brief Description of Projects Approved for Collection and Use: Terminal area deicing collection and concrete parking pads, Relocate taxiway H west and widen taxiways J and H east.

Brief Description of Project Approved for Collection: Land acquisition for parallel runway 10L/28R.

Decision Date: July 20, 1995.

FOR FURTHER INFORMATION CONTACT: Philip Brito, New York Airports District Office, (516) 295–9340.

Public Agency: Port of San Diego, San Diego, California.

Application Number: 95–01–C–00–SAN.

Application Type: Impose and use PFC revenue.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $108,176,000.

Charge Effective Date: October 1, 1995.

Estimated Charge Expiration Date: January 1, 2001.

Class of Air Carriers not Required to Collect PFC's: Part 135 air taxis.

Determination: Approved. Based on information submitted in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at San Diego International Airport, Lindbergh Field.

Brief Description of Projects Approved for Collection and Use: Expand west terminal, Expand aircraft apron, Modify airport roadways, School sound attenuation, Construct overnight apron, Upgrade heating, ventilating, and air conditioning in east and west terminals.

Brief Description of Projects Approved for Collection: East terminal addition, Second level roadway, East terminal expansion, Demolish lease buildings, USAir, Replace airport fire station.

Brief Description of Disapproved Projects: Expand west terminal.

Determination: Disapproved. The Port, in its response to carriers' disagreements on this project, makes several statements which raise concerns about the justification and feasibility of this project. Specifically, the Port states that ''the addition of gates on the NTC [Naval Training Center] side of the concourse * * * would only be pursued based on the needs of the airlines and if the NTC land is made available.'' The carriers had also questioned whether there was sufficient airfield capacity to accommodate the additional traffic which would use these additional gates. The Port responded by stating that ''airfield capacity simulation modeling will be pursued in the planning of the project * * *.'' The FAA has concluded that the Port's request for collection authority for this project is premature because of the Port's stated uncertainties and disapproved the project.

Construct NTC apron.

Determination: Disapproved. The project justification provided by the Port for this project states that the apron project is necessary to support the west terminal expansion project, which was also disapproved. This project is not justified as a stand-alone project. Therefore, this project is being disapproved at this time.

Modify NTC roadways.

Determination: Disapproved. The project justification provided by the Port for this project states that the roadways are necessary to support the west terminal expansion project, which was also disapproved. This project is not justified as a stand-alone project. Therefore, this project is being disapproved at this time.

Decision Date: July 26, 1995.

FOR FURTHER INFORMATION CONTACT: John Milligan, Western Pacific Region Airports Division Office, (310) 725–3621.

Public Agency: State of New York—Department of Transportation, Newburgh, New York.

Application Number: 95–01–C–00–SWF.

Application Type: Impose and use PFC revenue.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $12,541,999.

Charge Effective Date: November 1, 1995.

Estimated Charge Expiration Date: July 1, 2007.

Class of Air Carriers not Required to Collect PFC's: Unscheduled air taxi operators operating under Part 135.

Determination: Approved. Based on information submitted in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Stewart International Airport.

Brief Description of Projects Approved for Collection and Use of PFC Revenue: Twin dozer plow with truck, Four snow brooms with prime movers, Vacuum sweeper, airfield, Terminal building expansion, Replace southwest quadrant fuel farm, Runway 16 approach protection, phases I and II, Security access control system, Part 107, Phase III, cargo ramp expansion, Storm water management study, Field lighting control vault, Taxiway C relocation and removal of portion of Tower Hill, South cargo development, phase I, Two roll-over plows with sanders and trucks, Twenty-four foot plow truck, Snow broom, 4,000 gallon runway deicing truck, 4,000 ton per hour snow blowers (2), Partial parallel taxiway, runway 16/34—phase II—removal of a portion of Tower Hill, Northeast quadrant phase III ramp, Runway 16 approach protection, phase III, Rehabilitate First Street, 6,000 foot fence along NY State Route 17K, Rehabilitate perimeter road, Snow brooms (2), 19 foot plows with trucks (2), 19 foot plows with trucks (2).

Brief Description of Project Approved for Collection: Tower Hill obstruction removal.

Brief Description of Disapproved Project: Demolition of Hangar E.

Determination: Disapproved. This project has been determined to be ineligible under AIP cirteria in accordance with paragraph 592 of FAA Order 5100.38A. Accordingly, the project is disapproved for the collection and use of PFC revenue.

Decision Date: July 31, 1995.

FOR FURTHER INFORMATION CONTACT: Philip Brito, New York Airports District Office, (516) 295–9340.

Public Agency: Jackson County Airport Authority, Medford, Oregon.

Application Number: 95–03–C–MFR.

Application Type: Impose and use PFC revenue.

PFC Level: $3.00.

Total Approved Net PFC Revenue: $2,616,349.

Charge Effective Date: November 1, 1995.

Estimated Charge Expiration Date: November 1, 2000.

Class of Air Carriers not Required to Collect PFC'S: Air taxi operators.

Determination: Approved. Based on information submitted in the public agency's application, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at Rogue Valley International Airport.

Brief Description of Projects Approved for Collection and Use: Acquire passenger lift device, Ground level loading bridge with covered walkway, Rehabilitate air carrier ramp.

Decision Date: July 31, 1995.

FOR FURTHER INFORMATION CONTACT: Jerry Trujillo, Seattle Airports District Office, (206) 227–2629.

Public Agency: Port Authority of New York and New Jersey, New York, New York.

Application Numbers: 95–02–C–00–EWR; 95–02–C–00–JFK; 95–02–C–00–LGA.

Application Type: Impose and use PFC revenue.

PFC Level: $3.00 (at each airport).

Total Approved Net PFC Revenue to be Collected at Newark International Airport (EWR): $255,015,000.

Total Approved Net PFC Revenue to be Collected at John F. Kennedy International Airport (JFK): $226,395,000.

Total Approved Net PFC Revenue to be Collected at Laguaradia Airport (LGA): $193,590,000.

Charge Effective Date: October 1, 1995 (at each airport).

Estimated Charge Expiration Date: January 1, 2001 (at each airport).

Class of Air Carriers not Required to Collect PFC'S: Part 298 Air taxis, with the exception of commuter air carriers.

Determination: Approved. Based on information submitted in the public agency's applications, the FAA has determined that the proposed class accounts for less than 1 percent of the total annual enplanements at each airport. Although the Port Authority proposed the same class at each airport, the members of the class are different at each airport. Carriers should review the specific application or consult with the Port Authority to determine if they are members of the class excluded from PFC collection at either EWR, JFK, or LGA.

Brief Description of Project Approved for Use of PFC Revenue: EWR monorail.

Brief Description of Project Approved for Collection and use: EWR landside access project—phase 1A.

Brief Description of Project Approved for Collection: EWR ground access monorail-Northeast Corridor connection, Automated guideway transit (AGT) system—Howard Beach component.

Brief Description of Disapproved Project: AGT system—LGA on-airport component.

Determination: Disapproved. The Port Authority's justification for this project is entirely dependent on the construction of the entire AGT system. Completion of the entire system appears to be uncertain at this time. The Port Authority has not provided information showing that this project has independent utility as a separate on-airport system. Therefore, the FAA has determined that the LGA on-airport component does not meet the requirements of § 158.15(a) or (b), nor has the Port Authority provided adequate justification for the project as a stand-alone project as currently proposed.

Decision Date: July 31, 1995.

FOR FURTHER INFORMATION CONTACT: Philip Brito, New York Airports District Office, (516) 295–9340.

AMENDMENTS TO PFC APPROVALS

Amendment No., city, state	Amendment approved date	Amended approved net PFC revenue	Original approved net PFC revenue	Original estimated charge exp. date	Amended estimated charge exp. date
93–01–C–ORD, Chicago, IL.	07/07/95	$481,806,170	$531,187,544	10/01/99	09/01/98
94–01–C–CVG, Covington, KY.	07/07/95	23,847,550	$20,737,000	09/01/95	10/01/95
94–01–C–ILE, Killeen, TX.	06/09/95	321,200	321,200	05/01/97	05/01/97
93–01–C–PSC, Pasco, WA.	07/10/95	1,725,724	1,230,731	11/01/96	09/01/97

Issued in Washington, DC on August 4, 1995.

Sheryl Scarborough,

Acting Manager, Passenger Facility Charge Branch.

[FR Doc. 95–19905 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–13–M

National Highway Traffic Safety Administration

[Docket No. 93–93; Notice 2]

Century Products Co. Grant of Petition for Determination of Inconsequential Noncompliance

Century Products Company (Century) of Macedonia, Ohio, determined that some of its child safety seats failed to comply with the flammability requirements of 49 CFR 571.213, ''Child Restraint Systems,'' Federal Motor Vehicle Safety Standard (FMVSS) No. 213, and filed an appropriate report pursuant to 49 CFR part 573, ''Defect and Noncompliance Reports.'' Century also petitioned to be exempted from the notification and remedy requirements of 49 U.S.C. Chapter 301 (formerly the National Traffic and Motor Vehicle Safety Act) on the basis that the noncompliance is inconsequential as it relates to motor vehicle safety.

Notice of receipt of the petition was published on December 29, 1993, and an opportunity afforded for comment (58 FR 68985). No comments were received. This notice grants the petition.

Paragraph S5.7 of FMVSS No. 213 states that ''[e]ach material used in a child restraint system shall conform to the requirements of S4 of FMVSS No. 302 (Flammability of Interior Materials) (571.302).'' Paragraph S4.3(a) of FMVSS No. 302 states that ''[w]hen tested in accordance with S5, material described in S4.1 and S4.2 shall not burn, nor transmit a flame front across its surface, at a rate of more than 4 inches per minute.'' Paragraph S4.2.1 of FMVSS No. 302 states that ''[a]ny material that does not adhere to other material(s) at every point of contact shall meet the requirements of S4.3 when tested separately.''

From December 1991 to May 1993, Century manufactured and sold 192,824 Model 4594 and 4595 child safety seats that did not comply with the flammability requirements of FMVSS No. 213. On June 7, 1993, NHTSA informed Century that, when its Model 4595 child safety seat was tested by a NHTSA contractor, the fabric seat cover failed to meet the Standard No. 213 flammability requirements (Century's Model 4594 has the same construction as its Model 4595). The contractor tested six samples of the seat covers, yielding burn rates of between 6.3 and 7.6 inches per minute.

The seats in question are constructed of fabric, fiberfill, and backing. The covers on these seats are formed by sewing three sections together: The left side, the right side, and the center. Each section is fully sewn around its perimeter and the three sections are sewn together. The entire perimeter of the cover is then permanently and completely sewn together with an overlock to assure that the layers are securely attached. There is additional stitching surrounding the buckle openings and belt loop areas. Because of the construction of the seats, Century decided that testing the fabric, fiberfill, and backing together (composite testing) would be appropriate. However, Century subsequently agreed that the exterior material of the seat cover ''does not adhere to other material(s) at every point of contact,'' and that therefore, pursuant to Paragraph S4.2.1 of FMVSS No. 302, the seat covers are ''required to meet the requirements of S4.3 when tested separately.''

Century supported its petition for an exemption from the recall requirements of the statute with the following arguments and also submitted test reports. All of these submissions are available for review in the NHTSA docket.

Under FMVSS No. 213, Section S5.7, ''each material used in a child restraint system shall conform to the requirements of S4 of FMVSS No. 302.'' 49 CFR 571.213 S5.7 (1992). FMVSS No. 302 sets the standard for the flammability of materials used in the interior of motor vehicles. The purpose of FMVSS No. 302 is to ''reduce the deaths and injuries

to motor vehicle occupants caused by vehicle fires, especially those originating in the interior of the vehicle from sources such as matches or cigarettes.''

When FMVSS No. 302 was originally proposed, materials used in the interior of motor vehicles were to be tested separately regardless of how the materials were used. FMVSS No. 302 was revised prior to its release to require testing as a composite if the surface material is ''bonded, sewed or mechanically attached to the underlying material.'' 36 FR 290 (1971). The purpose of the revision was to eliminate ''an element of complexity found unnecessary for safety purposes.'' Under this version of FMVSS No. 302, Century's infant restraint would have been tested as a composite and readily passed the standard.

However, in 1975, the testing procedure was again revised, and the standard now in place was adopted. 40 FR 14,318 (1975). Under the revised standard, materials are tested as a composite only if the material ''adhere[s] to other materials(s) at every point of contact.'' 49 CFR 571.302 S4.2.1. The standard was revised to take into account some omissions in the testing scheme ''and to reduce the complexity of testing single and composite materials.'' 40 FR 14,319 (1975). The standard was not revised because former FMVSS No. 302 was found to be inadequate to meet the safety standards of the Act, but to reduce the complexity of the testing.

The current version of FMVSS No. 302 may go further than necessary to prevent the ''unreasonable risk of injury or death.'' This is evidenced by the results of a study completed by Failure Analysis Associates in March of 1991. A study of the U.S. CPSC NEISS database and the NHTSA Complaint File back to 1978 revealed not one instance in which an infant or child was injured because a car seat ignited. Failure Analysis Associates, Inc., *Flammability Tests and Examination of Accident/Injury and Complaint Data* 11 (1991). A study conducted by James H. Shanley, Jr. in conjunction with Fisher-Price's petition for determination of inconsequential noncompliance also found no instances in which a vehicle fire started in a child safety seat. *Fisher-Price*, Dkt. No. 93–79, 58 FR 59,511 (1993) (Notice of Receipt of Petition for Determination of Inconsequential Noncompliance). Century realizes that the facts in their case are different from Fisher-Price and only cites the document for the purpose stated in this Petition. Moreover, in 1971 a much larger portion of our society smoked. Now, with fewer and fewer Americans smoking, the risks that an infant or child restraint would be set on fire by lighted cigarettes or matches is becoming more remote.

The Agency could submit that the reason there have been no fires is because of FMVSS 302 and their aggressive enforcement of the standard. But, it is important to remember that the Agency standard does not require nonflammable materials; it only requires material which burns slowly. Hence, the standard, while admirable, would not explain the fact that there has been no recorded evidence of a fire.

The frequency of incidents involving nonconforming or defective equipment is a factor in determining whether defects or noncompliance has an impact on safety. See, *e.g., United States* v. *General Motors Corp.*, 656 F. Supp. 1555 (D.D.C. 1987), *aff'd*, 841 F.2d 400 (D.C. Cir. 1988) (premature wheel lockup in 1980 X-cars was not a ''safety related defect'' when the risk of failure was no worse than, and in most instances better than, the rate for all cars); *United States* v. *General Motors Corp.*, 561 F.2d 923 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 1033 (1978) (government presented evidence of a disproportionately high number of replacement parts (35,366) and inferred, in the absence of challenge by General Motors, that replacement part sales were due to a disproportionately high rate of failures and concluded that defect safety-related). The fact that no child has been injured by fire caused by a child car seat for the last 15 years militates strongly against a finding that Century's noncompliance has an effect on safety.

NHTSA has recognized that some technical violations of NHTSA standards do not affect safety and (has) exempted manufacturers from the notice and remedy requirements of the Act. See, *e.g., General Motors Corp.*, Dkt No. 92–23, 57 FR 45,866 (1992) (one test point on side reflex reflector failed to meet standard, but when values for reflector considered overall, noncompliance inconsequential). Another example, in *General Motors Corp.*, Dkt. No. 91–10–IP–No. 2, 56 FR 33,323 (1991), NHTSA found that the technical violation at issue had an inconsequential effect on safety because the potential hazards were so remote.

In *General Motors Corp.*, General Motors' high beam telltale in its 1990 Oldsmobile Toronado was not in compliance with NHTSA standards because when the cigar lighter was in use, the telltale dimmed or extinguished. The Agency granted GM's petition for inconsequential noncompliance because problems would occur only under a particular set of circumstances:

The noncompliance could only manifest itself during upper beam use when the cigar lighter was also in use. But only a comparatively small portion of driving occurs at night, the time of headlamp activation. Because of State and local laws prohibiting upper beam use, only a very small percentage of nighttime driving is performed using the upper beam. The 25-second use of the cigar lighter would comprise only a limited amount of the time the upper beam is in use. The safety hazard most likely to be created by the noncompliance is glare in the eyes of oncoming driver on a two or three-lane road, but, if discomforted, the instinctive reaction of that driver would be to flash the upper beams, alerting the noncompliant vehicle to lower that vehicle's upper beams. *The probability of all these facts occurring simultaneously is low.* (Emphasis added.) *Id.* at 33,324.

The ''probability of all these facts occurring simultaneously'' in this Century case is exceedingly low. When tested as a composite, Century's Model 4594 and 4595 infant restraints fall within NHTSA's burning rate. The components of the infant restraint are securely sewn together. In order for Century's infant restraint to pose a hazard to a passenger, (1) the seat would have to have somehow torn apart around the numerous sewn seams; (2) the fabric would have to be frayed in such a way that the fabric is sticking up away from the fiberfill; and (3) the source of ignition would have to land on the exposed fabric. Again, the ''probability of all these facts occurring simultaneously'' is low. Coupling the need for these unlikely probabilities with the fact that there has never been a fire caused by a child car seat ignition should make this a case where fairness requires a granting of the Petition.

Under the standard as enacted in 1971, Century's infant restraint would have been tested as a composite, and therefore, would be in compliance with NHTSA standards. FMVSS No. 302 was revised in 1975, not to address safety concerns, but simply for purposes of administrative ease. The fact that the requirements of FMVSS No. 302 are in excess of those needed to ensure the safety of the restraint's occupants was dramatically demonstrated by the results of a study performed by Patrick Kennedy, an expert retained by Fisher-Price. Mr. Kennedy's study revealed that typical children's clothing burns at a rate far in excess of the standard imposed by FMVSS No. 302. Therefore, an infant sitting in Century's infant restraint is at far greater risk from the clothing he or she wears than from the infant restraint itself.

Century's infant restraints do not pose an unreasonable risk to the infants they hold. The question of whether Century's infant restraint meets the objectives of the Act could be phrased in this fashion: Would a reasonable parent, after being made aware of all the facts and circumstances surrounding this noncompliance, still be willing to place his or her infant in the Model 4594 or 4595 infant restraint? Century is satisfied that a reasonable parent would use their Model 4594 and 4595 restraints without any hesitation.

Century understands how serious the flammability issue is to the Agency and commends the Agency for its vigilance. Century is also serious about the issue, and would not consider selling a product that would place a child at risk. Century strongly believes that if there is a risk in this case, it is not an unreasonable risk as required by the Act. As Century's tests have shown, the seat pad on the infant restraint as a composite burns well within the burn rate acceptable to the Agency. Furthermore, the seat pad is constructed in a way that makes tears unlikely. Because Century's infant restraints meet the objectives of the Act, Century's noncompliance is inconsequential as it relates to motor vehicle safety. For these reasons, Century respectfully requests that NHTSA grant its petition for exemption.

The agency has reviewed Century's petition and has determined that the noncompliance is inconsequential to motor vehicle safety. NHTSA agrees with Century that the noncompliant seat covers are unlikely to pose a flammability risk when they are securely sewn to the seat, which is the normal condition for these seats.

Century supported this point by performing flammability testing under two conditions: first on the seat and cover as a composite, *i.e.*, as it exists on a child seat with the two items sewn together; and second, by bunching or gathering the noncompliant seat cover and attempting to ignite it. In both cases the seat cover burned at a rate below the four inches per minute maximum set out in FMVSS No. 302.

The agency granted a petition for inconsequential noncompliance submitted by PACCAR (57 FR 45868) in which the circumstances were similar to those in this petition. PACCAR manufactures mattresses for the sleeper areas of certain truck tractors. A small portion of the material used in the construction of the mattresses, and subject to the requirements of FMVSS No. 302, failed the burn rate test. The agency determined that ignition of the noncompliant material was unlikely and, due to the small volume of the material, would not pose the threat of a serious fire if ignited. As a result of this analysis, the PACCAR petition was granted.

The circumstances here are similar to those in which the agency granted a petition for inconsequentiality by General Motors in connection with a noncompliance of the upper beam indicator. 56 FR 33323 (1991). The indicator was noncompliant only when the cigarette lighter was operating. The agency determined that the possibility of the upper beams being operated simultaneously with the cigarette lighter posed a very limited safety hazard. Similarly, it is unlikely that sections of the noncompliant cover fabric large enough to cause serious burn injuries would be separated from the cushion lining. Even if a large section of the fabric was torn away, NHTSA considers the possibility that this material would be exposed to a potential ignition source to be extremely remote.

Although it is possible that fuel-fed fires from vehicle crashes could consume a vehicle's interior, the flammability of the seat cover materials would be irrelevant to the severity of such a fire and to the potential injuries incurred by a child.

NHTSA's evaluation of the consequentiality of this noncompliance should not be interpreted as a diminution of the agency's concern for child safety. Rather, it represents NHTSA's assessment of the gravity of the noncompliance based upon the likely consequences. Ultimately, the issue is whether this particular noncompliance is likely to increase the risk to safety. Although empirical results are not determinative, the absence of any reports of fires originating in these child restraints supports the agency's decision that the noncompliance does not have a consequential effect on safety.

For the above reasons, the agency has determined that Century has met its burden of persuasion that the noncompliance at issue here is inconsequential to motor vehicle safety and its petition is granted. Accordingly, Century is hereby exempted from the notification and remedy provisions of 49 U.S.C. 30118 and 30120.

Authority: 49 U.S.C. 30118(d), 30120(h); delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: August 8, 1995.

Barry Felrice,

Associate Administrator for Safety Performance Standards.

[FR Doc. 95–19897 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–59–P

[Docket No. 93–48; Notice 4]

Cosco, Inc.; Grant of Appeal of Denial of Petition for Determination of Inconsequential Noncompliance

On April 30, 1993, Cosco, Inc. (Cosco), of Columbus, Indiana, determined that some of its child safety seats failed to comply with flammability requirements of Federal Motor Vehicle Safety Standard (FMVSS) No. 213, ''Child Restraint Systems,'' and filed an appropriate report pursuant to 49 CFR part 573, ''Defect and Noncompliance Reports.'' On May 28, 1993, Cosco petitioned to be exempted from the notification and remedy requirements of 49 U.S.C. Chapter 301 (formerly the National Traffic and Motor Vehicle Safety Act) on the basis that the noncompliance was inconsequential as it relates to motor vehicle safety.

Notice of receipt of the petition was published in the **Federal Register** on July 7, 1993 (58 FR 36510). On March 22, 1994, NHTSA denied Cosco's petition, stating that the petitioner had not met its burden of persuasion that the noncompliance is inconsequential as it relates to motor vehicle safety (59 FR 14443, March 28, 1994). Cosco appealed that denial. On June 15, 1994 (59 FR 30831), NHTSA published a notice providing an opportunity for public comment on that appeal. No comments were received. This notice grants Cosco's appeal.

Paragraph S5.7 of Standard No. 213 states that ''[e]ach material used in a child restraint system shall conform to the requirements of S4 of FMVSS No. 302 ('Flammability of Interior Materials') (571.302).'' Paragraph S4.3(a) of Standard No. 302 states that ''[w]hen tested in accordance with S5, material described in S4.1 and S4.2 shall not burn, nor transmit a flame front across its surface, at a rate of more than 4 inches per minute.''

Fabric used in the shoulder straps of certain models of Cosco's child restraints exceeded this limit by an average of .3 inches per minute when tested by NHTSA contractors in early 1993. Apparently, the noncompliance was due to the manner in which the fabric was treated during the process in which the straps were molded into a urethane shield. The company that performed this process for Cosco is the same company that performed the identical process for Fisher-Price, Inc., another manufacturer of child restraints whose request for an inconsequentiality exemption from the recall requirements of the statute is granted elsewhere in today's **Federal Register**.

In its 1993 noncompliance notice, Cosco stated that it had produced 133,897 add-on (as opposed to built-in) child restraints whose shoulder straps did not comply with Standard No. 213. On appeal of the inconsequentiality denial, it stated that only 23,449 restraints seats should have been covered by the notice, the remainder having been shipped to its Canadian subsidiary.

On March 22, 1994, NHTSA denied Cosco's inconsequentiality petition (59 FR 14443, March 28, 1994). That notice contains a full discussion of the noncompliance, the company's petition, and the agency's rationale for its denial of the petition.

On June 15, 1994, NHTSA published in the **Federal Register** Cosco's appeal of the agency's denial pursuant to 49 CFR 556.7. In the appeal, Cosco contended that it is extremely unlikely that straps of its child restraints would ignite independently of an interior fire that was already in progress from another source. It argued that NHTSA based its denial of the petition on hypothetical situations rather than confirmed reports of child restraint fires.

NHTSA has evaluated Cosco's arguments as well as the new materials submitted by Fisher-Price in support of its appeal. For the reasons set out in the notice granting Fisher-Price's appeal, which is published elsewhere in today's **Federal Register** (Docket No. 93–79; Notice 5), the agency has determined that Cosco has met its burden of persuasion that the noncompliance at issue here is inconsequential to motor vehicle safety. Accordingly, Cosco is hereby exempted from the notification

and remedy provisions of 49 U.S.C. 30119 and 30120.

Authority: 49 U.S.C. 30118(d), 30120(h); delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: August 8, 1995.

Barry Felrice,

Associate Administrator for Safety Performance Standards.

[FR Doc. 95–19898 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–59–P

[Docket No. 93–79; Notice 6]

Fisher-Price, Inc.; Grant of Appeal of Denial of Petition for Determination of Inconsequential Noncompliance

On September 16, 1993, Fisher-Price, Inc. (Fisher-Price), of East Aurora, New York, filed a petition for an exemption from the notification and remedy provisions of 49 U.S.C. Chapter 301 on the ground that the noncompliance of certain of its child restraints with the flammability requirements of Federal Motor Vehicle Safety Standard (FMVSS) No. 213, ''Child Restraint Systems,'' was inconsequential as it relates to motor vehicle safety. On March 22, 1994, the National Highway Traffic Safety Administration (NHTSA) denied Fisher-Price's petition (59 FR 23253; May 5, 1994).

On May 6, 1994, Fisher-Price appealed that denial. Notice of the appeal was published on June 16, 1994 (59 FR 30957), and an opportunity was afforded for comment. However, on August 12, 1994, before the agency reached a decision on the appeal, Fisher-Price notified NHTSA that it was taking the position that it had never formally determined that a noncompliance existed. In response, on August 17, 1994, the agency terminated the inconsequentiality proceeding (59 FR 42326), as its regulations require that a determination of noncompliance exist before an inconsequentiality petition may be filed. See 49 CFR 556.4(b)(6).

Following this termination, on September 26, 1994, NHTSA's Associate Administrator for Enforcement published an initial decision, pursuant to 49 U.S.C. 30118(a), that the child restraints at issue failed to comply with FMVSS No. 213 (59 FR 49100). The agency then conducted a public proceeding on October 21, 1994 to allow Fisher-Price and other interested persons the opportunity to present information, views, and arguments on whether a noncompliance existed. Prior to the agency's final decision on this issue, on July 10, 1995, Fisher-Price submitted a Noncompliance Report in accordance with 49 CFR part 573, that memorializes its formal determination that, under NHTSA's interpretation of the applicable test procedures, the seats in question fail to comply with S5.7 of FMVSS No. 213.

In view of the fact that a determination of noncompliance has been made, the agency may now consider Fisher-Price's petition for an inconsequentiality exemption. Moreover, rather than require Fisher-Price to file a new petition, NHTSA has decided to reinstate the proceeding at the same stage it was at when it was terminated.

For the reasons set forth below, the agency has decided to grant Fisher-Price's appeal. Thus, Fisher-Price will not be required to conduct a recall campaign. However, as part of the resolution of this matter, Fisher-Price has agreed to pay $35,000 to the United States in settlement of NHTSA's claim that it violated 49 U.S.C. 30118(c) and 30119(c) by failing to notify the agency in a timely manner after it should, in good faith, have determined that these child restraints did not comply with the standard.

Paragraph S5.7 of FMVSS No. 213 states that ''[e]ach material used in a child restraint system shall conform to the requirements of S4 of FMVSS No. 302 (''Flammability of Interior Materials'') (571.302).'' Paragraph S4.3(a) of FMVSS No. 302 states that ''[w]hen tested in accordance with S5, material described in S4.1 and S4.2 shall not burn, nor transmit a flame front across its surface, at a rate of more than 4 inches per minute.''

Fabric used in the shoulder straps in some models of Fisher-Price's child restraints exceeded this limit by .3 to .6 inch per minute when tested by NHTSA contractors in the spring of 1993 and when retested by Fisher-Price in the summer of 1993. Apparently, the noncompliance was due to the manner in which the fabric was treated during the process in which the straps were molded into a urethane shield. The company that performed this process for Fisher-Price is the same company that performed the identical process for Cosco, Inc., another manufacturer of child restraints whose request for an inconsequentiality exemption from the recall requirements of the statute is granted elsewhere in today's **Federal Register**.

In its September 16, 1993 letter to NHTSA, Fisher-Price acknowledged that it had ''become aware of information suggesting that the molded shoulder belt webbing on its Model AO9101, DO9101, 9103, 9149, 9173, 9179 and 9180 car seats may not comply with the requirements of FMVSS 302.'' At the same time, pursuant to 49 U.S.C. 30118(d) and 30120(h), Fisher-Price sought an exemption from the notification and remedy requirements of the statute on the ground that any such noncompliance was inconsequential as it relates to motor vehicle safety.

On March 22, 1994, NHTSA denied Fisher-Price's inconsequentiality petition (59 FR 23253, May 5, 1994). That notice contains a full discussion of the noncompliance, the company's petition, and the agency's rationale for its denial of the petition.

On May 6, 1994, Fisher-Price submitted an appeal of the agency's denial pursuant to 49 CFR 556.7. The appeal contains an analysis of the agency's decision, the affidavit of Gail E. McCarthy, Ph.D., P.E., of Failure Analysis Associates (FaAA), and a summary of the supplemental information Fisher-Price had submitted on February 25, 1994, March 17, 1994, and March 24, 1994 that had not been considered by the agency in its denial.

The February 25, 1994 submission contained information on the location of mold release compound on the shoulder webbing and its possible dissipation over time.

The March 17, 1994 submission contained research conducted by FaAA for Fisher-Price, including burn tests and a search of the literature and accident data regarding child seat fires. The submission also included a calculation of an alleged incremental risk associated with a recall of the noncompliant seats.

The March 24, 1994 submission, entitled ''Supporting Documentation for Evaluation of the Fire Safety of Fisher-Price, Inc. Child Restraint Shoulder Harness Webbing,'' contained the detailed data and test results on which the material in the March 17, 1994 document was based.

In its May 6, 1994 appeal, Fisher-Price raised the following points: (1) Fisher-Price claimed that it had not determined that its child restraints failed to comply with FMVSS No. 213. (In view of Fisher-Price's recent acknowledgement that a noncompliance exists, this issue is now moot.) (2) Fisher-Price claimed that NHTSA had considered its petition under a stricter standard for inconsequentiality exemptions than is provided by statute because it involved child restraints. (3) Fisher-Price asserted that NHTSA's past precedent in granting inconsequentiality petitions compels a grant of this petition. (4) Fisher-Price contended that the data it submitted in support of its argument that the flammability of children's clothing

poses a much greater risk to safety than the noncompliant shoulder belt webbing were not adequately refuted.

In her affidavit submitted with the appeal, Dr. McCarthy asserted the following: (1) The shoulder belt webbing should properly be viewed as meeting the requirements of FMVSS No. 302; (2) any noncompliance that might be deemed to exist has no impact on motor vehicle safety; and (3) possible remedial measures would create substantially greater risk of injury to children than that presented by the webbing.

No comments were received on the appeal.

The agency has carefully reviewed all the data and arguments comprising the record of this case and has decided that the facts warrant granting the appeal. First, the margin of noncompliance is small, falling outside the standard's maximum by less than an inch per minute. (The agency wishes to emphasize that the failure to meet a performance requirement by a minimal amount does not in itself support an inconsequentiality determination; each petition must be considered in the context of all relevant facts.)

Second, the portions of the child restraint that do not comply with the standard, the shoulder straps, are a small part of the child restraint itself, and a minimal part of the fabric present in a vehicle's interior. Although it is possible that fuel-fed fires from vehicle crashes could consume a vehicle's interior, the flammability of the shoulder straps would be irrelevant to the severity of such a fire and to the potential injuries incurred by a child.

The primary purpose of NHTSA's flammability requirements is to prevent fires from ''originating in the interior of the vehicle from sources such as matches or cigarettes.'' See paragraph S2 of 49 CFR 571.302. While it is theoretically possible that ashes from smoking materials could land upon the shoulder straps, the angle at which the straps normally rest makes this very unlikely.

NHTSA's reevaluation of the consequentiality of this noncompliance should not be interpreted as a diminution of the agency's concern for child safety. Rather, it represents NHTSA's reassessment of the gravity of the noncompliance based upon the likely consequences. Ultimately, the issue is whether this particular noncompliance is likely to increase the risk to safety compared to child restraints with shoulder straps that meet the four inches per minute requirement. Although empirical results are not determinative, the absence of any reports of fires originating in the over three million restraints in which this noncompliance exists supports the agency's decision that the noncompliance does not have a consequential effect on safety.

For the above reasons, the agency has determined that Fisher-Price has met its burden of persuasion that the noncompliance at issue here is inconsequential to motor vehicle safety, and its appeal of the agency's original denial is granted. Accordingly, Fisher-Price is hereby exempted from the notification and remedy provisions of 49 U.S.C. 30119 and 30120.

Authority: 49 U.S.C. 30118(d), 30120(h); delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: August 8, 1995.

Barry Felrice

Associate Administrator for Safety Performance Standards.

[FR Doc. 95–19899 Filed 8–10–95; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

List of Specially Designated Terrorists Who Threaten to Disrupt the Middle East Peace Process; Additional Name

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice of blocking.

SUMMARY: The Treasury Department is adding the name of an individual to the list of blocked persons who have been found to have committed, or to pose a risk of committing, acts of violence that have the purpose of disrupting the Middle East peace process or have assisted in, sponsored, or provided financial, material or technological support for, or service in support of, such acts of violence, or are owned or controlled by, or to act for or on behalf of other blocked persons.

EFFECTIVE DATE: August 11, 1995 or upon prior actual notice.

FOR FURTHER INFORMATION: J. Robert McBrien, Chief, International Programs, Tel.: (202) 622–2420; Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Ave., N.W., Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document is available as an electronic file on *The Federal Bulletin Board* the day of publication in the **Federal Register**. By modem dial 202/512–1387 and type ''/GO/FAC'' or call 202/512–1530 for disks or paper copies. This file is available for downloading in WordPerfect 5.1, ASCII, and Postscript formats. The document is also accessible for downloading in ASCII format without charge from Treasury's Electronic Library (''TEL'') in the ''Business, Trade and Labor Mall'' of the FedWorld bulletin board. By modem dial 703/321–3339, and select self–expanding file ''T11FR00.EXE'' in TEL. For Internet access, use one of the following protocols: Telnet = fedworld.gov (192.239.93.3); World Wide Web (Home Page) = http://www.fedworld.gov; FTP = ftp.fedworld.gov (192.239.92.205).

Background

On January 24, 1995, President Clinton signed Executive Order 12947, ''Prohibiting Transactions with Terrorists Who Threaten to Disrupt the Middle East Peace Process'' (60 FR 5079, Jan. 25, 1995—the ''Order'' or ''E.O. 12947''). The Order blocks all property subject to U.S. jurisdiction in which there is any interest of 12 Middle East terrorist organizations included in an Annex to the Order. In addition, the Order blocks the property and interests in property of persons designated by the Secretary of State, in coordination with the Secretary of Treasury and the Attorney General, who are found 1) to have committed or to pose a significant risk of disrupting the Middle East peace process, or 2) to assist in, sponsor or provide financial, material, or technological support for, or services in support of, such acts of violence. The order further blocks all property and interests in property subject to U.S. jurisdiction in which there is any interest of persons determined by the Secretary of the Treasury, in coordination with the Secretary of State and the Attorney General, to be owned or controlled by, or to act for or on behalf of any other person designated pursuant to the Order (collectively ''Specially Designated Terrorists'' or ''SDTs''). An initial list of SDTs was published on January 25, 1995 (60 FR 5084).

The order also prohibits any transaction or dealing by a United States person or within the United States in property or interests in property of SDTs, including the making or receiving of any contribution of funds, goods, or services to or for the benefit of such persons.

Designations of persons blocked pursuant to the Order are effective upon the date of determination by the Secretary of State or his delegate, or the Director of the Office of Foreign Assets Control acting under authority delegated by the Secretary of the Treasury. Public

notice of blocking is effective upon the date of publication in the Federal Register, or upon prior actual notice.

The following name is added to the list of Specially Designated Terrorists:

SALAH,Mohammad Abd El–Hamid Khalil (a.k.a. SALAH, Mohammad Abdel Hamid Halil) (a.k.a. AHMAD, Abu) (a.k.a. AHMED, Abu) (a.k.a. SALAH, Muhammad A.); 9229 South Thomas, Bridgeview, Illinois 60455, U.S.A.; P.O. Box 2578, Bridgeview, Illinois 60455, U.S.A.; P.O. Box 2616, Bridgeview, Illinois 60455–6616, U.S.A.; Israel; DOB 30 May 1953; SSN 342–52–7612; Passport No. 024296248 (U.S.A.)

Dated: July 27, 1995.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: August 1, 1995.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff & Trade Enforcement).

[FR Doc. 95–19831 Filed 8–7–95; 5:03 pm]

BILLING CODE 4810–25–F

Public Information Collection Requirements Submitted to OMB for Review

August 2, 1995.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Special Request: In order to conduct the survey described below in mid to late August, the Department of Treasury is requesting Office of Management and Budget (OMB) review and approval of this information collection by August 15, 1995. To obtain a copy of this survey, please write to the IRS Clearance Officer at the address listed below.

Internal Revenue Service (IRS)

OMB Number: 1545–1432
Project Number: PC:V 95–012–G
Type of Review: Revision
Title: Internal Revenue Service Buffalo District Point of Contact Interviews
Description: The primary purpose of the interviews is to determine what currently unavailable products and/or services are needed by taxpayers or what changes or improvements to current products and/or services taxpayers perceived as being beneficial. The customers' perceptions and assessment of service will be obtained and used to improve systems and services.
Respondents: Individuals or households, Business or other for-profit
Estimated Number of Respondents: 1,666
Estimated Burden Hours Per Respondent: 2 minutes
Frequency of Response: Other
Estimated Total Reporting Burden: 56 hours
Clearance Officer: Garrick Shear, (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224
OMB Reviewer: Milo Sunderhauf, (202) 395–7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 95–19921 Filed 8–10–95; 8:45 am]

BILLING CODE 4830–01–P

Public Information Collection Requirements Submitted to OMB for Review

August 2, 1995.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Internal Revenue Service (IRS)

OMB Number: 1545–0128
Form Number: IRS Form 1120–L
Type of Review: Revision
Title: U.S. Life Insurance Company Income Tax Return
Description: Life insurance companies are required to file an annual return of income and compute and pay the tax due. The data is used to insure that companies have correctly reported taxable income and paid the correct tax.
Respondents: Business or other for-profit
Estimated Number of Respondents/Recordkeepers: 2,440
Estimated Burden Hours Per Respondent/Recordkeeper:
Recordkeeping—87 hr., 32 min.
Learning about the law or the form—26 hr., 17 min.
Preparing the form—42 hr., 50 min.
Copying, assembling, and sending the form to the IRS—4 hr., 1 min.
Frequency of Response: Annually
Estimated Total Reporting/Recordkeeping Burden: 392,010 hours

OMB Number: 1545–1026
Form Number: IRS Form 8645
Type of Review: Extension
Title: Soil and Water Conservation Plan Certification
Description: Form 8645 is used to certify that conservation expenses claimed as a deduction on Schedule F, (Form 1040), Form 4835, Form 1040–PR, and Form 1040–SS are part of an approved plan for their farm area. The approved plan requirement comes under Code section 175(c)(3).
Respondents: Farms
Estimated Number of Respondents/Recordkeepers: 85,000
Estimated Burden Hours Per Respondent/Recordkeeper:
Recordkeeping—7 min.
Learning about the law or the form—5 min.
Preparing the form—8 min.
Copying, assembling, and sending the form to the IRS—11 min.
Frequency of Response: Annually
Estimated Total Reporting/Recordkeeping Burden: 44,200 hours

OMB Number: 1545–1038
Form Number: IRS Form 8703
Type of Review: Extension
Title: Annual Certification of a Residential Rental Project
Description: Operators of qualified residential projects will use this form to certify annually that their projects meet the requirements of Internal Revenue Code (IRC) section 142(d). Operators are required to file this certification under section 142(d)(7).
Respondents: Business or other for-profit
Estimated Number of Respondents/Recordkeepers: 6,000
Estimated Burden Hours Per Respondent/Recordkeeper:
Recordkeeping—3 hr., 50 min.
Learning about the law or the form—35 min.
Preparing and sending the form to the IRS—41 min.
Frequency of Response: Annually
Estimated Total Reporting/Recordkeeping Burden: 30,660 hours

OMB Number: 1545–1124
Regulation ID Number: INTL–704–87 Final
Type of Review: Extension
Title: Certain Corporate Distributions to Foreign Corporations Under Section 367(e)

Description: The regulations require domestic corporate taxpayers to file statement with tax returns in order to secure nonrecognition on certain distributions to foreign persons. The Service needs this information to ensure that the income from taxable dispositions will be reported.
Respondents: Business or other for-profit
Estimated Number of Respondents: 202
Estimated Burden Hours Per Respondent: 8 hours
Frequency of Response: Annually
Estimated Total Reporting Burden: 1,604 hours

OMB Number: 1545–1265
Regulation ID Number: IA–120–86 Final
Type of Review: Extension
Title: Capitalization of Interest
Description: The regulations require taxpayers to maintain contemporaneous written records of estimates, to file a ruling request to segregate activities in applying the interest capitalization rules, and to request the consent of the Commissioner to change their methods of accounting for the capitalization of interest.
Respondents: Individuals or households, business or other for-profit
Estimated Number of Recordkeepers: 50
Estimated Burden Hours Per Recordkeeper: 2 hours
Frequency of Response: On occasion
Estimated Total Recordkeeping Burden: 116,767 hours

OMB Number: 1545–1343
Regulation ID Number: PS–100–88 Final
Type of Review: Extension
Title: Valuation Tables
Description: The regulations will require individuals or fiduciaries to report information on Forms 706 and 709 in connection with the valuation annuity, an interest for life or a term of years, or a remainder rear reversionary interest.
Respondents: Individuals or households
Estimated Number of Respondents: 6,000
Estimated Burden Hours Per Respondent: 45 minutes
Frequency of Response: Single
Estimated Total Reporting Burden: 4,500 hours

OMB Number: 1545–1352
Regulation ID Number: PS–276–76 Final
Type of Review: Extension
Title: Treatment of Gain from Disposition of Certain Natural Resource Recapture Property
Description: The regulations prescribe rules for determining the tax treatment of gain from the disposition of natural resource recapture property. Gain is treated as ordinary income in an amount equal to the intangible drilling and development costs and depletion deductions taken with respect to the property.
Respondents: Business or other for-profit, individuals or households
Estimated Number of Respondents: 100
Estimated Burden Hours Per Respondent: 5 hours
Frequency of Response: On occasion
Estimated Total Reporting Burden: 2,000 hours

OMB Number: 1545–1430
Form Number: IRS Forms 945 and 945–A
Type of Review: Extension
Title: Annual Return of Withheld Federal Income Tax (945); Annual Record of Federal Tax Liability (945–A)
Description: Form 945 is used to report income tax withholding on nonpayroll payments including backup withholding and withholding on pensions, annuities, IRA's, military retirement and gambling winnings. Form 945–A is used to report nonpayroll tax liabilities.
Respondents: Business or other for-profit, individuals or households, not-for-profit institutions, farms, Federal Government, State, Local or Tribal Government
Estimated Number of Respondents/Recordkeepers: 193,468
Estimated Burden Hours Per Respondent/Recordkeeper:

	Form 945	Form 945–A
Recordkeeping	5 hr., 59 min.	8 hr., 37 min.
Preparing and sending the form to the IRS	6 min.	8 min.

Frequency of Response: Annually
Estimated Total Reporting/Recordkeeping Burden: 1,632,511 hours
Clearance Officer: Garrick Shear, (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224
OMB Reviewer: Milo Sunderhauf, (202) 395–7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 95–19922 Filed 8–10–95; 8:45 am]

BILLING CODE 4830–01–P

Public Information Collection Requirements Submitted to OMB for Review

August 3, 1995.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Internal Revenue Service (IRS)

OMB Number: 1545–0820
Regulation ID Number: EE–86–88 NPRM (Previously LR–279–81)
Type of Review: Extension
Title: Incentive Stock Options
Description: The affected public includes corporations that transfer stock to employees after 1979 pursuant to the exercise of a statutory stock option. The corporation must furnish the employee receiving the stock with a written statement describing the transfer. The statement will assist the employee in filing their tax returns.
Respondents: Business or other for-profit
Estimated Number of Respondents: 50,000
Estimated Burden Hours Per Respondent: 20 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 16,650 hours

OMB Number: 1545–0834
Form Number: None
Type of Review: Extension
Title: Regulations Under Tax Conventions—Ireland
Description: This information is needed to secure for individuals and businesses the benefits to which they are entitled under the tax convention and to facilitate the administration and enforcement of the tax laws of the United States.

Respondents: Business or other for-profit, Individuals or households
Estimated Number of Respondents: 80
Estimated Burden Hours Per Respondent: 15 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 20 hours

OMB Number: 1545–1374
Form Number: IRS Form 8834
Type of Review: Revision
Title: Qualified Electric Vehicle Credit
Description: Form 8834 is used to compute an allowable credit for qualified electric vehicles placed in service after June 30, 1993. Section 1913(b) under Public Law 102–1018 created new section 20.
Respondents: Individuals or households, Business or other for-profit
Estimated Number of Respondents/Recordkeepers: 500
Estimated Burden Hours Per Respondent/Recordkeeper:
Recordkeeping—6 hr., 13 min.
Learning about the law or the form—24 min.
Preparing, copying, assembling, and sending the form to the IRS—31 min.
Frequency of Response: Annually
Estimated Total Reporting/Recordkeeping Burden: 3,565 hours
Clearance Officer: Garrick Shear, (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224
OMB Reviewer: Milo Sunderhauf, (202) 395–7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 95–19923 Filed 8–10–95; 8:45 am]

BILLING CODE 4830–01–P

Public Information Collection Requirements Submitted to OMB for Review

August 4, 1995.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Internal Revenue Service (IRS)

OMB Number: 1545–0923
Regulation ID Number: IA–31–85 NPRM and LR–124–84 Temporary
Type of Review: Extension
Title: Tax-Exempt Entity Leasing
Description: The regulations are necessary to implement Congressionally enacted legislation and elections for certain previously tax-exempt organizations and certain tax-exempt controlled entities.
Respondents: Not-for-profit institutions, State, Local or Tribal Government
Estimated Number of Respondents: 2,000
Estimated Burden Hours Per Respondent: 30 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 1,000 hours

OMB Number: 1545–0985
Regulation ID Number: PS–128–86 NPRM and PS–127–86 Temporary
Type of Review: Extension
Title: Generation-Skipping Transfer Tax Regulations Under Tax Reform Act of 1986
Description: This regulation provides rules relating to the effective date, return requirements, definitions, and certain special rules covering the generation-skipping transfer tax.
Respondents: Individuals or households
Estimated Number of Respondents: 7,500
Estimated Burden Hours Per Respondent: 30 minutes
Frequency of Response: Annually and Other
Estimated Total Reporting Burden: 3,750 hours

OMB Number: 1545–1076
Form Number: IRS Form 8807
Type of Review: Revision
Title: Certain Manufacturers and Retailers Excise Taxes
Description: Form 8807 is used to compute the excise tax on fishing equipment, bows and arrows, trucks and trailer chassis and bodies and tractors and the luxury tax on aircraft, boats, passenger vehicles, furs, and jewelry. This form enables IRS to monitor the excise tax liability on these articles. (Internal Revenue Code (IRC) sections 4051, 4161, 4001, 4002, 4003, 4006, and 4007.)
Respondents: Business or other for-profit, Individuals or households
Estimated Number of Respondents/Recordkeepers: 27,000
Estimated Burden Hours Per Respondent/Recordkeeper:

	8807 Part I	8807 Part II	Worksheet I	Worksheet II
Recordkeeping	3 hours, 7 mins	2 hours, 38 mins	1 hour, 26 mins	1 hour, 40 mins.
Learning about the law or the form	0 hours, and 6 mins	0 hours, 6 mins	0 hours, and 0 mins	0 hours, and 0 mins.
Preparing and sending the form to the IRS	9 mins	9 mins	1 min	2 mins.

Frequency of Response: Quarterly
Estimated Total Reporting/Recordkeeping Burden: 502,680 hours

OMB Number: 1545–1384
Form Number: IRS Form 3911
Type of Review: Extension
Title: Taxpayer Statement Regarding Refund
Description: If taxpayer inquires about their nonreceipt of refund (or lost or stolen refund) and the refund has been issued, the information and taxpayer signature are needed to begin tracing action.
Respondents: Individuals or households, Business or other for-profit, Not-for-profit institutions
Estimated Number of Respondents: 520,000
Estimated Burden Hours Per Respondent: 5 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 43,160 hours
Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, N.W., Washington, DC 20224
OMB Reviewer: Milo Sunderhauf (202) 395–7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 95–19924 Filed 8–10–95; 8:45 am]

BILLING CODE 4830–01–P

Sunshine Act Meetings

Federal Register
Vol. 60, No. 155
Friday, August 11, 1995

This section of the FEDERAL REGISTER contains notices of meetings published under the ''Government in the Sunshine Act'' (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 11:45 a.m. on Tuesday, August 8, 1995, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and supervisory activities.

In calling the meeting, the Board determined, on motion of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), seconded by Vice Chairman Andrew C. Hove, Jr., concurred in by Director Eugene A. Ludwig (Comptroller of the Currency) and Chairman Ricki Helfer, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550–17th Street, N.W., Washington, D.C.

Dated: August 9, 1995.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 95–19992 Filed 8–9–95; 11:10 am]

BILLING CODE 6714–01–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

''FEDERAL REGISTER'' Citation of Previous Announcement: 60 FR 39989, August 4, 1995.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m., Wednesday, August 9, 1995.

CHANGES IN THE MEETING: The open meeting has been canceled, and the scheduled items were handled via notation voting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: August 9, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–19988 Filed 8–9–95; 11:08 am]

BILLING CODE 6210–01–P

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, August 16, 1995.

PLACE: William McChesney Martin, Jr. 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. Federal Reserve Bank and Branch director appointments.
2. Proposed acquisition of check image system within the Federal Reserve System.
3. Proposed acquisition of an automated materials handling system within the Federal Reserve System.
4. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
5. 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 9, 1995.

William W. Wiles,

Deputy Secretary of the Board.

[FR Doc. 95–19989 Filed 8–9–95; 11:08 am]

BILLING CODE 6210–01–P

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of August 14, 1995.

A closed meeting will be held on Tuesday, August 15, 1995, at 10:00 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meetings. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Wallman, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Tuesday, August 15, 1995, at 10:00 a.m., will be:

Institution of administrative proceedings of an enforcement nature.
Settlement of administrative proceedings of an enforcement nature.
Institution of injunctive action.
Opinion.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary (202) 942–7070.

Dated: August 9, 1995.

Jonathan G. Katz,

Secretary.

[FR Doc. 95–20646 Filed 8–9–95; 3:49 pm]

BILLING CODE 8010–01–M

Corrections

Federal Register

Vol. 60, No. 155

Friday, August 11, 1995

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Parts 30 and 150

[CGD 95-900]
RIN 2115-AF07

Bulk Hazardous Materials; Correction

Correction

In rule document 95–18764 beginning on page 39267 in the issue of Wednesday, August 2, 1995, and corrected in the issue of Monday, August 7, 1995, further corrections are being made as follows:

1. On page 39267, in the second column, in paragraph 3., in the second line, after ''column,'' insert ''first line,''.

2. On the same page, in the same column, in paragraph 6., in the correction to paragraph s., the fifth line should read ''Poly(2-8)alkylene glycol monoalkyl (C1-''.

3. On the same page, in the third column:

a. In the second line from the top, ''removed'' should read ''moved''.

b. In paragraph 11., in the third line, ''pathalates'' should read ''phthalates''.

c. In paragraph 12., in the 6th line, ''*Tetrapropylbenzene*'' was misspelled; in the 7th line, ''Alkly(69+)benzens'' should read ''Alkyl(C9+) benzenes''; and in the 13th line, ''phosphate'' was misspelled.

d. In paragraph 14., in the first entry, in the first line, ''Bromochlorone-thane'' should read ''Bromochlorome-thane''.

d. In paragraph 14., in the fourth entry, the fourth line, should read ''Methoxy-1-*methyl* ethyl)-2-ethyl-6-''.

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

48 CFR Part 219

Defense Federal Acquisition Regulation Supplement; Subcontracting Plans

Correction

In rule document 95–5959 beginning on page 13074 in the issue of Friday, March 10, 1995, make the following correction

219.703 [Corrected]

On page 13075, in the second column, in section 219.703(a), in the fourth line, ''Commission'' should read ''Committee''.

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

48 CFR Part 227

[Defense Acquisition Circular (DAC) 91-8]

Defense Federal Acquisition Regulation Supplement; Rights in Technical Data

Correction

In rule document 95–15251 beginning on page 33464 in the issue of Wednesday, June 28, 1995, make the following corrction:

227.7103-6 [Corrected]

On page 33475, in the second column, in section 227.7103-6(b)(2), remove ''Facilitated by the Government; and''

BILLING CODE 1505–01–D

federal register

Friday
August 11, 1995

Part II

Department of Transportation

Federal Aviation Administration

14 CFR Part 1, 61, et al.

Pilot, Flight Instructor, Ground Instructor, and Pilot School Certification Rules; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 1, 61, 141, and 143

[Docket No. 25910; Notice No. 95–11]

RIN: 2120–AE71

Pilot, Flight Instructor, Ground Instructor, and Pilot School Certification Rules

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revise the Federal Aviation Regulations that prescribe the certification and training requirements for pilots, flight instructors, and ground instructors and the operation of pilot schools approved by the FAA. In order to be more compatible with the current operating environment and the evolving demands of the National Airspace System, the proposals are intended to update training, certification, and recency of experience requirements. The proposals respond to comments to the FAA from the public, internal FAA review, and comments from the International Civil Aviation Organization.

DATES: Comments must be received on or before December 11, 1995.

ADDRESSES: Comments on the proposals may be delivered or mailed in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC–10), Docket No. 25910, 800 Independence Avenue, SW., Washington, DC 20591. All comments must be marked ''Docket No. 25910.'' Comments may be examined in the Rules Docket, Room 915G, weekdays between 8:30 a.m. and 5 p.m., except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: John Lynch, Certification Branch, AFS–840, General Aviation and Commercial Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3844.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments as they desire. Comments relating to the potential economic, environmental, energy, or federalism impact of the proposals contained in this notice are also invited.

The comments should identify the regulatory docket or notice number and should be submitted in triplicate to the Rules Docket address specified above. All comments received on or before the closing date for comments will be considered by the Administrator before action is taken on the proposed amendments, and the proposals contained in this notice may be changed in light of comments received. All comments received as well as a report summarizing any substantive public contact with FAA personnel on this rulemaking will be filed in the docket. The docket is available for public inspection before and after the closing date for submitting comments. The FAA will acknowledge receipt of a comment if the commenter submits with the comment a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 25910.'' When the comment is received, the postcard will be dated, time stamped, and returned to the commenter.

The FAA has proposed specific flight and ground time requirements in various sections of this NPRM. These specific time requirements may be modified in light of the comments received in response to this NPRM.

Availability of the NPRM

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–220, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–3484. Requests should be identified by the NPRM number or docket number of this proposed rule. Persons interested in being placed on a mailing list for future proposed rules should also request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

General Aviation Policy Statement

On September 8, 1993, Administrator David R. Hinson issued a general aviation policy statement in which he recognized that the general aviation industry is a critically important part of the nation's economy and the national transportation system. Administrator Hinson stated the following:

> General aviation plays a crucial role in flight training for all segments of aviation and provides unique personal and recreational opportunities. It makes vital contributions to activities ranging from business aviation, to agricultural operations, to Warbird preservation, to glider and balloon flights. Accordingly, it is the policy of the FAA to foster and promote general aviation while continuing to improve its safety record. These goals are neither contradictory nor separable. They are best achieved by cooperating with the aviation community to define mutual concerns and joint efforts to accomplish objectives. We will strive to achieve the goals through voluntary compliance and methods designed to reduce the regulatory burden on general aviation.

The FAA's general aviation programs will focus on:

1. Safety—To protect recent gains and aim for a new threshold.
2. FAA Services—To provide the general aviation community with responsive, customer-driven certification, air traffic, and other services.
3. Product Innovation and Competitiveness—To ensure the technological advancement of general aviation.
4. System Access and Capacity—To maximize general aviation's ability to operate in the National Airspace System.
5. Affordability—To promote economic and efficient general aviation operations, expand participation, and stimulate industry growth.

Accordingly, this rulemaking project was and is designed to meet these general aviation goals and provide economic relief from unnecessary, burdensome regulations. Throughout the development of this notice, the FAA has been in partnership with the general aviation community in developing and revising the rules in parts 61, 141, and 143 to ensure aviation safety and yet delete unnecessary, burdensome rules. The FAA is committed to this partnership with our general aviation constituents, and will continue the partnership through the notice and final rule phases of this rulemaking action.

Table of Contents for the Preamble

A. Background
  1. NPRM No. 92–10, Aircraft Flight Simulator Use in Pilot Training, Testing, and Checking at Training Centers.
  2. Experimental Aircraft Association (EAA) Petition
  3. General Discussion of Principal Issues
B. Part 61 Issues
  1. Definition of Terms
  a. Aeronautical Experience
  b. Airman Certificate
  c. Authorized Ground Instructor
  d. Authorized Flight Instructor
  e. Cross-Country Time
  f. Examiner
  g. Flight Training
  h. Ground Training
  i. Instrument Approach
  j. Instrument Training
  k. Knowledge Test
  l. Practical Test
  m. Supervised Pilot-in-Command (PIC) Time

n. Training time
2. Areas of Operation
3. New Aircraft Category, Classes
a. Powered-Lift
b. Glider Class Ratings
4. New Instrument Ratings
a. Airship Instrument Rating
b. Instrument ratings-airplanes
c. Instrument rating-Powered-lift
5. Lighter-Than-Air Flight Instructor Certificate
6. Revision of Ground Instructor Certificates and Ratings; Inclusion in Part 61.
7. Eligibility and Tests
8. Training Requirements
9. Proficiency
10. Privileges and Limitations
11. Records
12. Recency of Experience
13. Conversion to New System of Ground Instructor Certificate
14. Medical Certificates
15. Required Pilot Possession of Pilot and Medical Certificates
16. Issuance of U.S. Pilot Certificates on the Basis of Foreign Pilot Licenses
17. Logging Flight Time
18. Recency of Experience Requirements
19. Instrument Currency
20. English Language Ability Requirements
21. Flight Training Given by a Flight Instructor Not Certificated by the FAA
22. Second-in-Command (SIC) Training and Recent Experience
23. Knowledge Tests
24. Standardized Syllabus
25. Training and Endorsements
26. Endorsement for Complex and High Performance Airplanes
27. Aircraft Type Specific Training
28. Human Factors
29. Aeronautical Decision Making and Judgment Training
30. Windshear Avoidance
31. Aeronautical Experience Requirements
32. Instrument Rating
33. Recreational Pilot Certificate
34. Preflight Planning
35. Limitations on Cross-Country Endorsements
36. Night Flight Training
37. Private Pilot Limitations
38. Glider Towing
39. Eligibility for Commercial Pilot Certificate
40. Use of Turbojet Airplanes for Commercial Pilot Certification
41. Commercial Pilot Experience—Cross Country Training Flight
42. ATP Requirements
43. Pilot in Command Hour Requirement for Initial Flight Instructor Applicants
44. Experience Required for Training Flight Instructor Candidates
45. Flight Instructor Renewal Requirements
46. Flight Instructor Duty Time Limitations
47. Flight Training from a Control Seat
C. Part 141 Issues:
1. Approval of Training Courses That Permit Pilot Schools to Train to a Standard
2. Check Instructors
3. Quality of Training Requirements
4. Temporary Chief Instructor
5. Transfer Between Part 141 Schools
6. Maintenance Requirements
7. Ground School Instructor Requirements
8. Instructor Proficiency Requirements
9. Renewal of Certificate
10. Recordkeeping Requirements for Pilot Schools with Examining Authority
11. Reorganization of Requirements for Courses that are Approved Under Part 141
12. Appendix A—Recreational Pilot Certification Course
13. Appendix B—Private Pilot Certification Course
14. Appendix C—Instrument Rating Course
15. Appendix D—Commercial Pilot Certification Course
16. Appendix E—Airline Transport Pilot Certification Course
17. Appendix F—Flight Instructor Certification Course
18. Appendix G—Flight Instructor Instrument (Aircraft Category and Class) Certification Course
19. Appendix H—Ground Instructor Certification Course
20. Appendix I—Aircraft Category or Class Rating Course
21. Appendix J—Aircraft Type Rating Course, other than airline transport pilot
22. Appendix K—Special Preparation Courses
23. Appendix L—Pilot Ground School Course
D. Section by section discussion of Part 1—Definitions and Abbreviations
1. Balloon
2. Flight Time
3. Pilot in command
E. Section by section discussion of Part 61—Certification: Pilots, Flight Instructors, and Ground Instructors
F. Section by section discussion of Part 141—Pilot Schools

A. Background

Since September of 1987, the FAA has been conducting a regulatory review of parts 61, 141, and 143 of the Federal Aviation Regulations (FAR). These regulations pertain to certification and training requirements for pilots, flight instructors, and ground instructors and the operation of pilot schools that are approved by the FAA. This regulatory review is being undertaken in response to advancements in aviation technology, training, and changes in the National Airspace System (NAS) that have occurred since the last major revisions to these parts in the early 1970's. The FAA has received numerous petitions for exemption and letters from the public suggesting changes to the current regulations. To date, there have been 41 amendments and approximately 3,616 exemption actions to parts 61 and 141. Recommendations and comments from the National Transportation Safety Board (NTSB), the public, and the FAA have also demonstrated the need for the regulatory review. A major goal of the review is to identify differences between the rules and the level of training demanded of pilots in today's aviation environment.

In support of this regulatory review, the FAA completed a historical review of parts 61, 141, and 143 in January 1988. During this review, the FAA also received input from pilot schools and college and university aviation departments operating under parts 61 and 141. Three major areas were identified during this review: first, issues of immediate concern recommended by the NTSB and public comments; second, the requirements for aircraft operations in today's environment; and finally, the requirements for pilots in the year 2010 and beyond. Accordingly, the regulatory review was divided into three phases corresponding to the needs identified above. The final rule for Phase 1, Amendment Nos. 61–90 and 141–4 (56 FR 11308; March 15, 1991; effective on April 15, 1991), contained the following:

1. New requirement to obtain training and a flight instructor endorsement to serve as pilot in command of a tailwheel airplane;

2. New requirement to obtain training and a flight instructor endorsement to serve as pilot in command of a pressurized airplane capable of high altitude flight above 25,000 MSL;

3. New requirement for an applicant to complete a training curricula and receive a flight instructor endorsement prior to qualifying in an airplane that requires a type rating;

4. New requirement to permit completion of a phase of the WINGS program as satisfactory completion of a biennial flight review (BFR);

5. New requirement for pilot applicants to receive ground training on stall awareness, spin entry, spins, and spin recovery techniques;

6. New requirement for pilot applicants to receive flight training on flights at slow airspeeds with realistic distractions and the recognition of and recovery from stalls;

7. New requirement for flight instructor applicants to receive and demonstrate actual spin training;

8. New requirement for flight instructor applicants to perform a spin demonstration on retests when the reason for the failure was due to deficiencies of knowledge or skill relating to stall awareness, spin entry, spins, or spin recovery techniques;

9. New requirement that FAA inspectors and designated pilot examiners may accept instructor endorsements for the spin demonstration on practical tests for flight instructor applicants;

10. New requirement in part 141 that a chief or assistant chief flight instructor only has to be available by telephone, radio, or other electronic means during the time that instruction is given for an approved course of training;

11. New requirement in part 141 for initial designation of assistant chief flight instructors that are one half the requirements of chief flight instructors;

12. New requirement to eliminate the 100-hour currency experience requirement in part 141 for chief flight instructors to obtain initial designation; and

13. New requirement to eliminate the 25 mile distance restriction for establishing satellite bases in part 141.

This NPRM represents Phase 2 of the regulatory review. Phase 2 addresses issues affecting parts 1, 61, 141, and 143. Prior to drafting and publishing this NPRM, the FAA issued a notice of hearing (54 FR 22732; May 25, 1989) that announced 4 public hearings and outlined the general topics for this NPRM. Four public hearings were held before the drafting and publishing of this NPRM as part of Phase 2. The hearings were held in Washington, DC (September 12–13, 1989); Chicago, Illinois (September 19–20, 1989); Los Angeles, California (October 3–4, 1989); and Orlando, Florida (October 16–17, 1989).

Phase 2 also involves a Pilot and Flight Instructor Job Task Analysis (JTA), completed on March 31, 1989, which consolidated the results of a study on areas of pilot knowledge, skills, abilities, and attitudes required in today's aviation environment. The JTA provided the framework for this phase of the regulatory review and provides information for use in training programs and practical test standards. A copy of the JTA is available for examination in Docket No. 25627 and for purchase on a diskette through the National Technical Information Service (NTIS), Springfield, Virginia 22161, (703) 487–4650. The cost of the diskette is $55 in the United States and the NTIS order number is PB89–167845CAU.

Most of the JTA consisted of data, based on experts' opinions, used to quantify the relative importance of knowledge, skills, abilities, and attitudes. The JTA also included a panel that discussed current and future pilot training needs. A transcript of the panel's deliberations is contained in Docket No. 25627. The panel's objective was to project pilot training needs 3 to 10 years into the future. The panel discussed changing technology, airline pilot requirements, airspace, training, instructors, and aviation economics.

In addition, on February 9 and 10, 1993, the FAA conducted information gathering meetings with a number of aviation organizations and schools on the comments received in Docket No. 25627. These meetings concerned issues raised during the public hearings that were held in Washington, DC (September 12–13, 1989); Chicago, Illinois (September 19–20, 1989); Los Angeles, California (October 3–4, 1989); and Orlando, Florida (October 16–17, 1989), and the information received during the JTA that was completed on March 31, 1989. Because so much time had passed since the time of the hearings, receipt of comments to the docket, and the JTA, the FAA decided to update its information. The invitees were selected as a result of their organizations' and schools' past involvement in this regulatory review. The FAA is committed to developing rules that are fair and reasonable, and yet maintain a high degree of pilot training and qualification. The following organizations and schools attended these meetings: General Aviation and Manufacturing Association (GAMA), National Air Transport Association (NATA), Jeppesen-Sanderson, National Association of Flight Instructors (NAFI), Balloon Federation of America (BFA), Farrington Aircraft, Aircraft Owners and Pilots Association (AOPA), AOPA Safety Foundation, Experimental Aircraft Association (EAA), Helicopter Association International (HAI), Soaring Society of America (SSA), Embry Riddle Aeronautical University (ERAU), Parks College of St. Louis, and American Flyers.

There have been some preliminary discussions for conducting a Phase 3 of this regulatory review. However, no schedule has been established for Phase 3. If a Phase 3 is conducted, it would be a comprehensive, long-term effort to address pilot, flight instructor, and ground instructor requirements for the year 2010 and beyond.

1. Notice No. 92–10, Aircraft Flight Simulator Use in Pilot Training, Testing, and Checking at Training Centers

On August 11, 1992, the FAA issued notice of proposed rulemaking (NPRM) No. 92–10, ''Aircraft Flight Simulator Use in Pilot Training, Testing, and Checking at Training Centers'' (57 FR 35888–35938). Although the flight simulator NPRM contains several issues related to this NPRM, the FAA has tried to make these rulemaking projects separate and distinct from one another. Despite the efforts to coordinate these two rulemaking actions, some overlap still exists. However, if any discrepancies have occurred, the matter will be resolved in the final rule.

2. Experimental Aircraft Association (EAA) Petition

On January 3, 1994, the FAA published, without comment or endorsement, a petition for rulemaking submitted by EAA (59 FR 31). In their petition, the EAA requested the following changes to the recreational pilot certificate:

(1) Eliminating the requirement that a recreational pilot hold at least a 3rd-class medical certificate;

(2) Requiring a recreational pilot to self certify that he or she has no known medical deficiency that would make him or her unable to fly;

(3) Eliminating the 50 nautical mile limitation for those pilots who obtain additional training;

(4) Permitting a pilot with a higher certificate or rating who no longer has a medical certificate, but who self certifies that he or she is physically fit to fly, to exercise the privileges of a recreational pilot certificate, subject to the limitations of the recreational pilot certificate; and

(5) Eliminating the recreational pilot certificate limitations for cross country, night flight, and flight into airspace requiring communication with air traffic control for those pilots with higher certificates and ratings who no longer have medical certificates, but who self certify that they are physically fit to fly.

The comment period for the EAA petition closed on March 4, 1994. There were over one thousand comments received. The majority of commenters voiced overwhelming support for the petition, but did not provide any data or analysis. Some commenters, including the Civil Aviation Medical Association (CAMA), opposed the EAA petition. CAMA expressed concern with the impact on public health and welfare of the proposed elimination of medical standards for pilots who exercise the privileges of a recreational pilot certificate. One specific concern of those commenters who opposed the EAA petition was the carrying of passengers by a pilot who does not hold a medical certificate. The FAA has reviewed all comments received in developing this rulemaking action. The vast majority of commenters responding to this petition were individual members of the aviation community and many were members of the EAA.

In this notice, the FAA is proposing to permit most of what EAA has requested. The FAA is not proposing to eliminate the recreational pilot limitations for cross country, night flight, and flight into airspace requiring

communication with air traffic control for those pilots with higher certificates and ratings who no longer have medical certificates, but who self certify that they are physically fit to fly. The FAA may reconsider this issue, however, based on comments received.

3. General Discussion of Principal Issues in This NPRM

This NPRM incorporates many of the concepts developed through the public hearings, the JTA, and the public comments received in Docket Nos. 25627 and 25910.

Docket No. 25627 was established to receive comments throughout the entire regulatory review and will remain open until the FAA publishes a notice of its closing. This docket facilitates the orderly flow of collecting comments, recommendations, and ideas from the public. Docket No. 25910 was established to receive specific comments from the public on NPRM No. 89–14, which was the Phase 1 proposal.

The proposals in this NPRM cover a broad range of issues. The major proposals included in this NPRM are as follows: (1) Clarify and standardize terminology; (2) establish a new powered-lift category rating; (3) establish separate class ratings for nonpowered and powered gliders; (4) establish a flight instructor certificate in the lighter-than-air category; (5) establish instrument ratings for single-engine airplanes, multiengine airplanes, airships, and powered-lifts; (6) revise the recency of experience requirements; (7) revise recreational pilot certification and authorization requirements; (8) require human factors training for all certificates and ratings; (9) replace flight proficiency requirements for training and certification with more general approved areas of operation; (10) revise the training times for the aeronautical experience requirements to permit the student and the instructor to tailor the training to the individual student's needs; (11) remove and reserve part 143 and establish a new subpart I in part 61 for ground instructors; (12) require ground instructor certificates to be based on aircraft category; (13) require applicants for a ground instructor certificate to accomplish a practical test; (14) revise the certification and test courses in part 141 to accommodate all aircraft categories and new technology; (15) establish a check instructor position to perform student and instructor checks and tests at part 141 pilot schools; (16) delete exceptions that permit pilots to be certified without meeting the English language fluency requirements; (17) revise the medical eligibility requirements for applying for all certificate levels and ratings by only requiring applicants to hold a third class medical certificate; and (18) delete the requirement for recreational pilots to hold a medical certificate.

Due to the length of this notice, the preamble addresses the proposed changes to parts 61, 141, and 143 in two major sections. First, a general subject discussion of major issues is presented. Second, proposed changes are discussed briefly in a section-by-section analysis.

It should be noted that parts 61 and 141 are republished here in their entirety. All sections, except those specifically noted, include a modified format, standardized terminology, and the deletion of gender references. Several sections, which are noted in the section-by-section discussion contain no revisions or editorial changes. Three of these sections, §§ 61.58, 61.63, and 61.67, have been proposed to be revised in NPRM No. 92–10, ''Aircraft Flight Simulator Use in Pilot Training, Testing, and Checking at Training Centers,'' (57 FR 35888–35938; August 11, 1992). In addition to proposed additions, deletions, and substantive changes to the regulations, the FAA seeks in this proposal to continue its policy of simplifying regulations through editorial style changes. Wherever possible, the rules are broken down into brief sentences and outline format. Therefore, some section numbering would change under this proposal. In addition, the FAA has proposed numerous non-substantive changes to the regulations, and where necessary has proposed numerous revisions involving clarity and conformity.

B. Part 61 Issues

1. Definition of Terms

The FAA proposes to establish a new § 61.1a, ''Clarification of Terms.'' The intent of the section is to ensure more consistent use of terms throughout the text under part 61. The terms to be clarified include:

a. Aeronautical Experience

This term means pilot time obtained in an aircraft, flight simulator, or flight training device for meeting the appropriate training and flight time for an airman certificate, rating, flight review, or recency of flight experience, of part 61.

b. Airman Certificate

This term describes a pilot certificate (other than a student pilot certificate), flight instructor certificate, or a ground instructor certificate that is issued under part 61. This would not include other airmen as described in the Federal Aviation Act of 1958, as amended, which also applies the term to repairmen, mechanics, aircraft dispatchers, parachute riggers, other flight crewmembers, and air traffic controllers.

c. Authorized Ground Instructor

This proposal includes a provision to incorporate part 143, Ground Instructors, into part 61. The term would describe a person who holds a current ground instructor certificate with ratings that apply to the training being given, and who is authorized by the Administrator to give that training.

d. Authorized Flight Instructor

This term would clarify that a flight instructor must hold a current flight instructor certificate with ratings that apply to the training being given, and be authorized by the Administrator to give that training.

e. Cross-Country Time

The FAA proposes to describe cross country time for three separate circumstances: (1) For persons who hold a private, commercial, or airline transport pilot certificate; (2) for persons applying for a private or commercial pilot certificate or instrument rating; and (3) for military pilots. These issues are addressed further in the discussion of logging of pilot time.

f. Examiner

The term would refer to persons authorized to conduct practical tests or knowledge tests under part 61.

g. Flight Training

The term would refer to training received from an authorized flight instructor in actual flight in an aircraft.

h. Ground Training

The term would refer to training other than flight training received from either an authorized ground instructor or an authorized flight instructor.

i. Instrument Approach

This term would define an instrument approach as an approach procedure defined in part 97 and conducted to an established minimum descent altitude (MDA) or decision height (DH), or if necessary, to a higher altitude selected for safety reasons by ATC.

j. Instrument Training

The term would refer to time in which instrument training is received from an authorized flight instructor under actual or simulated instrument flight conditions.

k. Knowledge Test

The term ''knowledge test'' would replace ''written test.'' The FAA believes the term ''knowledge test'' is a more inclusive term, referring to either tests administered with pencil and paper or by computer on the aeronautical knowledge areas in part 61.

l. Practical Test

The term ''practical test'' would include both oral and flight testing or testing in an approved flight simulator or flight training device on the approved areas of operation for an airman certificate, rating, or authorization.

m. Supervised Pilot-in-Command (PIC) Time

The term ''supervised PIC time'' would mean aeronautical experience flight time in an aircraft that applies to either a student pilot or pilot who is not rated in the aircraft, but is under the supervision and authorization to conduct the flight from an authorized flight instructor. The purpose for this proposal is to permit student pilots and pilots who are not rated in the aircraft, to log PIC time when the sole manipulator of the controls. This will be a change to the FAA's existing policy on who can log PIC time. In the past, the logging of PIC time in § 61.51 required the person to be a rated pilot, the sole manipulator of the controls, and be rated in the aircraft. Furthermore, depending on the crew compliment specifications set forth in the aircraft's flight manual, the flight instructor may be onboard the aircraft in an assigned crewmember position. The flight instructor is expected to perform essential crew member functions, evaluate the person's ability to act as a PIC, and as always perform essential safety-related functions in the case of emergencies.

n. Training Time

A definition of the term ''training time'' would mean training received: (1) In actual flight from an authorized flight instructor; (2) on the ground from an authorized ground or flight instructor; or (3) in a flight simulator or flight training device from an authorized ground or flight instructor.

2. Areas of Operation

The FAA proposes a significant change in the regulatory descriptions of the procedures and maneuvers required of applicants for the various pilot certificates and ratings. Under the proposed new concept, the FAR would specify general areas of operation to be covered in flight training and practical tests for pilot and flight instructor certificates and ratings and in training and testing for ground instructors. Many specific flight proficiency requirements currently in the FAR would be deleted. The specific tasks for the training and practical tests would be listed in the standards for each practical test for each certificate and rating. The purpose of this approach is to permit greater flexibility in updating the training and testing maneuvers and procedures required of pilot and flight instructor applicants.

For example, under current § 61.107 an applicant for a private pilot certificate with an airplane category and single-engine class rating must receive training on ''emergency operations, including simulated aircraft and equipment malfunctions.'' The proposed areas of operation for the same applicant would require training on ''emergency operations;'' however, the tasks for the required training and practical test for an airplane category and single-engine class rating would include a task for emergency approach and landing (simulated) and a task for system and equipment malfunctions.

For convenience, the areas of operation for each category and, in some cases, for each class of aircraft under each certificate or rating would be listed separately. This would result in a certain amount of redundancy because many areas of operation would be common to more than one category and class of aircraft. However, the FAA proposes this method of listing areas of operation to avoid requiring users to consult more than one list to identify the areas pertinent to their individual situation.

In conjunction with using general terms to refer to maneuvers, the term ''slow flight'' would be used in place of previously used terms such as ''minimum controllable airspeed'' and the more recent term, ''flight at slow airspeeds with realistic distractions.'' The FAA is not proposing a change in the concept; the details of the maneuvers and procedures will continue to be established through the appropriate practical test standards.

The use of areas of operation is consistent with public response to the issue addressed in the Notice of Hearings of whether the specific tasks or requirements in the Practical Test Standards (PTS) should be included in the FAR. The FAA believes the PTS should remain separate from the regulations to maintain the flexibility needed for revising and updating the PTS. Some commenters suggested listing specific areas of operation rather than specific pilot operations in the regulations regarding pilot operations.

The use of areas of operation would permit the practical test requirements, and hence, specific training requirements, to keep pace with technological change. For example, the current rule lists pilot operation procedures for equipment that is no longer common and does not include procedures for newer equipment (e.g., Electronic Flight Instrument System (EFIS), LORAN–C).

3. New Aircraft Category, Classes

This proposal would establish a new aircraft category for pilot certification—the powered-lift. The FAA also proposes to establish two aircraft classes within the glider category: powered glider and nonpowered glider.

a. Powered-Lift

The FAA anticipates that one of the most significant future developments in the NAS will be the introduction of a new category of aircraft, the powered-lift, into civil application. According to the FAA's Interim Airworthiness Criteria Powered-Lift Transport Category Aircraft (Department of Transportation, Federal Aviation Administration, Southwest Region, July 1988), powered-lifts resemble airplanes and rotorcraft in many respects. The document addresses airworthiness standards for multiengine turbine transport category aircraft that use power for lift, propulsion, and control.

Powered-lift aircraft have vertical take-off and landing and hovering capability like helicopters, but they also may fly at higher airspeeds like airplanes. The low airspeed capability may be provided by either aircraft configuration changes (tilt-wing, tilt-rotor, tilt-propeller), thrust vectoring, direct-lift engines, or other powered-lift concepts.

Powered-lift aircraft will require a new set of pilot knowledge, skills, and abilities. Therefore, the FAA proposes to create a new powered-lift aircraft category rating in § 61.5 for certification of private, commercial, and airline transport pilots, and for flight instructor and ground instructor certificates. The FAA also proposes to create a corresponding instrument rating for powered-lift aircraft. The FAA does not propose to extend recreational pilot certification in proposed subpart D to include the powered-lift category rating.

The FAA has considered various approaches to pilot certification for powered-lift aircraft. For example, the FAA considered whether powered-lift should be a separate category, with or without class ratings, such as tilt-rotor, tilt-wing, ducted fan, and vectored thrust. Another approach considered

was creating a powered-lift class rating within the rotorcraft category. The FAA also considered proposing to require a type rating for every make and model of powered-lift aircraft.

Based on available information, the FAA has concluded that safety needs will be met by establishing a separate aircraft category only. Under proposed § 61.31, type ratings would not be required for powered-lift aircraft except for large aircraft or as specified by the Administrator under aircraft type certificate procedures. The FAA has determined that requiring additional requirements beyond this type rating requirement at this time might discourage the development of smaller powered-lift aircraft intended for general aviation. Thus, it does not appear feasible to establish class ratings at this time.

In general, the aeronautical experience hour-requirements for powered-lift category ratings would parallel those for airplanes and helicopters. For example, proposed § 61.87, Solo flight requirements, would require powered-lift student pilots to meet the same requirements as both airplane and helicopter student pilots. Similar overlap would occur in the areas of operation for private and commercial pilot training and certification.

Aeronautical knowledge requirements for commercial pilot certification would be the same as those for helicopters (a single set of aeronautical knowledge areas is proposed for all aircraft categories at the private pilot level). Areas of operation for the instrument rating under proposed § 61.65 would be the same as for airplanes.

b. Glider Class Ratings

The FAA proposes to divide the glider category into two classes for pilot certificates and ratings: powered glider and nonpowered glider. The term ''powered glider'' includes self-launching sailplanes, powered sailplanes, motorized sailplanes, and motorgliders. Some of these aircraft are designed primarily for high performance and competitive flying; others are more suitable for training. The low power-to-weight ratio and relatively low wing loadings generally found in powered gliders produce performance characteristics that are similar to low-powered, light fixed-wing aircraft. Specific knowledge and skills are needed for the safe and efficient operation of these aircraft in the NAS.

Powered gliders may be flown long distances and through complicated airspace by pilots holding only glider category ratings, which does not imply knowledge of communication or radio navigation procedures. Powered gliders require knowledge levels similar to those of powered aircraft. The FAA believes that another option to establishing glider class ratings would be to treat powered gliders as single-engine airplanes. However, the FAA believes that treating powered gliders as airplanes would be a more restrictive approach. Therefore, the FAA proposes to pursue the class rating approach.

The FAA proposes to convert current glider pilot and flight instructor certificates to the new class ratings over a 2-year period. A person who currently holds a private or commercial pilot certificate with a glider category rating could also obtain a nonpowered class rating if the person passed a practical test in a nonpowered glider, or obtain a powered class rating if the person passed a practical test in a powered glider.

Currently, the FAR does not address powered gliders. For example, §§ 61.107 and 61.127, which address flight proficiency for private and commercial pilot applicants, require training in glider launches by ground (auto or winch) or aero tows, and limits the applicant's certificate to the type of tow selected. The PTS for gliders include a powered glider self-launch limitation and specific tasks for powered gliders. The FAA also has addressed the unique characteristics of powered gliders in Advisory Circular (AC) 61–94, ''Pilot Transition Course for Self-Launching or Powered Sailplanes (Motorgliders).'' The AC recommends procedures and standards for glider pilots who want to accomplish a practical test in powered gliders.

For holders of a flight instructor-glider certificate, the conversion would be based on the type of training the instructor has given. To obtain a flight instructor certificate for nonpowered gliders, an instructor would be required to have given at least 20 hours of flight training in a nonpowered glider and recommended at least one student for a practical test for a glider category rating (the proposed rule does not specify powered or nonpowered), and that student would have to have passed. To obtain a flight instructor certificate for powered gliders, a flight instructor with a glider category rating could be eligible to obtain a flight instructor certificate with a glider category and powered class rating if the instructor had given 20 hours of flight training in a powered glider and recommended at least one student for a practical test for a glider category and powered class rating, and that student would have to have passed.

4. New Instrument Ratings

The FAA proposes to amend § 61.5 to establish four additional instrument ratings: Airship, single-engine airplane, multiengine airplane, and powered-lift. Corresponding flight instructor instrument ratings for those specific aircraft also are proposed.

a. Airship Instrument Rating

Under the current FAR, the commercial pilot certificate for airships includes training and testing on instrument flight maneuvers and procedures and instrument flight rules (IFR). Currently, there is no separate instrument rating for airship pilots. The proposal to establish a separate instrument rating for airships is in response to current trends in design and certification of airships. These trends are toward smaller airships with specific intended uses, such as daytime aerial advertising. These airships are not designed or equipped for flight in instrument conditions, and therefore, pilots who train in these aircraft must either incur the expense of training in IFR-equipped airships or seek an exemption from the regulation. Industry experience indicates that the smaller, non-IFR-equipped airships in which the pilots train are generally the same airships those pilots will fly when they are certificated. Therefore, the FAA has concluded it is reasonable to separate the instrument rating requirements from the commercial pilot certification requirements.

Historically, the airship industry has consisted of larger blimps and dirigibles that are certificated for operations including IFR, visual flight rules (VFR), and day and night flight. But very few airships operate in the United States, and the growth of the industry has been slow, with few pilots being certificated. However, the FAA notes that smaller, foreign-built airships are being operated in the United States. It is hoped that these signs of growth of the industry will be accompanied by the need for more airship pilots. A separate airship instrument rating will remove an obstacle to certification of commercial airship pilots desiring to fly these smaller airships, and help foster growth of this small segment of the aviation industry.

The FAA proposes to delete airship instrument knowledge requirements from existing § 61.125 and delete current § 61.135, which refers to aeronautical experience requirements. The FAA proposes to incorporate in § 61.65, flight training and skill requirements for airship instrument ratings. For pilots who do not hold an

airship instrument rating, § 61.139 would be amended to require a limitation to the commercial pilot certificate-airship that prohibits the carriage of passengers for hire in airships on cross-country flight or at night.

The proposal includes a system of conversion of current commercial certificates to commercial certificates with an instrument rating. Under proposed § 61.5, ''Certificates and ratings issued under this part,'' the holder of a commercial pilot certificate with a lighter-than-air category rating and an airship class rating would be permitted to exchange that certificate for a certificate with an instrument-airship rating, if that person receives an endorsement from an authorized flight instructor who holds an instrument-airship rating on the flight instructor certificate, and that flight instructor has observed that person perform 10 hours of PIC time in an airship under IFR, or that person passes the instrument proficiency test of § 61.57 in an airship, and the test was conducted by an examiner.

b. Instrument Ratings—Airplanes

The FAA proposes to amend § 61.5 to establish separate instrument ratings for single-engine and multiengine airplanes and to establish corresponding instrument ratings for flight instructor certificates.

Under the proposal a person who passes the practical test for an instrument rating in a single-engine airplane would be issued a pilot certificate with an instrument-airplane single-engine rating. If that person holds a multiengine airplane class rating and desires an instrument-airplane multiengine rating, the person would be required to pass a practical test for an instrument rating in a multiengine airplane. The proposal would permit a person who holds both a single engine and multiengine airplane class rating and passes a practical test for an instrument-airplane multiengine rating, to be allowed to exercise instrument privileges in single-engine airplanes.

In addition, a person who desires to train students who want an instrument-airplane single-engine rating would be required to pass a practical test for a flight instructor certificate with an instrument-airplane single-engine rating. If that person desires to train students who want an instrument-airplane multiengine rating, the person would be required to pass a practical test for a flight instructor certificate with an instrument-airplane multiengine rating. A person who passes a practical test for a flight instructor-instrument-airplane multiengine rating and also holds a flight instructor single-engine airplane class rating would be permitted to train students for an instrument-airplane single-engine rating.

This proposal is consistent with FAA policy in effect since October 1984, which requires applicants for multiengine airplane class ratings to demonstrate instrument proficiency on their multiengine practical test if they have an airplane instrument rating and desire IFR privileges for their multiengine rating. The policy was instituted based on an NTSB recommendation that followed an investigation of a 1981 multiengine airplane accident. The NTSB concluded that the accident may have been caused by excessive airloads generated by a nose-up control input by the pilot at high speed. This resulted in an in-flight breakup of the aircraft. The pilot had acquired his instrument rating in a single engine airplane, had limited experience in operation of multiengine airplanes in instrument meteorological conditions, and had no multiengine instrument training.

Under the current FAA policy, applicants for a multiengine airplane class rating who hold an instrument rating for airplanes are required to demonstrate instrument proficiency in multiengine airplanes. If the applicant chooses not to demonstrate instrument proficiency, their multiengine airplane rating is limited to VFR privileges only. If an applicant with single-engine and multiengine class ratings takes the instrument practical test in a multiengine airplane, no restriction is added to the certificate. For example, a certificated pilot who holds a multiengine class rating with instrument privileges for airplanes, and who applies for an airplane single-engine class rating, may, upon successful completion of the airplane single-engine practical test, exercise instrument privileges in both classes of aircraft without showing instrument proficiency in single-engine airplanes.

The FAA proposes to allow 2 years for pilots and flight instructors who currently hold single-engine and multiengine airplane class ratings and an instrument—airplane rating to convert to the new single-engine and multiengine instrument ratings. With the exception of those pilots who received an instrument rating before the current policy became effective, the proposed conversion would ensure that pilots who obtain instrument privileges in multiengine airplanes have demonstrated instrument proficiency in multiengine airplanes.

Under the proposed rule, a person who holds a private or commercial pilot certificate with an airplane category rating and an instrument—airplane rating would be permitted to exchange that certificate for the new proposed certificate. The new private or commercial pilot certificate, as appropriate, would have either an instrument—airplane single-engine rating or instrument—multiengine class rating. For example, a person would be entitled to obtain an instrument—airplane single-engine rating if that person had an airplane single-engine class rating and had satisfactorily completed the practical test for an instrument rating in a single-engine airplane.

Under the proposal, a person could exchange their certificate for a certificate with an instrument-airplane multiengine rating if one of the following conditions were met:

(1) That person had an airplane multiengine class rating and had satisfactorily completed the practical test for an instrument rating in a multiengine airplane;

(2) That person had an airplane multiengine class rating and had satisfactorily completed the practical test for an instrument rating in a single engine airplane and also demonstrated instrument proficiency during the practical test for the multiengine class rating such that the person's certificate did not bear the limitation ''Airplane Multiengine VFR Only;'' or

(3) That person had an airplane multiengine class rating and had satisfactorily completed the practical test for an instrument rating in a single-engine airplane before October 1, 1984, the date on which the FAA policy, which requires multiengine candidates to demonstrate instrument proficiency when seeking instrument privileges, took effect.

Under the proposal, in any of the above three cases, a pilot with a single-engine airplane class rating would also be entitled to the privileges of an instrument-airplane single-engine rating. A person with a flight instructor certificate and an instrument-airplane rating would be able to obtain a flight instructor certificate with an instrument-airplane single-engine or an instrument-airplane multiengine rating.

A person would be able to receive a flight instructor certificate with an instrument-airplane single-engine rating by having given at least 20 hours of flight training in a single-engine airplane for the issuance of an instrument-airplane rating as a certificated flight instructor. The person also would be required to have

recommended at least one student for a practical test for the issuance of an instrument-airplane rating and the recommended student would have had to pass the practical test.

A person would be able to receive a flight instructor certificate with an instrument-airplane multiengine rating by having given at least 20 hours of flight training in a multiengine airplane for the issuance of an instrument-airplane rating as a certificated flight instructor. The person also would be required to have recommended at least one student for a practical test for the issuance of an instrument-airplane rating and the recommended student would have had to pass the practical test.

The FAA invites comments on the conversion process proposed for the instrument-airplane ratings.

c. Instrument Rating—Powered-lift

In addition to proposing a new powered-lift aircraft category rating, the FAA proposes to amend § 61.5 to establish a new instrument rating for powered-lift. The FAA also proposes to establish a corresponding powered-lift instrument rating for the flight instructor certificate. The FAA invites comments on the proposal to establish this new instrument-powered-lift rating and the powered-lift instrument rating for the flight instructor certificate.

5. Lighter-Than-Air Flight Instructor Certificate

Under current regulations, any commercially licensed lighter-than-air pilot may provide flight training in the class of aircraft in which commercial privileges are held (i.e., airship or free balloon). A lighter-than-air commercial pilot who gives training under the authority of existing § 61.139 is not bound by any of the recordkeeping requirements, authorizations, and limitations that apply to certificated flight instructors for the other categories of aircraft. Under the current PTS, commercial lighter-than-air applicants must be tested in all phases of the flight instructor area even if the applicant does not plan to train.

Several balloon operators who made presentations at the public hearings or submitted comments to the docket favored the establishment of a flight instructor-balloon rating. Two balloon organizations indicated that, with the exception of those instructors associated with part 141 schools, the current training in balloons does not provide quality control measures for flight instructors. Several commenters said that the training and renewal requirements for balloon instructors should be the same or similar to those required of other aircraft flight instructors. The commenters also recommended that a proposal for a flight instructor-balloon rating should require: (1) A minimum number of hours as PIC; (2) a biennial renewal requirement; and (3) a passing grade on written and practical tests. In addition, the commenters recommended that such a proposal should provide for existing balloon instructors to convert to the new system.

Comments also were submitted to the docket that opposed the addition of a flight instructor-balloon rating. One commenter stated a majority of balloon instructors would not elect to obtain a flight instructor certificate, creating a hardship for future pilots. Several commenters also disagreed with the suggestion that a specific number of hours as PIC should be required of current commercial pilots to obtain their flight instructor certificates. The commenters stated that existing commercial pilots have earned instructor privileges in accordance with today's FAR and that there is no need for a minimum hour cutoff.

The FAA has determined that a flight instructor certificate should be created for the lighter-than-air category. The present system of incorporating training privileges into commercial certificates is a burden on commercial pilots who do not instruct. The intent of this proposal is to ensure that those who perform flight training in all aircraft categories and classes are subject to flight instructor training and renewal requirements. The FAA proposes to revise § 61.5 to establish a flight instructor-airship rating and a flight instructor-balloon rating.

The proposed revision to § 61.3 includes a clause to permit holders of a commercial certificate with an airship or a free balloon class rating to train in the appropriate aircraft for 2 years after issuance of the final rule. A revision to § 61.187 is proposed that would require a person who trains an applicant for a lighter-than-air flight instructor certificate to meet the same requirements as a person who trains other flight instructor applicants.

Under the FAA's proposal, a person who trains flight instructor applicants for a lighter-than-air category rating would be required to have held a flight instructor certificate for at least 24 months and to have given at least 20 hours of flight training. This is the same minimum-hour requirement recommended by the Great Eastern Balloon Association during the public hearings. The FAA also has included a provision for a person who trains flight instructor applicants in an FAA-approved course. This person could either meet the 24-month and 20-hour requirement or: (1) Have trained and endorsed at least 5 persons for a pilot certificate or rating practical test; (2) have a record that reflects that at least 80 percent of the persons whom the flight instructor has endorsed for a practical test passed that test on their first attempt; and (3) have given at least 40 hours of flight training as a certificated flight instructor.

The proposal also includes a provision for practicing lighter-than-air instructors (with commercial certificates) that requires them to obtain flight instructor certificates with lighter-than-air category ratings without passing a practical test. The proposal would revise § 61.201 to provide a 2-year transition period for holders of a commercial certificate with an airship or a free balloon class rating to obtain a flight instructor certificate with an airship or a balloon rating. If this proposal is adopted, the FAA is considering allowing the conversion process to begin before the effective date of the proposed rule.

Under the proposal, to obtain a flight instructor certificate with a lighter-than-air category rating, an applicant would need to present a valid commercial certificate with a lighter-than-air category rating and the appropriate class rating and have given at least 20 hours of flight training in airships or free balloons, as appropriate, as a commercial pilot. The applicant would also be required to have recommended at least one student for the issuance of a rating in an airship or balloon, as appropriate, and the student would have had to pass the practical test.

The proposal includes a revision to § 61.125 to remove the requirements for applicants for a commercial certificate, with a lighter-than-air category rating and an airship or balloon class rating, to obtain knowledge on training.

6. Revision of Ground Instructor Certificates and Ratings; Inclusion in Part 61

Part 143, ''Ground Instructors,'' is outdated and inadequate for defining ground instructors' privileges and limitations, or their training and certification requirements. Under the current system, the ground instructor certificate is obtained on the basis of written tests only, with no practical test. Although a recency of experience requirement exists, there is no provision for renewal of ground instructor certificates. In addition, ground instructor certificates will be revised to distinguish ratings on the basis of

aircraft category (i.e., ground instructor-airplane, ground instructor-rotorcraft, ground instructor-glider, etc).

To make the ground instructor certificate more compatible with the demands of current training requirements, the FAA proposes to revise regulations on ground instructors and address the ground instructor certificate in a new subpart I in part 61. Current part 143, Ground Instructors, would be removed and reserved. Under the proposal, ground instructor certificates would be specific to aircraft categories. A practical test, as well as a knowledge test, would be required. The ground instructor certificate would still not expire, but new recency of experience requirements are proposed in order for a person to continue exercising the privileges of the certificate. This proposal would establish recordkeeping requirements for ground instructors and clarify ground instructors' privileges and limitations.

During the public hearings, commenters agreed that parts 61 and 143 could be combined, provided the ground instructor certificate is retained. Commenters, including Embry-Riddle Aeronautical University (ERAU), Experimental Aircraft Association (EAA), and General Aviation Manufacturers Association (GAMA) recommended that applicants for a ground instructor certificate be required to pass a practical test. The test would include an oral segment, but not a flight segment.

This proposal is based largely on the public comment. The proposal also reflects guidance contained in FAA Order 8700.1, ''General Aviation Operations Inspector's Handbook,'' chapter 159, ''Issuance of Ground Instructor Certificate and Added Ratings.'' subpart I is modeled on existing and proposed regulations for training and certification of flight instructors. The intent of the proposal is to recognize the importance of proper ground training and to make the ground instructor certificate more meaningful.

A number of issues, particularly administrative issues, currently addressed in part 143, such as replacement of a lost certificate, testing procedures, and change of address, are addressed in there respective categories in the proposal, along with other certificates and ratings. The proposed subpart I primarily addresses issues unique to the ground instructor certificate. Some of the major differences between proposed subpart I and part 143 would include the following:

7. Eligibility and Tests

The proposal for the ground instructor certificate and rating would establish a requirement for English-language ability, and would include the testing requirements. The required tests would include a test on the fundamentals of instructing, except for persons who are certificated teachers at or above the seventh grade level, employed as college or university instructors, or already hold a ground or flight instructor certificate. An additional knowledge test specific to the aircraft rating sought and an instrument knowledge test in the case of an instrument rating, would be required as well as a practical test.

Another proposed provision would preclude the holder of a flight instructor certificate from taking tests for and obtaining a ground instructor certificate with the same aircraft category as already specified on the person's flight instructor certificate. This provision is needed because the ground instructor certificate would not grant additional privileges, but the process of obtaining it only adds to the FAA's workload because of the additional tests. However, the applicant may seek a ground instructor rating for a different aircraft category (i.e., a person who holds flight instructor-airplane single engine may apply for a ground instructor-rotorcraft, etc.).

Some commenters recommended that a single ''aviation instructor certificate,'' be established in lieu of separate flight or ground instructor certificates. An aviation instructor certificate could specify ground or flight instructor privileges or both. After reviewing this recommendation, the FAA believes the required knowledge, skills, and abilities needed to instruct in the different aircraft categories and classes and differences between flight instructing and ground instructing makes this difficult to comprehend how this would be better than the current system. However, the FAA does request comments on this issue.

8. Training Requirements

An applicant for a ground instructor certificate would have to receive ground training on required aeronautical knowledge areas and fundamentals of instructing from a person who meets minimum experience requirements. The person giving the training would have to have at least 24 months experience as a ground instructor or flight instructor, and have given at least 40 hours of flight or ground training. However, if the ground instructor candidate is receiving training in a course approved under part 141, the person giving the training could either meet the 24-month and 40-hour experience requirement, or could have given 100 hours of ground or flight training. As an alternative, the applicant, under the proposal, could also accomplish the preparation through an independent, or home study program. Such preparation would have to be reviewed by an authorized instructor who meets the same experience requirements; the instructor would be required to sign an endorsement of the applicant's independent course of study.

9. Proficiency

The practical test for a ground instructor certificate would cover approved areas of operation including preparing and conducting lesson plans, evaluating student knowledge, and analyzing and correcting common student errors. An applicant would be required to teach a ground school lesson as part of the practical test. The training for the practical test would have to be given by a person who meets the same minimum experience requirements as for the knowledge test, although no minimum amount of training would be specified. The practical test would be administered by an examiner. An applicant for an additional ground instructor rating would not be required to take a practical test.

10. Privileges and Limitations

Subject to the limitations specified in part 61, a ground instructor would be permitted to give ground training for aeronautical knowledge areas; give endorsements required for pilot, ground instructor, and flight instructor certificates and ratings; give the ground training portion of the flight review; and give recommendations for knowledge tests.

11. Records

Under the proposed recordkeeping requirements, a ground instructor would note in a student's logbook or training record information for each training session; i.e., the amount of time of the lesson, date, and topics. The ground instructor would be required to maintain a record of the following information: the name of each student whose logbook or training record that instructor endorsed for satisfactory completion of a course; the name of each student endorsed for a knowledge test and the results of the test; the name of each student endorsed or recommended for a practical test and the date of the endorsement or recommendation; and a copy of the training syllabus for each student trained. The records would be required

to be kept for 3 years. In addition, although the proposed rule does not specify this, ground instructors should log the time during which they give ground training, to demonstrate sufficient experience giving ground training to ground instructor applicants.

12. Recency of Experience

Existing § 143.19 specifies that a ground instructor may not perform the duties of a ground instructor unless, within the 12 months before intending to perform the duties, the instructor has served for at least 3 months as a ground instructor, or the FAA has determined that the instructor meets the standards prescribed in part 143. Proposed § 61.225, ''Recency of experience for a holder of a ground instructor certificate,'' would state that a person's ground instructor certificate remains current for providing ground training for airman certification purposes, provided that person has either: (1) Trained at least one student and endorsed that student for a practical test; or (2) received an endorsement from a flight instructor or ground instructor indicating that the person had demonstrated satisfactory knowledge in the areas of operation that apply to the person's ground instructor ratings. The FAA believes these provisions will ensure that ground instructors stay current on industry developments, without imposing significant costs and burdens on persons who hold ground instructor certificates.

13. Conversion to New System of Ground Instructor Certificate

The proposal would establish a 2-year period during which holders of ground instructor certificates could convert those certificates to the new system. The holder of a ground instructor certificate with a basic rating or an advanced rating would be permitted to exchange that certificate for a ground instructor certificate with an airplane category rating. The holder of a ground instructor certificate with an advanced rating and an instrument rating would be permitted to exchange that certificate for a ground instructor certificate with an airplane category rating and instrument rating. The holder of a ground instructor certificate who also holds a flight instructor certificate would be permitted to exchange the ground instructor certificate for a ground instructor certificate with the same aircraft category and instrument ratings as on that person's flight instructor certificate.

14. Medical Certificates

a. Medical Eligibility Requirement for Applying for a Pilot or Flight Instructor Certificate

The FAA proposes to change the medical certificate requirements for eligibility for pilot and flight instructor certificates. Under the proposed revision to § 61.23 and other sections, applicants would only need a third-class medical certificate to be eligible to apply for a private, commercial, or an airline transport pilot or flight instructor certificate. Requirements for exercising the privileges of each certificate would remain as they are now. That is, a second-class medical certificate still would be required to exercise the privileges of a commercial pilot certificate, and a first-class medical certificate would be required to exercise the privileges of an ATP certificate.

The concept behind the proposed changes is that pilots should be encouraged to continue training and earning new pilot certificates, regardless of whether they intend to use the certificates. In some cases, pilots may qualify for a third-class medical certificate, which is sufficient for undergoing training and taking a practical test for a commercial or ATP certificate, but may not meet the requirements for a second- or first-class medical certificate. The FAA believes that lack of the more stringent medical certificate should not prevent the pilots from earning the more advanced pilot certificates and enhancing their pilot skills and proficiency.

The FAA proposes to include a provision in § 61.39, ''Prerequisites for practical tests,'' requiring an applicant to hold at least a third-class medical certificate, if a medical certificate is required. Section 61.39 currently requires a practical test applicant to hold a current medical certificate that applies to the certificate sought or, in the case of a rating to be added to a pilot certificate, at least a valid third-class medical certificate. Corresponding changes are also proposed to the subparts addressing the various certificates and ratings.

b. Medical Requirements for Recreational Pilots and Holders of a Higher Pilot Certificate Exercising the Privileges of a Recreational Pilot Certificate

The FAA is proposing to allow pilots who hold recreational pilot certificates and those higher rated pilots who elect only to exercise recreational pilot privileges to operate aircraft without a medical certificate. Specifically, this proposal would include student pilots who are seeking a recreational pilot certificate, holders of a recreational pilot certificate, and holders of a higher pilot certificate who elect only to exercise the privileges of a recreational pilot certificate. This proposal would be a significant departure from long-standing FAA policy.

Since the early 1930s all pilots, except glider and balloon pilots, have been required to hold medical certificates in order to exercise the privileges of their pilot certificates. The FAA determined that medical certificates were required for the purpose of ensuring the safety of the pilot in command and passengers, and also for the safety of people and property on the ground. As a result of the EAA petition discussed earlier and the interest shown in the general aviation community, the FAA is seeking wider comment on whether recreational pilots and holders of a higher pilot certificate who elect to exercise the privileges of a recreational pilot certificate should be required to hold medical certificates. The FAA is also seeking data on any safety or other public interest concerns that may arise from obviating any review of medical qualifications by medical professionals.

Pilots applying for a recreational pilot certificate would be required to certify at the time of application that they have no known medical condition or deficiency that makes them unable to operate the aircraft in a safe manner. This requirement parallels the provisions that are now provided to balloon and glider pilots under the current rules. This proposal would prohibit pilots from exercising the privileges of a recreational pilot certificate if they have a known medical condition or deficiency that would make them unable to operate the aircraft in a safe manner or if they are taking any medication or receiving other treatment for a medical condition that would make them unable to operate the aircraft in a safe manner. (This ongoing obligation is discussed in more detail under the section-by-section analysis.) The FAA is not proposing specific medical standards for this pilot self-evaluation but instead are proposing that pilots self-evaluate prior to each flight whether they have any medical conditions that would inhibit their ability to operate the aircraft in a safe manner. The FAA would rely on the pilot's knowledge and judgment as to their medical fitness for conducting each flight. The FAA strongly encourages the public to comment on whether there should be specific medical standards upon which the pilot should base their self-evaluation. If so, what should those standards be? In

particular, the FAA would like comments in response to the following questions:

(1) Should the rule specifically prohibit holders of pilot certificates who do not also hold medical certificates from flying if they know or should know that they have certain conditions? For example, should the rule exclude persons who believe that they have no known medical deficiencies even if they know, or have any reason to know, that they have:

(a) A visual problem, e.g., vision uncorrectable to at least 20/30?

(b) An equilibrium problem?

(c) Alcoholism to the extent that the intake of alcohol has caused damage to their physical health, personal or social functioning, or is required to enable them to perform normal functions?

(d) A drug dependence?

(e) A personality disorder, neurosis, or a mental condition that makes them unable to safely operate a vehicle or machinery?

(f) Epilepsy or a disturbance of consciousness without satisfactory medical explanation of the cause?

(g) A convulsive disorder, disturbance of consciousness, or neurologic condition that makes them unable to safely operate a vehicle or machinery?

(h) A myocardial infarction (heart attack), angina pectoris, or a coronary heart disease?

(i) Diabetes?

(j) An organic, functional, or structural disease, defect, or limitation that makes them unable to safely operate a vehicle or machinery?

(k) Any other serious medical problem that makes them unable to safely operate a vehicle or machinery?

(2) Should the rule state that pilots who have failed a medical examination by the FAA be prohibited from claiming that they have no known medical deficiencies?

(3) Should the rule state that pilots who have had their medical certificate revoked or suspended be prohibited from claiming that they have no known medical deficiencies?

(4) Should the rule state that pilots who hold or have held a medical special issuance be prohibited from claiming that they have no known medical deficiencies?

(5) What, if any, documentation should the FAA require persons without an airman medical certificate to execute in order to identify that they have evaluated their medical fitness to fly and that, to the best of their knowledge and belief, they are medically qualified to pilot an aircraft? How often (before each flight, annually)? What kind of documentation?

(6) How, if at all, should the FAA require pilots without a medical certificate to disclose to passengers that they have not been medically certificated by the FAA?

The FAA recognizes that broad scale medical self-evaluation could create substantial obstacles to the FAA's ability to enforce § 61.53. Therefore, the FAA also requests comments on the following issues:

(7) How would the FAA enforce and monitor compliance with § 61.53(b)?

(8) Should pilots who do not hold medical certificates be obligated to provide the FAA with their medical history/records upon request, either as part of a specific investigation or randomly as part of a compliance program?

(9) Should the FAA be able to require pilots who do not hold medical certificates to undergo medical testing when any uncertainty exists as to whether or not they have any medical problems?

Under this proposal, pilots with an airplane, rotorcraft, or a glider rating and who elect to only exercise recreational pilot privileges would be eligible to conduct ''recreational pilot'' operations without having to hold or obtain a medical certificate. Therefore, a person's pilot certificate may represent apparent authority to conduct those operations even when that person may not be medically qualified under part 67 of this chapter. Under the current rule, these operations would require the pilots to hold and have in their possession a current medical certificate. Because of the possible enforcement problems associated with determining an individual's actual authority to operate, the FAA is also seeking comments on the following:

(10) Should pilots who have known medical deficiencies be required to surrender their airman certificates?

(11) If pilots are allowed to keep their airmen certificates when they have a known medical deficiency, should the FAA require the airmen certificates to be stamped ''NOT VALID UNLESS ACCOMPANIED BY A CURRENT MEDICAL CERTIFICATE?'' The FAA is strongly encouraging the public to express their concerns regarding these questions as well as any other issues pertinent to this proposal.

The FAA requests comments on whether the limited operational scope of a recreational pilot certificate, under which all the above pilots would be required to operate, makes requiring these pilots to submit to medical examinations an unnecessarily burdensome process. Section 61.101 lists the limitations of a recreational pilot certificate, which includes, among other things, the following limitations:

A recreational pilot may not operate an aircraft—with more than one passenger on board the aircraft; that is certificated for more than 4 occupants; with more than one powerplant; with a powerplant of more than 180 horsepower; with a retractable landing gear; that is classified as a multiengine airplane, powered-lift, glider, airship, or balloon; carrying a passenger or property for compensation or hire nor may the pilot operate for compensation or hire; in furtherance of a business; between sunset and sunrise; in airspace in which communication with air traffic control is required; at an altitude of more than 10,000 feet MSL or 2,000 feet AGL, whichever is higher; when the flight or surface visibility is less than 3 statute miles; without visual reference to the surface; on a flight outside the United States; to demonstrate that aircraft in flight to a prospective buyer; used in a passenger-carrying airlift and sponsored by a charitable organization; and that is towing any object.

The FAA is also proposing to allow recreational pilots who have received the cross-country training required for private pilot certification to fly beyond the 50 nautical mile limit which is now required by the current § 61.101.

The FAA acknowledges that there are a number of difficult issues surrounding this concept, and that the data and analysis currently developed are limited at best. The FAA is therefore requesting comments that provide supporting data and analysis on the likely effects of changing the FAA's long-standing medical certification policy for pilots. In particular, the FAA would like comments on the potential impact on safety.

On November 17, 1994, the National Transportation Safety Board (NTSB) provided the FAA with general aviation accident data involving medical incapacitation since 1982 for balloon and glider pilots. There have been a total of 7 accidents involving balloon and glider pilots since 1982 where a finding was made on medical incapacitation as a cause or factor involved in the accident. Out of those 7 accidents, 4 pilots had valid medical certificates, 2 pilots had held a medical certificate but the certificates were expired, and only 1 pilot did not hold a medical certificate. There were 5 fatalities, 1 serious injury, and 1 minor injury. The NTSB's data and brief summaries showed the following information:

(1) Date: June 18, 1983, Category of Aircraft: Balloon, Crew Injuries: 1 fatal, Passenger/Gnd personnel injury: 0,

Medical Certification: Yes, Miscellaneous statistics: Male, age 58, Brief summary: After takeoff, the pilot collapsed to the floor of the gondola and had difficulty breathing. The balloon hit the porch of a house and was substantially damaged. The pilot died from acute myocardial infarction.

(2) Date: February 20, 1986, Category of Aircraft: Glider, Crew Injuries: 1 fatal, Passenger/Gnd personnel injuries: 0, Medical Certification: Yes, Miscellaneous statistics: Male, age 65, Brief summary: Medical examination of the pilot revealed that the pilot had a history of heart condition and at the time of the accident the pilot experienced an heart arrhythmia associated with a myocardial infarction.

(3) Date: February 24, 1990, Category of Aircraft: Glider, Crew Injuries: 1 fatal, Passenger/Gnd personnel injury: 0, Medical Certification: None, Miscellaneous statistics: Male, age 53, Brief summary: Pilot had a history of epileptic seizures. Toxicological analysis revealed the drug carbamazepine present in the blood and urine samples at therapeutic levels. The drug was an anticonvulsant which causes drowsiness.

(4) Date: July 31, 1990, Category of Aircraft: Glider, Crew Injuries: 1 minor, Passenger/Gnd personnel injury: 0, Medical Certification: Yes, Miscellaneous statistics: Female, age 56, Brief summary: Pilot had reported she had injured her right arm during flight into turbulent conditions. She stated she was unable to control the pitch of the glider due to her injuries and had to parachute out.

(5) Date: July 19, 1991, Category of Aircraft: Glider, Crew Injuries: 1 fatal, Passenger/Gnd personnel injury: 0, Medical Certification: Medical certificate had lapsed, Miscellaneous statistics: Male, age 63, Brief summary: An autopsy revealed the pilot had cardiovascular disease, including coronary atherosclerosis with thrombosis of bypass graft.

(6) Date: July 31, 1991, Category of Aircraft: Glider, Crew Injuries: 1 fatal, Passenger/Gnd personnel injury: 0, Medical Certification: Unknown, Miscellaneous statistics: Male, age 25, Brief summary: Pilot reported a midair collision with another glider. The NTSB's finding determination was the failure of the pilot to maintain an adequate visual lookout and the collision induced incapacitation.

(7) Date: September 21, 1991, Category of Aircraft: Glider, Crew Injuries: 1 serious, Passenger/Gnd personnel injury: 0, Medical Certification: Medical certificate had lapsed, Miscellaneous statistics: Male, age 72, Brief summary: Pilot reported that he blacked out.

In addition, the NTSB supplied the FAA with the following total general aviation aircraft accident data and statistics involving medical incapacitation as a cause or factor in their finding during the years 1982 through 1993:

	Aircraft	Accidents	Fatal Accidents	Injuries			
				Fatal	Serious	Minor	None
1982	10	10	8	11	1	0	42
1983	7	7	5	6	1	0	6
1984	15	15	10	21	6	2	21
1985	14	14	9	11	2	4	117
1986	12	12	7	9	1	1	307
1987	14	14	11	56	0	0	112
1988	13	13	7	7	6	3	104
1989	7	7	6	7	0	0	2
1990	7	7	6	8	0	1	0
1991	20	20	14	15	6	5	23
1992	13	13	10	19	4	1	69
1993	6	6	3	3	1	0	209
Totals	132	132	96	170	28	17	1012

*This data does not differentiate between those pilots who held current, valid medical certificates at the time of the accident and those who allowed their medical certificates to lapse or never held medical certificates. Furthermore, this data did not filter out those accidents that were a result of a medical incapacitation involving an injury sustained during the flight or alcohol or illegal drug incapacitation.

15. Required Pilot Possession of Pilot and Medical Certificates

The FAA proposes to clarify the requirement in § 61.3 that a pilot, flight instructor, ground instructor, or medical certificate must be in the person's ''personal possession'' whenever that person exercises the privileges of the certificate. The FAA's intent is to have pilots and instructors carry their certificates on or near their person while exercising the privileges of that certificate.

A legal decision has demonstrated that the current requirement can be interpreted in more than one manner. For example, ''personal possession'' was interpreted to permit a pilot to exercise the privileges of a pilot certificate while the certificate remained behind in the pilot's residence or automobile. The general purpose of the regulation, however, is to enable pilots or required flight crewmembers to present their certificate to an authorized person upon request and at the time of that request.

The FAA proposes to replace the reference ''personal possession'' with the requirement that a certificate be in the ''person's physical possession or readily available.'' This way, a pilot certificate would be available when requested by an authorized person. Additionally, a person who carries their pilot and medical certificates in their briefcase or in a purse aboard the aircraft would still be in compliance with the rule. However, this does not mean that person could state their pilot and medical certificates are located at their home in a desk drawer and still be in compliance with the term in the ''person's physical possession or readily available.''

16. Issuance of U.S. Pilot Certificates on the Basis of Foreign Pilot Licenses

The FAA proposes several changes to § 61.75, regarding issuance of a U.S. pilot certificate on the basis of a foreign pilot license. The FAA proposes to amend § 61.75 to require that when a foreign pilot certificate is not in the English language, the person must provide a signed English transcription of the license and its limitations from the foreign government's aviation agency. An English-language transcription would help avoid incorrect issuance of a U.S. pilot

certificate, letter of authorization, or appropriate ratings through inaccurate translations. This amendment would also help to ensure that all requirements of § 61.75 are met and there is no endorsement on the certificate stating that the pilot has not met all of the standards of the International Civil Aviation Organization (ICAO) for that license. This proposal would require evidence of meeting medical standards on which foreign certificates are based and an English-language transcription of the foreign medical certificate.

The FAA also proposes to revise § 61.75 to eliminate the issuance of commercial pilot certificates when issuing U.S. pilot certificates on the basis of a foreign pilot license. Under the proposed amendment, the U.S. would honor or accept a foreign-issued pilot certificate for the issuance of a U.S. private pilot certificate only. This would replace the current practice of issuing a private pilot certificate to the holder of a foreign private pilot license, and a commercial pilot certificate to the holder of a foreign commercial, senior commercial, or ATP license. This change would be mainly for clarification because current policy is to endorse the U.S. commercial pilot certificate as ''not valid for operations for compensation or hire,'' which effectively limits the certificate to private pilot privileges only. The proposed rule would delete language specifically disallowing the U.S. certificate to be used for agricultural operations. However, persons who have been issued commercial pilot certificates on the basis of their foreign pilot certificate prior to the effective date of this rule would be allowed to continue to hold that pilot certificate. However, if the person seeks an additional rating, then the certificate would be reissued at the private pilot certificate level.

The FAA also proposes to revise § 61.75 to delete language that bases the pilot privileges on those authorized by the foreign pilot license. Under the proposal, the holder of a U.S. private pilot certificate issued under § 61.75 would be permitted to act as a pilot of a U.S.-registered civil aircraft in accordance with private pilot privileges authorized by part 61 that are placed on the U.S. certificate. This will clarify that operating authority is derived from the U.S. private pilot certificate issued, which contains the privileges and limitations. Any additional limitations and restrictions (e.g., weight of aircraft) that are on the foreign pilot license are incorporated by reference onto the U.S. private pilot certificate. The proposed rule language would further clarify that personal possession of the foreign pilot license is required in order to exercise the privileges of the U.S. private pilot certificate. Finally, the proposal would clarify that the pilot would not be allowed to exercise the privileges on the U.S. certificate if the foreign pilot license was revoked or suspended.

Under current § 61.75, FAA practice permits persons who cannot read, speak, write, and understand the English language to be issued a pilot certificate with certain limitations restricting operations in airspace requiring the use of the English language. In accordance with this proposal, the practice would be discontinued and persons issued certificates under this section would be required to be able to read, speak, write, and understand the English language. However, those persons who cannot read, speak, write, and understand the English language and who have been issued pilot certificates with limitations that restrict operations in airspace requiring the use of the English language prior to the effective date of this rule would be allowed to continue to hold that certificate. If the person seeks an additional rating or higher level pilot certificate, then the certificate would not be issued unless the person is able to read, speak, write, and understand the English language.

The regulation currently requires evidence that the applicant meet the medical standards for the foreign pilot license on which the application for a U.S. certificate is based. This evidence may include a U.S. medical certificate. The proposed rule would state specifically that the applicant must hold a current medical certificate, either issued under part 67, or issued by the state that issued the foreign pilot license.

Special Purpose Pilot Authorization

The FAA proposes to revise the rules regarding the issuance of special purpose pilot certificates for the operation of U.S.-registered civil airplanes leased by a person who is not a U.S. citizen. The FAA proposes to replace the issuance of special purpose pilot certificates with the issuance of special purpose pilot authorizations that will be issued by a Flight Standards District Office (FSDO). Persons who have been issued special purpose pilot certificates, prior to effective date of this rule, would continue to be allowed to exercise the privileges of that certificate until the certificate expires. However, once the special purpose pilot certificate expires, the pilot would be required to surrender the certificate for a special purpose pilot authorization and comply with the provisions contained in proposed § 61.77.

Standardization of the ''Age 60 Limitation'' for Airmen Employed by Foreign Air Carriers in Scheduled International Air Services or Non-Scheduled International Air Transport Operations

The FAA proposes to clarify §§ 61.3 and 61.77 relating to the ''Age 60 Limitation'' with part 121. This proposal will cover all U.S. and foreign pilots, who are 60 years of age or older, and who are employed by a foreign air carrier that operates U.S.-registered civil aircraft for compensation or hire in scheduled international air services and non-scheduled international air transport operations. This proposal will make the rules of part 61 consistent with the standards contained in part 121.

17. Logging Flight Time

The FAA proposes revisions in the logging of pilot flight time. The proposals are contained in § 61.1a, Clarification of terms, and in § 61.51, Pilot logbooks.

The FAA proposes these revisions largely in response to public concern regarding various aspects of the rules on logging flight time. Many of the participants at the public hearings encouraged the FAA to clarify the existing regulations. For example, some recommended that the term ''solo flight time'' be deleted and that student pilots be permitted to log ''solo'' time as PIC time.

Proposed § 61.1a would clarify that pilot time is any time a person operates as a required pilot, receives training from an authorized instructor, or gives training in an aircraft, flight simulator, or flight training device. Flight time would be clarified as pilot time that commences when an aircraft moves under its own power for the purpose of flight and ends when the aircraft comes to rest at the point of landing. The FAA proposes that in the case of a nonpowered glider, flight time would begin when the nonpowered glider commences being towed for the purpose of flight and would end when the nonpowered glider comes to rest at the destination.

In § 61.1a, the FAA proposes to describe cross-country time for three separate circumstances: For persons who hold a private, commercial, or airline transport pilot certificate; for persons applying for a private or commercial pilot certificate or instrument rating; and for military pilots. For holders of private, commercial, or airline transport pilot

certificates, the criteria for cross-country flight would include landing at a point other than the point of departure and use of dead reckoning, pilotage, or navigation aids to navigate. No minimum distance would be specified. However, for persons applying for a private or commercial pilot certificate or for an instrument rating, the point of landing would be required to be more than 50 nautical miles from the point of departure. For a military pilot who holds or is qualified for a private or commercial pilot certificate under § 61.73, cross-country time would be flight over a distance of more than 50 nautical miles. However, the FAA recognizes that military flight operations may require pilots to navigate and fly considerable distances without landing at a point other than the point of departure. Therefore, proposed § 61.1a would not require that a landing occur at any point other than the departure point.

Proposed § 61.51 would eliminate reference to ''solo'' time as a type of pilot experience or training equivalent to PIC time. The proposal would permit student pilot certificate holders to log PIC time when they: are the sole occupant of the aircraft; have a supervised PIC flight endorsement; and are undergoing a course of training for a pilot certificate or rating or are logging PIC time toward a certificate or rating. The description of solo flight time in current § 61.51 would be eliminated under the proposal.

The proposal would specify that, except when a flight instructor gives flight training, only one person at a time may log PIC flight time. This provision is intended to eliminate current confusion, particularly regarding the current provision that permits any pilot to log PIC time when acting as PIC of an aircraft on which more than one pilot is required under the regulations under which the flight is conducted.

Instead, the proposal would state that the holder of a pilot certificate may log PIC time only when that pilot: (1) Has the final authority and responsibility for the operation and safety of the flight; (2) holds the appropriate ratings; (3) has been designated PIC before the flight; and (4) the PIC time occurred in actual flight conditions and in an aircraft.

Although the current regulation also specifies that a flight instructor may log as PIC time all flight time during which the person acts as a flight instructor, the proposed rule would provide more detail regarding the conditions under which this occurs. For example, the flight instructor would have to be authorized to conduct the training; hold at least a third-class medical certificate; and occupy a pilot station with functioning flight controls. To log PIC time the certificated pilot receiving flight training would have to be qualified to conduct the flight in accordance with the FAR; manipulate the controls of the aircraft; and be undergoing a course of training for the issuance of a certificate or rating or obtaining recency of experience requirements. In addition, the aircraft would have to have dual functioning flight controls and engine controls that could be reached from either pilot station.

The proposal would not significantly alter the current requirements regarding logging of instrument time. However, the proposal would state that if a safety pilot is required, the name and pilot certificate number of the safety pilot must be recorded and the location and kind of each completed instrument approach. The current rule does not require the safety pilot's certificate number.

The proposal would specify the information that should be recorded regarding flight training toward a certificate, rating, or flight review. This would include a description of the training given, the length of the lesson, the instructor's signature, certificate number, and certificate expiration date.

The proposal would modify the current provision of § 61.51 that applies to the requirement for presentation of the person's logbook. The proposal would list the other records a person must present, in addition to the logbook, upon the request of an authorized official. The other documents include the pilot certificate, medical certificate, or any other record required under part 61. Both the current rule and proposed rule refer to officials representing the Administrator and the NTSB. However, the current rule also refers to a State or local law enforcement officer; the proposal would expand this to include any law enforcement officer.

18. Recency of Experience Requirements

The FAA proposes to modify a number of the recency of experience requirements in § 61.57.

The current requirement for three takeoffs and three landings within the preceding 90 days would be modified to allow night takeoffs and landings to also count for daytime currency. However, the takeoffs and landings would have to be to a complete stop, whether accomplished during day or night or in an airplane with tailwheel landing gear or tricycle landing gear. In retaining the current requirements, night operations will involve knowledge, skill, and ability that are sufficient for currency for daytime operations. However, safety will be better served if the regulation requires full-stop landings, at least for the purpose of meeting the requirements of proposed § 61.57, rather than encouraging ''touch-and-go'' operations. A landing is not completed until the airplane is stopped and off the runway. As an example, crosswinds may cause a wing to lift suddenly, or mistakes can be made during a hasty effort to ''clean up'' the airplane (i.e., retract flaps, turn off carburetor heat, etc.).

Additional language is proposed that would require each takeoff and landing to involve a flight in the traffic pattern at the recommended traffic pattern altitude for the airport. This language is intended for pilots of helicopters and powered-lift aircraft, which could takeoff and land in virtually one spot. However, the intent of the rule is that pilots perform a complete takeoff and landing operation, including operating in the airport traffic pattern.

19. Instrument Currency

In addition, the FAA proposes to revise the requirements for instrument currency. Currently, § 61.57 sets the minimum requirements for recent instrument flight experience. For aircraft other than gliders, a pilot must have logged at least 6 hours of instrument time under actual or simulated IFR conditions, at least 3 of which were in flight in the category of aircraft involved, within the past 6 calendar months. The pilot must also have conducted at least six instrument approaches in that time. A pilot who does not meet the requirement of 6 hours and six approaches during the prescribed time or 6 months thereafter must pass an instrument proficiency test.

The revision in instrument currency requirements proposed here for aircraft other than gliders is based on a petition for rulemaking from Newton W. Miller, who advocates changing the requirements to emphasize instrument approaches and reduce the number of hours flown under simulated or actual instrument conditions to meet recency of experience requirements. The petition, summarized in the **Federal Register** on October 25, 1984 (49 FR 42943; Docket No. 24247), advocates decreasing the required flight hours to 2 or 3 hours (including at least 1 hour in the category of aircraft involved) and increasing the number of required approaches to 10 or 12. The petitioner argues that the 6 hours of simulated instrument flight may be flown largely in straight and level flight, which probably is relatively unchallenging to most instrument-rated pilots and does

not significantly contribute to maintaining instrument proficiency. The petitioner also states that 6 hours is an economic burden to many pilots and encourages pilots ''to fly while not legally current.'' The petitioner states that aircraft control combined with the complex demands of following approach plates and communicating with ATC are much more germane to IFR proficiency. Therefore, the petitioner states, the number of required approaches should be increased. The petitioner states that 10 or 12 approaches could be conducted in 2 hours of flight time.

One comment was submitted in response to that petition. In that comment, the Air Line Pilots Association (ALPA) stated that the present regulation does not ensure proficiency, because a pilot may take an instrument proficiency test and not fly in instrument conditions for up to 6 months but still be legally current.

The petitioner raises an important issue in focusing on the quality of the time spent in instrument flight, especially simulated instrument flight, although the FAA disagrees that the current regulation encourages pilots to disregard the FAR and fly illegally. Therefore, the FAA proposes to revise the instrument recency of experience requirements. Under the proposal, to act as PIC under IFR, or in weather conditions less than the minimums prescribed for VFR, within the preceding 6 calendar months for aircraft other than gliders, a pilot would be required to have performed and logged: (1) At least six precision instrument approaches; (2) at least six nonprecision instrument approaches, (3) holding procedures; (4) intercepting and tracking VOR radials and NDB bearings; (5) recovery from unusual flight attitudes; and (6) flight by reference to instruments. However, these maneuvers and procedures would not be required to be performed in actual or simulated instrument flight. No minimum number of hours of simulated or actual instrument flight time would be specified.

Proposed § 61.1a would define an instrument approach as an approach procedure defined in part 97 and conducted to an established minimum descent altitude (MDA) or decision height (DH), or if necessary, to a higher altitude selected for safety reasons by ATC. Part 97 prescribes Standard Instrument Approach Procedures (SIAP) for instrument letdown to airports in the United States.

These proposed requirements could be met either in actual flight and in the category of aircraft for which instrument privileges are sought, or in an approved flight simulator or flight training device representative of the category of aircraft for which instrument privileges are sought.

Instrument recency of experience in gliders would change mainly in format under the proposal. Pilots would be required to perform and log at least 3 hours of instrument time in actual flight, of which at least one-half must have been in a glider or single-engine airplane if the pilot does not carry passengers. If the pilot does carry passengers, the pilot must have performed and logged at least 3 hours of instrument time in a glider.

The FAA also proposes to clarify the requirements for an instrument proficiency test. Currently, the instrument proficiency test would be required for a person who has not met the instrument recency requirements within the prescribed time or within 6 calendar months after that time. The FAA proposes to clarify this issue by amending § 61.57 to require that the test include a representative number of tasks required for original certification of an instrument rating.

The FAA issued an NPRM on April 11, 1994 (59 FR 17162) to waive the recency of experience requirements of § 61.57 for PICs of parts 121 and 135 operators. Specifically, that NPRM proposed relief to PICs of parts 121 and 135 operators from having to comply with the recency of experience requirements, (i.e., general, night, and instrument) of § 61.57. Parts 121 and 135 have recency of experience requirements that are at least equivalent to the recency of experience requirements of § 61.57, so duplication of these requirements are unnecessary. The final rule is scheduled for issuance in 1994.

The proposals in this NPRM would extend the exception requirements for the general and night recency experience requirements of § 61.57 to PICs of part 125 operators, but not the instrument recency experience requirements. The FAA believes the training programs and structured operational controls placed on PICs in part 125 operations are adequate in ensuring that there will not be a degradation in safety. The FAA believes that the redundant recency of experience requirements in part 125, in addition to the structured training programs and operational controls placed on PICs of part 125 operators more than adequately cover any safety concerns provided by exempting these PICs from the recency of experience requirements of § 61.57.

20. English Language Ability Requirements

The FAA proposes to standardize English language fluency requirements for all certificates and ratings and to eliminate exceptions in certain rules that permit pilots to be certificated without meeting English language fluency requirements, under certain restrictions.

The proposal to eliminate exceptions to the English language requirements would affect all pilot and flight instructor applicants. This proposal would be addressed in each of the eligibility paragraphs of each pilot certificate level and would require all applicants to be able to read, speak, and understand the English language. Under the proposal, the reference to operating limitations would be deleted, and all applicants would be required to meet the language requirements. A similar provision in current § 61.75, which provides for placement of limitations on a pilot certificate issued on the basis of a foreign pilot license, also would be deleted. As with the pilot certificates and ratings, the applicant for a U.S. pilot certificate, on the basis of a foreign pilot license, would have to be able to read, speak, write, and understand the English language.

The FAA has grown increasingly concerned that pilots' inability to sufficiently read, speak, and understand English during radio communication and in dealing with air traffic control poses a serious safety hazard. The exceptions referred to have not effectively kept such pilots out of airspace in which command of the English language is essential, and for safety reasons, the FAA believes all pilots who operate in the National Airspace System (NAS) should meet the English language requirements. Current holders who cannot read, speak, write, and understand the English language, but have been issued pilot certificates with limitations that restrict operations in airspace requiring the use of the English language prior to effective date of this rule would be allowed to continue to hold that certificate. If the person seeks an additional rating or higher level pilot certificate, then the certificate will not be issued unless the person is able to read, speak, write, and understand the English language.

The proposal would eliminate, as superfluous, current language in § 61.151 that requires applicants for the ATP certificate to speak English without accent or speech impediment that would interfere with two-way radio conversation. The FAA believes that the requirement to speak English means

speak well enough to participate clearly and safely in radio communications.

21. Flight Training Given by a Flight Instructor Not Certificated by the FAA

Existing § 61.41, ''Flight instruction received from flight instructors not certificated by the FAA,'' permits flight training received by a flight instructor who is not certificated by the FAA to be credited toward the requirements for a U.S. pilot certificate or rating. However, the instructor is required to either be a: (1) Member of an Armed Force of either the United States or a foreign contracting State to the Convention on International Civil Aviation in a program for training military pilots; or (2) flight instructor authorized to give that flight training by the licensing authority of a foreign contracting State to the Convention on International Civil Aviation and the flight training is given outside the United States.

Section 61.41 contradicts existing § 61.3, which states that flight training must be given by the holder of a flight instructor certificate issued by the Administrator. The exceptions to this requirement do not include flight instructors who are not certificated by the FAA. The absence of an exception for these flight instructors has caused confusion in relation to § 61.41. Currently, the FAA permits flight training received by a flight instructor who meets the requirements of § 61.41 to be credited toward the requirements found in part 61.

The FAA proposes to revise § 61.3 to ensure that, under certain circumstances, the recipient of flight training from a flight instructor who is not certificated by the FAA, may credit that flight training toward the requirements in part 61. Such a privilege is granted in the existing regulation but is subject to misinterpretation.

22. Second-in-Command (SIC) Training and Recent Experience

The FAA proposes to clarify the familiarization review requirements under § 61.55 for pilots serving as SIC of an aircraft that requires more than one pilot. Under the proposal, a person serving as SIC would be required to have completed, within the previous 12 calendar months, a familiarization review on specific subjects for the type of aircraft in which privileges are requested. As with other issues in this proposal, the FAA seeks greater structure and standardization.

The proposed section would maintain current provisions providing exceptions to the training requirements. For example, the training requirements do not and would not apply to pilots qualified as PIC or SIC under parts 121, 125, or 135. In addition, pilots designated as SIC for the purpose of receiving flight training required under § 61.55, where no passengers or cargo are carried on the aircraft do not and would not have to meet the training requirements. Exceptions to the training requirements would also continue to be made for pilots holding a commercial pilot or ATP certificate in the case of ferry flights, test flights, or evaluation flights, provided no persons or cargo unnecessary for conducting the flight are carried aboard the aircraft.

23. Knowledge Tests

As discussed in the section on Clarification of Terms, the FAA proposes to use the term ''knowledge test'' to replace the term ''written test.'' Knowledge tests will include tests administered by computer, which already are acceptable to the FAA; this term will update the FAR terminology to conform with the educational community.

In addition, the FAA proposes to require that applicants for knowledge tests obtain a logbook endorsement from an instructor in order to be eligible to take a knowledge test. This will end the current practice in which applicants request an FAA inspector from a FSDO to review and discuss their home study materials as evidence that they have completed a home study course. This practice constitutes an unnecessary workload for the FAA and is a role more properly filled by ground or flight instructors. Home study would still be acceptable; the only change would be that an instructor's endorsement would be required, but a review by the FAA would not.

The FAA proposes to continue requiring an endorsement to take the knowledge test to dissuade applicants from taking the test with inadequate preparation, again, to avoid undue administrative burden. Many applicants taking and retaking the knowledge tests might delay grading and response time, which would be unfair to applicants who completed courses and prepared for the tests.

24. Standardized Syllabus

The Notice of Hearings (54 FR 22732; May 25, 1989) invited public comment on whether parts 61 and 141 should be consolidated into one regulation and whether all training should be performed from a standardized curriculum. Under the current system, pilot and flight instructor training is conducted to meet the criteria and requirements of aeronautical knowledge and flight proficiency, as set out in part 61 and the PTS. There is no requirement in part 61 for an applicant to complete an FAA-approved ground and flight training syllabus before obtaining a pilot or instructor certificate or rating.

Part 141 provides a specific method for meeting the part 61 requirements through training programs conducted at approved schools that offer standardized curricula and are monitored by the FAA to ensure quality training. Part 61 requires specific course structure and organization, detailed recordkeeping, increased standardization of training, and increased supervision of training. Testing standards are the same for pilots trained at non-approved schools or by independent instructors.

Although many of the comments received in response to the Notice of Hearings and at the public hearings supported consolidating parts 61 and 141, many commenters also wanted to maintain the current system of approving FAA pilot schools under part 141 and having schools and independent instructors operate under part 61 only.

However, during the public hearings, many participants agreed that performing training under a standard curriculum or syllabus may be beneficial. Nevertheless, they disagreed on whether the written training program should be prepared by the FAA or developed by industry and approved by the FAA. Many recommended that outlines be generated by the school and approved by the FAA. Some commenters noted that peculiarities of geographic area may not be included in a syllabus generated by the FAA. Participants suggested that a general syllabus could be published in an advisory circular format as guidance.

Based on the public comments and its own study of the issue, the FAA believes that part 61 and part 141 should not be combined or consolidated. However, the FAA is proposing that all training for pilot, flight instructor, and ground instructor certificates and ratings should be performed according to a written syllabus. The intent of this proposal is to encourage all training to be conducted according to a more organized and standardized format. This approach to training would give students and trainees the benefit of more structured training programs, an advantage that currently exists in training conducted under part 141 (or parts 121 and 135). The FAA believes that many independent instructors and pilot schools conducting training under part 61 already understand this and use

written syllabi although no regulatory requirement exists. However, the FAA would like to see this approach become the industry norm.

The FAA proposes to establish a new § 61.9 to require an instructor who provides training for an airman certificate or rating issued under part 61 to use a written syllabus that includes a summary of total training time; planned training time for each lesson; a detailed description of training to be covered in each lesson; and the aeronautical knowledge areas and approved areas of operation that apply to the airman certificate or rating. Because this requirement would apply to training conducted under part 61, and schools that conduct training under part 61 are not directly subject to FAA approval or certification, the instructor would bear responsibility for ensuring that all necessary areas of aeronautical knowledge and operation were covered in the training program. The proposal also would require the instructor to give a copy of the syllabus to the student at the outset of the training and ensure that the student completed the syllabus before the practical test.

The FAA does not, at this time, propose to require instructors to submit the syllabi for FAA approval. This would constitute a major administrative workload for the FAA and for instructors. However, the instructor would be required to maintain a copy of the syllabus, make it available for FAA inspection upon request, and provide each student with a record of the training accomplished. This proposal would revise § 61.189 to require each flight instructor to retain for 3 years a copy of the syllabus for each person trained by that instructor. Proposed § 61.219 would include the same requirement for ground instructors.

The FAA does not intend for each instructor to produce a personal syllabus for each course of training, although there is nothing to preclude such an effort should an instructor prefer to do that. Syllabi could be based on training courses published by manufacturers and training organizations.

The FAA believes that the use of training syllabi would provide more continuity in training conducted under part 61. This is particularly important for students who change instructors in the midst of a training program.

25. Training and Endorsements

The FAA proposes several initiatives to enhance pilot training and preparation. These efforts include additional training and instructor endorsements that cover human factors training, windshear avoidance training, and special aircraft certification training for pilots. In addition, current endorsement requirements for complex and high performance airplanes would be clarified under the proposal.

26. Endorsement for Complex and High Performance Airplanes

The FAA proposes to amend current § 61.31, which deals with high performance and complex airplanes. Under this proposed revision, complex and high performance airplane endorsements would be discussed in separate paragraphs of § 61.31. One endorsement would be required for a pilot flying an airplane with retractable landing gear, flaps, and a controllable propeller (commonly referred to as a ''complex airplane''). A separate endorsement would be required to operate a high performance airplane, which would be redefined from ''more than 200 hp'' to ''200 hp or more.'' This proposed requirement for separate endorsements, one for complex airplanes and one for high performance airplanes, could be achieved simultaneously in a complex airplane of 200 horsepower (hp) or more.

Before giving the endorsements prescribed by § 61.31, the instructor would be required to provide both ground and flight training in the airplane to ensure the pilot is proficient on the operation and systems of the airplane.

In addition, § 61.31 currently requires endorsements only for holders of private or commercial pilot certificates. The FAA proposes to extend this requirement to holders of ATP certificates because it is possible to earn the certificate in a low horsepower, non-complex, single-engine airplane.

27. Aircraft Type Specific Training

In December 1991, the FAA issued a Special Certification Review Report on the Piper Malibu and Mirage airplanes. This review was a result of seven in-flight structural breakups involving Piper Malibu and Mirage airplanes. Although the review process did not discover any major design deficiencies, the special certification team that reviewed the airplane did make approximately 60 recommendations concerning design improvements and operational clarifications on the airplane.

The Special Certification Review team consisted of FAA engineers, inspectors, and pilots who were tasked with reviewing the certification process, service history, and operation of the Malibu and Mirage airplanes. The report issued on the airplanes was reviewed by the FAA's Small Airplane Directorate and an action plan was developed. The plan included some possible airworthiness directives and recommendations for improved pilot training, policy revision, and rulemaking. Both the review team and Small Airplane Directorate concluded there is a need to improve the education and training of pilots in these high performance, complex airplanes. The FAA stated in the report that both the aviation community and the FAA have the responsibility for ensuring that pilots have the knowledge, skills, and abilities to operate these kinds of airplanes in normal, abnormal, and emergency situation.

In response to this Special Certification Review of the Piper Malibu and Mirage, the FAA is proposing to amend § 61.31 by adding a new paragraph that will require aircraft type specific training and a flight instructor endorsement for any aircraft that the Administrator has determined is necessary to ensure that pilots are adequately trained in normal, abnormal, and emergency situations on these kinds of airplanes. The FAA believes that pilots need this additional training to possess the necessary knowledge, skills, and abilities to operate these kinds of high performance, complex airplanes. The FAA proposes to require additional training and a flight instructor endorsement for a person to serve as a PIC of an aircraft that the Administrator has determined requires type specific training.

28. Human Factors

The FAA proposes to introduce human factor training requirements for all levels of pilot certification. The training requirements would include aeronautical decision making (ADM) and judgment training for pilots at all certificate levels. Although research on aeronautical human factors has been underway for many years, these concepts represent relatively recent advances in training methodology. The traditional approach to training is to focus on technical aspects of aerodynamics, aircraft characteristics and systems, airspace, meteorology, and regulations. The presumption is that the flight crewmembers will integrate these subject areas to respond properly to the situations faced in actual flight conditions.

The intent of adding the benefits of human factors training research to the pilot training regimen is to assist pilots in integrating available information and arriving at correct decisions. Based on this research, it is now feasible to systematically and explicitly study

ADM and judgment, rather than relying on pilots to adopt these practices intuitively or relying completely on their experience. Much of this research is based on accident investigations that indicate that decision making processes contributed to or caused the accident. The FAA believes that pilots in the future will benefit from accident analysis and training methodologies designed to overcome lapses in judgment.

29. Aeronautical Decision Making and Judgment Training

The training manual ''Aeronautical Decision Making for Student and Private Pilots,'' prepared by the AOPA Air Safety Foundation for the FAA (Report No. DOT/FAA/PM–86/41), divides pilot activities into three basic categories. First are procedural activities, including management of the powerplant, fuel, navigation, communications, and other aspects of aircraft configuration. The second category is perceptual and motor activities, including aircraft control, and geographic orientation. The third category is decision making activities. The training manual covers self assessments of skill, knowledge, physical and psychological capabilities, hazard assessment, navigation planning, and flight priority assessment. The FAA has determined that aeronautical decision making is necessary, because flying involves a continuous stream of decisions about the crew, aircraft, environment, and operation. These decisions include pre-flight, ''go/no-go'' decisions, and in-flight decisions, which are designed to neutralize (by eliminating or reducing) risks in flight.

Of the three pilot activity categories, decision making accounted for 51.6 percent of fatal accidents in an analysis of data for a 5-year period, according to the AOPA manual. The objective of the manual, and aeronautical decision making (ADM) and judgment training in general, is to teach pilots to avoid situations that require luck or skill beyond their capabilities, and to reduce the level of judgment-related accidents.

With a solid base of conventional skills and knowledge, aeronautical decision making and judgment training can provide a structured approach to pilot reaction to event changes in flight. This training can be especially valuable to pilots with less experience to help confront the unexpected. These ''event changes,'' in addition to preflight decisions, may include mechanical problems, new instructions from Air Traffic Control, or unexpected weather. These changes call for decisions in which poor judgment may entail a high degree of risk. A common example of the target of such training is the non-instrument-rated private pilot who either fails to obtain a complete weather briefing or unexpectedly encounters poor weather but nevertheless is inclined to continue a flight into instrument meteorological conditions.

Aeronautical decision making and judgment training follow a three-pronged approach:

- Provide an analytical method for making decisions and evaluating risks.
- Address pilots' hazardous attitudes and substitute attitudes that promote good judgment.
- Address the need to overcome high stress, which reduces judgment and decision-making abilities.

Under the proposal, the requirement for ADM and judgment training would be placed under the knowledge requirements for all pilot certificate levels and all instrument ratings in proposed parts 61 and 141. The aviation community is directed to existing FAA-sponsored guidance material as well as additional educational materials available from other sources. Furthermore, the FAA plans to issue an advisory circular that will address the essential elements of ADM and judgment training that pertain to the various certificate levels.

30. Windshear Avoidance

The FAA believes that understanding windshear would enhance safety for general aviation pilots and, therefore, proposes to require ground training on windshear for all pilot certificate levels and the instrument rating. This proposal is based on the increased information available on windshear and industry expert opinion obtained through the FAA Pilot and Flight Instructor JTA, in which windshear is listed as a critical area of pilot knowledge.

The proposal would add a knowledge requirement on windshear avoidance to the current requirements on recognition of critical weather situations and the proposed aeronautical knowledge areas for an instrument rating, a recreational, private, commercial, and an ATP certificate. In the commercial pilot requirements of § 61.125, ''*airplanes*,'' the windshear knowledge requirement would be added as part of a new meteorology knowledge requirement because this paragraph, unlike the paragraphs relating to rotorcraft, gliders, airships, and balloons, currently does not mention meteorology or weather as a knowledge requirement. The aviation industry's awareness of the importance of the windshear phenomenon and its understanding of the problem has increased markedly in recent years. A National Research Council (NRC) study stated that windshear is ''an infrequent but highly significant hazard to aircraft landing or taking off,'' [1] and recommended a series of measures to reduce windshear accidents.

As a result of the study and the Council's recommendations, the FAA sponsored the development of a comprehensive Windshear Training Aid. Advisory Circular 00–54, ''Pilot Windshear Guide,'' constitutes one section of the two-volume Windshear Training Aid and was issued on November 25, 1988. In addition, the FAA has implemented and expanded ground and flight training requirements for flightcrew members employed in parts 121 and 135 air carrier and commercial operations. In air carrier operations, the FAA pursues a ''systems concept'' that includes an improved low-altitude windshear weather forecasting technique, ground-based windshear detection equipment, airborne windshear detection equipment, and improved pilot training.

The NRC report stressed, however, that all classes of pilots should understand the windshear phenomenon, including general aviation pilots. The report noted that general aviation pilots usually are not as well trained as air transport pilots and that they rarely have access to advanced training simulators. According to the report, ''the most practical and immediate solution appears to be an extensive education program to warn general aviation pilots of the hazards associated with low-altitude windshear and to teach both avoidance and escape procedures.'' [2] In the report, NRC stated that the risk posed by windshear can be reduced ''very soon by an education campaign directed at all classes of pilots.'' [3] The lack of awareness regarding windshear—including the origins, nature, and potential hazards of downbursts and wind variability—was found to be most acute within the general aviation community because of the diverse pilot skill and training levels. The report also stressed the need for standardized terminology for pilot-controller transmissions on windshear conditions and reports.

NTSB statistics indicate that general aviation has an average of 16 windshear-related accidents per year based on figures for 1979 through 1988. Those 16 accidents, including 1.3 fatal accidents, have resulted in an average of 3.8 fatalities and 4.4 serious injuries related

[1] United States. National Research Council. Low-Altitude Wind Shear and Its Hazard to Aviation. Washington: National Academy Press, 1983. Page 1.

[2] Ibid., p. 1.

[3] Ibid., p. iii.

to windshear per year. However, the NRC report noted that low-altitude windshear may have been a factor in additional accidents that were described as weather-caused or weather-related. According to the report, ''The rarity and lack of a reliable statistical data base on windshear-related accidents, shear encounters, or even the frequency of occurrence of potentially hazardous wind shears does not diminish the importance or severity of the safety problem. The potentially catastrophic consequences of an encounter during takeoff or approach and landing require that wind shear always be taken into account as a primary safety consideration when weather conditions are such that strong wind shears may be present. The widespread lack of appreciation among pilots, traffic controllers, and aircraft operations personnel of the seriousness of the possible safety hazards has exacerbated the problem.''[4]

Currently, FAA written examination questions on windshear are primarily limited to weather theory questions focusing on the definition of windshear and the effect of windshears on aircraft during final approach. This proposal would broaden windshear training to include at least the following elements: Windshear weather, particularly microbursts, and clues that indicate its presence; effects of windshear on aircraft; windshear recognition from the cockpit and avoidance techniques; necessary precautions and standard operating techniques when windshear is suspected; and recovery techniques to be used in inadvertent windshear encounters.

Several sources of information are available for this proposed ground training requirement, and if the proposal is adopted, the FAA plans to issue a new advisory circular addressing avoidance for general aviation. In Advisory Circular 00–54, the FAA stresses the need to learn to recognize signs of windshear and avoid encountering the condition. Other reference material, such as AC 61–23B, ''Pilot's Handbook of Aeronautical Knowledge,'' and AC 00–6A, ''Aviation Weather,'' have basic discussions of windshear.

Although part 61 currently does not specifically require windshear avoidance training for the ATP certificate, part 121 contains windshear requirements for air carrier flight crewmembers. Beginning January 1, 1991, part 121 air carrier flight crewmembers were required to receive ground training in recognizing and avoiding severe weather and escaping severe weather, in case of inadvertent encounters, including low-altitude windshear (§§ 121.404 and 121.419). Flight training in windshear avoidance maneuvers and procedures also is required by §§ 121.424 and 121.427. Pilots working in part 135 (air taxi and commercial operators) operations are required to receive sufficient ground training in meteorology to ensure a practical knowledge of weather phenomena, including the principals of frontal systems, icing, fog, thunderstorms, windshear, and, if appropriate, high altitude weather situations (§ 135.345). As previously mentioned, the prescribed knowledge in § 61.153 regarding weather for ATP candidates does not specifically state windshear avoidance training. Therefore, the FAA, to avoid any misunderstanding, proposes to add a knowledge requirement on windshear avoidance to § 61.153.

31. Aeronautical Experience Requirements

The FAA proposes to revise the minimum flight training hours of aeronautical experience and minimum solo flight hours of aeronautical experience that are required for the recreational and private pilot certificates and ratings under parts 61 and 141. Additional flexibility, under certain conditions, is proposed for pilot schools operating under part 141.

Under parts 61 and 141, the FAA proposes to revise the amounts of required dual and solo hours for the recreational and private pilot certificates and ratings. In part, this is based on information from the Sierra Academy of Aeronautics, a part 141 pilot school. In addition, the FAA believes that solo flight time is often not used constructively in training programs. Therefore, the FAA is proposing to permit the instructor and student to tailor the dual and solo training time requirements toward the individual student's needs. For example, a student who is seeking a private pilot certificate, and who has previous aviation experience and takes readily to the training may be able to complete training for a private pilot certificate with only the minimum 40 hours of flight time that includes at least 20 hours of flight training time from an authorized flight instructor and 20 hours of supervised PIC flight time. However, a student pilot who does not have previous aviation experience or who trains infrequently may need more time than the minimum 40 hours of flight time, 20 hours of flight training time from an authorized flight instructor, and 5 hours of supervised PIC flight time. The student pilot and flight instructor may need to tailor the training to require 35 hours of flight training time from an authorized flight instructor and 5 hours of supervised PIC flight time.

Under proposed § 61.113, ''Airship rating: Aeronautical experience,'' the requirement for 5 hours of PIC flight training while under the supervision of an authorized flight instructor is not intended to mean the instructor must be present in the aircraft. For example, if the airship required a SIC, the SIC could be a qualified pilot who was not necessarily an instructor, as long as the flight instructor provided flight supervision.

Finally, the proposed aeronautical experience requirements would place greater emphasis on experience in category and class of aircraft.

32. Instrument Rating

The FAA proposes several significant changes in the requirements to obtain an instrument rating. The FAA proposes to eliminate the requirement for a minimum of 125 hours of total flight time experience before a person may apply for an instrument rating. The FAA believes that this requirement should be eliminated to encourage more pilots to seek an instrument rating. This parallels current ICAO standards, which do not prescribe minimum pilot flight experience as a prerequisite for an instrument rating. The FAA believes that safety benefits were realized when the requirement was reduced to 125 hours and that allowing pilots to become eligible for the instrument rating as soon as possible will produce further benefits. The proposal would also delete the requirement for the minimum of 50 hours of cross-country flight time to more closely align the instrument rating eligibility requirements with ICAO standards.

In 1985, the FAA issued Amendment No. 61–75 (50 FR 19290: May 7, 1985) which reduced the total flight experience requirements for the issuance of an instrument rating. At that time, the FAA stated that the amendment was in response to recognized current training technology and that the FAA supported the concept of training to prescribed standards for an instrument rating. The FAA stated in the amendment that it recognized many pilots delay starting instrument training until they have accumulated 150 to 160 hours of flight time. The FAA estimated that it would take a pilot 3 to 4 years to accumulate 150 to 160 hours of flight time. During the development of Amendment No. 61–75, the FAA

[4] Ibid's, p. 130.

conducted a training experiment to examine the relationship of pilot experience, as defined by total flight time, to the acquisition of instrument skills. The results of that experiment concluded that the: (1) Amount of prior flight time had no effect on the acquisitions and demonstration of instrument flight skills within the pre-instrument flight experience ranges examined in connection with the experiment; and (2) reduction of the former required total flight experience, prior to the issuance of Amendment No. 61–75, for an instrument rating to a lower total flight experience encouraged pilots to obtain their instrument ratings. In light of the ever increasing complex NAS that pilots are required to operate in, it should encourage pilots to start their instrument training as soon as possible.

In Amendment No. 61–75, the FAA cited a 1981 study conducted by Walton Graham, ''A Study of General Aviation Safety,'' part II, Volume 1, prepared for Trans Urban East Organization, New York, by Questek, Inc., November 1981. In that study, the FAA noted the following accident rates:

Fatal/Serious Accident Rates, IFR Rated Pilots Compared to Non-IFR Rated Pilots

Flight Under IFR Conditions By:	
Non-IFR Rated Plt.	1 Acc./1,449 hours
IFR Rated Plt	1 Acc./12,186 hours
Flight Under VFR Conditions By:	
Non-IFR Rated Plt.	1 Acc./61,900 hours
IFR Rated Plt	1 Acc./94,819 hours

The FAA stated the statistics in that study supported the need for Amendment No. 61–75. As in the case of Amendment No. 61–75, the FAA believes this proposal will encourage non instrument-rated pilots to seek instrument training at an earlier stage in their aviation training, and will result in:

(1) A higher level of safety and competency in coping with sophisticated aircraft equipment, navigation aids, and communication systems;

(2) The restructuring of flying courses under parts 61 and 141 to provide supervised instrument flight rule experience during the training curriculum; and

(3) The encouragement of continued training to meet both the currency and higher certification levels.

The proposal would continue to require at least 40 hours of simulated or actual instrument flight training, which may include 20 hours in an approved flight simulator or flight training device and 15 hours of instrument flight training in the aircraft for an instrument rating.

Proposed § 61.65 also would state that a person who completes an instrument rating practical test for a multiengine airplane, while holding a single-engine airplane class rating would be considered to have met the single-engine airplane instrument rating requirements. The currently required flight instruction and skill would be addressed under proposed areas of operation. A significant proposed change for airplanes is that proposed § 61.65 would add a requirement that the 250-nautical mile (nm) IFR cross-country flight contain one route greater than 100 nm between airports, and that this cross-country flight include an instrument approach at each airport. However, the proposal would delete the language in the current rule that requires the cross-country flight to be in ''simulated or actual IFR conditions.'' The FAA intends that the flight be conducted under instrument flight rules but not necessarily under actual or simulated instrument conditions. An instrument approach would be required at each airport, and approaches using VOR, NDB, and ILS radio navigation aids would be required during the flight.

Similarly, for the instrument rating-helicopter, the cross-country requirement would be 100 nm under IFR but not necessarily simulated or actual instrument conditions. The proposal would add the requirement that one of the routes be greater than 50 nm between airports, and that an instrument approach be conducted at each airport on the route.

The requirements of the proposed areas of operation would be very similar to the current requirements, although in certain cases they would be more general. For example, the requirement that the applicant be endorsed as having been trained and found competent in instrument approaches to published minimums using VOR, ADF, and ILS systems would be replaced with a requirement that the applicant receive and log training in instrument approach procedures. This would permit the PTS to specify, as required, other types of approach procedures appropriate to the IFR environment.

The instrument rating areas of operation are listed separately by aircraft. Although this causes some redundancy, it is similar to the organization of the current regulation, and is intended to assist users by eliminating or minimizing cross-referencing. The proposed rule contains areas of operation for airplane category (the practical test would vary between single-engine and multiengine), helicopter class, airship class, and powered-lift category.

Applicants for the instrument rating would be required to present endorsements for the knowledge and practical tests as well as pass the required knowledge test. The required areas of aeronautical knowledge would remain similar to the currently required areas of ground instruction, including applicable FAR, the ''Airman's Information Manual,'' the air traffic control system, IFR navigation and approaches, IFR en route and approach procedure charts, aeronautical decision making and judgment, weather, and windshear avoidance.

33. Recreational Pilot Certificate

The FAA proposes to revise the eligibility requirements for the recreational pilot certificate as follows: (1) must be able to read, speak, write, and understand the English language, with no provisions or limitations to the contrary; and (2) would not be required to hold a medical certificate. In addition, an applicant would have to affix a signed and dated statement to the application certifying they do not have any known medical limitations that prevent the person from operating the aircraft for the aircraft category and class rating sought.

The FAA is proposing to allow holders of recreational pilot certificates and holders of a higher pilot certificate who elect to only exercise the privileges of a recreational pilot certificate to operate without holding medical certificates. This action is responsive to the EAA petition and the interests of the general aviation community, as discussed earlier. The FAA is requesting comments on this proposal and the accompanying proposed changes to § 61.53. For more details see the section-by-section analysis for § 61.53.

The FAA proposes to revise the aeronautical experience requirements for a recreational pilot certificate by requiring an applicant to accomplish and log at least 30 hours of flight time that includes at least 15 hours of flight training time from an authorized flight instructor and 3 hours of supervised PIC flight time. The purpose for this proposal is to respond to comments heard during the public hearings to allow the student and the flight instructor to tailor the required training to individual student needs.

For example, a student who has previous aviation experience and takes readily to the training may be able to complete training for a recreational pilot certificate with only the minimum 30

hours of flight time that includes at least 15 hours of flight training time from an authorized flight instructor and 15 hours of supervised PIC flight time. However, a student pilot who does not have previous aviation experience or who trains infrequently may need more time than the minimum 30 hours of flight time, 15 hours of flight training time from an authorized flight instructor, and 3 hours of supervised PIC flight time. The student pilot and flight instructor may need to tailor the training to require 27 hours of flight training time from an authorized flight instructor and 3 hours of supervised PIC flight time.

The FAA proposes to revise the privileges and limitation requirement for a recreational pilot certificate by allowing a recreational pilot to act as PIC of an aircraft on a flight that exceeds 50 nautical miles from the departure airport, without receiving training for a private pilot certificate. However, the pilot would be required to receive the proposed training and an endorsement to conduct a flight that exceeds 50 nautical miles.

These proposed revisions will improve interest in the recreational pilot certificate and will encourage more people to seek pilot certification.

34. Preflight Planning

The FAA proposes to revise the aeronautical knowledge areas for a recreational or private pilot certificate to reflect the requirements for preflight action found in § 91.103.

The current aeronautical knowledge requirements for the private pilot certificate applicant with an airplane or rotorcraft category rating include VFR navigation, using pilotage, dead reckoning, and radio aids. These requirements have been interpreted to include the preflight action items in § 91.103. The proposal to add the items found in § 91.103 to the proposed aeronautical knowledge areas would avoid any misinterpretation of the applicant's aeronautical knowledge requirements.

35. Limitations on Cross-Country Endorsements

The FAA proposes to revise § 61.93 to clarify the cross-country flight requirements for students and recreational pilots seeking a private pilot certificate. Under the proposal, the limitations placed in the student's logbook for a supervised PIC cross-country flight would have to be met at the time of the student's departure.

The existing rule, which requires that each supervised PIC cross-country flight be subject to conditions listed in the student's logbook is ambiguous. Incidents have occurred where a student has departed on a cross-country flight without adhering to limitations in the student's logbook. Also, the dispatching flight instructor may not be the student's principal instructor and may not be familiar with the student's personal limitations. The proposal would permit the principal instructor to list limitations considered necessary for the safety of flight (e.g., weather minimums, maximum crosswind components, time frames for departure and completion) that would have to be met before a student could depart on a cross-country flight.

This proposal also would require a revision of the language in § 61.195 on flight instructor authorizations to be compatible with language proposed in § 61.93.

36. Night Flight Training

The FAA proposes to clarify and modify night flight training requirements for private pilot and commercial pilot applicants. The FAA proposes to require night operations as an area of operation for airplanes, powered-lift, and rotorcraft ratings.

An exception would be permitted for pilots whose training and certification occurs in geographic latitudes where there is no nighttime for extended periods. In the United States, this only applies to persons who receive their training in Alaska. The proposed rule would permit a 1-year exception for these pilots. Within 1 year after receiving their certificate with a night flying limitation, pilots would be required to obtain the minimum 3 hours of night flight training and have the restriction removed.

Another exception would be proposed for persons with medical restrictions against night flight, because of vision problems. Persons in this group would be permitted to carry the night flight limitation on their certificates indefinitely.

This proposal would require more pilots to gain exposure to night flight. Experience shows that, even if pilots have no intention of flying at night, situations arise in which they might encounter delays and be tempted to complete a trip after dark. It is critical for pilots to understand how different night operations are from daytime operations and to understand their personal limitations.

However, a person who has been issued a pilot certificate without meeting the night flying requirements of this proposal, prior to effective date of this rule, would be allowed to continue to hold that pilot certificate with the night flying limitation. If the person seeks an additional rating or higher pilot certificate level, the person would be required to comply with the night flying requirements that are appropriate to the pilot certificate level.

37. Private Pilot Limitations

The FAA proposes several significant changes to the current § 61.118 [proposed § 61.113], ''Private pilot privileges and limitations: Pilot in command.''

Under the current regulation, a private pilot may serve the public in humanitarian-type missions, if the pilot is not compensated. The FAA has granted exemptions to public service organizations to permit reasonable reimbursement to volunteer private pilots for expenses incurred for serving the public in such flights. The FAA proposes to permit private pilots to be reimbursed for aircraft operating expenses (i.e., fuel, oil, and airport expenditures) incurred while serving the public in certain public humanitarian missions (i.e., Civil Air Patrol, Sheriff Department, etc.).

Under the proposal, search and location activity would be permitted when the activity is under the direction and control of local, state, and federal law enforcement agencies. The FAA believes that skilled private pilots are a valuable resource to enforcement agencies conducting search and location missions and that this resource should be available under controlled conditions. The proposal is intended to permit private pilots to conduct searches in conjunction with search and location operations. The FAA considers a search and location operation as a flight or series of flights authorized by and under the direction and control of local, state, or federal law enforcement agencies for the purpose of searching for lost or injured persons and communicating the location of these persons to the appropriate authorities. The proposal is intended to include a pilot and the minimum essential number of persons required to perform observation, map reading, and communication duties. For example, under the proposal, a private pilot could act as PIC of an aircraft carrying fire fighters searching for a fire. This proposed paragraph would not permit a private pilot to transport fire fighters from one location to another. In addition, the proposal is not intended to involve private pilots in the transportation of emergency response personnel and victims.

The FAA also proposes to clarify how a private pilot may share expenses with passengers. Under the current rules, a

private pilot may only share the operating expenses of a flight with passengers. The FAA proposes to specify that these operating expenses be restricted to fuel, oil, and airport parking expenditures only, and that these expenses be shared equally between the pilot and the passengers.

The FAA also proposes to clarify the provisions permitting private pilots to conduct flight operations for charitable events. Under the proposal, the regulation would specify that, if a private pilot functioned as a PIC of an aircraft for a passenger-carrying airlift sponsored by a charitable organization, the sponsor of the airlift would have to provide a signed letter with information on the event, and a photocopy of the pilot's pilot certificate, medical certificate, and logbook entries showing compliance with recency of experience requirements and the 200-hour minimum total experience requirement.

Other aspects of the provisions for private pilots' operations in charitable events would remain largely the same. Aircraft maintenance would be required to be in accordance with subpart E of part 91, although the specific reference in current rule to a required 100-hour inspection and compliance with § 91.409 would be deleted. Nevertheless, those requirements are applicable and would continue under the proposal. In addition, reference to specific U.S. Department of Treasury documents would be replaced with a more general requirement that the charitable organization be identified as such by the Department of the Treasury.

Under this proposal, specific reference to private pilots engaged in aircraft sales would be deleted. The existing rule states that a private pilot, who is an aircraft salesman and who has logged at least 200 hours of flight time, is permitted to demonstrate an aircraft in flight to a prospective buyer. This proposed revision does not eliminate this private pilot privilege, however, because it is covered in the proposed § 61.113(b).

Finally, a new provision would be added to clarify that a private pilot who meets the requirements of § 61.69 may act as PIC of an aircraft towing a glider and log that flight time. This is consistent with current and proposed § 61.69.

38. Glider Towing

Section 61.69, ''Glider towing: Experience and instruction requirements,'' currently provides two means for a person to qualify as a PIC of an aircraft towing a glider. The proposed rule would retain the first alternative in § 61.69, which requires the person to have made and logged at least three flights as sole manipulator of the controls of an aircraft towing a glider while accompanied by a qualified pilot. Under this proposal, the second alternative in § 61.69, would be removed. This alternative allows for the person to have made at least three flights as sole manipulator of the controls of an aircraft simulating glider towing flight procedures and at least three flights as pilot or observer in a glider being towed by an aircraft. The FAA believes that safety will be better served if a person's first experience actually towing a glider occurs while that person is accompanied by a qualified pilot, rather than flying solo, as may be the case currently.

39. Eligibility for Commercial Pilot Certificate

The FAA proposes changes to current § 61.123, ''Eligibility requirements: General'' and § 61.129, ''Airplane rating: Aeronautical experience.'' Section 61.123 currently requires applicants for the commercial pilot certificate with an airplane category rating either to have a private pilot certificate or to have passed the private pilot written and practical tests. Under this proposal, § 61.123 would list the private pilot certificate as a prerequisite for commercial pilot certificate applicants for all aircraft categories. This would, in effect, require applicants to take the private and commercial practical tests separately, so that applicants actually have a private pilot certificate when they apply for the commercial pilot certificate.

The proposed change is not intended to require that the private pilot certificate necessarily be in the same category and class of aircraft for which the applicant seeks a commercial pilot certificate.

The other proposed changes to eligibility requirements for commercial pilot certificate applicants would affect English language ability; applicants would be required to read, speak, write, and understand the English language, and no exceptions would be made. In addition, a third-class medical certificate, rather than a second-class medical certificate, would be required. Proposed § 61.23 would require, as is currently the case, that a person hold at least a second-class medical certificate to exercise the privileges of a commercial pilot certificate.

Current holders who cannot read, speak, write, and understand the English language, but have been issued pilot certificates with limitations that restrict operations in airspace requiring the use of the English language, would be allowed to continue to hold their certificates. However, if a person seeks an additional rating or higher level pilot certificate, then the certificate will not be issued unless the person is able to read, speak, write, and understand the English language.

40. Use of Turbojet Airplanes for Commercial Pilot Certification

The FAA proposes to revise § 61.129, the aeronautical experience requirements for a commercial pilot certificate with an airplane category rating, to permit the use of turbine powered airplanes. The existing rule requires a minimum of 10 hours of flight training and practice given by an authorized instructor in operations in airplanes with retractable landing gear, flaps, and a controllable pitch propeller. However, some commercial pilot applicants may wish to complete their training in turbine-powered airplanes, and some military pilots may not have demonstrated procedures pertaining to the use of a controllable pitch propeller. Because a turbine-powered airplane does not necessarily have a propeller, training and demonstration of flight proficiency in such an airplane does not satisfy existing requirements. However, a turbine-powered airplane clearly meets the regulatory intent of requiring an applicant to demonstrate proficiency in a relatively complex airplane.

As proposed, an applicant could perform the 10 hours of flight training and practice given by an authorized instructor in either a turbine powered airplane or an airplane with retractable landing gear, flaps, and a controllable pitch propeller. The 10 hours of flight training and practice could also be met with a combination of hours in the two airplanes.

Existing § 61.127, which requires demonstration of flight proficiency in an airplane equipped with a retractable landing gear, flaps, and controllable propeller(s), would be revised to include turbine-powered airplanes.

41. Commercial Pilot Experience—Cross Country Training Flight

The FAA proposes to establish two new cross-country flight training requirements for commercial pilot certificate applicants for airplane, helicopter, gyroplane, airship, and powered-lift ratings: a daytime VFR cross-country flight and a nighttime VFR cross-country flight. Both flights would have to be in the same category and class of aircraft for which the commercial pilot certificate was sought.

The FAA proposes these additional cross-country requirements because current training requirements appear

inadequate and are outdated. The intent of the proposals is to increase applicants' exposure to the demands and pressures of cross-country navigation under both day and night conditions, in increasingly complex airspace conditions, and at commercial pilot level standards. The FAA believes that this additional experience under flight instructor supervision will help produce better trained commercial pilot applicants.

42. ATP Requirements

The FAA proposes several changes in the eligibility requirements for the ATP certificate. The English language capability requirement would be simplified and standardized with other certificate levels. The reference in current § 61.151 to accent or speech impediment that would interfere with two-way radio conversation would be deleted. At least a third-class medical certificate, rather than a first-class medical certificate, would be required for the certificate (although a first-class medical certificate still would be required to exercise the privileges of the certificate). In addition, the current requirement in § 61.151 for a high school education or equivalent would be deleted. The FAA believes that because of the higher levels of education typically attained by ATP certificate applicants, this is now an obsolete requirement.

The provision in current § 61.157 permitting ATP certificate applicants to obtain an instrument rating in conjunction with the ATP certificate is obsolete. Therefore, the FAA proposes to require in § 61.151 that an applicant for an ATP certificate either must hold a commercial pilot certificate *and* instrument rating that applies to the category and class of aircraft for which the ATP certificate is sought or, if a U.S. military pilot, meet the requirements of § 61.73 for a commercial pilot certificate and instrument rating. An applicant who holds a foreign pilot license would be required, under the proposal, to hold either a foreign ATP certificate or commercial pilot license and instrument rating with the appropriate aircraft category and class rating. Currently, it is rare for an ATP applicant to lack an instrument rating, and in the current NAS an instrument rating is, for practical purposes, a prerequisite for the ATP certificate.

Under the proposal, applicants under 23 years of age could continue to take the knowledge test for the ATP certificate. The proposal would eliminate the current provision in § 61.153 that requires applicants to meet the eligibility requirements (other than the age minimum) before taking the written, or knowledge, test. Thus, in this NPRM, it would not be necessary to meet any of the eligibility requirements to take the knowledge test, but the eligibility requirements would apply to a person seeking to take the practical test. However, an applicant would have to be at least 23 years old to take the practical test; the FAA proposes to delete the exception to this requirement currently found in § 61.39. This revision proposes that an applicant meet the 23 year old age requirement to be eligible to take the practical test for an ATP certificate.

The FAA also proposes to clarify, reorganize, and update the aeronautical knowledge areas covered under § 61.153. Whereas airplane and rotorcraft aeronautical knowledge currently is covered under separate sections that are cross-referenced, the proposal would list a single set of required aeronautical knowledge areas. The current reference to ''air navigation facilities on Federal airways such as rotating beacons, course lights, and radio ranges'' would be deleted. Other items, such as flight crew physiological factors and aeronautical decision making, judgment, and windshear avoidance would be added.

Aeronautical skill areas currently addressed in §§ 61.157 (airplane rating) and 61.163 (rotorcraft) would be addressed in proposed § 61.155, ''Flight proficiency.'' This proposed section contains a single set of areas of operation for the single-engine airplane, multiengine airplane, helicopter, and powered-lift ATP ratings.

The practical test for the ATP certificate-airplane, rotorcraft, or powered-lift—would be based on the approved areas of operation listed in proposed § 61.155.

To apply for a practical test for an ATP certificate, a person must meet the eligibility requirements for the certificate, as well as meet the aeronautical knowledge and experience requirements.

An applicant who is seeking a type rating on an ATP certificate or adding a type rating to a ATP certificate would be required to receive and log ground and flight training on the approved areas of operation and receive a logbook endorsement that the training was completed, except in the case of an employee of a part 121 or 135 certificate holder. In that case, the employee would be permitted to present a training record that shows satisfactory completion of the certificate holder's approved PIC training program for the aircraft type rating sought.

The areas of operation contained in the rules are written in general terms to align it with the standards for practical tests. The FAA believes this will permit flexibility in the test and reflect current needs of the NAS environment in which the holder of the ATP certificate would operate. Applicants would prepare for the test, in part, by referring to the appropriate practical test standards. As an example, the areas of operation include preflight preparation and procedures; inflight procedures; instrument procedures; takeoff and departure; landings; normal, abnormal, and emergency procedures; and postflight procedures.

Under the proposal, aeronautical experience requirements would be reorganized for clarity and easier reference. The proposal would not change the specific hour requirements.

Powered-lift requirements would be patterned on the airplane requirements. However, for powered-lift, no provision is contained in the proposed rule for flight engineer time to be credited toward the required 1,500 hours of total time as a pilot. The reasons that provisions for flight engineer time is not being allowed for the powered-lift rating is because to date, the existing powered-lifts under development are not designed with a flight engineer station.

In proposed § 61.157, ''Aeronautical experience: Airplane category rating,'' SIC time acquired in an airplane with a flight manual or type certificate that requires more than one pilot would still count toward meeting the pilot time experience requirements. All SIC time in an airplane for a part 121 or 135 certificate holder for which a SIC was required also would be counted.

The FAA proposes to delete the provision that requires a pilot who seeks an airline transport pilot certificate in a small helicopter to obtain a helicopter type rating. The FAA believes that small helicopters should not be treated differently than the other small aircraft. Historically, the FAA policy on requiring a pilot who seeks an airline transport pilot certificate in a small helicopter to obtain a helicopter type rating was based on the operating requirements of part 127, ''Certification of Operations of Scheduled Air Carriers with Helicopters.'' Specifically, § 127.173(a) is the rule the FAA based its determination on requiring a pilot who seeks an airline transport pilot certificate in a small helicopter to obtain a helicopter type rating. Upon a closer reading of existing § 61.5(b)(5)(iii), however, it is stated that ratings are issued under this part for, ''Small helicopters for operations requiring an airline transport pilot certificate.''

Currently, part 127 is not active, and there are not any part 127 scheduled air carriers with helicopters. The FAA has determined that it is not necessary for a person who seeks an airline transport pilot certificate in a small helicopter to obtain a helicopter type rating. The continuation of this past policy places an additional restriction on small helicopters that is not required of other small aircraft and can no longer be justified. Therefore, the FAA proposes to treat the type rating requirements for helicopters as it currently does for the other aircraft, which only requires a type rating if the aircraft is a large aircraft (other than lighter-than-air), turbojet-powered airplanes, or other aircraft type ratings specified by the Administrator through the aircraft type certification procedures.

43. Pilot in Command Hour Requirement for Initial Flight Instructor Applicants

The FAA proposes to require an applicant for a flight instructor certificate to have logged at least 15 hours as PIC in the category and class of aircraft for which the rating is sought. This is also required in existing § 61.191 for a flight instructor to apply for an additional flight instructor rating. However, such a requirement does not exist for the application of an original flight instructor certificate. The FAA believes that an applicant for any flight instructor rating should have logged at least 15 hours as PIC in the category and class of aircraft for the rating sought. This proposal will not impose any additional economic burden on flight instructor candidates, who normally obtain their original flight instructor certificate in an aircraft in which they have received most of their training. The proposal is intended to eliminate an area of inconsistency in the regulation.

44. Experience Required for Training Flight Instructor Candidates

In addition to adding the generalized areas of operation to the flight instructor requirements of § 61.187, the FAA proposes two amendments to the current § 61.187. The first is a clarification of the requirement that persons giving flight training to flight instructor candidates have 24 months experience. Second, an exception would be specified for that 24-month requirement.

Section 61.187 currently requires that persons who give flight training to flight instructor candidates have a minimum base of experience. They must have given at least 200 hours of flight training, and they must have held a flight instructor certificate during the 24 months immediately preceding the date the training is given to a flight instructor candidate. This current rule may be read to mean that a person who had been active as a flight instructor for 2 years or more, but then became inactive as a flight instructor, might be excluded from giving flight training to flight instructor candidates upon resuming flight training activity.

The FAA does not interpret § 61.187 in this manner, particularly when it is read in conjunction with § 61.19. To clarify this issue, the proposed change would eliminate the words ''immediately preceding.'' This proposal would clarify that the 24 months of experience are cumulative time and need not be accumulated consecutively and immediately preceding the giving of training to flight instructor candidates. However, an instructor who otherwise meets the 24-month and 200-hour experience criteria would need to have their flight instructor certificate reinstated before giving such flight training.

A further proposed change to this rule would apply to flight instructors serving in an FAA-approved course. This provision would allow such flight instructors either to meet the 24-month and 200-hour experience requirement, or to meet other prerequisites. The alternative qualifications would be to have trained and endorsed at least 5 persons for a pilot certificate or rating practical test; have a record reflecting that at least 80 percent of the persons whom the flight instructor has endorsed for a practical test passed that test on their first attempt; and have given a minimum amount of flight training. In the case of airplanes, the minimum amount of flight training given would be 400 hours; in the case of gliders, the minimum amount of flight training given would be 100 hours; and in the case of lighter-than-air, the minimum amount of flight training given would be 40 hours.

The intent of this option is to permit a person who has held a flight instructor certificate for less than 24 months to give training to flight instructor candidates. For example, the FAA believes that some full-time instructors may meet the 400-hour requirement before accumulating 24 months of training experience. Within the structure of an approved training program, the FAA believes that such instructors should be permitted to train flight instructor candidates. The FAA has determined that the second option would provide at least an equivalent level of safety to the current minimum of 24 months and 200 hours of experience.

45. Flight Instructor Renewal Requirements

The FAA proposes to modify procedures for renewal of the flight instructor certificate. Under the proposal, § 61.197 would be revised to clarify current requirements.

The current regulation requires flight instructors to pass the practical test for a flight instructor certificate and the rating involved, or portions of that test as determined by the FAA, or to renew their certificates through several other methods. Similarly, the proposal would state that a person who holds an unexpired flight instructor certificate would be permitted to renew that certificate for an additional 24 calendar months by passing a practical test for renewal of that certificate. The proposal would add that passing a practical test for an additional flight instructor rating also would be acceptable for renewal of the expiring flight instructor certificate.

Current § 61.197 also states that flight instructors may renew their certificates without taking the practical test if their record of instruction shows they are competent flight instructors. The proposal would specify what the FAA considers an acceptable record of training, for the 24-calendar month duration period of the instructor's certificate, the instructor would have to have endorsed at least 5 students for a practical test for a certificate or rating and at least 80 percent of the students would have to have passed their tests on the first attempt.

The proposal would modify one other possible method of renewing a flight instructor certificate. Under the current rule, a person may renew a flight instructor certificate, without taking the practical test, if the person has a satisfactory record as a company check pilot, chief flight instructor, PIC of an aircraft operated under part 121, or other activity involving the regular evaluation of pilots. This would be somewhat modified, a proposal that would include any person who has served, during the preceding 24-calendar month duration period of the person's flight instructor certificate, as a company check pilot, chief flight instructor, company check airman or flight instructor in a part 121 or 135 operation, or a comparable position involving the regular evaluation of pilots. Similar to the current rule, the proposal would stipulate that the person demonstrate to a FSDO of having satisfactory knowledge of current pilot training, certification, and standards.

46. Flight Instructor Duty Time Limitations

One issue discussed under this regulatory review was whether to limit instructor flight and duty time by limiting the hours of training given in simulators and ground trainers, as well as training given in flight. The FAA has decided to propose one change in the current flight time limitation for flight instructors, but does not propose to limit duty time involving training given in flight simulators and flight training devices.

Section 61.195 currently states that a flight instructor may not conduct more than 8 hours of flight instruction in any 24-consecutive hour period. The FAA proposes to revise this section by proposing that a flight instructor may not conduct more than 8 hour of flight instruction, other commercial flying, or any combination of both in any 24-consecutive hour period.

47. Flight Training From a Control Seat

Section 91.109 lists the requirements an aircraft must meet to be used in flight training. However, no regulation requires a flight instructor to be in a control seat of the aircraft while giving flight training. The FAA proposes to revise §§ 61.51 and 61.195 to require that all flight training be given from a control seat in the aircraft.

Section 91.109 requires, with the exception of a balloon, that the aircraft have fully functioning dual controls. The regulation provides that instrument flight training be given in a single-engine airplane equipped with a single, functioning, throwover control wheel in place of fixed, dual controls of the elevator and ailerons. Section 91.109 also requires a safety pilot to be in a control seat during simulated instrument flight conditions.

In § 61.51, the FAA proposes to require a flight instructor to occupy a pilot station in the aircraft that has functioning flight controls to log PIC flight time. The FAA also proposes to amend § 61.195 to require that all flight training be given from a control seat of an aircraft that meets the requirements of § 91.109.

C. Part 141 Issues

1. Approval of Training Courses That Permit Pilot Schools To Train to a Standard

The FAA proposes to permit pilot schools certificated under part 141 to train students to a performance standard without necessarily meeting the minimum hours of training prescribed in the appendices. However, these proposed courses would not be permitted for pilot schools with provisional pilot school certificates or for courses in which pilot schools have examining authority.

Pilot schools would be required to specify planned ground and flight training time requirements for these courses. These time requirements would include cross-country flight time, night flight time, and any additional ground and flight training. Students would have to meet these planned time requirements to complete the course.

To apply for initial approval of a course that trains students to a standard, the school would be required to meet the following requirements, which appear in proposed § 141.55: (1) Hold a pilot school certificate and have held that certificate for at least the prior 24 calendar months; and (2) have an FAA inspector or a designated examiner who is not an employee of the school give the practical or knowledge test. The initial approval would be for 24 calendar months.

Under proposed § 141.55, a course that received initial approval could receive final approval by complying with the following: The school would be required to demonstrate that, during the time the course was conducted under initial approval, the school trained at least 10 students for a pilot, flight instructor, or ground instructor certificate or rating and at least 80 percent of those students passed the practical test on the first attempt. The practical test must have been conducted by an FAA inspector, or by a designated examiner who is not an employee of the school.

The FAA's experience indicates that most applicants require more than the minimum number of hours required under part 61 or part 141 to attain normal performance standards as reflected in the practical test standard (PTS) and as practiced throughout the flight training industry. Nevertheless, a number of pilot schools have students who are ready to accomplish the practical tests prior to reaching the minimum number of flight hours specified in the FAR. The FAA's experience with pilot schools that have similar courses approved under exemption indicates that such flexibility presents no detriment to safety, under the closely supervised training environment of these schools.

The proposal to permit pilot schools to train students to a standard follows a precedent established with the Advanced Qualification Program (AQP) in Special Federal Aviation Regulation (SFAR) No. 58, which applies to personnel trained under parts 121 and 135. The AQP was created partially in response to recommendations the Administrator received on June 8, 1988, from the Joint Government-Industry Task Force on flight crew performance. One of the recommendations was to provide for the approval of training programs based on course content and training rather than using specific program hours.

This proposal also addresses a petition for rulemaking submitted April 20, 1990, by the Sierra Academy of Aeronautics, which was summarized in the **Federal Register** on June 12, 1990 (55 FR 23749; Docket No. 26221). No comments on the petition were received. The petitioner requested to adjust the ratio of dual flight training to solo training in its training course for a commercial pilot certificate in helicopters. The Sierra Academy stated that it prefers to conduct all flight training in helicopters, even though appendix F permits 100 hours of the total 150 hours of flight training in aircraft other than helicopters or gyroplanes. The Sierra Academy requested the decrease of the solo flight training requirement from 100 hours to 70 hours and the increase of the dual flight training from 50 hours to 80 hours. The Sierra Academy stated that the increase in the number of dual flight training hours is necessary because many of the maneuvers and procedures required under the PTS necessitate that an instructor be on board the aircraft for safety reasons. The petition stated that the change would make FAA-approved commercial pilot training conducted exclusively in helicopters economically viable, as well as safer. Under the proposed revision to § 141.55, the Sierra Academy would be able to apply for approval of courses to train students as described in its petition.

2. Check Instructors

Currently, pilot or provisional pilot schools are required to designate a chief instructor for each approved training course. In addition, pilot schools may designate an assistant chief instructor for an approved training course. The FAA proposes to establish a check instructor position that a pilot school could designate an instructor to perform instructor proficiency checks, stage checks, and end-of-course tests—the check instructor position.

The FAA has determined that the proposed check instructor position would be necessary at larger schools. Often the chief instructors at these schools need to designate more responsibility to other instructors. Under this proposal, a school would be required to have an enrollment of at

least 50 students at the time the check instructor is designated.

The check instructor would be required to meet certain minimum criteria and be approved by the FAA FSDO that has jurisdiction over the school. For checks and tests that relate to either flight or ground training courses, a check instructor would be required to have passed an oral test given by the chief instructor on: (1) Teaching methods; (2) the applicable provisions of the ''Airman's Information Manual,'' parts 61, 91, and 141; and (3) the objectives and course completion standards of the approved training course for the designation sought.

A person who desires to become a check instructor for tests and checks that relate to a flight training course would be required to: (1) Hold a commercial pilot certificate or an ATP certificate; (2) hold a current flight instructor certificate with category and class ratings appropriate to the designation sought; (3) hold the appropriate instrument rating for the training course, if required; (4) hold at least a current second-class medical certificate, if the course is for a rating in an aircraft other than a glider or balloon; (5) present a signed and dated statement by the person certifying that the person has no known medical defects that make the person unable to pilot a glider or balloon, if the course is for a rating in a glider or balloon; (6) meet the PIC recent flight experience requirements of § 61.57; and (7) pass a flight test, given by the chief instructor, on the flight procedures and maneuvers of the approved training course for the designation sought. A person who desires to become a check instructor for tests and checks that relate to ground training courses would be required to hold a current ground instructor certificate with category and class ratings appropriate to the designation sought.

Commenters to NPRM No. 89–14, in which the FAA proposed to reduce the experience criteria for chief and assistant chief instructor candidates, noted that such actions enhance the status of instructors by permitting them to apply for a supervisory position earlier in their careers. The proposed check instructor position would permit instructors to apply for supervisory positions and to be given increased responsibility.

The proposal to establish the check instructor position would help the FAA clarify to whom a chief instructor can designate the authority to conduct student stage checks, end-of-course tests, and instructor proficiency checks. The FAA would also eliminate the term ''designated assistant.'' During the public hearings, commenters noted that the term is interpreted differently. Under the proposed revisions to §§ 141.79, 141.81, and 141.85, the chief instructor, assistant chief instructor, or check instructor would give instructor proficiency checks, stage checks, and end-of-course test.

3. Quality of Training Requirements

In response to comments provided at the public hearings, the FAA proposes to clarify the existing requirements for a pilot school to apply for and to maintain a pilot school certificate.

Current § 141.63 requires a pilot school that applies for examining authority in a particular course to demonstrate that 9 of the 10 most recent graduates of that particular course had passed an interim or final test on the first attempt.

Current § 141.83 requires that each holder of a provisional or pilot school certificate provide a high enough quality of training so that at least 8 out of the 10 of the school's students or graduates that were most recently tested, by an FAA inspector or designated pilot examiner, passed an interim or a final test on the first attempt.

Commenters at the public hearings noted that the existing requirement for a specific number of students to pass an interim or stage check may reduce a school's ability to monitor student and instructor performance. For example, the commenters noted that these interim or stage checks are used to: (1) Evaluate a student's performance; and (2) ensure that instructors train students according to the school's procedures and performance standards. The commenters stated that the quality of training criteria should be based on experience with the students who have completed a training course, not students who are enrolled in a training course. Some commenters even noted that, under this requirement, pilot schools would not be able to develop tests that exceed the standards set in the PTS. Other commenters noted that the existing regulations have been interpreted to mean that the requirement for the 10 most recent students to pass any test on the first attempt must be met continuously. For example, if two students in a row failed a test, the school may risk losing its examining authority.

The FAA has determined that a pilot school should be permitted to evaluate its own students and instructors throughout the training course without jeopardizing the school's certificate or examining authority. Therefore, the FAA proposes to revise the current regulation on the number of students who are required to pass the practical or knowledge test and to eliminate the requirement for interim tests to be used to evaluate a school's quality of training. The number of students who pass the practical test would apply to training courses that require the applicant to pass a practical test to obtain a certificate or rating. The number of students who pass the knowledge test would apply to ground training courses.

Proposed § 141.63 would require 90 percent of the graduates of a flight course, in which the school desires to obtain examining authority or retain examining authority, to pass a final test given by an FAA inspector, or by a designated examiner who is not an employee of the school, on the first attempt. Under this proposal if 40 students graduate from an approved course, but only 10 of those students receive a final test given by an FAA inspector, or by a designated examiner who is not an employee of the school, then 90 percent of those 10 students would have had to have passed the test on the first attempt. The 90 percentage would be applicable for the 24-calendar months duration period of the school's examining authority. If the school only conducts ground school courses, then at least 90 percent of the school's students must have passed the required knowledge test given by the FAA, or by a designated examiner who is not an employee of the school.

The FAA proposes similar revisions to §§ 141.5, 141.27, 141.55 and 141.83. These revisions would require that an applicant seeking approval or renewal of a training course have at least 80 percent of their graduates from the course to have passed the practical test on the first attempt. The 80 percent is not required to be based on all students, but only on those students who take the practical test given by an FAA inspector, or by a designated examiner who is not an employee of the school.

4. Temporary Chief Instructor

The FAA proposes to revise § 141.87, ''Change of chief instructor,'' to allow the assistant chief instructor to act in the capacity of the chief instructor for 60 days and to permit the assistant chief instructor or check instructor to perform stage and end-of-course tests.

The current rule requires that, pending designation and approval of a new chief instructor, each stage and end-of-course test be given by an FAA inspector or a designated pilot examiner. Commenters at the public hearings noted that this requirement could be an administrative burden to

the pilot school, its students, and the FAA.

The FAA has determined that an assistant chief instructor would be a safe temporary substitute for a chief instructor, because of their familiarization with school operations and they are already approved by the FAA. This proposal would provide a time frame for a new chief instructor to be designated and would provide stability to the pilot school's students.

5. Transfer Between Part 141 Schools

The FAA proposes to revise § 141.67 to delete the current requirement for a student at a pilot school with examining authority to complete all of the training course at the same school. The proposal would permit up to one-half of a student's credits to be transferred from another pilot school. The amount of credits that could be transferred would be based on the student's performance on a test given by the receiving pilot school. This test could include a flight check, a review of the student's aeronautical knowledge, or both. This criteria, as well as the other criteria proposed for the transfer between part 141 schools, is similar to the current criteria in § 141.77 for the transfer between pilot schools that do not have examining authority.

6. Maintenance Requirements

The FAA proposes to revise § 141.39 by expanding the maintenance requirements for aircraft used by a pilot school for flight training and solo flights.

Current § 141.39 requires applicants for a pilot or provisional pilot school certificate to maintain and inspect all aircraft in accordance with the requirements of part 91 that apply to aircraft used to give flight training for hire.

Section 91.409 requires all aircraft used to give flight training for hire to receive an inspection every 12 calendar months or every 100 hours in service. A pilot school may inspect aircraft under a progressive inspection program approved by the FAA in lieu of the requirements in § 91.409.

Aircraft used by pilot schools often receive greater wear and deterioration than other general aviation aircraft. For example, because of the high number of takeoffs and landings, training aircraft are subject to frequent and abrupt changes in engine power settings. This could cause rapid and extreme cylinder head temperature fluctuations resulting in premature wear and possible powerplant failure. Incidents of powerplant failure have been the cause of some pilot school accidents and incidents. In one incident, an aircraft engine that had been operated for 97 hours beyond the manufacturer's recommended time between overhauls sustained internal failure, and the aircraft was forced to land.

The inspection of pilot schools during the National Aviation Safety Inspection Program (NASIP) found training aircraft to be in a generally safe condition for flight; however, some airworthiness problems were found. Examples included pilot schools that have: (1) Not complied with Airworthiness Directives (ADs), especially those required on a recurring basis; (2) not recorded time in service on aircraft engines or propellers; (3) exceeded inspection intervals; and (4) performed modifications that were not approved.

The FAA proposes to revise § 141.39 by: (1) Clarifying that the rule would apply to all pilot and provisional pilot schools, as opposed to applicants; (2) clarifying that aircraft would have to be maintained in accordance with subpart E of part 91, which includes requirements for maintenance, preventive maintenance, and alterations; and (3) requiring aircraft to be maintained in accordance with an inspection program for each airframe, aircraft engine, propeller, appliance, and component part.

This proposed inspection program, which a pilot school may currently use under § 91.409, could be: (1) A current inspection program recommended by the manufacturer; (2) an inspection program that is currently in use by the holder of a certificate issued under part 121 or part 135; or (3) an inspection program established by the applicant and approved by the Administrator.

If an applicant desires to establish an inspection program, the program would be required to be in writing and would need to include at least: (1) Instructions and procedures for the conduct of inspections for the particular make and model of aircraft, including necessary tests and checks; (2) instructions and procedures for inspecting the parts and areas of each airframe, aircraft engine, propeller, appliance, and component part required to be inspected, including survival and emergency equipment; and (3) a schedule for performing the required program inspections, expressed in terms of the time in service, calendar time, number of system operations, or any combination of these.

The FAA also proposes that all aircraft used for the demonstration of instrument skills be equipped and maintained for operations under IFR. This revision would revise the current rule, which requires that: (1) Aircraft for use in en route operations under IFR and instrument approaches be equipped and maintained for operations under IFR operations; and (2) aircraft used for training in control and precision maneuvering by reference to instruments be equipped as provided for in the approved course of training.

7. Ground School Instructor Requirements

The FAA proposes to eliminate: (1) The requirement in § 141.35 for a ground school instructor to have 1 year of experience prior to serving as a ground school's chief instructor; and (2) the requirement in § 141.36 for a ground school instructor to have 6 months of experience prior to serving as a ground school's assistant chief instructor.

The FAA has granted exemptions to this requirement in existing § 141.35 for persons who have equivalent experience to meet the level of safety required by part 141. The FAA has stated in those grants of exemption that an applicant for a chief or assistant chief ground instructor who is approved by the Administrator would not need to meet these experience requirements.

8. Instructor Proficiency Requirements

The FAA proposes to revise the initial and recurrent proficiency checks a flight instructor is required to accomplish. The current rule requires each flight instructor to accomplish a proficiency check in each type of aircraft every 12 months.

The FAA proposes to revise § 141.79 by: (1) Permitting the assistant chief instructor and the check instructor to give these checks; (2) requiring the initial check for each course of training to be accomplished in the make and model of aircraft used in that training course; and (3) requiring recurrent checks to be accomplished in any make and model of aircraft in which the instructor trains students. Under the proposal, a flight instructor who trains students in a Cessna 172 and a Piper Arrow, for example, would be required to accomplish an initial check in each airplane. However, the recurrent check could be in either the Cessna 172 or the Piper Arrow.

This proposal also responds to a comment from Tar Heel Aviation to DOT's Regulatory Review, request for comments (57 FR 4744; February 7, 1992), which was in response to the President's request for comments on regulations that obstruct economic growth. The commenter suggested that each flight instructor accomplish: (1) One annual standardization flight in any aircraft in which the instructor trains students; or (2) one annual standardization flight that alternates

between complex and non-complex aircraft.

9. Renewal of Certificate

Currently, § 141.27 states that a pilot school that meets the requirements under part 141 for the issuance of the pilot school certificate will have its certificate renewed for 24 months. The FAA proposes to clarify the requirements a pilot school needs to meet to have its certificate renewed.

Under the proposal, the FAA would determine if: (1) The school's personnel, aircraft, facility, airport, approved training courses, and training records meet the requirements of part 141; (2) within 24 months prior to the date application is made for renewal of its pilot school certificate, the school trained at least a total of 10 students in any of its approved training courses and recommended those students for a certificate, rating, or a qualification, and those students completed a practical test, knowledge test, or end-of-course test; and (3) within 24 months prior to the date application is made for renewal of its pilot school certificate, at least 80 percent of the school's students passed the required practical test for the pilot, flight instructor, or ground instructor certificate or rating sought. The proposal would permit a pilot school that does not meet the renewal requirements listed in items (2) and (3) to apply for a provisional pilot school certificate.

In addition, the FAA proposes to eliminate the requirement that a provisional pilot school apply for a pilot school certificate not less than 30 days prior to the expiration of the provisional pilot school certificate. The purpose for this proposal is to encourage schools to apply for their pilot school certificate as soon as they meet the requirements and thus will give FAA FSDO's more time to complete certification of the school in a timely manner. In the past, some schools have complained that they have had to wait for their certificates, because of the heavy workloads in their local FAA FSDO. The FAA believes this proposal will benefit the schools by allowing the FAA to respond to school applications in a more timely manner.

10. Recordkeeping Requirements for Pilot Schools With Examining Authority

The FAA proposes to revise the recordkeeping requirements in § 141.67 for pilot schools with examining authority. The current rule requires a pilot school with examining authority to submit a copy of the appropriate training record for each person recommended by the pilot school for a pilot certificate or rating to the FAA FSDO.

The FAA proposes to eliminate the current requirements and to require pilot schools with examining authority to: (1) Maintain a record of all temporary airmen certificates it issues; (2) submit each graduate's application for airman certificate within 7 days after the graduate passes the required knowledge or practical test; (3) make the proposed record of all temporary airman certificates available to the Administrator on request; and (4) surrender the proposed record of all temporary airman certificates to the Administrator on expiration of the school's examining authority.

These proposed records of all temporary airmen certificates would have to be a chronological listing that includes: (1) The name of each student to whom a temporary airman certificate was issued; (2) the date of issuance; (3) the student's permanent mailing address and telephone number; (4) the title of the training course; (5) the name of the person who conducted the knowledge or practical test; (6) the type of temporary airman certificate or rating issued; and (7) the date the graduate's airman application file was sent to the FAA for processing of a permanent airman certificate.

In addition the school would be required to maintain a photocopy record containing each student's: (1) Graduation certificate; (2) airman application; (3) temporary airman certificate; (4) superseded airman certificate (if applicable); and (5) knowledge or practical test results.

11. Reorganization of Requirements for Courses That Are Approved Under Part 141

The FAA proposes to reorganize in the part 141 appendixes the criteria for training courses a pilot school could offer. This proposal would eliminate some courses, expand other courses, and establish criteria for new courses. The FAA proposes to give pilot schools and provisional pilot schools that request approval for a training course within the first year after the effective date of this rule the option to request approval of their current training courses or their proposed training courses. This option would give pilot schools and provisional pilot schools up to 3 years to request approval for a training course based on this NPRM.

The FAA's proposed reorganization would: (1) Eliminate test courses; (2) replace test preparation courses with special preparation courses; (3) expand the proposed special preparation courses to include additional subjects; and (4) propose additional courses. Each course is discussed later according to the title of the proposed appendix.

The proposal to eliminate test courses would delete existing appendix B, ''Private Test Course,'' and appendix E, ''Commercial Test Course.'' FAA Order 8700.1 chapter 141 defines a test course as ''a course of training for students who have accomplished more than half of the required time under part 61.'' The FAA believes that criteria for such courses would not be necessary. A pilot school that desires to offer a similar course could apply for approval of a course that would train students to a performance standard.

The proposed kind of special preparation courses are: (1) Agricultural aircraft operations; (2) rotorcraft external-load operations; (3) pilot refresher; (4) flight instructor refresher; (5) ground instructor refresher; (6) special operations; and (7) test pilot.

The private pilot and commercial pilot certification courses would be revised to apply to all aircraft categories, rather than only to the airplane category. This would eliminate appendix F, ''Rotorcraft, Glider, Lighter-Than-Air Aircraft, and Aircraft Rating Courses.'' The FAA also proposes to add the following certification courses: (1) Recreational pilot; (2) airline transport pilot; (3) flight instructor; (4) flight instructor instrument; and (5) ground instructor. Unlike current certification courses, the revised course would include minimum eligibility requirements, which are discussed later.

Revisions to the courses would correspond to the proposals in part 61 to: (1) Establish a powered-lift category rating; (2) establish separate class ratings for nonpowered gliders and powered gliders; (3) establish an instrument rating for airships; (4) establish instrument ratings for single-engine and multiengine airplanes; (5) establish a flight instructor certificate in the lighter-than-air category; (6) certificate ground instructors under part 61; (7) revise ground instructor ratings; (8) revise aeronautical knowledge areas; and (9) replace flight proficiency requirements with approved areas of operation.

The proposed appendixes would require students who desire to enroll in the flight portion of the course to meet specific eligibility requirements. They would require an applicant to hold: (1) The necessary pilot or flight instructor certificate; (2) the necessary medical certificate or present a signed and dated statement by the person certifying that the person has no known medical defects that make the person unable to pilot a glider or balloon, as required; and (3) any necessary ratings on the

pilot or flight instructor certificate. For example, a person who desires to enroll in the flight portion of a private pilot certification course would be required to hold at least a student pilot certificate and a third-class medical certificate or the proposed medical requirements for a rating in a glider or balloon. The proposed requirements are similar to the eligibility requirements found in part 61 for pilot, flight instructor, and ground instructor applicants. The proposed eligibility requirements would not impose on applicants new requirements that are not found in part 61. Part 141 would still contain the certification requirements for pilot schools and part 61 would still contain the certification requirements for pilot, flight instructor, and ground instructor applicants.

The proposal for these eligibility requirements would permit students who do not meet the minimum eligibility requirements of part 61 or part 141 to enroll in the ground portion of a course. The FAA believes that any person should be able to enroll in the ground portion of a course to enhance aeronautical knowledge.

In the past, there have been instances in which a student has desired to enroll in the ground portion of a course prior to meeting the minimum eligibility requirements for the certificate. For example, a student who desires to enroll in the ground portion of the flight instructor certification course may not hold a commercial pilot certificate. However, that student may be scheduled to accomplish the practical test for the commercial pilot certificate, which would let the student meet the eligibility requirements. In another example, a student may desire to enroll in the ground portion of a flight instructor certification course to see if flight training is a career alternative. Currently, the FAA has issued an exemption to Cochise Community College in Douglas, Arizona, that permits its students to enroll in the ground portion of the school's flight instructor certification course while the student waits for scheduling of the commercial pilot practical test.

The FAA proposes, throughout the appendixes, to replace the term ''solo practice'' with ''supervised PIC practice.'' The FAA believes this phraseology will more clearly define the flight instructor's responsibilities when their students are performing solo flight. The intent of this proposed phraseology is to ensure that flight instructors more closely monitor and direct their students when they are performing solo flight.

12. Appendix A—Recreational Pilot Certification Course

The FAA proposes to establish criteria for courses that provide a means for students to receive training and for pilot schools to give training for a recreational pilot certificate under part 141.

To enroll in the flight portion of the course, a person would be required to hold a student pilot certificate.

The course would require a minimum of 20 hours of ground training on the same aeronautical knowledge areas that are proposed in part 61 for a recreational pilot certificate. The knowledge area would include ground training on:

(1) The applicable FAR for recreational pilot privileges, limitations, and flight operations that apply to the aircraft rating sought;

(2) Accident reporting requirements of the NTSB;

(3) Use of the applicable portions of the ''Airman's Information Manual'' and FAA advisory circulars;

(4) Use of aeronautical charts for VFR navigation using pilotage with the aid of a magnetic compass;

(5) The recognition of critical weather situations from the ground and in flight, windshear avoidance, and the procurement and use of aeronautical weather reports and forecasts;

(6) The safe and efficient operation of aircraft, including collision avoidance, and recognition and avoidance of wake turbulence;

(7) The effects of density altitude on takeoff and climb performance;

(8) Weight and balance computations;

(9) Principles of aerodynamics, powerplants, and aircraft systems;

(10) Stall awareness, spin entry, spins, and spin recovery techniques, if applying for an airplane-single engine rating;

(11) Aeronautical decision making and judgment; and

(12) Preflight action that includes—

a. How to obtain information on runway lengths at airports of intended use, data on takeoff and landing distances, weather reports and forecasts, and fuel requirements;

b. How to plan for alternatives if the planned flight cannot be completed; and

c. Proper planning procedures for possible traffic delays.

The proposed course would consist of at least a minimum of 30 hours of flight training (of which 15 hours must be with an authorized flight instructor and 3 hours must be supervised PIC training), which is the same as in the proposed part 61 requirements. The difference between the total minimum flight training hours (30 hours) and the hours of training with an authorized flight (15 hours) and supervised PIC training (3 hours) is 12 hours, which will allow the schools to develop their recreational pilot certification course with the individual student in mind. For example, a student who has previous aviation experience and takes readily to the training may be able to complete training for a recreational private pilot certificate with only the minimum 30 hours of flight time that includes at least 15 hours of flight training time from an authorized flight instructor and 15 hours of supervised PIC flight time. However, a student pilot who does not have previous aviation experience or who trains infrequently may need more time than the minimum 30 hours of flight time, 15 hours of flight training time from an authorized flight instructor, and 3 hours of supervised PIC flight time. The student pilot and flight instructor may need to tailor the training to require 27 hours of flight training time from an authorized flight instructor and 3 hours of supervised PIC flight time, or some combination of those hours.

The FAA has elected to remain silent on the matter of the maximum time that may be credited for stage and end-of-course tests for the approved training course requirements. The FAA believes that the individual school and the local FAA FSDO is the better place for deciding how much time should be permitted for stage checks and end-of-course tests for each syllabus. The school and the approving FAA FSDO should evaluate each syllabus, and determine how much time a certain stage check or end-of-course test may be credited toward the total approved course requirement. After receiving course approval, the FAA and the school must continue to monitor the average length of time that it takes to conduct a specific stage check or end-of-course test, and be prepared to modify the syllabus when needed.

13. Appendix B—Private Pilot Certification Course

The FAA proposes to establish this appendix, which would include certification courses for a private pilot certificate with all category and class ratings. It would include courses currently found in appendix A and sections C.II, D.II, E.II, and E.III of appendix F. The proposed appendix would reflect the proposals in part 61 to establish a powered-lift category rating, and to establish separate class ratings for nonpowered gliders and powered gliders.

Persons who desire to enroll in the flight portion of a course would be required to hold: (1) A student pilot certificate; and (2) a third-class medical certificate, or in the case of course of training for glider or balloon rating, have a signed and dated application that they have no known medical defects that makes them unable to pilot a glider or balloon.

The proposed minimum ground training requirements would consist of the same aeronautical knowledge areas proposed in part 61 for a private pilot certificate.

The proposed flight training would consist of the same approved areas of operation proposed in part 61 for a private pilot certificate. The FAA is proposing to permit each school to tailor the course requirements around the individual student's needs. For example, a student who is seeking a private pilot certificate, and who has previous aviation experience and takes readily to the training may be able to complete training for a private pilot certificate with only the minimum 35 hours of flight time that included 20 hours of flight training time from an authorized flight instructor and 15 hours of supervised PIC flight time. However, a student pilot who does not have previous aviation experience or who trains infrequently may need more time than the minimum 35 hours of flight time, 20 hours of flight training time from an authorized flight instructor, and 5 hours of supervised PIC flight time. The student pilot and flight instructor may need to tailor the training to require 30 hours of flight training time from an authorized flight instructor and 5 hours of supervised PIC flight time, or some combination of those hours.

Current appendix A requires an applicant for a private pilot certificate with an airplane category rating to perform five takeoffs and five landings at night. The FAA proposes to require an applicant for a private pilot certificate with an airplane, rotorcraft, or powered-lift category rating to receive at least 3 hours and 10 takeoffs and 10 landings night flight training. However, the FAA proposes to include the provision in § 61.110 of this chapter that will exempt certain applicants from the night flying certification requirements.

The proposed time with a flight instructor on the areas of operation or in supervised PIC practice differ from the current requirements. The FAA proposes few minimum requirements or no minimum requirements. However, the training course would be required to include hours or flights for students to receive training on the approved areas of operation and for students to perform directed PIC practice that helps the student develop proficiency, resourcefulness, self-confidence, and self-reliance.

The existing appendix contains provisions that permit a school to credit stage checks and end-of-course tests toward the total hour course requirements. Currently, a maximum of 3 hours may be credited toward the total ground portion of the approved private pilot course requirements. A maximum of 4 hours may be credited toward the total flight portion of the approved private pilot course requirements. Under this proposal, the FAA has elected to remain silent on the maximum time that may be credited for a specific stage check and end-of-course test for the approved training course requirements. The FAA believes that the individual school, after receiving approval from their FAA FSDO, is the better place for deciding how much time should be permitted for a specific stage check and end-of-course test of each syllabus. The school and the approving FAA FSDO should evaluate each syllabus, and determine how much time a certain stage check or end-of-course test may be credited toward the total approved course requirement. After receiving course approval, the FAA and the school must continue to monitor the average length of time that it takes to conduct a specific stage check or end-of-course test, and be prepared to modify the syllabus when needed.

14. Appendix C—Instrument Rating Course

The FAA proposes to revise appendix C to include all instrument ratings, rather than the airplane only. It includes courses currently found in appendixes C, F, and H.

The proposed appendix would include courses for the proposed instrument-powered-lift rating, instrument-airship rating, instrument-airplane single-engine rating, and instrument-airplane multiengine rating.

To enroll in the flight portion of the course, a student would be required to hold: (1) A private pilot certificate with an aircraft category and class rating appropriate to the instrument rating for which the course applies; and (2) at least third-class medical certificate.

The proposed ground training content would be the same as proposed in part 61 for an instrument rating, and includes windshear avoidance and aeronautical decisionmaking and judgment. The appendix would require the same amount of ground training that currently exists for an initial instrument rating, which is the same as currently required for an airplane-instrument rating. As a result of this reorganization of the appendixes of part 141, this would, in effect, lower the minimum required ground training requirements from 35 hours to 30 hours for an initial instrument rating in a helicopter. A proposed 20 hours of ground training would be required if the course is for an additional instrument rating, which differs from the current requirement for 15 hours in the test preparation course. Because of the lowering of the pilot experience requirements for applying for an instrument rating, the different knowledge, skills, and abilities required for the different instrument ratings, and the emphasis for more detailed ground training requirements, the FAA believes the increase is necessary.

The flight training would be on the same approved areas of operation as proposed in part 61 for an instrument rating. In addition, the revised appendix would clarify the existing requirement for a cross-country flight by requiring a minimum straight-line distance between airports for one of the legs; this is also proposed in part 61.

A minimum of 35 hours of flight training would be required for all five types of instrument ratings, which is the same amount currently required for an instrument rating in an airplane or a helicopter. A percentage of the minimum hours in a course for a rating in an airplane, rotorcraft, or powered-lift could be given in a flight training device by an authorized flight instructor.

The existing appendix contains provisions that permit stage checks and end-of-course tests to be credited toward the total hour course requirements. Under this proposal, the FAA has elected to remain silent on the maximum time that may be credited for a specific stage check and end-of-course test for the approved training course requirements. The FAA believes that the individual school, after receiving approval from their FAA FSDO, should decide how much time should be permitted for a specific stage check and end-of-course test for each syllabus. The school and the approving FAA FSDO should evaluate each syllabus, and determine how much time a certain stage check or end-of-course test may be credited toward the total approved course requirement. After receiving course approval, the FAA and the school must continue to monitor the average length of time that it takes to conduct a specific stage check or end-of-course test, and be prepared to modify the syllabus when needed.

15. Appendix D—Commercial Pilot Certification Course

The FAA proposes to establish this appendix, which includes certification courses for a commercial pilot certificate with all category and class ratings. It would include courses currently found in appendix D and in sections C.III, D.III, E.IV, and E.V of appendix F. The proposed appendix would include the proposals in part 61 to establish a powered-lift category rating and to establish separate class ratings for nonpowered gliders and powered gliders.

To enroll in the flight portion of the course, a person would be required to: (1) Hold a private pilot certificate with the category and class rating appropriate to the ratings for which the course applies; and (2) hold at least a third-class medical certificate or present a signed and dated statement by the person certifying that the person has no known medical defect that makes the person unable to pilot a glider or balloon.

In addition, if the course is for a rating in an aircraft other than a gyroplane, glider, or balloon, the student would be required to: (1) Hold an instrument rating appropriate to the aircraft category and class rating for which the course applies; or (2) be concurrently enrolled in an instrument rating course for which the course applies and satisfactorily accomplish the required practical test prior to completing the commercial pilot practical test.

The proposed ground training would be the same aeronautical knowledge areas as proposed in part 61 for a commercial pilot certificate. The proposed ground training would also permit an applicant for an airplane category rating to complete ground training on an airplane with flaps, retractable landing gear, and a controllable propeller or an airplane with a turbine-powered engine, which is also proposed in part 61. The minimum hours of ground training are the same as in current commercial pilot courses. A minimum of 100 hours of training would be required for the powered-lift category rating, which is currently required for an airplane category rating.

The proposed flight training would be the same as the approved areas of operation proposed in part 61 for a commercial pilot certificate. In addition, the revised appendix would include the proposed modifications to the cross-country flight requirements in part 61.

The proposed time with a flight instructor on the areas of operation or in supervised PIC practice parallel the proposals for commercial pilot certification in part 61. The training course would be required to include hours or flights for students to receive training on the approved areas of operation and for students to perform supervised PIC practice that helps develop proficiency, resourcefulness, self-confidence, and self-reliance.

The existing appendix contains provisions that permit stage checks and end-of-course tests to be credited toward the total hour course requirements. The FAA has elected to remain silent on the maximum time that may be credited for stage and end-of-course tests for the same reasons stated in appendix A.

16. Appendix E—Airline Transport Pilot Certification Course

The FAA proposes to establish appendix E as a certification course for an airline transport pilot certificate. It includes information currently found in appendix H, section 6. The proposed appendix would include the proposal in part 61 to establish a powered-lift category rating.

To enroll in the flight portion of the course a person would be required to: (1) Hold a commercial pilot certificate with the category and class ratings for which the course applies and hold no restrictions; (2) hold at least a third-class medical certificate; and (3) upon completion of the course, meet the aeronautical requirements in part 61 for an ATP certificate that is appropriate to the ratings for which the course applies.

The proposed ground training would consist of the same elements as those proposed in part 61 for an ATP certificate, including windshear avoidance, aeronautical decisionmaking and judgment. The course would continue to require 40 hours of ground training.

The proposed flight training would consist of the same approved areas of operation as proposed in part 61 for an ATP certificate. The course would continue to require 25 hours of flight training with at least 15 hours of instrument flight training. The FAA has elected to remain silent on the maximum time that may be credited for stage and end-of-course tests for the same reasons previously stated in appendix A.

17. Appendix F—Flight Instructor Certification Course

The FAA proposes to establish a separate appendix for certification courses for an initial flight instructor certificate with a category and class rating and for an additional category or class rating on a flight instructor certificate. The course for an instrument rating on a flight instructor certificate is addressed in proposed appendix G. The course in this appendix is currently found in appendix H, sections 3 and 4.

This proposed appendix would include the proposals in part 61 to: (1) Establish a powered-lift category rating; (2) establish separate class ratings for nonpowered gliders and powered gliders; and (3) establish a flight instructor certificate for the lighter-than-air category.

To enroll in the flight portion of the course, a person would be required to hold: (1) A commercial or an ATP certificate with an aircraft category and class rating appropriate to the rating for which the course applies; (2) an instrument rating in an aircraft that is appropriate to the aircraft category and class for which the course applies (this would be required for an airplane, airship, or powered-lift rating); and (3) at least a third-class medical certificate or a signed and dated statement by the person certifying that the person has no known medical defect that makes the person unable to pilot a glider or balloon, as appropriate.

The proposed ground training would consist of the same aeronautical knowledge areas as proposed in part 61 for a flight instructor certificate. The course would continue to require a minimum of 40 hours of ground training for an initial flight instructor certificate and 20 hours for an additional flight instructor rating.

The proposed flight training would consist of the same approved areas of operation as proposed in part 61 for a flight instructor certificate. The minimum hours of flight training required would vary with the category or class of aircraft. A course for a rating in an airplane, a rotorcraft, or an airship would require a minimum of 25 hours of training. A course for a rating in a nonpowered glider would require 10 hours and 10 flights of training. A course for a rating in a powered glider would require 10 hours of training. A course for a balloon class rating would require 8 flights of training. The FAA has elected to remain silent on the maximum time that may be credited for stage check and end-of-course tests for the same reasons previously stated in the earlier discussion.

18. Appendix G—Flight Instructor Instrument (Aircraft Category and Class) Certification Course

The FAA proposes to establish a separate appendix for certification courses for a flight instructor certificate with an instrument rating. This proposed appendix would include the proposals in part 61 to: (1) Establish a powered-lift category and instrument

rating; (2) establish an instrument rating for airships; (3) establish instrument ratings for single-engine and multiengine airplanes; and (4) establish a flight instructor certificate for the lighter-than-air category.

To enroll in the flight portion of the course, a person would be required to hold: (1) A commercial or an ATP certificate with an aircraft category and class rating appropriate to the rating for which the course applies; (2) a flight instructor certificate with an aircraft category and class rating that is appropriate to the instrument rating for which the course applies; and (3) at least a third-class medical certificate.

The proposed course would require a minimum of 15 hours of ground training on the same aeronautical knowledge areas as proposed in part 61 for a flight instructor certificate. The proposed course would also require a minimum of 15 hours of flight training on same approved areas of operation as proposed in part 61 for a flight instructor certificate. The FAA has elected to remain silent on the maximum time that may be credited for stage check and end-of-course tests for the same reasons previously stated in the earlier discussion.

19. Appendix H—Ground Instructor Certification Course

The FAA proposes to establish this appendix for the approval of a certification course for a ground instructor certificate. An equivalent course is not found in current part 141.

This proposed appendix would include the proposals in part 61 to: (1) Revise ground instructor ratings; (2) include ground instructors under part 61; (3) establish a powered-lift category rating; (4) establish separate class ratings for nonpowered gliders and powered gliders; (5) establish an instrument rating for airships; and (6) establish instrument ratings for single-engine and multiengine airplanes.

The proposed course would require ground training on the same aeronautical knowledge areas as proposed in part 61. A person who enrolls for an initial ground instructor certificate would be required to receive a minimum of 20 hours of ground training. A person who enrolls for an additional ground instructor rating would be required to receive a minimum of 10 hours of ground training. The current provision in appendix H, section 3, ''Flight Instructor Certification Course,'' states that the initial ground training can be lowered by one-half if the person has prior experience in education is proposed to apply also to ground instructors. Reference the maximum time that may be credited for stage checks and end-of-course tests, the FAA has elected to remain silent on this matter for the same reasons previously stated in appendix A.

20. Appendix I—Aircraft Category or Class Rating Course

The FAA proposes to establish an appendix for certification courses for adding either a category or a class rating on a pilot certificate. The course in this appendix is currently found in sections F.II and F.III of appendix F. The proposed appendix includes proposals in part 61 to establish a powered-lift category rating, and to establish separate class ratings for nonpowered gliders and powered gliders.

To enroll in the flight portion of the proposed course, a person would be required to hold: (1) The minimum level pilot certificate that is appropriate to the additional category or class aircraft rating for which the course applies; and (2) at least a third-class medical certificate for aircraft ratings that require a medical certificate for that pilot certificate level to obtain an additional rating at the recreational pilot certificate level or an additional glider or balloon rating, persons must provide a signed and dated statement certifying that they have no known medical defects that makes them unable to pilot the aircraft.

Each course approved under this appendix would be required to consist of the minimum requirements found under appendixes A, B, C, D, or E for the category or class rating for which the course is approved at the appropriate pilot certificate level.

21. Appendix J—Aircraft Type Rating Course, Other Than Airline Transport Pilot

The FAA proposes to establish appendix J for certification courses for adding a type rating on a pilot certificate. The course in this appendix is currently found in appendix F, section F.IV. The proposed course would include the proposal in part 61 to establish a powered-lift category rating.

To enroll in the flight portion of the proposed course, a person would be required to: (1) Hold at least a private pilot certificate; (2) hold at least a third-class medical certificate, if a medical certificate is required for the type of aircraft rating sought; and (3) hold an instrument rating or be concurrently enrolled in a course for an instrument rating in the category and class that is appropriate to the aircraft type rating for which the course applies (if the aircraft does not hold a VFR limitation). A person who is concurrently enrolled in a course for an instrument rating would be required to satisfactorily accomplish the required practical test concurrently with the aircraft type rating practical test.

The minimum number of hours of ground training proposed would include at least 15 hours of training. The minimum number of hours of flight training proposed would include at least 25 hours of flight training of which at least 15 hours must be instrument flight training in the aircraft for which the course applies.

22. Appendix K—Special Preparation Courses

The FAA proposes to establish special preparation courses within appendix K. These courses are similar to the current test preparation courses, but would expand the concept of specialized courses. The proposed appendix would include the proposals in part 61 to: (1) Certificate ground instructors under part 61; (2) revise aeronautical knowledge areas; and (3) replace flight proficiency requirements with approved areas of operation.

The proposed appendix would establish: (1) Flight instructor refresher courses; (2) ground instructor refresher courses; (3) special operations courses; and (4) test pilot courses.

To enroll in the flight portion of the proposed courses, a person would be required to hold: (1) A pilot certificate that is appropriate to the operating privileges or authorizations that graduation from the course covers; and (2) at least a third-class medical certificate, if a medical certificate is required in part 61 of this chapter; or a signed and dated statement by the person certifying that the person has no known medical defect that makes the person unable to pilot a glider or balloon.

As noted above, a person who enrolls in the flight portion of the proposed courses would be required to hold a pilot, flight instructor, or ground instructor certificate that is appropriate to the operating privileges or authorization that graduation from the course covers. For example, if after graduation the person operates an aircraft under part 133—Rotorcraft External-Load Operations, that person would be required to hold at least a commercial pilot certificate with a rotorcraft-helicopter rating. Each student enrolled in these courses would be required to satisfactorily accomplish stage checks and end-of-course tests to graduate.

The proposed agricultural aircraft operations would continue to require a

minimum of 25 hours of ground training and 15 hours of flight training as found in appendix H, section 8. This proposal would eliminate the option in appendix H to include up to 5 hours of supervised PIC practice. The ground training requirements would be clarified and expanded to include: (1) Agricultural aircraft operations; (2) safe operating procedures for handling and dispensing agricultural and industrial chemicals, including operating in and around congested areas; and (3) applicable provisions of part 137. The flight training requirements would be clarified to include training on maneuvers and procedures applicable to agricultural aircraft operations.

The proposed course on rotorcraft external-load operations would continue to require a minimum of 10 hours of ground training and 15 hours of flight training, as found in current appendix H, section 9. The ground training requirements would be clarified to include: (1) Rotorcraft external-load operations; (2) safe operating procedures for external-load operation, including operating in and around congested areas; and (3) applicable provisions of part 133. The flight training requirements would be clarified to include training on maneuvers and procedures applicable to external-load operations.

The FAA proposes to establish basic criteria for a test pilot course. The proposed course requirements would include ground training on the following: (1) Aircraft maintenance, quality assurance, and certification test flight operations; (2) safe operating practices and procedures for performing aircraft maintenance, quality assurance, and certification test flight operations; (3) appropriate parts of the FAR that pertain to aircraft maintenance, quality assurance, and certification tests; and (4) test pilot duties and responsibilities. The minimum number of hours required for the ground training would be approved by the FAA Flight Standards District Office (FSDO). The course would also require a minimum of 15 hours of flight training on test pilot duties and responsibilities. However, in accordance with proposed § 141.55, a school may submit a syllabus that is less than the minimum hours.

The FAA proposes to establish minimum criteria for special operations courses, including pipeline patrol, shoreline patrol, and aerial photography. The criteria in appendix K would be general. The specifics of each course would be approved by the FAA FSDO. The intent of the proposal is to provide an incentive and flexibility for part 141 pilot schools to develop specialized courses and improve business opportunities.

The FAA proposes to revise the pilot refresher course in appendix H, section 7. The course would continue to require 4 hours of ground training and 6 hours of flight training. The proposed course would not specifically include the current option for up to 2 hours of the 6 hours to be directed solo practice, but would permit the school more flexibility in designing a syllabus that best fits the student's needs. The ground training requirements would include: (1) Aeronautical knowledge areas that are applicable to the student's pilot certificate level, aircraft category and class rating, or instrument rating, as appropriate; (2) safe operating pilot practices and procedures; and (3) applicable provisions of parts 61 and 91 for pilots. The flight training requirements would be clarified to include flight training on the approved areas of operation that are applicable to level of the student's pilot certificate, aircraft category and class rating, or instrument rating, as appropriate, for performing pilot-in-command duties and responsibilities.

On April 6, 1994, the FAA issued amendment No. 61–95, ''Renewal of Flight Instructor Certificates'' (59 FR 17646). In that final rule, the FAA revised § 61.197(c) by deleting the current 24-hour requirements for an approved flight instructor refresher course. In light of that final rule action, the FAA is proposing similar rulemaking action in this notice to parallel amendment No. 61–95. In this appendix, the FAA proposes establishing a flight instructor refresher course that would require ground training, flight training, or any combination of ground and flight training similar amendment No. 61–95. The ground training would include the: (1) Aeronautical knowledge areas of part 61 that apply to student, recreational, private, and commercial pilot certificates and instrument ratings; (2) aeronautical knowledge areas that apply to flight instructors; (3) safe pilot operating practices and procedures, including airport operations and operating in the National Airspace System (NAS); and (4) applicable provisions of parts 61 and 91 that apply to holders of pilot and flight instructor certificates. The flight training course would include a review of: (1) The approved areas of operations that are applicable to student, recreational, private, and commercial pilot certificates and instrument ratings; and (2) the necessary skills, competency, and proficiency for performing flight instructor duties and responsibilities.

In addition, the FAA proposes to establish criteria for ground instructor refresher courses. The proposed contents of this course would require ground training on the following: (1) Aeronautical knowledge areas of part 61 that apply to student, recreational, private, and commercial pilot certificates and instrument ratings; (2) aeronautical knowledge of areas that apply to ground instructor certificates; (3) safe pilot operating practices and procedures, including airport operations and operating in the NAS; and (4) applicable provisions of parts 61 and 91 that apply to pilots and ground instructor certificates.

23. Appendix L—Pilot Ground School Course

The FAA proposes to revise existing appendix G, ''Pilot Ground School Course,'' and move it to proposed appendix L. The current provision to permit stage and end-of-course tests to be credited toward the overall training course requirements would not be specifically included in the revised appendix. However, the FAA has elected to remain silent on the maximum time that may be credited for stage and end-of-course tests for the same reasons previously stated in the earlier discussions of appendixes A, B, C, and D.

D. Section by Section Discussion of Part 1—Definitions and Abbreviations

The FAA proposes to clarify and redefine certain definitions in part 1. The intent of this proposal is to ensure more consistent use of terms throughout the text of parts 61 and 141. The terms to be clarified include:

1. *Balloon* means:

Balloon is an aircraft that is not engine driven, but sustains flight with either gas buoyancy or with an airborne heater.

The term, ''balloon'' would replace the term ''free balloon.'' The term ''balloon'' will include gas balloons and balloons with an airborne heater. The FAA believes the term ''balloon'' is more descriptive in defining this class of aircraft.

This definition coincides with the FAA proposal to delete references to the phrase ''hot air balloon without airborne heaters'' throughout part 61, and classify balloons as ''gas balloons'' and ''balloons with airborne heaters.'' The phrase ''hot air balloon without an airborne heater'' is a balloon that was in existence at one time, but is no longer available. Accordingly, the FAA would establish separate practical tests for ''gas balloon'' and tests in ''balloons with airborne heaters.'' Administratively, this

proposal will, in effect, permit a person who receives the required training and performs the practical test in a gas balloon to be limited to operating a gas balloon. Accordingly, that person's certificate would contain a limitation, ''Limited to gas balloons.'' Vice versa, a person who receives the required training and performs the practical test in a balloon with an airborne heater would be limited to operating a balloon with an airborne heater. Accordingly, that person's certificate would contain a limitation, ''Limited to a balloon with an airborne heater.''

2. *Flight time* means:

a. Pilot time that commences when an aircraft moves under its own power for the purpose of flight and ends when the aircraft comes to rest after landing; or

b. For a nonpowered glider, that time when the glider commences being towed for the purpose of flight and ends when the glider comes to rest after landing.

The term is being rewritten to apply to nonpowered aircraft as well as powered aircraft. For powered aircraft, flight time would mean pilot time commencing when an aircraft moves under its own power for the purpose of flight and ending when the aircraft comes to rest after landing. For a nonpowered glider, the term would refer to the time when the glider commences being towed for the purpose of flight until the glider comes to rest after landing.

3. *Pilot in command* means:

a. A person who has final authority and responsibility for the operation and safety of the flight;

b. A person who holds the appropriate category, class, and type rating, if appropriate;

c. A person who has been designated as pilot in command before or during the flight; and

d. Involves a flight that occurs in actual flight conditions in an aircraft.

This proposal would clarify the definition to allow only one person at a time to log PIC time.

E. Section by Section Discussion of Part 61—Certification: Pilots, Flight Instructors, and Ground Instructors

The FAA proposes to change the title of part 61 to ''Certification: Pilots, Flight Instructors, and Ground Instructors.'' The reason for this change is the proposed elimination of part 143 and the relocation of the certification of ground instructors into part 61.

Subpart A—General

Section 61.1 Applicability

Proposed § 61.1 would be revised by adding the term ''authorization.'' Proposed § 61.1 would be revised by deleting the reference to § 61.71 and inserting a reference to ''training courses specifically approved by the Administrator under other parts of this chapter.'' This would include training programs under SFAR 58, proposed training centers, and part 141 pilot schools.

Section 61.1a Clarification of Terms

Proposed § 61.1a would be established to clarify terms used throughout part 61. The clarified terms are: Aeronautical experience; airman certificate; authorized ground instructor; authorized flight instructor; cross-country time; examiner; flight training; ground training; instrument approach; instrument training; knowledge test; pilot time; training time; supervised PIC time; and practical test.

Section 61.2 Certification of Foreign Pilots, Flight Instructors, and Ground Instructors

Proposed § 61.2 would include a provision for ground instructor certificates under part 61. In addition, the significant revisions in proposed § 61.2 would permit a person who is not a citizen of the United States or a resident alien of the United States to: (1) Complete a knowledge or practical test outside the United States; (2) Be issued an additional category, class, instrument, or type rating, as applicable on a U.S. pilot certificate; and (3) Be issued an additional, renewal, or reinstatement of a category, class, or instrument rating for a U.S. flight instructor or ground instructor certificate.

This proposal is a result of FlightSafety International's (FSI) petition for exemption from § 61.2. FSI's petition requested relief from § 61.2 to be allowed to issue type ratings to foreign nationals who hold U.S. pilot certificates at its training facility located in Velizy, Villacoublay, France. On February 22, 1989, the FAA granted FSI's petition permitting additional ratings to be added to foreign nationals' U.S. pilot certificates while located outside the United States. The current provisions of § 61.2 limit FSI and other U.S. training and airplane manufacturing companies from expanding their business into the international aviation market.

Section 61.3 Requirement for Certificates, Ratings, and Authorizations.

The significant proposed changes in § 61.3 are as follows:

(1) Includes the certification of ground instructor certificates and ratings in part 61;

(2) Establishes an instrument rating for airships;

(3) Establishes a flight instructor certificate for the lighter-than-air category;

(4) Replaces the phrase ''personal possession'' with ''physical possession, or readily accessible in the aircraft;''

(5) Clarifies the ''age 60 limitation'' that is applicable to persons who serve as pilot crewmembers for a foreign air carrier when that carrier is operating a U.S.-registered civil aircraft with more than 30 passenger seats, excluding any required crewmember seat, and/or a 7500 pound payload capacity for compensation or hire in scheduled international air services or non-scheduled international air transport operations;

(6) Clarifies that a person who acts as a PIC or as a required flight crewmember of a civil aircraft of U.S. registry would be required to hold either an airman certificate or a special purpose flight authorization;

(7) Addresses the pilot certificate requirements for operating aircraft of foreign registry within the United States;

(8) Clarifies the requirements for a person to have their medical certificate in their physical possession or readily accessible in the aircraft. Furthermore, this proposal would specifically identify when it is permitted for a person *not* to have their medical certificate in their physical possession or readily accessible in the aircraft;

(9) Parallels the provisions of § 61.41 for allowing training received from a flight instructor who is not certificated by the FAA;

(10) Provides that a flight instructor certificate is not necessary, if the:

a. Training is in accordance with a part 121 or part 135 air carrier approved training program;

b. Training is given by the holder of an ATP certificate under § 61.169 of this part; and

c. Person receiving the training and the person giving the training are employees of that air carrier. This proposal would provide that a flight instructor certificate is not necessary, if the training was conducted in accordance with the provisions of § 61.41.

(11) Replaces the references to each instrument rating needed for each class of aircraft category with the phrase ''appropriate aircraft category, class, type rating, if required, and instrument rating.'' Because of the proposed instrument rating for an airship, the existing requirement for a pilot to hold a commercial certificate with a lighter-than-air category and airship class rating

to operate an airship under instrument flight rules (IFR) or instrument meteorological conditions (IMC) would be deleted. Pilots of gliders would still be required to hold an instrument rating for a single-engine airplane;

(12) Aligns the ''age 60'' rules of part 121 to part 61. This proposal states that a pilot who is 60 years of age or older may not act as a pilot crewmember while engaging in any scheduled international air services, non-scheduled international air transportation, or common carriage operation for compensation or hire in a civil aircraft that has a passenger seating configuration of more than 30 seats, excluding any required crewmember seat or payload capacity of more than 7500 pounds (3400 kg);

(13) Requires a pilot that is required to hold a special purpose pilot authorization, issued in accordance with § 61.77, to have that authorization in their possession in the aircraft when exercising the privileges of that authorization; and

(14) Permits the following exceptions during the proposed 2-year transition period of these rule changes:

a. A pilot with a commercial pilot certificate with a lighter-than-air category rating, which was issued before the effective date of this rule, would be permitted to give training in an airship or balloon, as appropriate;

b. A pilot with a commercial pilot certificate with a lighter-than-air category rating and airship class rating would be permitted to operate an airship under IFR or IMC; and

c. A pilot with a commercial or private pilot certificate with an instrument-airplane rating would be permitted to operate an airplane under IFR or IMC.

Section 61.5 Certificates and Ratings Issued Under This Part

The significant proposed changes in § 61.5 are as follows:

(1) Includes ground instructor certificates and ratings in part 61;

(2) Revises ground instructor certificates and ratings;

(3) Establishes a powered-lift category rating;

(4) Establishes an instrument rating for powered-lifts;

(5) Establishes nonpowered and powered class ratings under the glider category;

(6) Establishes separate instrument ratings for single-engine and multiengine airplanes;

(7) Establishes an instrument rating for airships;

(8) Establishes a flight instructor certificate for the lighter-than-air category;

(9) Deletes the word ''small'' in the reference to turbojet airplanes in the paragraph that applies to aircraft type ratings. The word ''small'' is unnecessary because current requirements require the PIC of all turbojet airplanes to have a type rating whether it is a large or small turbojet airplane;

(10) Eliminates the reference to Advisory Circular 61–1, ''Aircraft Type Ratings.'' The reference is obsolete because the advisory circular has been revised. The list of type ratings is incorporated into Advisory Circular No. 61–89D, ''Pilot Certificates: Aircraft Type Ratings,'' which also consists of type rating curricula;

(11) Deletes the provision that requires a pilot who seeks an ATP certificate in a small helicopter to obtain a helicopter type rating. Small helicopters should not be treated differently than the other small aircraft. Historically, the FAA policy on requiring a pilot who seeks an ATP certificate in a small helicopter to obtain a helicopter type rating was based on the operating requirements of part 127, ''Certification of Operations of Scheduled Air Carriers with Helicopters.'' Specifically, § 127.173(a) requires a pilot who seeks an ATP certificate in a small helicopter to obtain a helicopter type rating. However, a closer reading of existing § 61.5(b)(5)(iii) states, ''small helicopters for operations requiring an ATP certificate.'' Currently, part 127 is not active, and there are not any part 127 scheduled air carriers with helicopters. The FAA has determined that it is not necessary for a person who seeks an ATP certificate in a small helicopter to obtain a helicopter type rating. Continuing this past policy places an additional restriction on small helicopters that is not required of other small aircraft and can no longer be justified. Therefore, the FAA proposes to treat the type rating requirements for helicopters as it currently does for the other aircraft, which would only require a type rating if the aircraft is a large aircraft other than lighter-than-air, turbojet-powered airplanes, or is another aircraft type rating that is specified by the Administrator through the aircraft type certification procedures;

(12) Includes a provision for allowing a pilot to exchange a current pilot certificate for a pilot certificate with the proposed instrument ratings and glider class ratings; and

(13) Allows a pilot with a flight or ground instructor certificate to exchange that certificate for a flight or ground instructor certificate with the proposed ratings in §§ 61.201 and 61.227.

Section 61.7 Obsolete Certificates and Ratings

The FAA proposes to revise § 61.7 by adding a new paragraph that would list the category, class, and instrument ratings that are proposed to be eliminated. In this section, the FAA also proposes to:

(1) Revise ground instructor certificates and ratings;

(2) Establish nonpowered and powered class ratings under the glider category; and

(3) Establish separate instrument ratings for single-engine and multiengine airplanes.

Section 61.9 Written Syllabus for Conducting Training

The FAA proposes to eliminate existing § 61.9, ''Exchange of obsolete certificates and ratings for current certificates and ratings.'' This section, which lists the requirements for exchanging the certificates and ratings that were adopted in 1973, is no longer necessary.

The FAA proposes a new § 61.9 that would establish requirements for written training syllabus. This syllabus would be required by an instructor who gives flight or ground training to a pilot for an airman certificate or rating.

Section 61.11 Expired Pilot Certificates and Reissuance

Minor editorial and format changes are proposed.

Section 61.13 Awarding of Airman Certificates, Ratings, and Authorizations

The FAA proposes to replace the title of § 61.13, ''Application and qualification,'' with the title ''Awarding of airman certificates, ratings, and authorizations'' and to revise the format of this section.

The significant proposed changes in this section are as follows:

(1) Includes ground instructor certificates in part 61;

(2) Replaces the phrase ''flight proficiency requirements'' with ''approved areas of operation'';

(3) Deletes the provision that permits the use of aircraft for a practical test that cannot perform all of the approved areas of operation for that practical test because of limitations listed in that aircraft's type certificate; and

(4) Clarifies that a limitation placed on a person's airman certificate may be removed if the pilot demonstrates to an examiner satisfactory proficiency in the area of operation for which the airman certificate level and rating are sought.

Section 61.14 Refusal to Submit to a Drug Test

No modifications are proposed.

Section 61.15 Offenses Involving Alcohol or Drugs

No modifications are proposed.

Section 61.16 Refusal to Submit to an Alcohol Test or to Furnish Test Results

No modifications are proposed.

Section 61.17 Temporary Certificate

The FAA proposes to revise this section to include the ground instructor certificate in part 61. The existing 90-day limit on temporary ground instructor certificates or ratings in existing § 143.5 would, in effect, be increased to 120 days, which is the current limit for the other temporary pilot and flight instructor certificates and ratings.

Section 61.19 Duration of Pilot and Instructor Certificates

The significant proposed changes in this section are as follows:

(1) Include ground instructor certificates under part 61; and

(2) Change the title of proposed § 61.19, ''Duration of pilot and flight instructor certificates'' to read, ''Duration of pilot and instructor certificates.''

Section 61.21 Duration of a Category II Pilot Authorization

The FAA proposes editorial and format changes.

Section 61.23 Duration and Requirement for a Medical Certificate

The significant proposed changes in this section are as follows:

(1) Change the title of this section from ''Duration of medical certificates'' to ''Duration and requirement for a medical certificate'';

(2) Redesignate the current paragraphs of this section;

(3) Permit a pilot to apply for any pilot or flight instructor certificate, for which a medical certificate is required, with a third-class medical certificate. A higher medical certificate level would continue to be required for flight operations requiring an ATP certificate or a commercial pilot certificate;

(4) Clarify current requirements for a person who is exercising the privileges of their flight instructor certificate while serving as a PIC or as a required crewmember, then that person would be required to hold a third-class medical certificate. However, if the flight instructor is not serving as a PIC or as a required crewmember, then that person would not be required to hold a medical certificate; and

(5) Permit student pilots who are seeking a recreational pilot certificate and certificated recreational pilots to operate aircraft without a medical certificate, provided they have an application on file that certifies they do not have any known medical deficiencies that make them unable to pilot the aircraft. This would also permit higher certificated pilots who are only exercising the privileges of a recreational pilot certificate to be afforded the same privileges.

Section 61.25 Change of Name

Format and minor editorial changes are proposed.

Section 61.27 Voluntary Surrender or Exchange of Certificate

This section would be revised by dividing the existing language into two paragraphs. The purpose of this proposal, as throughout this notice, is to rewrite the rules in an outline format instead of the current narrative format.

Section 61.29 Replacement of a Lost or Destroyed Airman or Medical Certificate or Knowledge Test Report

The proposed revisions to § 61.29 are as follows:

(1) Change the title of the section to ''Replacement of a lost or destroyed airman or medical certificate or knowledge test report'';

(2) Delete listing the cost of replacing a lost or destroyed airman or medical certificate. This proposal would establish the procedures for obtaining a lost or destroyed airman certificate, medical certificate, or knowledge test report. The cost for replacement of lost or destroyed airman certificate, medical certificate, or knowledge test report would be in part 187, ''Cost of Services and Transfer of Fees to part 187 from parts 47, 49, 61, 63, 65, and 143''; and

(3) Delete some unnecessary explanations of the procedures for replacing a lost or destroyed airman or medical certificate. These existing provisions are merely explanatory and are not of a regulatory nature, so the FAA proposes to delete them.

Section 61.31 Type Rating, Additional Training, and Authorization Requirements

The FAA proposes to change the title of this section from ''General limitations'' to ''Type rating, additional training, and authorization requirements.''

The significant proposed revisions to this section are as follows:

(1) Delete the provision requiring a type rating in helicopters for operations requiring an ATP certificate. This proposal will parallel helicopters with the other classes of aircraft that only require a type rating for: Large aircraft (except lighter-than-air), turbojet-powered airplanes, and those aircraft specified by the Administrator through aircraft type certificate procedures;

(2) Establish an aircraft category rating for the new powered-lift aircraft;

(3) Replace the current requirement for a pilot to receive training and an endorsement in an airplane with ''more than 200 horsepower'' to ''200 horsepower or more'';

(4) Separate the current requirements for a pilot to receive training and an endorsement to operate an airplane that has a retractable landing gear, flaps, and controllable propeller and an endorsement to operate a high performance airplane that has an engine of 200 horsepower or more;

(5) Establish a requirement for a pilot to receive aircraft type specific training. The purpose of this proposal, as earlier discussed in the ''General Discussion of Principal Issues'' under the paragraph title of this notice noted as ''Aircraft Type Specific Training,'' would require a person to receive additional training and a flight instructor endorsement for that person to serve as a PIC of an aircraft that the Administrator has determined requires type specific training;

(6) Require pilots to receive additional training for operating ''pressurized aircraft.'' Current provisions only require pilots to receive additional training in ''pressurized airplanes.'' This proposal is to capture the possible development of pressurized ''powered-lift,'' and any other pressurized aircraft that may be manufactured in the future;

(7) Require a pilot seeking an aircraft type rating to perform to ATP standards. This proposal will codify the existing policy for FAA pilot certification standards; and

(8) Add an exception in proposed paragraph (j), to include the powered-lift aircraft, because no class ratings are being established. In addition, the powered-lift would be added as an exception to the category and class rating requirements of this section for aircraft not type certificated as airplanes, rotorcraft, gliders, powered-lift, or lighter-than-air aircraft.

Section 61.33 Tests: General Procedure

This section would revise the format by replacing the phrase ''persons, designated by the Administrator'' with the word ''examiners.''

Section 61.35 Knowledge Test: Prerequisites and Passing Grades

Proposed § 61.35 would be retitled to read, ''Knowledge test: Prerequisites and passing grades,'' instead of ''Written test prerequisites and passing grades.''

The proposed revisions to § 61.35 are as follows:

(1) Replace the term ''written test'' with ''knowledge test'';

(2) Require an applicant to receive an endorsement that states the applicant completed ground training or a home study course on the aeronautical knowledge requirements for each certificate or rating and that the applicant is prepared for the knowledge test;

(3) Include and clarify the current requirements for the presentation of personal identification found in FAA Order 8700.1. These identification procedures were established in response to the Drug Enforcement Assistance Act of 1988 (Pub. L. 100–690, November 18, 1988). The proposal would require an applicant's identification to consist of:

a. The applicant's photograph;

b. The applicant's signature;

c. The applicant's date of birth, which shows the applicant meets or will meet the age requirements for the certificate sought before the expiration date of the knowledge test report; and

d. The applicant's actual residential address, if different from the applicant's mailing address.

Acceptable types of identification include, but are not limited to, a driver's license, a government identification card, a passport, or other forms of identification that meet the personal identification criteria. The photograph of the applicant would be reproduced on the airman identity card portion of the airman certificate; and

(4) Include applicants for ATP certificates and ratings into proposed § 61.35. Currently, § 61.35 does not apply to the written test for an ATP certificate or a rating associated with that certificate. The passing requirements for a written test for an ATP certificate or a rating associated with that certificate are found in existing § 61.167. Existing § 61.167 states that an applicant for an ATP certificate or rating must pass the knowledge test with a 70 percent minimum passing grade. Under § 61.35, the minimum passing grade is specified by the Administrator. The FAA has determined provisions in § 61.35 and § 61.167 are similar, and therefore, duplication is not necessary.

Section 61.37 Knowledge Tests: Cheating or Other Unauthorized Conduct

The phrase ''Except as authorized by the Administrator'' is proposed to be deleted.

Section 61.39 Prerequisites for Practical Tests

The significant proposed changes to § 61.39 are as follows:

(1) Replace the words ''flight test'' or ''oral test'' with the word ''practical test'';

(2) Replace the words ''written test'' with ''knowledge test'';

(3) Permit an applicant to hold at least a third-class medical certificate to be eligible for a practical test;

(4) Clarify that applicants for an ATP certificate be at least 23 years of age at the time of the practical test;

(5) Revise the existing provision for applicants for ATP certificates and ratings to allow them to take a practical test with an expired airman knowledge test report;

(6) Include the current prerequisites for practical tests procedures found in FAA Order 8700.1. The proposal would require an applicant to:

a. Present the airman knowledge test report at the time the applicant applies for the practical test; and

b. Complete and sign the application form.

(7) Clarify the eligibility prerequisites for a practical test, but the proposal does not contain any additional requirements from the existing requirements;

(8) Clarify the current provision for an applicant who is employed as a flight crewmember under part 121, part 125, or part 135, or as a flight crewmember in military transportation service to take a practical test with an expired airman knowledge test report. The proposal would clarify that to be afforded the relief provided by proposed § 61.39, the applicant would have to either:

a. Be employed as a flight crewmember by a U.S. air carrier or commercial operator under parts 121, 125, or 135 of this chapter and be employed by such a certificate holder at the time of the practical test and—

(i) Have satisfactorily accomplished that operator's approved PIC aircraft qualification training program, which is appropriate to the certificate and rating sought; and

(ii) Have satisfactorily accomplished that operator's approved requalification training requirements, which are appropriate to the certificate and rating sought; or

b. Be employed as a flight crewmember by a U.S. scheduled military air transportation service operator and—

(i) Be employed by such an operator at the time of the practical test; and

(ii) Have accomplished that operator's PIC aircraft qualification training program, which is appropriate to the certificate and rating sought.

Section 61.41 Flight Training Received From Flight Instructors Not Certificated by the FAA.

The FAA proposes to revise § 61.41 for the purposes of simplifying this section. The proposal would replace the word ''instruction'' with the word ''training,'' and clarify that flight instructors not certificated by the FAA are not authorized to give any of the endorsements required under part 61, only the training.

Section 61.43 Practical Tests: General Procedures

The significant proposed changes to § 61.43 are as follows:

(1) Replace the term ''flight test'' with ''practical test'' and ''maneuvers and procedures'' with ''approved areas of operation.''

(2) Include applicants for ATP certificates or ratings by replacing the phrase ''an applicant for a private or commercial pilot certificate, or for an aircraft or instrument rating on that certificate'' with ''an applicant for a certificate or rating, issued under this part.''

(3) Modify the wording of this section for clarity and simplicity purposes. Proposed § 61.43 would be revised to state that an applicant would be required to:

a. Perform the approved areas of operation for the certificate or rating sought within the approved standards;

b. Demonstrate mastery of the aircraft throughout the practical test with the successful outcome of each task performed never seriously in doubt;

c. Demonstrate satisfactory airmanship throughout the practical test;

d. Demonstrate sound judgment throughout the practical test; and

e. Demonstrate single-pilot competence if the aircraft is type certificated for single-pilot operations.

(4) Require an applicant, who wants to accomplish a practical test in an aircraft that is type certificated for single-pilot operations, to demonstrate single-pilot competence. The proposal would require an applicant for a certificate or rating to demonstrate single-pilot competence in the aircraft in which the practical test is taken, if that aircraft is type certificated for one pilot. Most aircraft that are type

certificated for one pilot are currently operated by one pilot. However, some aircraft (e.g., the Cessna Citation 501 and 551) are type certificated for one pilot, but are operated by either one- or two-pilot crews. The FAA realizes that some pilots may desire to operate an aircraft type certificated for one pilot with a two-pilot crew. In this situation, the applicant would have the option not to demonstrate single-pilot competence, but a limitation would be placed on the applicant's airman certificate that states a SIC is required. This limitation could later be removed if the pilot demonstrates single-pilot competence. This proposal is consistent with FAA Order 8700.1, ''General Aviation Operations Inspector's Handbook,'' regarding aircraft that are type certificated for one pilot, but are operated with both one- and two-pilot crews. The proposal would not change regulations for applicants that apply for a certificate or rating in aircraft that are usually operated by one pilot. These applicants already are required to demonstrate single-pilot competence on the practical test; and

(5) Codify the procedures, which are currently found in FAA Order 8700.1, that address the issue of the examiner or the applicant may discontinue the practical test due to inclement weather conditions, aircraft airworthiness, or other flight safety concerns.

Section 61.45 Practical Tests: Required Aircraft and Equipment

Proposed § 61.45 would be retitled to read, ''Practical tests: Required aircraft and equipment,'' instead of ''Flight tests: Required aircraft and equipment.'' The FAA proposes to revise this section by replacing the term, ''flight test'' with ''practical test'' and ''flight proficiency requirements'' with ''approved areas of operation.''

The significant proposed changes to § 61.45 are as follows:

(1) Exclude explicitly the use of ultralights and hang gliders as acceptable aircraft for use in practical tests. The use of ultralights and hang gliders are unacceptable aircraft for use in pilot certificate tests. Aircraft other than ultralights, and the pilots who operate them, are subject to extensive Federal regulations found throughout the FAR. Ultralights are subject to separate standards in part 103, which provides that ultralights are not required to meet the airworthiness certification, pilot certification, aircraft registration, or aircraft marking requirements of the other aircraft. Section 103.1 states, in part, that ultralight vehicles ''are used or intended to be used for recreation or sport purposes only'';

(2) Exclude balloons from the current requirement for pilot seats in an aircraft used for the practical test. Section 61.45 currently requires that the aircraft used for a flight test have ''pilot seats with adequate visibility for each pilot to operate the aircraft safely.'' Most balloons do not have seats and this requirement is customarily waived for balloon practical tests;

(3) Require a lighter-than-air aircraft used for a practical test to have required controls easily reached and operable in a normal manner by both pilots. Permit an examiner to waive the requirement that states ''controls easily reached and operable in a normal manner''. However, the examiner must determine that the lighter-than-air aircraft used for the practical test can be operated safely; and

(4) Require applicants for any practical test to perform the test in a two-place aircraft. This would eliminate the provision for an applicant for a gyroplane class rating to accomplish the practical test in a single place gyroplane. In the past, the FAA has permitted examiners to observe the practical test from the ground when the aircraft was a single-place aircraft. Predominately, gyroplanes were single-place aircraft that required examiners to monitor the practical test from the ground. However, the FAA has determined there are a significant number of two-place gyroplanes that render the current provisions no longer necessary. After discussions with many of the primary manufacturers of gyroplanes, the FAA believes that there are an adequate number of two-place gyroplanes that make the existing rule unnecessary. The FAA believes the importance of the practical test makes it extremely necessary that examiners be able to observe applicants during the practical test.

(5) Permit the use of aircraft with a primary airworthiness certificate to be used for a flight test. The purpose for this proposal is a result of an oversight that occurred during the issuance of the Primary Aircraft Final Rule (57 FR 41360; September 9, 1992). In the **SUPPLEMENTARY INFORMATION** section (in the paragraphs entitled ''Rental and Flight Instruction'' and ''Pilot Certification'') of that final rule, the FAA stated that the use of primary aircraft are permitted to be used for rental, flight instruction, and pilot certification. However, the FAA did not provide for this in that final rule.

Section 61.47 Status of an Examiner Who is Authorized by the Administrator to Conduct Practical Tests

The FAA proposes to change the title of the section from ''Flight tests: Status of FAA inspectors and other authorized flight examiners'' to ''Status of an examiner who is authorized by the Administrator to conduct practical tests.'' Additionally, this section would contain minor editorial and format revisions.

Section 61.49 Retesting After Failure

The FAA proposes to reformat this section. In addition, the FAA proposes to delete the existing requirement for an applicant to wait 30 days before reapplying for a practical test following a second and subsequent disapprovals. In lieu of the 30-day waiting period, the applicant would be required to receive an endorsement from an authorized ground or flight instructor, as appropriate.

Section 61.51 Pilot Logbooks

The significant proposed changes to this section are as follows:

(1) Clarifies the procedure in logging PIC flight time;

(2) Eliminates the term ''solo flight time'' and replaces it with the term ''supervised PIC time'';

(3) Clarifies when a flight instructor and a certificated pilot who are on board an aircraft at the same time may each log PIC flight time;

(4) Permits student pilots who meet certain provisions to log PIC flight time;

(5) Requires the pilot who logs SIC flight time to meet the requirements of § 61.55;

(6) Specifies the necessary information when a pilot logs instrument time for the purpose of meeting the instrument currency requirements;

(7) Specifies the necessary information when a pilot logs training time; and

(8) Specifies the requirements that a flight instructor would need to meet to log PIC flight time.

Section 61.53 Operations During Medical Deficiency

The FAA is proposing to make two significant changes to this section. First, in response to the proposed changes that would permit pilots to exercise the privileges of a recreational pilot certificate without holding a medical certificate, the FAA is proposing to divide § 61.53 into two paragraphs. Paragraph (a) would apply to operations that require pilots to hold medical certificates issued under part 67. Paragraph (b) would apply to operations

in which pilots are not required to hold medical certificates. While paragraph (b) was developed primarily in response to FAA's petition that proposes to permit a pilot without a medical certificate to exercise the privileges of a recreational pilot certificate, it also if adopted, would apply to glider and balloon operations.

Under proposed paragraph (b), a pilot who chooses to exercise recreational pilot privileges or flight in a glider or balloon would not be required to obtain a medical certificate. The pilot, however, still would be required to self evaluate themselves on their current medical condition prior to exercising their pilot certificate privileges. As long as the pilot had no reason to believe that they were not medically fit for piloting, the pilot would be able to conduct these limited operations. As a result, a pilot who fails a medical exam given by an aviation medical examiner (AME) would be able to exercise their pilot certificate provided the pilot exercised recreational pilot privileges only or was piloting a glider or balloon operations. Pilots would be required to self evaluate themselves utilizing their judgment that they are medically fit to fly. In addition, pilots who hold special issuance medical certificates, which require routine check-ups by an AME, may decide to give up their medical certificates and only fly in recreational pilot operations if they believe that they are medically fit to fly. Pilots experiencing medical symptoms that would prevent them from safely exercising the privileges of their certificate, or that raise a reasonable concern, would be on notice that they cannot claim they have no known medical deficiencies. As an example, a pilot who is under physician's care for, or is currently suffering from angina pectoris or a coronary heart disease would not be able to exercise their pilot certificate as the pilot in command or as a required flight crewmember under the provisions of this proposed rule. Another example would be a pilot who is under a physician's care for, or is currently suffering ''blackouts'' would not be able to exercise their pilot certificate as the pilot in command or as a required flight crewmember under the provisions of this proposed rule. The proposed rule changes will require each pilot to self evaluate their current medical condition and then exercise reasonable judgment prior to exercising their pilot certificate. The FAA has not established a list of disqualifying medical conditions because the intent of this proposal is not to establish another class of medical certification to replace the 3rd class medical certificate. However, depending on the responses received from the public on this proposal, the FAA reserves the right to establish a list of disqualifying medical conditions in the final rule if there is a need shown for it. The FAA recognizes that many of its regulations require pilots to exercise reasonable judgment and is dependent on all pilots adhering to an unwritten ''honor code.''

Section 61.55 Second in Command Qualifications

The FAA proposes to revise this section by being more specific about the SIC training requirements.

Section 61.56 Flight Review

This section is being reprinted without changes. Amendment No. 61–93 ''Amendment of the Annual and Biennial Flight Review Requirements'', which became effective on August 31, 1993 (58 FR 40562; July 28, 1993), revised this entire section. Amendment No. 61–93 amended this section by deleting the requirement that recreational pilots and noninstrument-rated private pilots with fewer than 400 hours of flight time (hereafter, the ''affected pilots'') receive 1 hour of ground and 1 hour of flight instruction annually. The final rule amended the biennial flight review by requiring all pilots to receive a minimum of 1 hour of ground instruction and 1 hour of flight instruction. Additionally, the final rule provided that flight instructors who renew their flight instructor's certificate by means of an approved flight instructor refresher course need not accomplish the 1 hour of ground instruction previously required in the BFR.

Section 61.57 Recent Flight Experience: Pilot in Command

The proposed changes in this section are as follows:

(1) Require each pilot to make at least three takeoffs and three landings to a full stop within the preceding 90 days;

(2) Require the three takeoffs and three landings made to a full stop to involve a flight in the traffic pattern at the recommended traffic pattern altitude for the airport;

(3) Delete the clarification of night (the definition already exists in § 1.1);

(4) Modify the requirements for recent instrument experience;

(5) Modify the requirements for the instrument proficiency test; and

(6) Extend the exception requirements for the general and night recency experience requirements of § 61.57 to PICs of part 125 operators as that afforded PICs of part 121 and part 135 operators.

Section 61.58 Pilot-in-Command Proficiency Test: Operation of Aircraft Requiring More Than One Required Pilot

This section has been addressed in a separate NPRM that is entitled, ''Aircraft Flight Simulator Use in Pilot Training, Testing, and Checking at Training Centers,'' and was issued on July 15, 1992 (57 FR 35915; August 11, 1992).

The existing section is republished with minor editorial and format modifications. Those minor editorial modifications would include a proposal to revise existing § 61.58(b)(3), (c)(2), and (e) by eliminating reference to part 127, because there are no part 127 operators and haven't been for years. Furthermore, the FAA proposes to add part 125 operators to existing § 61.58(b)(3), (c)(2), and (e) in reference to persons conducting operations under part 125. Part 125 operators were not addressed in this section when the part was initially established on February 3, 1981, and therefore the FAA proposes to include part 125 pilots. Section 61.59 Falsification, reproduction, or alteration of applications, certificates, logbooks, reports, or records.

The only proposed change to this section involves § 61.59(a)(2) by revising the word ''or'' to ''of'' in the phrase ''* * * exercise of the privileges, or any certificate * * *'' to read ''* * * exercise of the privileges of any certificate * * *'' The purpose for this change is to correct the mistake in the rule that occurred when the rule was first issued. Other than for this minor change, no further changes are anticipated.

Section 61.60 Change of Address

This section would be revised to include ground instructor certificates under part 61.

Subpart B—Aircraft Ratings and Special Certificates

Section 61.61 Applicability

Because the issuance of an additional rating for a flight instructor certificate is contained in subpart H of part 61, the FAA proposes to delete the words ''or instructor'' from this section. Subpart B prescribes the requirements for additional aircraft ratings.

Section 61.63 Additional Aircraft Ratings (Other Than Airline Transport Pilot)

The significant proposed changes in this section are as follows:

(1) Change the title of paragraph (c) of this proposed section to read

''Additional type rating, or an addition of an aircraft type rating associated with an additional aircraft class rating,'' and rewrite the provisions for an additional aircraft type rating.

(2) Revise the required aeronautical experience and training for persons seeking an additional aircraft category and class rating. Regarding the required aeronautical experience and training for an additional category rating, a person would not be required to perform the supervised PIC time, but would be required to meet the specified aeronautical experience and training time required for the category and class rating sought and pilot certificate level held. As an example, a person who holds a private pilot certificate with an airplane single engine land rating, and seeks to add a rotorcraft category with a helicopter class rating to that person's pilot certificate, would be required (in addition to the eligibility and endorsement requirements of § 61.103) to comply with the following aeronautical experience and training of subpart E:

a. Receive training on the aeronautical knowledge areas listed in § 61.105(b), that apply to the helicopter rating sought;

b. Receive training in a helicopter on the approved areas of operation listed in § 61.107(d);

c. Accomplish the following training—

(i) Three hours of cross-country flight training in a helicopter;

(ii) Except as provided in § 61.110, 3 hours of night flight training in a helicopter that includes—

(A) One cross country flight of at least more than 50 nautical miles duration; and

(B) Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of flight training in preparation for the practical test in a helicopter, which must have been performed within the 60-day period preceding the date of the test; and

d. Satisfactorily accomplish a practical test in a helicopter on the approved areas of operation listed in § 61.107(d).

(3) Eliminate the provision that requires a person to meet the specified aeronautical experience and training time required for the class rating sought. The person would be required to receive the required training, but no specified amount of training would be required. The person would be trained to the standards established for the aircraft rating sought and the pilot certificate level held. As an example, a person who holds a private pilot certificate with an airplane category and single engine land class rating, who seeks to add an airplane category and multiengine land class rating to the pilot's certificate would be required (in addition to the eligibility and endorsement requirements of § 61.103) to comply with the following aeronautical experience and training of subpart E:

a. Receive training on the aeronautical knowledge areas listed in § 61.105(b) that apply to the aircraft rating sought;

b. Receive training in a multiengine airplane on the approved areas of operation listed in § 61.107(c); and

c. Satisfactorily accomplish a practical test in a multiengine airplane on the approved areas of operation listed in § 61.107(c).

(4) Clarify when an applicant would be required to accomplish a knowledge test. The proposal would specify that an applicant who already holds an airplane, rotorcraft, powered-lift, or airship rating, and is only seeking an additional aircraft category, class, and type rating, would not be required to accomplish another knowledge test. However, an applicant would still be required to have an endorsement in the applicant's logbook or training record from an authorized flight instructor or ground instructor, and that endorsement must attest that the person is competent on the aeronautical knowledge areas, that relate to the pilot certificate for the aircraft category/class rating sought.

(5) Restrict the issuance of ''VFR only'' limitation for an aircraft type rating to only those aircraft that cannot be used to accomplish the practical test under IFR, because its type certificate makes the aircraft incapable of operating under IFR.

(6) Reformat the section for clarity.

Section 61.65 Instrument Rating Requirements

The significant proposed changes in this section are as follows:

(1) Includes revised aeronautical knowledge areas and areas of operation for an instrument rating for the airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, lighter-than-air category-airship class rating, and powered-lift category rating.

(2) Includes revised instrument training for an instrument rating for the airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, lighter-than-air category-airship class rating, and powered-lift category rating. A person who applies for an instrument rating must have received and logged the following training:

a. At least 40 hours of instrument training from an authorized flight instructor-instrument or ground instructor-instrument on the approved areas of operation of this section;

b. At least 20 hours of the instrument training may be met by training received from an authorized flight instructor-instrument or ground instructor-instrument in an approved flight simulator or training device;

c. At least 5 hours of instrument flight training from an authorized flight instructor-instrument in the category and class aircraft for the instrument rating sought;

d. Instrument training specific to airplanes on cross-country flight procedures that includes at least one cross-country IFR flight in the class airplane for the instrument rating sought and consists of—

(i) A distance of at least 250 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 100 nautical miles between airports;

(ii) An instrument approach at each airport; and

(iii) Approaches using VOR, NDB, and ILS radio navigation aids.

e. Instrument training specific to helicopters on cross-country flight procedures that includes at least one cross-country IFR flight in a helicopter and consists of—

(i) A distance of at least 100 nautical miles along airways or ATC-directed routing, with one of the routes being at least a straight-line distance of 50 nautical miles between airports;

(ii) An instrument approach at each airport; and

(iii) Approaches using VOR, NDB, and ILS radio navigation aids.

f. Instrument training specific to airships on cross-country flight procedures that includes at least one cross-country IFR flight in an airship and consists of—

(i) A distance of at least 50 nautical miles along airways or ATC-directed routing, with one of the routes being at least a straight-line distance of 25 nautical miles between airports;

(ii) An instrument approach at each airport; and

(iii) Approaches using VOR, NDB, and ILS radio navigation aids.

g. Instrument training specific to powered-lift on cross-country flight procedures that includes at least one cross-country IFR flight in a powered-lift and consists of—

(i) A distance of at least 250 nautical miles along airways or ATC-directed routing, with one of the routes being at

least a straight-line distance of 100 nautical miles between airports;

(ii) An instrument approach at each airport; and

(iii) Approaches using VOR, NDB, and ILS radio navigation aids.

(3) Requires applicants to be able to write in the English language.

(4) Includes training in windshear avoidance, aeronautical decision making and judgment in the aeronautical knowledge requirements, and flight deck resource management, to include crew communications and coordination.

(5) Replaces the term ''flight proficiency requirements'' with ''approved areas of operation.''

(6) Requires an applicant to receive training or complete a home study program, and receive an endorsement from a ground or flight instructor on the required aeronautical knowledge areas of this section that are appropriate to the instrument rating sought.

(7) Specifies that an applicant is not required to accomplish another knowledge test, when that person is seeking an additional instrument rating. However, the applicant would still be required to have received and logged ground training from an authorized flight instructor-instrument or ground instructor-instrument, or have accomplished a home study course of training on the approved aeronautical knowledge areas that apply to the instrument rating sought. In addition, the applicant would still be required to have received a logbook or training record endorsement, from the authorized instructor, who gave that person training or reviewed their home study course, certifying the person is prepared to satisfactorily accomplish the required knowledge test.

(8) Specifies that an applicant for a practical test must receive an endorsement from the flight instructor who gave the applicant training and that endorsement must state the applicant is prepared for the practical test. The FAA believes this step-by-step listing of eligibility requirements would help the applicant and the examiner to determine readily which requirements are to be met.

(9) Specifies the minimum distance requirement for cross-country flight training should be measured from one airport to another. This proposal is in agreement with the current FAA interpretation on this issue.

(10) Deletes the requirement that the applicant for an instrument rating must have logged at least 125 hours of total flight time. This proposal would correspond with the current ICAO requirements for an instrument rating, which do not require a minimum amount of total flight time. The FAA also proposes to eliminate the requirement for an applicant to have logged at least 50 hours of cross-country flight as a rated pilot.

(11) Specifies that an applicant who completes an instrument practical test in a multiengine airplane and who holds an airplane category and single-engine class rating is considered to have met the requirements for an instrument rating in a single-engine airplane.

Section 61.67 Category II Pilot Authorization Requirements

This section has been addressed in a separate NPRM that is entitled, ''Aircraft Flight Simulator Use in Pilot Training, Testing, and Checking at Training Centers,'' and was issued on July 15, 1992 (57 FR 35918; August 11, 1992). The existing section is republished without change.

Section 61.69 Glider Towing: Experience and Training Requirements

The FAA proposes to revise the title of this section to read, ''Glider towing: Experience and training requirements.'' The title of existing § 61.69 reads ''Glider towing: Experience and instruction requirements.'' The significant proposed changes in this section are as follows:

(1) Clarifies the requirements for a pilot who desires to act as a PIC of an aircraft towing a glider and the requirements for a pilot who accompanies that person. The proposal clarifies that the accompanying pilot is required to have at least 10 flight hours as a PIC of an aircraft towing a flight, not the applicant. The present wording is confusing and has been misunderstood to mean that a pilot cannot be a PIC until the pilot has made and logged 10 flights as a PIC.

(2) Deletes the current alternative provision in paragraph (c) of this section that permits a pilot, who desires to act as a PIC of an aircraft towing gliders, to log three flights as the sole manipulator of the controls of an aircraft simulating glider towing flight procedures and three flights as a pilot or observer in a glider being towed by another aircraft. Merely logging three flights as sole manipulator of the controls of an aircraft while simulating glider towing flight procedures, or as a pilot or observer in a glider being towed by another aircraft, does not adequately maintain a pilot's proficiency for serving as a PIC towing a glider. The FAA proposes to require a pilot to make at least three flights as the sole manipulator of the controls of an aircraft towing a glider, while accompanied by a pilot who meets the requirements of this proposed section.

Section 61.71 Graduate of an Approved Training Program, Other Than Under This Part: Special Rules.

The title of this section is proposed to be changed from ''Graduates of certificated flying schools: Special rules'' to ''Graduate of an approved training program, other than under this part: Special rules.''

The significant proposed changes in this section are as follows:

(1) Permits the crediting of training conducted under parts 141- or 142-approved training programs.

(2) Permits the issuance of an ATP certificate, type rating, or both, to a person who has satisfactorily accomplished an approved training program and a PIC proficiency check for that aircraft type, in accordance with the PIC requirements of subparts N and O of part 121 of this chapter. The person must apply for that ATP certificate/type rating within 60 calendar days from the date the person satisfactorily completed the training program and PIC proficiency check in that airplane type. The FAA believes the training, checking, and qualification for a PIC, under subparts N and O of part 121, meet the requirements of part 61 for the ATP certificate/type rating.

For pilots of certain part 135 air carriers, on May 8, 1992, the FAA issued Exemption No. 5450 (57 FR 23253; June 2, 1992) to Regional Airline Association member airlines and similarly situated commuter air carriers that operate under part 135. That exemption permits a person who is an employee of a part 135 air carrier that operates airplane types requiring two pilots and having a passenger seating configuration of 10 seats or more (excluding any pilot seat) to train, check, and qualify under subparts N and O of part 121. This proposal will provide for pilots of part 135 air carriers in the same way that Exemption No. 5450 now provides for pilots who are employees of Regional Airline Association's member airlines and similarly qualified commuter air carriers to be issued ATP certificates and type ratings.

(3) Deletes the existing requirement for an applicant seeking instrument rating, who graduates from a pilot school certificated under part 141, to hold a commercial pilot certificate and a second-class medical certificate. This proposal would be in alignment with the proposed revision to § 61.65, and the current rules of ICAO Annex I. Under § 61.65 and ICAO Annex I, an applicant for an instrument rating will only be

required to hold a private pilot certificate. This proposal will keep the requirements for an instrument rating the same whether the applicant is trained under part 61 or part 141. The FAA also hopes to encourage more private pilots to seek instrument ratings. In 1975, the FAA lowered the minimum flight time requirement for an instrument rating from 200 hours to 125 hours with the stated goal of encouraging private pilots to seek instrument ratings. Because a commercial pilot certificate or a second-class medical certificate is not required to exercise private pilot privileges, the requirement for the applicant to hold these certificates conflicts with the FAA's goal.

(4) Deletes the requirement that graduates of pilot schools with examining authority must apply for a certificate or rating within 90 days. These graduates would have 60 days to apply, the same as graduates from pilots schools without examining authority.

Section 61.73 Military Pilots or Former Military Pilots: Special Rules

The significant proposed changes in this section are as follows:

(1) Clarifies the existing requirements for military or former military pilots who apply for a commercial pilot certificate or an aircraft category, class, instrument, or type rating. This proposal clarifies that military and former military pilots are required to have graduated from a military pilot training course or military pilot flight school and received official military aeronautical orders, before applying for their FAA pilot certificate. This, in effect, requires military pilots to have graduated from the course and have aeronautical orders in their possession, prior to applying for the required knowledge test or rating, as appropriate.

(2) Deletes the provision in existing § 61.73(a) that permits military pilots to apply for a private pilot certificate. Historically, military pilots have not chosen a private pilot certificate, because a commercial pilot certificate can be issued without any further requirements. Therefore, the provision allowing military pilots to be issued a private pilot certificate would be deleted, and only a commercial pilot certificate would be issued. A military pilot, who in the past elected a private pilot certificate instead of a commercial pilot certificate, would be permitted to retain that private pilot certificate.

(3) Deletes the last sentence in existing § 61.73(g)(6), ''However, a Tactical (Pink) instrument card issued by the U.S. Army is not acceptable.'' This sentence is obsolete because Tactical (Pink) Instrument cards were last issued by the Army in 1971.

(4) Moves the content of § 61.73(d)(2) to proposed § 61.73(d)(5) and deletes the phrase ''or his certificate is endorsed with the following limitation: VFR only.'' Since 1972, all U.S. military pilot training requires instrument qualification training, and so this phrase is no longer needed. Current and former military pilots who currently hold pilot certificates with the ''VFR only'' limitation would continue to remain valid. After demonstrating instrument competency in the type of airplane for which the type rating is sought, the limitation would be removed.

(5) Includes an administrative clarification for elevating type ratings on the superseded pilot certificate to the ATP certificate level.

(6) Modifies the format, deletes obsolete phraseology, and clarifies the wording of this section.

Section 61.75 Private Pilot Certificate Issued on Basis of a Foreign Pilot License

The title of proposed § 61.75 would be changed from ''Pilot certificate issued on basis of a foreign pilot license'' to ''Private pilot certificate issued on basis of a foreign pilot license.''

The significant proposed changes in this section are as follows:

(1) Deletes the existing provision that permits a pilot with a foreign commercial, senior commercial, or ATP license to apply for a U.S. commercial pilot certificate. The proposal would permit those pilots to apply only for a U.S. private pilot certificate when the issuance is based on their foreign pilot certificate.

(2) Adds a provision that would require pilots with a foreign pilot license to submit a transcription of their foreign pilot license and medical certificate in the English language, unless the licenses and limitations are in the English language.

(3) Deletes the existing provision that permits an applicant to receive a U.S. pilot certificate when the applicant cannot read, speak, write, and understand the English language.

(4) Adds a provision that restricts foreign pilot license holders from exercising their U.S. pilot certificate while under an order of revocation or suspension.

(5) Adds a provision that would permit applicants to use their medical certificate issued by the country that issued the foreign pilot license in lieu of a medical certificate issued under part 67.

(6) Adds a provision that states that a holder of a private pilot certificate, issued under this section, is limited to the privileges placed on that certificate by the Administrator.

(7) Adds a provision that states that a holder of a private pilot certificate, issued under this section, is subject to the limitations and restrictions on the person's U.S. certificate and foreign pilot license.

(8) Adds a provision that states that the U.S. private pilot certificate, issued under this section, is valid only when that person has their foreign pilot license in their personal possession or readily accessible in the aircraft.

Section 61.77 Special Purpose Flight Authorization: Operation of U.S.-Registered Civil Aircraft Leased by a Person Who Is Not a U.S. Citizen

The title of proposed § 61.77 would be changed from ''Special purpose pilot certificate: Operation of U.S.-registered civil aircraft leased by a person not a U.S. citizen'' to read ''Special purpose flight authorization: Operation of U.S.-registered civil aircraft leased by a person who is not a U.S. citizen.''

The significant proposed changes in this section are as follows:

The proposal replaces the issuance of special purpose pilot certificates with special purpose pilot authorizations and expands the use of a special purpose flight authorization to all aircraft. The proposal would also revise the eligibility requirements for a special purpose flight authorization and the related privileges.

The significant proposed changes in this section are as follows:

(1) Permits a pilot who holds an airman certificate or license, issued by another ICAO-member state, to operate a U.S.-registered civil aircraft in foreign air transportation operations with a special purpose pilot authorization, issued for 60 calendar months by the Administrator, in lieu of the current requirement of issuing special purpose pilot certificates. This proposal would eliminate the need to issue special purpose pilot certificates. The FAA believes this proposal will reduce administrative burdens and provide the relief that has been routinely granted through the exemption process. Persons who have been issued a special purpose pilot certificate, prior to the effective date of this rule, would continue to be allowed to exercise the privileges of that certificate until the certificate expires. However, once the special purpose pilot certificate expires, the pilot would be required to surrender the certificate for a special purpose pilot authorization and comply with the provisions contained in proposed § 61.77.

ICAO's Annex 1—''Personnel Licensing, Chapter 1—General Rules and Definitions Concerning Licenses,'' contains in part, standards and recommendations pertaining to the required licenses for flight crewmembers. Section 1.2.1 (authority to act as a flight crewmember) states that:

A person shall not act as a flight crewmember of an aircraft unless a valid license is held showing compliance with the specifications of this Annex and appropriate to the duties to be performed by that person. The license shall have been issued by the state of registry of that aircraft or by any other contracting State and rendered valid by the State of the registry.

Section 1.2.2 (Method of rendering a license valid) states that: When a contracting state renders valid a license issued by another contracting State, as an alternative to the issuance of its own license, it shall establish validity by suitable authorization to be carried with the former license accepting it as the equivalent of the latter the validity of the authorization shall not extend beyond the period of validity of the license.

The FAA's data shows that approximately 14,100 special purpose pilot certificates have been issued in accordance with § 61.77 and approximately 5,300 have been issued in accordance with § 63.23. The FAA believes the process for issuing certificates and the requirement for continued surveillance of these certificates involves considerable expenditure of human and budgetary resources at the FSDO.

(2) Permits a special purpose pilot authorization to be issued to persons to operate any size aircraft instead of the current requirement which limits the eligibility to pilots which operate aircraft with more than 30 passenger seats, excluding any required crewmember seat, and/or 7,500 pounds of payload capacity.

The current § 61.77 states, in part, that the holder of a foreign pilot certificate or license issued by a foreign contracting State to the Convention on International Civil Aviation, who meets the requirements of this section, may hold a special purpose pilot certificate authorizing the holder to perform pilot duties on a civil aircraft of U.S. registry, leased to a person not a citizen of the United States, carrying persons or property for compensation or hire. Currently, special purpose pilot certificates are issued under this section only for aircraft types that can have a maximum passenger seating configuration, excluding any flight crewmember seat, of more than 30 seats or a maximum payload capacity (as defined in § 135.2 of this chapter) of more than 7,500 pounds. The current rules do not permit the issuance of special purpose pilot certificates for the operation of aircraft having 30 or less passenger seats, excluding any required crewmember seat, and/or a payload capacity of 7,500 pounds (3400 kg) or less.

The FAA has received a number of petitions for exemption to § 61.77. The FAA has granted several exemptions to permit persons who are not citizens of the United States, to carry persons or property for compensation or hire in aircraft having 30 or less passenger seats, excluding any required crewmember seat, and/or a payload capacity of 7500 pounds (3400 kg) or less.

Section 305 of the FAA Act mandates that the FAA encourage and foster the development of civil aeronautics and air commerce in the U.S. and abroad. The FAA believes it is in the public interest to promote the use of U.S.-registered aircraft in foreign air transportation. Also, the FAA believes this proposal will encourage the leasing of these aircraft and may provide an important stimulus to the economy of the U.S. aviation industry.

Therefore, the proposal establishes general provisions for issuance of the special purpose pilot authorization and would not include the existing final sentence, which refers to airplanes with more than 30 passenger seats or a maximum payload capacity of more than 7,500 pounds. The FAA believes this restriction is no longer necessary and frequently grants exemptions.

(3) Validates the foreign airman's certificate by having a FSDO issue special purpose pilot authorizations for 60 calendar months. The FAA believes the current process of issuing special purpose pilot certificates, in accordance with § 61.77, should be eliminated. The special purpose pilot authorization would be in a letter format and would be required to be in the possession of the airman while operating the aircraft.

(4) Revises the eligibility requirements of § 61.77 to read as follows:

a. Hold a current foreign pilot certificate;

b. Hold a foreign pilot certificate that shows the appropriate category, class, instrument rating, and type rating, if appropriate;

c. Hold a medical certificate;

d. Surrender a special purpose flight authorization before being issued another authorization;

e. Require the applicant to present a logbook or flight record showing that the applicant meets the part 61 recency of experience requirements; and

f. Clarify that the documentation used to show the applicant has not reached the age of 60 should be ''a birth certificate or other official documentation''; and clarify that an authorization granted to an applicant who will reach the age of 60 years before the authorization's usual expiration date would expire the day before the applicant's 60th birthday.

g. Present documentation that shows the pilot is employed by the lessee and is qualified in the aircraft to be operated.

(5) Permits the use of the special purpose pilot authorization in lieu of a certificate;

(6) Establishes limitations for the use of a special purpose pilot authorization, which would:

a. Increase the current length of a special purpose pilot certificate from 24 months to special purpose pilot authorization to 60 calendar months;

b. Permit a pilot to only hold one special purpose pilot authorization;

c. Clarify that an authorization is for one flight or a series of flights for the time period stated on the authorization;

d. Require the carriage of the special purpose pilot authorization when exercising the privileges of the authorization; and

e. Align the ''age 60'' rule for pilots with the requirements of part 121 for all U.S. and foreign pilots, who are 60 years of age or older, and who are employed by a foreign air carriers that operate U.S.-registered civil aircraft for compensation or hire in scheduled international air services and non-scheduled international air transport operations.

(7) Establishes that a special purpose pilot authorization will expire:

a. With 60 calendar months after issuance, unless it is sooner superseded, revoked, or rescinded;

b. When the lease agreement for the aircraft expires or lessee terminates the employment of the person;

c. Whenever the person's pilot or medical certificate has been suspended, revoked, or is no longer valid; and

d. Whenever the pilot reaches the age of 60.

Subpart C—Student Pilots

The FAA proposes to establish separate subparts for student and recreational pilots. The title of subpart C would be revised from ''Student and Recreational Pilots'' to ''Student Pilots.''

Section 61.81 Applicability

This section is revised to delete the reference to recreational pilot certificates and ratings, which would be incorporated into proposed subpart D.

Section 61.83 Eligibility Requirements for Student Pilots

The significant proposed changes in this section are as follows:

(1) Requires applicants to be able to write in the English language;

(2) Rewords the medical requirements for applicants who desire a rating in a glider or balloon; and

(3) Requires all applicants to meet the English language requirements, which would eliminate the current provision that permits applicants who cannot read, speak, and understand the English language to receive a certificate with an operating limitation as deemed necessary by the Administrator.

Section 61.85 Application

No significant modifications are proposed.

Section 61.87 Supervised PIC Requirements for Student Pilots

The title of § 61.87 would be changed from ''Solo flight requirements for student pilots'' to ''Supervised PIC requirements for student pilots.''

The significant proposed changes in this section are as follows:

(1) Replaces the term ''solo'' with ''supervised PIC.'' The purpose of proposing to replace the term ''solo'' with ''supervised PIC'' is to reflect the intention of the FAA to permit student pilots to log PIC time while under the supervision of an authorized flight instructor. The FAA has reconsidered its position on this matter, and has concluded that if a student pilot is the sole occupant of an aircraft and is operating the controls of the aircraft, then that student pilot should be allowed to log PIC time. Throughout the public hearings on this rulemaking review, the public voiced the belief that student pilots should be allowed to log PIC time when they are the sole occupant of an aircraft and operating the controls of the aircraft. This proposal, in effect, would permit student pilots to log PIC time for the furtherance of a pilot certificate or rating. As example, the existing rules for a commercial pilot certificate-airplane category and class rating requires 100 hours of PIC time. Under the provisions of this proposal, PIC time logged as a student pilot would count toward the total PIC time for a commercial pilot certificate-airplane category and class rating;

(2) Establishes student pilot training for the proposed powered-lift category rating;

(3) Establishes student pilot training for the proposed nonpowered and powered class ratings under the glider category;

(4) Replaces the term ''written examination'' with the term ''test,'' when testing a student pilot on aeronautical knowledge areas prior to a student pilot being authorized to perform a supervised PIC flight. This would permit a school to perform the required test in a format other than on paper, e.g., computer response;

(5) Establishes standardization and clarification for student pilots being authorized to conduct supervised PIC flight at night; and

(6) Includes separate supervised PIC maneuvers and procedures for the—airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, rotorcraft category-gyroplane class rating, glider category-nonpowered class rating, glider category-powered class rating, lighter-than-air category-airship class rating, lighter-than-air category-balloon class rating, and powered-lift category rating.

Section 61.89 General Limitations

No modifications are proposed for this section.

Section 61.91 [Reserved]

The FAA proposes to delete ''§ 61.91 Aircraft limitations: Pilot in command,'' which permits student pilots to act as the PIC in airships requiring more than one flight crewmember. This section duplicates the requirements in proposed § 61.87 which covers all aircraft.

Section 61.93 Supervised PIC Cross-Country Flight Requirements for Student Pilots

The FAA proposes to change the title of § 61.93 from ''Cross-country flight requirements (for student and recreational pilots seeking private pilot certification)'' to ''Supervised PIC cross-country requirements for student pilots.''

The significant proposed changes in this section are as follows:

(1) Changes the term ''solo cross country flight'' to read ''supervised PIC country country flight.'' (This matter of student pilots logging PIC time was previously discussed in proposed § 61.89, and the FAA proposes to revise this section to reflect the conclusion discussed in that section);

(2) Deletes the provision that a student pilot may land at an airport other than the airport of takeoff in an emergency. This provision already exist in § 91.3, ''Responsibility and authority of the pilot in command'';

(3) Clarifies the language of the provision for performing supervised PIC flights to and from an airport within 25 nautical miles of the airport from which the flight originated;

(4) Clarifies the provision for performing repeated supervised PIC cross-country flights that are no more than 50 nautical miles;

(5) Clarifies existing requirements for endorsements on the student pilot's certificate and in the student pilot's logbook. The requirement for an endorsement on the student pilot certificate would not apply to a pilot with a pilot certificate who seeks privileges in another aircraft category, because a certificated pilot would not hold a student pilot certificate;

(6) Adds provisions for the use of radios for VFR navigation and two-way communications, procedures for diverting to alternate airports, and windshear avoidance; and

(7) Establishes separate supervised PIC cross country maneuvers and procedures for the—airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, rotorcraft category-gyroplane class rating, glider category-nonpowered class rating, glider category-powered class rating, lighter-than-air category-airship class rating, lighter-than-air category-balloon class rating, and powered-lift category rating.

Section 61.95 Operations in a Class B Airspace Area and at Airports Located Within a Class B Airspace Area

No substantive modifications are proposed. Minor editorial and standardization of terms are contained in this proposal.

Subpart D—Recreational Pilots

The FAA proposes to establish this as a separate subpart for recreational pilot certificates and ratings.

Section 61.96 Applicability

Proposed § 61.96 would describe provisions that are applicable for the recreational pilot certificates and ratings.

Section 61.96a Eligibility Requirements: General

The FAA proposes to add a new section entitled ''Eligibility requirements: General.'' The proposed § 61.96a would:

(1) Requires applicants to be able to write in the English language;

(2) Requires all applicants to meet the English language requirements, which

would eliminate the current provision that applicants who cannot read, speak, and understand the English language may receive a certificate with the operating limitation deemed necessary by the Administrator;

(3) Deletes the requirement for recreational pilots to hold a medical certificate. Persons who apply for a recreational pilot certificate would be required to affix a signed and dated statement to their application certifying they do not have any known medical defects that makes them unable to pilot the aircraft for the aircraft category and class rating sought; and

(4) Establishes eligibility requirements for the recreational pilot certificate and ratings. The eligibility requirements would require an applicant to:

a. Receive an endorsement from the ground or flight instructor who gave the applicant training or reviewed the applicant's home study course, and that endorsement must state that the applicant is prepared for the knowledge test;

b. Receive an endorsement from the flight instructor who gave the applicant training, and that endorsement must state the applicant is prepared for the practical test; and

c. Meet the aeronautical experience requirements in § 61.99. (The applicant would be required to pass the required knowledge test and practical test.)

Section 61.97 Aeronautical Knowledge

Proposed § 61.97 addresses added aeronautical knowledge requirements, which include ground training on: (1) windshear avoidance; (2) aeronautical decisionmaking and judgment; and (3) preflight actions found in § 91.103.

Section 61.98 Flight Proficiency

This proposed section would establish the approved areas of operation for all aircraft that are permitted to be operated by recreational pilot applicants.

Section 61.99 Aeronautical Experience

The FAA proposes to change the current title, ''Airplane rating: Aeronautical experience,'' to ''Aeronautical experience.'' Proposed 61.99 includes the aeronautical experience requirements for single engine airplanes, helicopters, and gyroplanes that are permitted to be operated by recreational pilot applicants. Proposed § 61.99 would revise the minimum aeronautical experience required for a person to be eligible for a recreational pilot certificate.

The FAA proposes that an applicant for a recreational pilot certificate must accomplish and log at least 30 hours of flight time that includes at least 15 hours of flight training time from an authorized flight instructor and 3 hours of supervised PIC flight time, on the approved areas of operation in § 61.98. This proposal responds to comments made during the public hearings to allow the student and the flight instructor to tailor the required training to individual student needs.

For example, a student who has previous aviation experience and takes readily to the training may be able to complete training for a recreational pilot certificate with only the minimum 30 hours of flight time that includes at least 15 hours of flight training time from an authorized flight instructor and 15 hours of supervised PIC flight time on the approved areas of operation in § 61.98.

However, a student pilot who does not have previous aviation experience or who trains infrequently may need more time than the minimum 30 hours of flight time, 15 hours of flight training time from an authorized flight instructor, and 3 hours of supervised PIC flight time. The student pilot and flight instructor may need to tailor the training to require 27 hours of flight training time from an authorized flight instructor and 3 hours of supervised PIC flight time, on the approved areas of operation in § 61.98 of this part.

Section 61.100 Pilots Based on Small Islands

The FAA proposes to replace the current title of this section from, ''Rotorcraft rating: Aeronautical experience,'' to read ''Pilots based on small islands.'' The proposed aeronautical experience requirements for a rotorcraft category rating would be found in proposed § 61.99.

Proposed § 61.100 would contain the provisions for pilots based on small islands that are currently found in § 61.99.

Section 61.101 Recreational Pilot Privileges and Limitations

The proposed revisions for this section are as follows:

(1) Restructures and edits some of the current paragraphs of this section.

(2) Rewords some portions of this section for clarity purposes.

(3) Rewords and relocates existing § 61.101(f) to proposed paragraph (h). This proposal would basically maintain the same provisions that are now currently in existing § 61.101(f), but would contain some rewording and reformatting for clarity purposes.

(4) Deletes the current restriction that prevents recreational pilots from flying more than 50 nautical miles from an airport where training was received. This proposal along with the proposal to delete the requirements for a medical certificate for recreational pilots, is intended to increase interest in the recreational pilot certificate. The FAA believes this proposal will not have an adverse effect on safety, considering that most of the aeronautical experience will be performed with an authorized flight instructor on board the aircraft.

This proposal would permit a recreational pilot to operate on a flight that exceeds 50 nautical miles from the departure airport, provided the pilot:

a. Has received ground and flight training from an authorized flight instructor on the cross country training requirements of subpart E of this part that apply to the aircraft rating held;

b. Has been found proficient in cross country flying, and has received a logbook endorsement from the authorized flight instructor, who gave the person the cross country training prescribed by subpart E of this part that apply to the aircraft rating held; and

c. Has received a logbook endorsement that certifies the person has received and been found proficient on the cross training requirements of subpart E of this part that apply to the aircraft rating held, which must be carried in their physical possession in the aircraft.

Subpart E—Private Pilots

The proposed establishment of separate subparts for student and recreational pilot certificates will require the regulations pertaining to private pilot certificates and ratings to be relocated from subpart D to subpart E.

Section 61.102 Applicability

No substantive changes are proposed for this section.

Section 61.103 Eligibility Requirements: General

The significant proposed changes in this section are as follows:

(1) Rewords the medical requirements for applicants who desire a rating in a glider or balloon.

(2) Requires all applicants to meet the English language requirements, including the ability to write, which would eliminate the current provision that applicants who cannot read, speak, and understand the English language may receive a certificate with the operating limitation, as deemed necessary by the Administrator.

(3) Requires an applicant to receive an endorsement from a ground or flight instructor who gave the applicant

training or reviewed the applicant's home study course, and that endorsement must state that the applicant is prepared for the knowledge test.

(4) Requires an applicant to receive an endorsement from a flight instructor who gave the applicant training, and that endorsement must state that the applicant is prepared for the practical test.

(5) Requires an applicant to meet the aeronautical experience requirements for the category and class rating sought, before applying for the practical test. The applicant would be required to pass the required knowledge test and practical test. The FAA believes this step-by-step listing of eligibility requirements would be beneficial to the applicant and the examiner.

Section 61.105 Aeronautical Knowledge

Proposed § 61.105 lists the revised aeronautical knowledge requirements for the private pilot certificate. The following aeronautical knowledge areas would be added as a requirement for the private pilot certification: (1) Windshear avoidance; (2) Aeronautical decision making and judgment; and (3) preflight actions found in § 91.103.

Section 61.107 Flight Proficiency

The proposed changes to this section are as follows: (1) Includes separate and revised areas of operation for the airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, rotorcraft category-gyroplane class rating, glider category-nonpowered class rating, glider category-powered class rating, lighter-than-air category-airship class rating, lighter-than-air category-balloon class rating, and powered-lift category rating.

(2) Replaces the term ''flight proficiency requirements'' with the term ''approved areas of operation.''

(3) Requires applicants for a glider category rating to receive training on the approved areas of operation, included in proposed § 61.107, on: Launches, approaches, and landings, if applying for a nonpowered class rating; or Takeoffs, landings, and go-arounds, if applying for a powered class rating.

Section 61.109 Aeronautical Experience

The proposed revisions to this section are as follows:

(1) Includes separate and revised aeronautical experience requirements for the airplane category-single engine class rating; airplane category-multiengine class rating, rotorcraft category-helicopter class rating, rotorcraft category-gyroplane class rating, glider category-nonpowered class rating, glider category-powered class rating, lighter-than-air category-airship class rating, lighter-than-air category-balloon class rating, and powered-lift category rating.

(2) Revises the aeronautical experience requirements for a private pilot certificate with an airplane, rotorcraft, or powered-lift category rating by requiring applicants to have accomplished and logged at least 40 hours of flight time, which includes at least 20 hours of flight training time from an authorized flight instructor and 5 hours of supervised PIC flight time on the approved areas of operation in § 61.107. This proposal responds to comments made during the public hearings requesting that the student and the flight instructor be allowed to tailor the required training to the student needs.

For example, a student who has previous aviation experience and takes readily to the training may be able to complete training for a private pilot certificate with only the minimum 40 hours of flight time, which includes at least 20 hours of flight training time from an authorized flight instructor and 20 hours of supervised PIC flight time, on the approved areas of operation in § 61.107.

However, a student pilot who does not have previous aviation experience or who trains infrequently may need more time than the minimum 40 hours of flight time, 20 hours of flight training time from an authorized flight instructor, and 5 hours of supervised PIC flight time. The student pilot and flight instructor may need to tailor the training to require 35 hours of flight training time from an authorized flight instructor and 5 hours of supervised PIC flight time, on the approved areas of operation in § 61.107.

(3) Includes revised aeronautical experience for:

a. An airplane single engine rating,—

(i) Three hours of cross-country flight training in a single engine airplane;

(ii) Three hours of night flight training in a single engine airplane that includes—

A. A cross country flight of at least 100 nautical miles duration; and

B. Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of instrument flight training in a single engine airplane;

(iv) Three hours of flight training in preparation for the practical test in a single engine airplane, which must have been performed within the 60-day period preceding the date of the test; and

(v) Supervised PIC flying in a single engine airplane, consisting of—

A. One supervised PIC cross-country flight of at least 100 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and

B. Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

b. An airplane multiengine rating,—

(i) Three hours of cross-country flight training in a multiengine airplane;

(ii) Three hours of night flight training in a multiengine airplane that includes—

A. One cross country flight of at least 100 nautical miles duration; and

B. Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of instrument flight training in a multiengine airplane;

(iv) Three hours of flight training in preparation for the practical test in a multiengine airplane, and must have been performed within the 60-day period preceding the date of the test; and

(v) Supervised PIC flying in a multiengine airplane, consisting of—

A. One supervised PIC cross-country flight of at least 100 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and

B. Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

c. A rotorcraft-helicopter rating—

(i) Three hours of cross-country flight training in a helicopter;

(ii) Three hours of night flight training in a helicopter that includes—

A. One cross country flight of at least 50 nautical miles duration; and

B. Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of flight training in preparation for the practical test in a helicopter, and must have been performed within the 60-day period preceding the date of the test; and

(iv) Supervised PIC flying in a helicopter, consisting of—

A. One supervised PIC cross-country flight of at least 50 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 25 nautical miles between the takeoff and landing locations; and

B. Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

d. A rotorcraft-gyroplane rating—

(i) Three hours of cross-country flight training in a gyroplane;

(ii) Three hours of night flight training in a gyroplane that includes—

A. One cross country flight of at least 50 nautical miles duration; and

B. Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of flight training in preparation for the practical test in a gyroplane, which must have been performed within the 60-day period preceding the date of the test; and

(iv) Supervised PIC flying in a gyroplane, and consisting of—

A. One supervised PIC cross-country flight of at least 50 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 25 nautical miles between the takeoff and landing locations; and

B. Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

e. A powered-lift rating—

(i) Three hours of cross-country flight training in a powered-lift;

(ii) Three hours of night flight training in a powered-lift that includes—

A. One cross country flight of at least 100 nautical miles duration; and

B. Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of instrument flight training in a powered-lift;

(iv) Three hours of flight training in preparation for the practical test in a powered-lift, which must have been performed within the 60-day period preceding the date of the test; and

(v) Supervised PIC flying in a powered-lift, consisting of—

A. One supervised PIC cross-country flight of at least 100 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and

B. Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

f. A glider rating—

(i) At least 10 hours of flight training and 20 flights, on the approved areas of operation listed in proposed § 61.107, that apply to the glider class rating sought; or at least 5 hours of flight training and 10 flights on the approved areas of operation listed in § 61.107 that apply to the glider class rating sought. If a person has logged 40 hours of flight time in heavier-than-air aircraft or holds a category and class rating in a glider;

(ii) At least two supervised PIC flights on the approved areas of operation listed in § 61.107 that apply to the glider class rating sought;

(iii) At least 3 flights of flight training in preparation for the practical test within the 60-day period preceding the test and in the class of glider for the rating sought; and

(iv) At least 5 training flight sessions and 2 supervised PIC flights in a nonpowered glider using a winch or auto tow on the appropriate approved areas of operation listed in proposed § 61.107(g). If a person who is applying for a glider category rating with a nonpowered class rating seeks privileges for ground launch procedures.

g. An airship rating, at least 25 hours of flight training in airships on the approved areas of operation listed in proposed § 61.107 (i), which consists of at least—

(i) Three hours of cross-country flight training in an airship;

(ii) Except as provided in proposed § 61.110, 3 hours of night flight training in an airship that includes—

A. One cross country flight of at least more than 25 nautical miles duration;

B. Five takeoffs and 5 landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport;

C. Three hours of instrument flight training in an airship;

D. Three hours of flight training in an airship in preparation for the practical test within the 60-day period preceding the date of the test; and

E. Five hours of supervised PIC flight training in an airship and with an authorized flight instructor.

h. A balloon rating, at least 10 hours of flight training that includes at least 6 flight training sessions on the approved areas of operation listed in proposed § 61.107(j), that includes—

(i) If the training is being performed in a gas balloon, the training must include at least two flights of two hours each that consists of—

A. At least one flight that covers the approved areas of operation appropriate to a gas balloon within 60 days prior to application for the rating; and

B. At least one supervised PIC flight in a gas balloon.

(ii) If the training is being performed in a balloon with an airborne heater, the training must include at least—

A. Two flights of one hour each that covers the approved areas of operation appropriate to a balloon with an airborne heater within 60 days prior to application for the rating; and

B. One supervised PIC flight in a balloon with an airborne heater.

(4) Deletes the exception for applicants not seeking night flying privileges. However, some exceptions from the required night training would still remain and are listed proposed § 61.110.

(5) Adds night cross country training to the aeronautical experience requirements for the private pilot certificate for the airplane, rotorcraft, airship, and powered-lift category ratings. § 61.110 Night flying exceptions for the private pilot certification.

Proposed § 61.110 would establish the night flying exceptions for private pilot certification. The allowable exceptions for the night training requirement are the following:

(1) An applicant with a medical restriction from operating an aircraft at night would not be required to meet the night flight training requirements and would be issued a certificate with a limitation prohibiting night flying; and

(2) An applicant who accomplishes flight training in Alaska would have 12 months after the issuance of the applicant's temporary airman certificate to comply with the night flight training requirements. Alaska is unique in that 6 months out of the year there is no nighttime. However, an applicant who receives flight training in Alaska and is unable to accomplish the night flying training required by proposed § 61.109, would be—

a. Issued a temporary pilot certificate for only 12 calendar months, with a limitation ''Night flying prohibited;'' and

b. Required to comply with the requirements of proposed § 61.110(c) within the 12 calendar month period after issuance of the temporary private pilot certificate, or the certificate will be suspended until the person complies

with the requirements of proposed § 61.110(c).

(3) Explain that the night flying prohibited limitation may be removed when persons—

a. Accomplish the night flight training requirements of proposed § 61.109 in the class of aircraft for which night flying privileges are sought;

b. Present to an examiner, a logbook or training record endorsement from an authorized flight instructor that verifies accomplishment of the night flying requirements of proposed § 61.109 in the class of aircraft for which night flying privileges are sought; and

c. Accomplish the night operations portion of the practical test for the class of aircraft for which night flying is sought.

As previously stated, the FAA does not intend to have persons who have been issued a pilot certificate without meeting the night flying requirements of this proposal, prior to effective date of this rule, to comply with this proposal. Those persons would be allowed to continue to hold that pilot certificate with the night flying limitation. However, if the person seeks an additional rating or higher pilot certificate level, the person would be required to comply with night flying requirements that are appropriate to the pilot certificate level.

Section 61.111 Cross-Country Flights: Pilots Based on Small Islands

The proposed changes to § 61.111 are minor editorial changes only.

Section 61.113 Private Pilot Privileges and Limitations: Pilot in Command

Proposed § 61.113 will be a re-designation of existing § 61.118.

The FAA proposes to eliminate the existing § 61.113, ''Rotorcraft rating: Aeronautical experience.'' The revised aeronautical experience requirements for a rotorcraft category rating will be incorporated in proposed § 61.109.

The proposed changes to this section are as follows:

(1) Permits private pilots to be reimbursed for their aircraft operating expenses for search and location operations that are sanctioned and under the direction and control of a local, State, or Federal law enforcement agency, or an organization involved in search and location operations.

(2) Permits a private pilot who acts as PIC when towing gliders to log the flight time.

(3) Specifies what are the flight operating expenses that a private pilot may share with passengers.

(4) Modifies the requirements for participation in an airlift sponsored by a charitable organization.

(5) Eliminates specific reference regarding a salesman who has logged at least 200 hours to demonstrate an aircraft in flight to a prospective buyer. Even though specific reference to this provision will be eliminated, the privilege will still be provided in proposed § 61.113(b)(1). A private pilot who is an aircraft salesperson will still be allowed to demonstrate aircraft to prospective buyers, but the requirement for the person to have logged at least 200 hours will be eliminated. Throughout this regulatory review, the FAA has attempted to delete and revise obsolete, unnecessary rules without compromising safety. On this issue, the FAA has determined that eliminating the requirement for private pilots to have logged at least 200 hours prior to demonstrating aircraft to prospective buyers is unnecessary and no data could be found to justify continuance of the rule. In effect, the proposed elimination of this requirement will enable private pilots increased use of their private pilot certificates.

Section 61.115 Balloon Rating: Limitations

Proposed § 61.115 will be a re-designation of existing § 61.119.

The FAA proposes to eliminate the existing § 61.115 ''Glider rating: Aeronautical experience.'' The revised aeronautical experience requirements for a glider category rating will be incorporated in proposed § 61.109.

The proposed changes to this section are as follows:

(1) Deletes references to the phrase ''hot air balloon without airborne heaters,'' and classifies balloons as either ''gas balloons'' or ''balloons with airborne heaters.'' The phrase ''hot air balloon without an airborne heater'' described a balloon that was in existence at one time, but is no longer available. A ''hot air balloon without an airborne heater'' is a balloon that involves heating the air inside the balloon's envelope from a ground-based fire. The balloon and its occupant then ascend until the balloon deflates, and the occupant exits the balloon by parachute.

(2) Incorporates the current operating limitations for private pilots who perform their practical test in a gas balloon as opposed to those who perform the test in a balloon with an airborne heater. The wording of the operating limitations specified in this section would clarify that persons requesting removal of the operating limitations off their certificate would be required to obtain the required aeronautical experience in that kind of balloon and receives a logbook endorsement from an authorized instructor who attests to the person's accomplishment of the required aeronautical experience and ability to satisfactorily operate that balloon. However, accomplishment of an additional practical test would not be required provided the person is not seeking a higher level of pilot certificate (i.e., a private pilot seeking to obtain a commercial pilot certificate).

Section 61.117 Private Pilot Privileges and Limitations: Second in Command of Aircraft Requiring More Than One Pilot

Proposed § 61.117 will be a re-designation of existing § 61.120 and § 61.120 will be placed in reserve.

The existing § 61.118 ''Private pilot privileges and limitations: Pilot in command'' will be redesignated as § 61.113, and § 61.118 will be placed in reserve.

The existing § 61.119, ''Free balloon rating: Limitations'' will be redesignated as § 61.115 and be retitled as ''Balloon rating: Limitations'' and § 61.119 will be placed in reserve.

The existing § 61.120, ''Private pilot privileges and limitations: Second in command of aircraft requiring more than one pilot'' will be redesignated as § 61.117, and § 61.120 will be reserved.

Subpart F—Commercial Pilots

The proposal to establish separate subparts for student and recreational pilot certificates would require the regulations for commercial pilot certificates and ratings to be relocated from subpart E to subpart F.

Section 61.121 Applicability

No substantive changes are proposed for this section.

Section 61.123 Eligibility Requirements: General

The significant proposed changes in this section are:

(1) Requires applicants to be able to write in the English language.

(2) Rewords the medical requirements for applicants who desire a rating in a glider or balloon.

(3) Requires all applicants to meet the English language requirements, which would eliminate the current provision under which applicants who cannot read, speak, and understand the English language may receive a certificate with the operating limitation as deemed necessary by the Administrator.

(4) Permits applicants to only hold a third-class medical certificate at the time of the practical test. However as currently required, the commercial pilot would still be required to hold a second-class medical certificate for operations requiring a commercial pilot certificate.

(5) Requires an applicant to hold a private pilot certificate, before applying for a commercial pilot certificate.

(6) Revises the eligibility requirements for the commercial pilot certificate and ratings by specifying that an applicant would be required to:

a. Receive from the ground or flight instructor who gave the applicant training or reviewed the applicant's home study course, an endorsement that states the applicant is prepared for the knowledge test;

b. Receive an endorsement from the flight instructor who gave the applicant training that states the applicant is prepared for the practical test; and

c. Meet the aeronautical experience requirements for the category and class rating sought before applying for the practical test. This is in addition to the current requirements for the applicant to pass the required knowledge test and practical test. The FAA is of the opinion that this step-by-step listing of eligibility requirements would be beneficial to the applicant and the examiner.

Section 61.125 Aeronautical Knowledge

The significant proposed changes in this section will:

(1) Include separate and revised aeronautical knowledge areas for the airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, rotorcraft category-gyroplane class rating, glider category-nonpowered class rating, glider category-powered class rating, lighter-than-air category-airship class rating, lighter-than-air category-balloon class rating, and powered-lift category rating.

(2) Modify the aeronautical knowledge requirements to include windshear avoidance, aeronautical decision making and judgment.

(3) Delete the existing aeronautical knowledge requirement of instrument procedures and the requirement for instrument flight training for an airship rating. This proposed deletion is a result of the proposal for the instrument-airship rating and the proposed flight instructor-airship rating.

Section 61.127 Flight Proficiency

The significant proposed changes in this section will:

(1) Include separate and revised areas of operation for the airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, rotorcraft category-gyroplane class rating, glider category-nonpowered class rating, glider category-powered class rating, lighter-than-air category-airship class rating, lighter-than-air category-balloon class rating, and powered-lift category rating.

(2) Replace flight proficiency requirements with approved areas of operation.

(3) Require an applicant for a glider category rating to receive training on:

a. Launches, approaches, and landings, if applying for a nonpowered class rating; or

b. Takeoffs, landings, and go-arounds if applying for a powered class rating.

Section 61.129 Aeronautical Experience

Proposed § 61.129 would be retitled, ''Aeronautical experience.'' Proposed § 61.129 would be reformatted by class of aircraft, and would contain separate and revised aeronautical experience for each class of aircraft.

The significant proposed changes in this section are as follows:

(1) Includes revised and separate aeronautical experience requirements for the airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, rotorcraft category-gyroplane class rating, glider category-nonpowered class rating, glider category-powered class rating, lighter-than-air category-airship class rating, lighter-than-air category-balloon class rating, and powered-lift category rating.

(2) Revises the aeronautical experience requirements for the single engine airplane to:

a. Twenty hours of training on the approved areas of operation in proposed § 61.127(b), which includes at least:

(i) Five hours of instrument training in a single engine airplane;

(ii) Ten hours of training in a single engine airplane that has a retractable landing gear, flaps, and a controllable pitch propeller, or is turbine-powered;

(iii) One cross-country flight in a single engine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iv) One cross-country flight in a single engine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(v) Three hours in a single engine airplane, in preparation for the practical test within 60 days preceding the date of the test.

b. Ten hours of supervised PIC flying in a single engine airplane on the approved areas of operation in proposed § 61.127(b), which includes at least—

(i) One cross-country flight, if the training is being performed in the state of Hawaii, that cross-country flight must involve landings at a minimum of three points and one of the routes must have a straight-line distance of at least 150 nautical miles;

(ii) One cross-country flight, if the training is being performed in a State other than Hawaii, then that cross-country flight must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(iii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower.

(3) Revises the aeronautical experience requirements for the multiengine airplane to:

a. Twenty hours of training on the approved areas of operation in proposed § 61.127(c), which includes at least—

(i) Five hours of instrument training in a multiengine airplane;

(ii) Ten hours of training in a multiengine airplane that has a retractable landing gear, flaps, and a controllable pitch propeller, or is turbine-powered;

(iii) One cross-country flight in a multiengine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iv) One cross-country flight in a multiengine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(v) Three hours in a multiengine airplane, in preparation for the practical test within 60 days preceding the date of the test.

b. Ten hours of supervised PIC flying in a multiengine airplane on the approved areas of operation in proposed § 61.127(c), which includes at least—

(i) One cross-country flight, if the training is being performed in the state of Hawaii, that cross-country flight must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(ii) One cross-country flight, if the training is being performed in a State other than Hawaii, that cross-country flight must involve landings at a minimum of three points and one of the routes must have a straight-line distance of at least 250 nautical miles; and

(iii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a

flight with a traffic pattern) at an airport with an operating control tower.

(4) Adds aeronautical experience requirements for the new powered-lift category rating to:

a. Twenty hours of training on the approved areas of operation in proposed § 61.127(f), which includes at least—

(i) Five hours of instrument training in a powered-lift;

(ii) One cross-country flight in a powered-lift of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iii) One cross-country flight in a powered-lift of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(iv) Three hours in a powered-lift, in preparation for the practical test within 60 days preceding the date of the test.

b. Ten hours of supervised PIC flying in a powered-lift on the approved areas of operation in proposed § 61.127(f), which includes at least—

(i) One cross-country flight, if the training is being performed in the state of Hawaii, that cross-country flight must involve landings at a minimum of three points and one of the routes must have a straight-line distance of at least 150 nautical miles;

(ii) One cross-country flight, if the training is being performed in a State other than Hawaii, that cross-country flight must involve landings at a minimum of three points and one of the routes must have a straight-line distance of at least 250 nautical miles; and

(iii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower.

(5) Revises the aeronautical experience requirements for the helicopter to:

a. Twenty hours of training on the approved areas of operation in proposed § 61.127(d), which includes at least—

(i) Five hours of instrument training in a helicopter;

(ii) One cross-country flight in a helicopter of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iii) One cross-country flight in a helicopter of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(iv) Three hours in a helicopter, in preparation for the practical test within 60 days preceding the date of the test.

b. Ten hours of supervised PIC flying in a helicopter on the approved areas of operation in proposed § 61.127(d), which includes at least—

(i) One cross-country flight with landings at a minimum of three points, and one of the routes having a straight-line distance of at least 50 nautical miles from the original point of departure; and

(ii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern).

(6) Revises the proposed aeronautical experience requirements for the gyroplane to:

a. Twenty hours of training on the approved areas of operation in proposed § 61.127(e), which includes at least—

(i) Five hours of instrument training in a gyroplane;

(ii) One cross-country flight in a gyroplane of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iii) One cross-country flight in a gyroplane of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(iv) Three hours in a gyroplane, in preparation for the practical test within 60 days preceding the date of the test.

b. Ten hours of supervised PIC flying in a gyroplane on the approved areas of operation in proposed § 61.127(e), which includes at least—

(i) One cross-country flight with landings at a minimum of three points, and one of the routes must have a straight-line distance of at least 50 nautical miles from the original point of departure; and

(ii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern).

(7) Revises the proposed aeronautical experience requirements for the airship to:

a. Twenty hours of training in airships on the approved areas of operation in proposed § 61.127(i), which includes at least—

(i) Three hours of flight training in an airship, in preparation for the practical test within the 60-day period preceding the date of the test;

(ii) Five hours of instrument training in airships;

(iii) One cross-country flight in an airship of at least 1 hour in duration, a total straight-line distance of more than 25 nautical miles from the original point of departure, and occurring in day-VFR conditions; and

(iv) One cross-country flight in an airship of at least 1 hour in duration, a total straight-line distance of more than 25 nautical miles from the original point of departure, and occurring in night-VFR conditions.

b. Ten hours of supervised PIC flight training with an authorized flight instructor in airships, on the approved areas of operation in proposed § 61.127(i), which includes at least—

(i) One cross-country flight with landings at a minimum of three points, and one of the routes having a straight-line distance of at least 25 nautical miles from the original point of departure; and

(ii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern).

(8) Revises the proposed aeronautical experience requirements for the nonpowered glider to—

a. Five hours of flight training or 10 flights on the approved areas of operation of proposed § 61.127(g) that must include 3 flights in preparation for the practical test within 60-day period preceding the date of the test.

b. Five supervised PIC flights in a nonpowered glider on the approved areas of operation of proposed § 61.127(g).

c. If an applicant with a glider category rating and a nonpowered class rating seeks privileges for ground launch procedures, that person must accomplish and log at least five flights of flight training and two supervised PIC flights in a nonpowered glider using a winch or auto tow on the approved areas of operations in proposed § 61.127(g).

(9) Adds aeronautical experience requirements for the powered glider to:

a. Twenty-five hours and 100 flights in gliders as PIC, which includes at least 10 flights in a powered glider;

b. Two hundred hours in heavier-than-air aircraft, and 20 flights in gliders as PIC, which includes at least 10 flights in a powered glider; or

c. The flight time requirements in proposed § 61.129(f) (1) or (2) must consist of at least the following flight training in a powered glider—

(i) Five hours of flight training or 10 flights on the approved areas of operation of proposed § 61.127(h), which includes 3 flights in preparation for the practical test within the 60-day period preceding the date of the test; and

(ii) Five supervised PIC flights in a powered glider on the approved areas of operation of proposed § 61.127(h).

(10) Revises the aeronautical experience requirements for the balloon to:

a. Accomplish and log at least 35 hours of flight time as a pilot, which includes at least the following requirements—

(i) Twenty hours in balloons;

(ii) Ten flights in balloons; and

(iii) Two flights in balloons as the PIC.

b. Ten hours of flight training that includes 10 flights of flight training in balloons on the approved areas of operation of proposed § 61.127(j), which consist of at least—

(i) If the training is received in a gas balloon, the training must include at least—

A. Two flights of 1 hour each in a gas balloon;

B. One flight in a gas balloon involving a controlled ascent to 10,000 feet above the surface;

C. Two flights in a gas balloon, in preparation for the practical test within the 60-day period preceding the date of the test; and

D. Two supervised PIC flights in a gas balloon on the approved areas of operation in proposed § 61.127(j).

(ii) If the training is received in a balloon with an airborne heater, the training must include at least—

A. Two flights of 30 minutes each in a balloon with an airborne heater;

B. One flight involving a controlled ascent to 5,000 feet above the surface in a balloon with an airborne heater; and

C. Two flights in a balloon with an airborne heater, in preparation for the practical test within the 60-day period preceding the date of the test; and

D. Two supervised PIC flights in a balloon with an airborne heater on the approved areas of operation in proposed § 61.127(j).

(11) Permits the use of a turbine powered airplane in lieu of the current provision for receiving training in an airplane that has flaps, retractable landing gear, and controllable propellers.

(12) Replaces the terms ''free balloon'' and ''hot air balloon'' with ''balloon'' only.

(13) Deletes references to the phrase ''hot air balloon without airborne heaters,'' and classifies balloons as ''gas balloons'' and ''balloons with airborne heaters.'' The phrase ''hot air balloon without an airborne heaters'' describes a balloon that is no longer available. A ''hot air balloon without an airborne heater'' describes a balloon that involved heating the air inside the balloon's envelope from a ground-based fire, then the balloon and its occupant ascend until the balloon deflates, and then the occupant exits the balloon by parachute.

Section 61.131 Exceptions to the Night Flying Requirements for the Commercial Pilot Certificate

Proposed § 61.131 would be a new section and entitled, ''Exceptions to the night flying requirements for the commercial pilot certificate.'' This proposal would delete the exception for applicants not seeking night flying privileges; however, an applicant with a medical restriction from operating an aircraft at night would not be required to meet the night flight training requirements and would be issued a certificate with a limitation. In addition, an applicant who accomplishes flight training in Alaska would have 12 months after the issuance of the applicant's temporary airman certificate to comply with the night flight training requirements.

The current provisions of § 61.131 ''Rotorcraft ratings: Aeronautical experience'' would be moved to proposed § 61.129.

Section 61.133 Commercial Pilot Privileges and Limitations: General

Proposed § 61.133 ''Commercial pilot privileges and limitations: General'' would be a redesignation of existing § 61.139. The current provisions of § 61.133 ''Glider rating: Aeronautical experience'' would be moved to proposed § 61.129.

The significant proposed changes in this section are as follows:

(1) Clarifies the privileges for persons who hold a commercial pilot certificate regarding the compensation or hire issue. This revision is in response to a petition for rulemaking from Beverly J. Cameron, who on June 20, 1992, petitioned the FAA to revise the rule. Ms. Cameron stated that the current wording of § 61.139 was misleading. The FAA agrees, and thus has proposed to revise § 61.139.

(2) Eliminates the privilege in existing § 61.139 for commercial pilots with a lighter-than-air category and associated class rating to give training in an airship or a free balloon, because of the proposed flight instructor certificate for the lighter-than-air category.

(3) Adds the limitation that is in existing § 61.129, which prohibits commercial pilots with an airplane category rating, but without an instrument-airplane rating, from carrying passengers for hire in airplanes on cross-country flights of more than 50 nautical miles or at night, would appear in this section. The same limitation is proposed for commercial pilots with a lighter-than-air category and an airship class rating but without an instrument—airship rating, and commercial pilots with a powered-lift category rating but without a instrument—powered-lift rating.

(4) Revises ''hot air balloon without airborne heaters,'' in existing § 61.139, to ''gas balloons'' and ''balloons with airborne heaters.'' The purpose for this proposal is to align the phraseology in this section with the other references to balloons throughout this notice.

(5) Revises the wording for the operating limitations that restrict the pilot privileges for the kind of balloon in which the person accomplishes the practical test. The person may remove the limitation by completing the required aeronautical experience in a gas balloon or a balloon with an airborne heater, as appropriate, and receives a logbook endorsement from an authorized instructor who attests to the person's accomplishment of the required aeronautical experience and ability to satisfactorily operate the specific kind of balloon.

Section 61.135 [Reserved]

The current provisions of § 61.135 ''Airship rating: Aeronautical experience'' would be moved to proposed § 61.129.

Section 61.137 [Reserved]

The current provisions of § 61.137 ''Free balloon rating: Aeronautical experience'' would be moved to proposed § 61.129.

Section 61.139 [Reserved]

The current provisions of § 61.139 ''Commercial pilot privileges and limitations: General'' would be moved to proposed § 61.133.

Section 61.141 [Reserved]

The current provisions of § 61.141 ''Airship and free balloon ratings: Limitation'' would be moved to proposed § 61.133.

Subpart G—Airline Transport Pilots

The proposal to establish separate subparts for student and recreational pilot certificates would require the regulations for ATP certificates to be relocated from subpart F to subpart G.

Section 61.151 Applicability

In order to align this subpart with the other subparts, the FAA proposes to establish an applicability section in subpart G.

Section 61.153 Eligibility Requirements: General

In order to accommodate proposed ''§ 61.151 Applicability,'' existing ''§ 61.151 Eligibility requirements: General'' would be renumbered § 61.153.

The significant proposed changes in this section are as follows:

(1) Eliminates the existing requirement for an applicant to be able to ''speak [the English language] without accent or impediment of speech that would interfere with two-way radio conversation.'' However, applicants would be required to read, speak, write, and understand the English language to be eligible to apply for the ATP certificate.

(2) Permits applicants to only hold a third-class medical certificate at the time of the practical test. However as currently required, an ATP would be required to hold a first class medical certificate for operations requiring an ATP certificate.

(3) Requires an applicant to hold a commercial pilot certificate and an instrument rating, before applying for the ATP certificate.

(4) Eliminates the requirement that an applicant be a ''high school graduate or its equivalent in the Administrator's opinion, based on the applicant's general experience and aeronautical experience, knowledge, and skill.''

(5) Includes a proposal to revise the eligibility requirements for all certificates and ratings by specifying that an applicant would be required to:

a. Meet the aeronautical experience requirements for the category and class rating sought before applying for the flight portion of the practical test;

b. Pass the required knowledge test; and

c. Pass the required practical test.

(6) Clarify that an applicant need not possess the aeronautical experience requirements for an ATP certificate before taking the knowledge test. Applicants for other certificates and ratings currently are not required to obtain aeronautical experience requirements before taking the appropriate knowledge test. However, current § 61.153 requires an applicant for an ATP certificate with an airplane rating to meet the experience requirements in § 61.155 before applying to take the ATP knowledge test. In keeping with procedures for other knowledge tests, proposed § 61.153 would permit applicants to take the ATP knowledge test before obtaining the hours necessary to become an ATP.

(7) Includes requirements found in existing § 61.155 for applicants who are military pilots and applicants who hold a pilot license issued by a member State of ICAO.

Section 61.155 Aeronautical Knowledge

In order to accommodate proposed ''§ 61.151 Applicability,'' existing ''§ 61.153 Airplane rating: Aeronautical knowledge'' would be renumbered § 61.155, and retitled to read ''Aeronautical knowledge.'' Proposed § 61.155 would combine the aeronautical knowledge requirements for applicants of airplane, helicopter, and powered-lift ratings.

The proposed revisions to this section are as follows:

(1) Establishes all of the required aeronautical knowledge areas in this section. Currently, the aeronautical knowledge areas are located in separate sections of subpart F.

(2) Adds aeronautical knowledge requirements on windshear avoidance and aeronautical decision making and judgment.

(3) Clarifies that an applicant for a type rating would not be required to take an additional knowledge test, if the applicant already holds an ATP certificate with the appropriate category ratings.

Section 61.157 Flight Proficiency

The FAA proposes to change the title of existing § 61.155 ''Airplane rating: Aeronautical experience'' to read § 61.157 ''Flight proficiency.'' The aeronautical experience requirements for an airplane rating would appear in proposed § 61.159. Proposed § 61.157 would combine the flight proficiency requirements for applicants of airplane, helicopter, and powered-lift ratings.

The significant proposed revisions in this section are as follows:

(1) Includes separate and revised areas of operation for the airplane category-single engine class rating, airplane category-multiengine class rating, rotorcraft category-helicopter class rating, and powered-lift category rating.

(2) Replaces the term, ''flight proficiency requirements'' with the term, ''approved areas of operation,'' so the terminology in this section is the same as the other rules of part 61.

(3) Includes an administrative clarification that the type ratings on the superseded pilot certificate for the category and class of aircraft that the person satisfactorily accomplished the ATP practical test in will be elevated to the ATP certificate level.

Section 61.159 Aeronautical Experience: Airplane Category Rating

The FAA proposes to revise and redesignate § 61.157, ''Airplane rating: Aeronautical skill,'' to read § 61.159 ''Aeronautical experience: Airplane category rating.''

Proposed § 61.159 would include the existing aeronautical experience requirements for an airplane category rating with no substantive changes.

Section 61.161 Aeronautical Experience: Rotorcraft Category and Helicopter Class Rating With a Type Rating

Existing ''§ 61.159 Rotorcraft rating: Aeronautical knowledge'' would be moved to proposed § 61.155. The FAA proposes to revise and redesignate § 61.161, ''Rotorcraft rating: Aeronautical experience,'' to read § 61.161, ''Aeronautical experience: Rotorcraft category and helicopter class rating with a type rating.'' Proposed § 61.161 will include the existing aeronautical experience requirements for a rotorcraft category rating with no substantive changes.

Section 61.163 Aeronautical Experience: Powered-Lift Category Rating

The FAA proposes to redesignate this section as § 61.163 ''Aeronautical experience: Powered-lift category rating.'' Proposed § 61.163 will list the aeronautical experience requirements for an ATP certificate with a powered-lift category rating. Existing § 61.161, ''Rotorcraft rating: Aeronautical skill,'' would be eliminated. The provisions of existing § 61.161 would be adequately covered by proposed §§ 61.43 and 61.153.

Section 61.165 Additional Aircraft Category Ratings

Proposed § 61.165 ''Additional aircraft category ratings'' would be a redesignation of existing § 61.165, ''Additional category ratings.''

The FAA proposes to add a powered-lift category rating to this section.

Section 61.167 General Privileges and Limitations

Proposed § 61.167 would be a redesignation of existing § 61.171. Proposed § 61.167 would contain the current limitation found in existing § 61.155(d). That limitation applies to applicants who credit SIC or flight engineer time in meeting the total time requirement for an ATP certificate. Existing § 61.167, ''Tests,'' would be eliminated. The rules for the knowledge and practical test are found in proposed §§ 61.35 and 61.43.

Section 61.169 [Reserved]

The FAA proposes to eliminate this section and place it in reserve. The FAA has determined the provisions of § 61.169, ''Instruction in air transportation service,'' are already addressed in §§ 121.411 and 135.337 of this chapter. Therefore, this section would no longer be necessary.

Section 61.171 [Reserved]

The provisions of existing § 61.171 would be moved to proposed § 61.167. This section would be placed in reserve.

Subpart H—Flight Instructors

The proposal to establish separate subparts for student and recreational pilot certificates would require moving the regulations for flight instructor certificates and ratings from subpart G to subpart H.

Section 61.181 Applicability

No substantive changes are proposed in this section.

Section 61.183 Eligibility Requirements

The significant proposed changes in this section are as follows:

(1) Requires applicants for a flight instructor certificate with an airplane rating or with a glider rating, to have demonstrated instructional proficiency in stall awareness, spin entry, spins, and spin recovery procedures prior to applying for the practical test.

(2) Permits applicants for a flight instructor certificate, who satisfactorily accomplish a flight instructor-instrument practical test in a multiengine airplane, and who also hold an airplane category and single-engine class rating on their flight instructor certificate will also be awarded a flight instructor instrument-airplane single engine rating.

(3) Requires applicants for flight instructor certificates to have logged at least 15 hours of PIC time in the category and class of aircraft that is appropriate to the flight instructor rating sought.

(4) Rewords the eligibility requirements for flight instructor certificates and ratings by specifying that an applicant would be required to:

a. Receive from the ground or flight instructor who gave the applicant training or reviewed the applicant's home study course, an endorsement that states the applicant is prepared for the knowledge test; and

b. Receive from the flight instructor who gave the applicant training, an endorsement that states the applicant is prepared for the practical test. These requirements are in addition to the current requirements for the applicant to pass the required knowledge test and practical test.

(5) Expands the current requirement for an applicant for a flight instructor certificate with an airplane or instrument rating to hold an instrument rating that is appropriate to the airplane class. Proposed § 61.183 would require applicants for an airship, helicopter, or a powered-lift rating to also hold an instrument rating that is appropriate to those aircraft ratings.

Section 61.185 Aeronautical Knowledge

Proposed § 61.185 contains the required aeronautical knowledge areas for a flight instructor certificate. The proposed revisions to this section are as follows:

(1) Requires flight instructor applicants to receive and log ground training on the aeronautical knowledge areas in which ground training is required for a recreational pilot certificate. This is an addition to the current requirements which only require aeronautical knowledge areas for a private and commercial pilot certificate.

(2) Requires flight instructor applicants to receive and log ground training on the aeronautical knowledge areas in which ground training is required for an instrument rating, if that person is applying for a flight instructor—airplane category and single-engine class rating; flight instructor—airplane category with an multiengine class rating; flight instructor—lighter-than-air category with an airship class rating; flight instructor—powered-lift category rating; flight instructor instrument—with the appropriate aircraft category and class rating.

Section 61.187 Flight Proficiency

The significant revisions being proposed for this section are as follows:

(1) Moves the requirement for the minimum experience requirements for a flight instructor who can train first-time flight instructor candidates to proposed § 61.195.

(2) Establishes separate and revised areas of operation for the flight instructor: -airplane category-single engine class rating, -airplane category-multiengine class rating, -rotorcraft category-helicopter class rating, -rotorcraft category-gyroplane class rating, -glider category-nonpowered class rating, -glider category-powered class rating, -lighter-than-air category-airship class rating, -lighter-than-air category-balloon class rating, and -powered-lift category rating.

Section 61.189 Flight Instructor Records

The proposed revision to this section is the requirement for a flight instructor to retain a copy of each syllabus they use to train students.

Section 61.191 Additional Flight Instructor Ratings

No substantive changes to this section are proposed. The requirement in existing § 61.191(a) that a flight instructor applicant for additional rating must hold an effective pilot certificate with ratings appropriate to the flight instructor rating sought would be moved to proposed § 61.183. The requirement in existing § 61.191(b) that a flight instructor applicant for an additional rating must have at least 15 hours of PIC time in the category and class of aircraft that is appropriate to the flight instructor sought would be moved to proposed § 61.183.

Section 61.193 Flight Instructor Endorsements and Authorizations

The FAA proposes to revise the title of this section from ''Flight instructor authorizations'' to read ''Flight instructor endorsements and authorizations.''

The proposed revisions to this section are as follows:

(1) Deletes the detailed listing of instructor endorsements. The listing would be replaced by more general language.

(2) Eliminates the amendment to existing § 61.193 that replaces ''terminal control area'' with ''Class B airspace area.''

Section 61.195 Flight Instructor Limitations and Qualifications

The FAA proposes to revise the title from ''Flight instructor limitations'' to read ''Flight instructor limitations and qualifications.''

The significant changes in this section are as follows:

(1) Revises the minimum experience requirements for a flight instructor who can train first-time flight instructor candidates.

(2) Makes editorial restructuring and rewording this section.

(3) Includes a revision to the current limitation that a flight instructor may not conduct more than 8 hours of flight training in 24 hours. The FAA proposes to limit a flight instructor to a total of 8 hours of commercial flying in a 24-hour period, and flight training would be considered commercial flying.

(4) Clarifies the current requirement that to give training in an aircraft that requires a type rating, the flight instructor must hold a type rating in

that aircraft. The existing rule implies that the flight instructor is required to hold a type rating on the instructor's pilot and flight instructor certificates. The proposal would specify that flight instructors are required to hold a type rating on their pilot certificate and not their instructor certificate.

(5) Clarifies that a flight instructor, who gives instrument flight training for the issuance of an instrument rating or a type rating that is not limited to VFR, is required to hold the instrument rating, for the category and class of aircraft for which the instrument training is being given, on both the instructor's pilot certificate and flight instructor certificate.

(6) Revises the current flight instructor endorsements. The requirement for a flight instructor to endorse a student pilot's certificate and logbook for supervised PIC cross-country flight would be clarified. Under this proposal, the flight instructor would be required to determine that the flight could be performed within any limitations in the student's logbook that the instructor considers necessary for the safety of flight. The intent of the proposal is to ensure that the dispatching flight instructor is aware of any special limitations pertaining to an individual student.

(7) Clarifies that the flight instructor who endorses a pilot's logbook for a flight review or an instrument proficiency test must have conducted that flight review or instrument proficiency test.

(8) Requires a flight instructor to give all training from a control seat that meets the requirements of § 91.109. Section 91.109 requires, with the exception of a balloon, that the aircraft have fully functioning dual controls. The regulation provides for instrument flight training to be given in a single-engine airplane equipped with a single, functioning, throwover control wheel in place of fixed, dual elevator and aileron controls. Section 91.109 also requires a safety pilot to be in a control seat during simulated instrument flight conditions.

(9) Expands the current rule that requires a flight instructor to have at least 5 flight hours of operating experience as a PIC in the specific make and model of multiengine airplane or helicopter to include powered-lift aircraft. The complexity and flight characteristics of these aircraft require that a flight instructor be proficient in the aircraft and requires that the flight instructor requirements for the powered-lift parallel those requirements for the multiengine airplane and helicopter.

(10) Clarifies that the aircraft in which training is given should have at least two pilot seats and be of the same category and class for which the rating is sought. The proposal would require a flight instructor who trains a person who desires to fly a single-place aircraft to perform the pre-solo training in an aircraft that has 2 pilot seats, is of the same category and class as the single-place aircraft, and has similar flight characteristics to that of the single-place aircraft; and

(11) Clarifies that a flight instructor may not make any self-endorsment for the furtherance of a certificate, rating, proficiency test, flight review, authorization, operating privilege, practical test, or knowledge test. Although this has not been a problem in the past, periodically the FAA receives questions concerning this matter. Because of ambiguities in the rules, the current rules do not specifically prohibit flight instructors from self-endorsing their own logbook to meet the requirements for a flight review, instrument proficiency test, or taking a written or practical test.

(12) Revises the current amendment in this section, by changing the term ''terminal control area'' to read ''Class B airspace area.''

Section 61.197 Renewal of Flight Instructor Certificates

On April 13, 1994, the FAA issued Amendment Nos. 61.95 and 141–5 (59 FR 17646) that amends current § 61.197. That amendment deletes the 24 hour training that holders of flight instructor certificates are required to receive in an approved flight instructor refresher clinic. That amendment is contained in this Notice with minor word changes.

The proposed revision to this section are as follows:

(1) Permits applicants for renewal to hold at least a third-class medical certificate at the time of the renewal or meet the proposed medical requirements in the case of an applicant for a glider or balloon rating renewal; and

(2) Revises the requirements for a person to renew a flight instructor certificate. This revision for renewing a flight instructor certificate proposes to state that a person may renew their flight instructor certificate without accomplishing a practical test by presenting to an FAA FSDO:

a. A record of training students that shows during the preceding 24 calendar months, the person has endorsed at least 5 students for a practical test for a certificate or rating, and at least 80 percent of those students passed that test on the first attempt.

b. A satisfactory record that shows during the preceding 24 calendar months, the person has served as a company check pilot, chief flight instructor, company check airman or flight instructor in a part 121 or part 135 operation, or a comparable position involving the regular evaluation of pilots, and provided the FAA FSDO is acquainted with that person's duties and responsibilities and has determined the person has satisfactory knowledge of current pilot training, certification, and standards. An example of a person who would hold a comparable position involving the regular evaluation of pilots would be a designated pilot examiner, pilot proficiency examiner, FAA Flight Standards Inspector, or FAA Aviation Standards Specialist involved with developing pilot training and testing standards.

c. A graduation certificate showing the person satisfactorily accomplished an approved flight instructor refresher course, provided the course was satisfactorily accomplished before the expiration date on the person's flight instructor certificate.

(3) Permits a person who satisfactorily accomplishes the flight instructor renewal requirements within 90 days before the expiration date of their certificate, to be considered to have accomplished the requirements in the month due, and the certificate will be renewed for an additional 24 calendar months beyond the expiration date.

Section 61.199 Expired Flight Instructor Certificates and Ratings

No substantive modifications are proposed in this section.

Section 61.201 Conversion to the Current Flight Instructor Ratings

The FAA proposes to revise the existing § 61.201 and replace it with provisions for earning the following flight instructor certificates and rating that are being proposed: (1) glider category and powered class rating; (2) glider category and nonpowered class rating; (3) lighter-than-air category and airship class rating; (4) instrument-airship rating; (5) lighter-than-air category and balloon class rating; (6) instrument-airplane single-engine; and (7) instrument-airplane multiengine.

Subpart I—Ground Instructors

The FAA proposes to include ground instructor certificates in part 61. This subpart would incorporate the regulations that are currently in part 143, which would be deleted.

Section 61.211 Applicability

This section would describe the applicability of proposed subpart I.

Section 61.213 Eligibility Requirements

This proposed section would:

(1) include ground instructor certificates and ratings in part 61;

(2) revise ground instructor certificates and ratings;

(3) require all applicants for a certificate or rating to read, write, speak, and understand the English language;

(4) clarify that all applicants for a certificate or rating need to pass a knowledge test; and

(5) require applicants for a ground instructor certificate or rating to pass a practical test.

The eligibility requirements would continue to waive the ''fundamentals of instruction'' portion of the knowledge test for certain applicants. (This provision is currently found in FAA Order 8700.1). The reference in existing § 143.11 for a ground instructor applicant to be of good moral character would be eliminated.

Under this section an applicant would not be eligible for a ground instructor certificate if the applicant holds a current flight instructor certificate for the same category and class of aircraft. A flight instructor is permitted to give ground training on the aircraft for which the person holds flight instructor ratings. Therefore, the FAA believes issuing a flight instructor certificate that has identical ground instructing privileges as a ground instructor certificate is unnecessary. A flight instructor would not receive any additional privileges by obtaining a ground instructor certificate in the same category and class.

Section 61.215 Aeronautical Knowledge

The requirements in existing § 143.11 would be clarified to include the minimum knowledge requirements on the fundamentals of instruction and the appropriate aeronautical knowledge areas for the aircraft category rating sought.

This section would require a person who trains a ground instructor applicant to meet minimum experience requirements.

Section 61.217 Ground Instructor Proficiency

This section would include the proposed proficiency requirements that an applicant would be required to meet to pass the proposed practical test.

Section 61.219 Ground Instructor Records

This proposed section would require a ground instructor to sign the records of students to whom ground training is given and retain a record of the training given.

Section 61.221 Additional Ground Instructor Ratings

This section proposes that the holder of a ground instructor certificate who applies for an additional rating on that certificate be required to pass a knowledge test on the subjects that pertain to the rating. Such a requirement (the requirement can be found in FAA Order 8700.1) is not expressed in existing part 143 but currently must be met when adding a rating on a ground instructor certificate.

Section 61.223 Ground Instructor Endorsements and Authorizations

This proposed section would list the endorsements and authorizations that a ground instructor could give. A similar section does not appear in part 143.

Section 61.225 Recency of Experience for a Holder of a Ground Instructor Certificate

This proposed section would establish the recency of experience requirements for a person who holds a ground instructor certificate. The proposal would establish recency of experience requirements that would require a ground instructor to:

1. Give a person training and has endorsed that person for a knowledge or practical test within the preceding 12 calendar months; or

2. Receive an endorsement from an authorized flight or ground instructor, which states that the person has demonstrated satisfactory competence in the knowledge and proficiency requirements listed in proposed §§ 61.215 and 61.217, that apply to the ground instructor ratings held.

Section 61.227 Conversion to the Current System of Ground Instructor Ratings

This proposed section would include the procedures for obtaining the proposed ground instructor ratings.

Appendix A to Part 61—Practical Test Requirements for Airplane Airline Transport Pilot Certificates and Associated Class and Type Ratings

The FAA proposes to delete appendix A from part 61. The proposal is a result of establishing areas of operation in part 61 to parallel the Practical Test Standards that cover the administering of practical tests for the ATP certificate with the airplane class and type ratings.

Appendix B to Part 61—Practical Test Requirements for Rotorcraft Airline Transport Pilot Certificates With a Helicopter Class Rating and Associated Type Ratings

On August 11, 1992, the FAA proposed deleting appendix B from part 61 in the NPRM No. 92–10, ''Aircraft Flight Simulator Use in Pilot Training, Testing, and Checking at Training Centers'' (57 FR 35888–35938). Therefore, appendix B of part 61 has not been reprinted in this rulemaking project.

F. Section by Section Discussion of Part 141—Pilot Schools

Subpart A—General

Section 141.1 Applicability

This proposed section contains format revisions only.

Section 141.3 Certificate required

No modifications are proposed for this section.

Section 141.5 Requirements for a Pilot School Certificate

The proposed changes for this section are as follows:

(1) Replaces the title ''Pilot school certificate'' with ''Requirements for a pilot school certificate;''

(2) Includes the proposed modification of a pilot school's quality of training requirements;

(3) Revises the current requirements for a pilot school certificate by specifying that the application is to be completed in a manner prescribed by the Administrator;

(4) Clarifies that an applicant for a pilot school certificate must hold a provisional pilot school certificate for at least 24 calendar months prior to applying for a pilot school certificate;

(5) Revises the current provisions that require in order for an applicant to be issued a pilot school certificate, that applicant must have trained at least 10 students for a certificate or rating and at least 8 of the 10 most recent graduates tested, by an FAA Inspector or examiner, passed that test the first time. The revision in the proposed § 141.5, would require an applicant to have trained and recommended at least 10 students for:

a. A practical or knowledge test for a pilot, flight instructor, or ground instructor certificate or rating, and at least a 80 percent passed the test on the first attempt, and the tests must have been conducted by an FAA inspector or an examiner who is not an employee of the school; or

b. An end-of-course test for a training course in appendix K.

This proposed school certificate issuance requirement deletes the requirement for 8 out of every 10 most recent graduates to have passed the practical or knowledge test on the first attempt. Using this percentage before a school is issued a certificate will ensure more quality of training than the current requirements which pressure schools into ensuring that every 8 out of its most recent 10 graduates passed on the first attempt. During the public hearings, some schools stated that the current requirements place a school in a dilemma by forcing them to pass 8 out of every 10 graduates or loose their school certificate. Under the current requirement, it is conceivable for a provisional pilot school to have graduated over 100 applicants for a practical or knowledge, and have 97 of those applicants pass the required knowledge or practical tests without one failure and then have the next 3 applicants fail the test. Under this scenario, the school would not be qualified to have their certificate issued. Under this proposed revision, the FAA believes quality of training would be maintained, but the schools would not be forced to pass 8 of every 10 graduates in order for a school to be issued. For example, this issuance method would work as follows:

A provisional school graduates 100 students from its part 141-approved courses within the 24 calendar-month period prior to the date application is made for the issuance of a pilot school certificate. Out of those 100 graduates, there were 50 knowledge tests attempted and 100 practical tests attempted for a total of 150 attempts. Out of those 150 practical and knowledge tests attempted, the school would be required to have at least an 80 percent pass rate on the first attempt, or in this case, at least 120 students would have had to pass on the first attempt in order for a pilot school certificate to be issued.

Another example is a provisional school provides only part 141-approved ground school training for an instrument rating course. It graduates only 10 students from its part 141 approved instrument rating ground school course within a 24 calendar month period prior to the date application is made for issuance of a pilot school certificate. Out of those 10 graduates, there were 10 knowledge tests attempted for a total of 10 attempts. Out of those 10 attempts, that provisional school would be required to have at least an 80 percent pass rate on the first attempt, or in this case, at least 8 students would have had to pass on the first attempt in order for a school certificate to be issued.

Another example is a provisional school that has part 141 course approval for a Private Pilot Certification Course under appendix A and also a Test Pilot Course under appendix K. The provisional school graduates 5 students from its Private Pilot Certification Course and 5 from its Test Pilot Course within the 24-calendar month period prior to the date application is made for issuance of a pilot school certificate. Out of those 5 private pilot graduates, there were 5 knowledge tests attempted and 5 practical tests attempted for a total of 10 attempts. There were 5 end-of-course tests accomplished by students enrolled the school's Test Pilot Course. In order for a pilot school certificate to be issued, the provisional pilot school would have to show an 80 percent pass rate on the first attempt for its private pilot applicants. Therefore, 4 private pilot graduates would have to pass the knowledge test on the first attempt, and 4 private pilot graduates would have had to have passed the practical test on the first attempt. Otherwise, the students enrolled in the Test Pilot Course or the other courses of appendix K only count for the recent activity of training requirements.

Section 141.7 Provisional Pilot School Certificate

No substantive changes are proposed for this section.

Section 141.9 Examining Authority

No modifications are proposed for this section.

Section 141.11 Pilot School Ratings

The FAA proposes to revise this section by revising the aeronautical knowledge areas, reorganizing the current certificate courses and eliminating the test courses, and replacing the term, ''flight proficiency requirement'' with ''approved areas of operations.''

The proposed changes for this section would establish the following courses:

(1) *Certification and rating courses:*

(i) Recreational pilot course.

(ii) Private pilot course.

(iii) Commercial pilot course.

(iv) Instrument rating course.

(v) Airline transport pilot course.

(vi) Flight instructor course.

(vii) Flight instructor instrument course.

(viii) Ground instructor course.

(ix) Additional aircraft category or class rating course.

(x) Aircraft type rating course.

(2) *Special preparation courses*:

(i) Pilot refresher course.

(ii) Flight instructor refresher course.

(iii) Ground instructor refresher course.

(iv) Agricultural aircraft operations course.

(v) Rotorcraft external-load operations course.

(vi) Special operations course.

(vii) Test pilot course.

(3) *Pilot ground school courses.*

Section 141.13 Application for Issuance, Amendment, or Renewal

Proposed § 141.13 would revise the existing requirement that requires a pilot school to submit three copies of a training course outline for the issuance or amendment of a pilot school certificate or rating. Two copies of the training course outline are sufficient.

Section 141.15 Location of Facilities

No substantive changes are planned. However, the wording of proposed § 141.15 has been changed to a more permissive language to parallel the proposed changes in § 61.2.

Section 141.17 Duration of Certificates and Examining Authority

The FAA proposes to replace the title ''Duration of certificates'' to read ''Duration of certificates and examining authority.'' The FAA also proposes to add the provision stating that a pilot school or provisional pilot school certificate expires whenever ''the Administrator has determined a school has not acted in good faith with a student to whom it has a contractual agreement to provide training.'' The proposal is a result of past events where some unscrupulous school operators have made contractual agreements with students and then have failed to meet those agreements. As an example, in the 1980's a part 141 school continued to advertise its services when the school was not financially capable. Students were fraudulently required to make payments for the entire course prior to beginning the course. The school requested payment under false pretenses as covering the entire cost of training, room, and board. When the students arrived to begin their training, they were informed the school was bankrupt, and they could only get their training if they would agree to pay for the fuel for the aircraft and pay their own room and board. The FAA was unable to stop this school operator from continuing this unscrupulous practice, because the current rules do not prevent it. Further investigation of this school operator showed that this was not the only time this operator had done this to students. This particular operator would

close up business in one area of the United States after defrauding students, and then begin business in another location. Although the majority of part 141 school operators provide professional flight training and are honorable, unscrupulous operators should not be allowed to continue in business. The FAA believes this proposal will permit it to close down unscrupulous operators in a more expeditious manner.

Section 141.18 Carriage of Narcotic Drugs, Marihuana, and Depressant or Stimulant Drugs or Substances

No modifications are proposed for this section.

Section 141.19 Display of Certificate

Format revisions are proposed for this section.

Section 141.21 Inspections

Format revisions are proposed for this section.

Section 141.23 Advertising Limitations

This section would be revised by clarifying that courses are approved under part 141.

Section 141.25 Business Office and Operations Base

Format revisions are proposed for this section.

Section 141.27 Renewal of Certificates and Ratings

The proposed changes for this section are as follows:

(1) Modifies a pilot school's quality of training requirements. As a result of information obtained during the public hearings and comments received in the docket on this matter, the FAA proposes to revise the quality of training requirements from 8 out of 10 of the most recent graduates pass rate to an 80 percent requirement;

(2) Eliminates the current requirement that the renewal of a certificate must be obtained no less than 30 days prior to the expiration of the provisional pilot school certificate;

(3) Clarifies the requirements for a school that does not meet the proposed renewal requirements may apply for a provisional pilot school certificate; and

(4) Revises the requirements for renewing a pilot school requirement and rating. A pilot school would be required to have trained and recommended at least 10 students for a practical or knowledge test for a pilot, flight instructor, or ground instructor certificate or rating, and at least 80 percent of the students must have passed the test on the first attempt, and the tests must have been conducted by an FAA inspector or an examiner who is not an employee of the school, or an end-of-course test for a training course in appendix K. As an example, see § 141.5.

Section 141.29 [Reserved]

This section would continue to be reserved.

Subpart B—Personnel, Aircraft, and Facilities Requirements

Section 141.31 Applicability

No substantive changes are proposed for this section.

Section 141.33 Personnel

The proposed changes for this section are as follows:

(1) Permits a pilot school to designate check instructors to conduct student stage checks, end-of-course tests, and instructor proficiency checks.

(2) Clarifies that the assistant chief instructor would be required to meet the requirements of proposed § 141.36.

Section 141.35 Chief Instructor Qualifications

Proposed § 141.35 would delete the current requirement for a person who applies as a chief ground instructor to have 1 year of experience as a ground instructor at a certificated pilot school.

Section 141.36 Assistant Chief Instructor Qualifications

Proposed § 141.36 would delete the current requirement for a person who applies as an assistant chief ground instructor to have 6 months of experience as a ground instructor at a certificated pilot school.

Section 141.37 Check Instructor Qualifications

The FAA proposes to redesignate current § 141.37, ''Airports'' to § 141.38. Proposed § 141.37, ''Check instructor qualifications'' would establish the proposed qualifications for a person to be designated as a check instructor.

Section 141.38 Airports

The FAA proposes to redesignate current § 141.37 to § 141.38. Proposed § 141.38 would permit pilot schools at seadromes to use adequate non-permanent lighting or shoreline lighting, approved by the Administrator, for night training flights in seaplanes. Few permanently lighted seadromes are in use. The FAA believes that the existing regulation for permanent lighting at all airports used by a pilot school for night training is not necessary at seadromes. Adequate non-permanent lighting or shoreline lighting is available for night seaplane takeoff and landing operations.

Section 141.39 Aircraft

The proposed changes for this section are as follows:

(1) Requires aircraft used by a pilot school or a provisional pilot school certificate holder be maintained in accordance with subpart E of part 91.

(2) Requires the school's aircraft to be under an inspection program for each airframe, aircraft engine, propeller, appliance, and component part be maintained.

(3) Requires that the school's aircraft used for the demonstration of instrument skills to be equipped and maintained for IFR operations.

(4) Revises the existing provisions that requires aircraft used for ''flight instruction and solo flights in a course of training for agricultural aircraft operations and similar aerial work operations'' do not have to hold a standard airworthiness certificate. The revised language would be more general and would permit each aircraft to hold a standard airworthiness certificate unless the Administrator determines that, because of the nature of the approved course, an aircraft not having a standard airworthiness certificate may be used.

(5) Permit the use of aircraft with a primary airworthiness certificate to be used by schools. The purpose for this proposal is a result of an oversight that occurred during the issuance of the Primary Aircraft Final Rule (57 FR 41360; September 9, 1992).

In the ''Supplementary Information'' section (in the paragraphs entitled ''Rental and Flight Instruction'' and ''Pilot Certification'') of that final rule, the FAA stated that the use of primary aircraft are permitted to be used for rental, flight instruction, and pilot certification. However, the FAA did not provide for this in that final rule.

Section 141.41 Flight Training Devices and Training Aids

This proposal would replace the title of the existing § 141.41 ''Ground trainers and training aids'' with ''Flight training devices and training aids.'' Otherwise, the section would include no substantive changes.

Section 141.43 Pilot Briefing Areas

Format modifications are proposed for this section.

Section 141.45 Ground Training Facilities

Format modifications are proposed for this section.

Subpart C—Training Course Outline and Curriculum

Section 141.51 Applicability

No modifications are proposed for this section.

Section 141.53 Approval Procedures for a Training Course: General

The FAA proposes to replace the title ''Training course outline: General'' with ''Approval procedures for a training course: General.'' The proposed section would require two copies of each training course outline to be submitted to the FAA. The existing rule requires an application for approval of an initial or amended training course outline to be in triplicate to the FAA. Two copies of the training course outline are sufficient and the FAA proposes that only two copies be submitted. Making three copies also causes more paper to be generated for any slight variance in a training course.

Commencing in 1 year after the effective date of this rule, proposed § 141.53 would require pilot schools or provisional pilot schools to only request approval for the new training courses.

Section 141.55 Training Course: Contents

The FAA proposed to replace the title ''Training course outline: Contents'' with ''Training course: Contents.'' The proposal would permit pilot schools to seek approval of training courses that train to a performance standard and would modify a pilot school's quality of training requirements.

Section 141.57 Special Curricula

No substantive changes are proposed for this section.

Subpart D—Examining Authority

Section 141.61 Applicability

Format modifications are proposed for this section.

Section 141.63 Examining Authority Qualification Requirements

The FAA proposes to replace the title ''Application and qualification'' with ''Examining authority qualification and requirements.''

The proposed changes for this section are as follows:

(1) Modifies the quality of training requirements for a pilot school to maintain examining authority.

(2) Deletes the requirement for a specific number of graduates to pass interim tests to retain examining authority. The FAA believes it is more important for students to receive quality training than to pressure schools into ensuring that every 9 out of its most recent 10 graduates passed on the first attempt.

(3) Specifies that pilot schools would not receive examining authority for training courses that train to a performance standard.

Section 141.65 Privileges

Proposed § 141.65 would permit a pilot school with examining authority to recommend graduates for all pilot, flight instructor, and ground instructor certificates. This would eliminate the existing restriction on examiners from performing practical tests for the flight instructor certificate, ATP certificate, and turbojet type ratings. This issue was raised by Harrison Hamer, who submitted a comment to the FAA in response to the DOT's request for comments (57 FR 4744; February 7, 1992). In addition, the FAA has issued numerous exemptions to this rule without any degradation in safety.

Section 141.67 Limitations and Reports

The proposed changes for this section are as follows:

(1) Deletes the current provision that requires a student at a pilot school with examining authority to accomplish all of the training courses at that school.

(2) Expands the existing requirement for a pilot school with examining authority to submit the training record of each graduate who is recommended for a certificate or rating to a FAA FSDO.

Subpart E—Operating Rules

Section 141.71 Applicability

No modifications are proposed for this section.

Section 141.73 Privileges

Proposed § 141.73 would be reformatted. Proposed § 141.73 would specify that pilot schools who hold examining authority would not be permitted to seek approval of training courses that train to a performance standard.

Section 141.75 Aircraft Requirements

(1) The FAA proposes to add the proposed test pilot and special operations courses to courses for which an aircraft certificated in the restricted category may be used.

(2) Permit the use of aircraft with a primary airworthiness certificate to be used by schools. The purpose for this proposal is a result of an oversight that occurred during the issuance of the Primary Aircraft Final Rule (57 FR 41360; September 9, 1992).

In the **SUPPLEMENTARY INFORMATION** section (in the paragraphs entitled ''Rental and Flight Instruction'' and ''Pilot Certification'') of that final rule, the FAA stated that the use of primary aircraft are permitted to be used for rental, flight instruction, and pilot certification. However, the FAA did not provide for this in that final rule.

Section 141.77 Limitations

This section would be revised by dividing the current section into two paragraphs. The current reference to ''flight check or written test, or both'' would be replaced with a ''proficiency test or knowledge test or both.'' The tests could include a flight check, a review of the student's aeronautical knowledge, or both.

Section 141.79 Flight Training

On April 13, 1994, the FAA issued Amendment Nos. 61.95 and 141–5 (59 FR 17646) that amends current § 61.197. That amendment deletes the 24 hour training that holders of flight instructor certificates are required to receive in an approved flight instructor refresher clinic. That amendment is contained in this Notice with minor word changes.

The proposed changes for this section are as follows:

(1) Replaces the term ''designated chief instructor or his assistant'' with ''chief instructor,'' ''assistant chief instructor,'' or ''check instructor.''

(2) Permits the assistant chief instructor or check instructor to administer proficiency checks to a school's instructors.

(3) Revises the flight and proficiency checks accomplished by flight instructors.

(4) Requires chief and assistant chief instructors to complete at least once every 12 calendar months an approved syllabus of training consisting of ground or flight training, or both, or an approved flight instructor refresher course.

Section 141.81 Ground Training

This section would be revised to replace ''designated chief instructor or his assistant'' with ''chief instructor,'' ''assistant chief instructor,'' or ''check instructor.''

Section 141.83 Quality of Training

The proposed revisions to this section are as follows:

(1) Reformats and rewords this section for clarity.

(2) Modifies the quality of training requirements. This proposal would require a school to provide training of such quality that at least 80 percent of their students for a practical or knowledge test were successful on the first attempt within the period of 24

calendar months prior to the date of application for the school certificate.

Section 141.85 Chief Instructor Responsibilities

The section would be revised by clarifying that the chief instructor serves a supervisory role at a pilot school. The current requirements for the chief instructor to ''conduct'' checks and tests would be revised for the chief instructor to ''ensure'' these checks and tests are accomplished. A new paragraph is proposed for this section that would permit the chief instructor to either conduct the check or delegate authority for conducting stage checks, end-of-course tests, and flight instructor proficiency checks to the assistant chief instructor or a check instructor.

Section 141.87 Change of Chief Instructor

Proposed § 141.87 would permit a pilot school or provisional pilot school to replace its chief instructor with an assistant chief instructor or a check instructor, and would permit the assistant chief instructor or check instructor to give stage and end-of-course tests for a maximum of 60 days until a new chief instructor is designated.

Section 141.89 Maintenance of Personnel, Facilities, and Equipment

Editorial modifications are proposed for this section.

Section 141.91 Satellite Bases

Editorial modifications are proposed for this section.

Section 141.93 Enrollment

The proposed revisions to this section would eliminate the requirement for a pilot school to send a copy of each enrollment certificate to its FAA FSDO. The school would be required to maintain a monthly listing of persons enrolled in each course at the school. This proposal would provide paperwork reduction.

Section 141.95 Graduation Certificate

Minor editorial modifications are proposed for this section.

Subpart F—Records

Section 141.101 Training Records

This section would be reformatted.

Appendix A—Recreational Pilot Certification Course

The FAA proposes to establish criteria for a new certification course for recreational pilot certificates. The course in existing appendix A, ''Private Pilot Certificate Course (Airplanes),'' would be moved to proposed appendix B.

Appendix B—Private Pilot Certification Course

The FAA proposes to establish criteria for a certification course for a private pilot certificate in all categories of aircraft. The course in existing appendix B, ''Private Test Course (Airplanes),'' would be eliminated.

Appendix C—Instrument Rating Course

The FAA proposes to establish criteria for an instrument rating course. The course in existing appendix C, ''Instrument Rating Course (Airplanes),'' would be included in this proposed course.

Appendix D—Commercial Pilot Certification Course

The FAA proposes to establish criteria for a certification course for a commercial pilot certificate. The course in the existing appendix D, ''Commercial Pilot Certificate Course (Airplanes),'' is included in this proposed certification course.

Appendix E—Airline Transport Pilot Certificate Course

The FAA proposes to establish criteria for a certification course for an ATP certificate with an airplane, helicopter, or powered-lift rating. The course in existing appendix E, ''Commercial Test Course (Airplanes),'' would be eliminated.

Appendix F—Flight Instructor Certification Course

The FAA proposes to establish criteria for a course for a flight instructor certification course. The courses in existing appendix F, ''Rotorcraft, Gliders, Lighter-Than-Air Aircraft and Aircraft Rating Courses,'' would be moved to proposed appendixes B, C, D, I, and J.

Appendix G—Flight Instructor Instrument (Aircraft Category and Class) Certification Course

The FAA proposes to establish criteria for a course for a flight instructor-instrument certification course. The course in existing appendix G, ''Pilot Ground School Courses,'' would be moved to proposed appendix L.

Appendix H—Ground Instructor Certificate Course

The FAA proposes to establish criteria for a course for a ground instructor certification. The courses found in existing appendix H, ''Test Preparation Courses,'' would be moved to proposed appendixes C, E, F, and G.

Appendix I—Additional Aircraft Category or Class Rating Course

The FAA proposes to establish criteria for an additional aircraft category or class rating courses for a person who desires to add an additional category or an additional class rating on their pilot certificate.

Appendix J—Aircraft Type Rating Course, for Other Than Airline Transport Pilot

The FAA proposes to establish criteria for an aircraft type rating course, for other than ATP, for a person who desires to add a type rating on their pilot certificate.

Appendix K—Special Preparation Courses

The FAA proposes to establish criteria for special preparation courses, which would be similar to the current appendix H, ''Test Preparation Courses.''

Appendix L—Pilot Ground School Course

This proposed appendix would be similar to current appendix G, ''Pilot Ground School Courses.''

International Civil Aviation Organization and Joint Aviation Regulations

During this regulatory review of parts 1, 61, 141, and 143, the FAA conducted a study that compares Federal Aviation Regulations and International Civil Aviation Organization Regulations. A copy of that comparison study is located at the Federal Aviation Administration, Office of the Chief Counsel, Rules Docket, Room 915G, under Docket No. 25910, 800 Independence Avenue, SW., Washington, DC 20591. Throughout this regulatory review, the FAA has attempted to propose rules that are in harmony with the international community. Where differences will occur, the FAA will comply with FAA Order 2100.13A, The FAA Regulatory Handbook. This Order directs the FAA to identify differences between the International Civil Aviation Organization Regulations and the Federal Aviation Regulations.

The Joint Aviation Regulations (JAR) pilot licensing rulemaking action, which was issued over one year ago and withdrawn, is on hold. To date, no harmonization comparison has been made with the JAR rulemaking action. However, when that rulemaking action is reissued, the FAA intends to conduct a comparison study and will attempt to negotiate conformity for those rules where there are significant differences.

Regulatory Evaluation Summary

Cost-Benefit Analysis

The FAA has considered the impact of this rulemaking action under E.O. 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document was reviewed under E.O. 12866, ''Regulatory Planning and Review.'' This section has been determined to be ''significant'' under the Department of Transportation's regulatory policies and procedures. The FAA prepared a preliminary Economic Assessment for the NPRM. The FAA has evaluated the anticipated costs and benefits, which are summarized below. For more detailed economic information, see the full regulatory evaluation contained in the docket.

Costs

The FAA estimates that the present value of the costs of this proposed rule discounted 7 percent over the next 10 years is $6.6 million. Proposed § 61.212 on increased recordkeeping requirements is the most costly provision at $437,000 annually representing 46 percent of the total annual cost of almost $950,000. Proposed § 61.217 on the practical test for instructor applicants is the second most costly provision at $435,000 annually, representing 43.9 percent of the total annual cost.

Benefits

The FAA also estimates that the present value of the benefits of this proposed rule discounted 7 percent over the next 10 years is $368.7 million. Proposed § 61.65 reducing the amount of flight time needed before applying for an instrument rating provides the greatest benefit in cost savings at $18.7 million annually representing 36 percent of the total annual benefits ($52.5 million annually). Various provisions that together provide numerous safety benefits result in annual benefits of $21.1 million or 40 percent of the total.

Economic Conclusions

Based upon the low compliance cost coupled with the large cost savings and the safety benefits, the FAA concludes that the proposed rule is cost beneficial.

Initial 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 government regulations. The RFA requires agencies to review rules that may have ''a significant cost impact on a substantial number of small entities.''

All of the major changes in the rules discussed in this NPRM affect pilots, flight instructors, and ground instructors, who are individuals rather than business or government entities. The revisions that impact pilot schools do not exceed the cost-threshold level, as found in the RFA. In fact, as this report shows, the proposed rule would result in net overall annual cost savings of about $3,000 per pilot school. The FAA has determined that the proposed revisions would not have a significant economic impact on a substantial number of small entities.

International Trade Impact Analysis

The Office of Management and Budget (OMB) requires Federal agencies to determine whether any proposed rule or regulation would have an impact on international trade. The revisions discussed in this NPRM primarily affect the domestic operations of individual pilots, flight instructors and ground instructors, not of business entities. In the case of pilot schools or aircraft operators, it is not likely that the services produced by these entities would involve the international trade flows of aviation products or services and thus do not impact trade opportunities for U.S. firms doing business overseas and foreign firms doing business in the United States. Thus, the FAA believes the proposed changes would have no impact on trade opportunities for both U.S. firms doing business overseas and foreign firms doing business in the United States. The FAA welcomes any comments on this issue.

Federalism Implications

The regulations proposed in this notice 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 amendment would not have federalism implications requiring the preparation of a Federalism Assessment.

Paperwork Reduction Act Approval

The reporting and recordkeeping requirements associated with this rule are being submitted to the Office of Management and Budget (OMB) for approval in accordance with 44 U.S.C. 35 under OMB No: ; Title: Pilot, Flight Instructor, Ground Instructor, and Pilot School Certification Rules; Form(s) None; Average Burden Hours per Respondent:

For Further Information Contact: The Information Requirements Division, M–34, Office of the Secretary of Transportation, 400 Seventh Street, SW., Washington, DC 20590; (202) 366–4735.

Comments on these information collection requirements should be submitted to the Office of Information and Regulatory Affairs OMB, Washington, DC 20503, Attention: Desk Officer for FAA. Comments submitted to OMB should also be submitted to the FAA docket.

Specific Time and Hour Requirements

The FAA has proposed specific time and hour requirements in various sections of this NPRM. These specific time and hour requirements may be modified in light of the comments received to the docket, thus modifying the scope of the NPRM.

Conclusion

For the reasons discussed in the preamble, and based on the findings in the Initial Regulatory Flexibility Determination and the International Trade Impact Analysis, the FAA has determined that this proposed regulation is a significant regulatory action under Executive Order 12866. In addition, it is certified that this proposal, if adopted, 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. This proposal is considered significant under Order DOT 2100.5, Policies and Procedures for Simplification, Analysis, and Review of Regulations. A draft regulatory evaluation of the proposal, including an initial Regulatory Flexibility Determination and International Trade Impact Analysis, has been placed in the docket. A copy may be obtained by contacting the person identified under **FOR FURTHER INFORMATION CONTACT.**

List of Subjects

14 CFR Part 1

General definitions, Abbreviations and symbols, Rules of construction.

14 CFR Part 61

Air safety, Aircraft, Aircraft pilots, Airmen, Airplanes, Aviation safety, Compensation, Education, Foreign persons, Helicopters, Pilots, Rotorcraft, Safety, Students, Teachers, Transportation.

14 CFR Part 141

Air safety, Air transportation, Aircraft pilots, Airmen, Airplanes, Aviation safety, Balloons, Education, Educational facilities, Helicopters, Pilots, Rotorcraft, Safety, Schools, Students, Teachers, Transportation.

14 CFR Part 143

Air safety, Air transportation, Airmen, Airplanes, Aviation safety, Education, Educational Facilities, Safety, Students, Teachers, Transportation.

The Proposed Amendments

In consideration of the foregoing, under the authority at 49 U.S.C. 40113, the Federal Aviation Administration proposes to amend parts 1, 61, 141, and 143 of the Federal Aviation Regulations (14 CFR Parts 1, 61, 141, and 143) as follows:

PART 1—DEFINITIONS AND ABBREVIATIONS

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

Authority: 49 U.S.C. 106(g); 49 U.S.C. 40101–40104, 40109, 40113, and 44701.

2. Section 1.1 is amended by revising the definitions of ''balloon'', ''flight time'', and ''pilot in command'' to read as follows:

§ 1.1 General Definitions.

* * * * *

Balloon is an aircraft that is not engine driven, but sustains flight with either gas buoyancy or with an airborne heater.

* * * * *

Flight time means:

(1) Pilot time that commences when an aircraft moves under its own power for the purpose of flight and ends when the aircraft comes to rest after landing; or

(2) For a nonpowered glider, that time when the glider commences being towed for the purpose of flight and ends when the glider comes to rest after landing.

* * * * *

Pilot in command means:

(1) A person who has final authority and responsibility for the operation and safety of the flight;

(2) A person who holds the appropriate category, class, and type rating, if appropriate;

(3) A person who has been designated as pilot in command before or during the flight; and

(4) Involves a flight that occurs in actual flight conditions in an aircraft.

* * * * *

Authority: 49 U.S.C. 106(g); 49 U.S.C. 40101–40104, 40109, 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45106, and 45301–45302.

3. Part 61 is revised to read as follows:

PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

Subpart A—General

Sec.

61.1 Applicability.
61.1a Clarification of terms.
61.2 Certification of foreign pilots, flight instructors, and ground instructors.
61.3 Requirement for certificates, ratings, and authorizations.
61.5 Certificates and ratings issued under this part.
61.7 Obsolete certificates and ratings.
61.9 Written syllabus for conducting training.
61.11 Expired pilot certificates and reissuance.
61.13 Awarding of airman certificates, ratings, and authorizations.
61.14 Refusal to submit to a drug test.
61.15 Offenses involving alcohol or drugs.
61.16 Refusal to submit to an alcohol test or to furnish test results.
61.17 Temporary certificate.
61.19 Duration of pilot and instructor certificates.
61.21 Duration of a Category II pilot authorization.
61.23 Duration and requirement for a medical certificate.
61.25 Change of name.
61.27 Voluntary surrender or exchange of certificate.
61.29 Replacement of a lost or destroyed airman or medical certificate or knowledge test report.
61.31 Type rating, additional training, and authorization requirements.
61.33 Tests: General procedure.
61.35 Knowledge test: Prerequisites and passing grades.
61.37 Knowledge tests: Cheating or other unauthorized conduct.
61.39 Prerequisites for practical tests.
61.41 Flight training received from flight instructors not certificated by the FAA.
61.43 Practical tests: General procedures.
61.45 Practical tests: Required aircraft and equipment.
61.47 Status of an examiner who is authorized by the Administrator to conduct practical tests.
61.49 Retesting after failure.
61.51 Pilot logbooks.
61.53 Operations during medical deficiency.
61.55 Second-in-command qualifications.
61.56 Flight review.
61.57 Recent flight experience: Pilot in command.
61.58 Pilot-in-command proficiency check: Operation of aircraft requiring more than one required pilot.
61.59 Falsification, reproduction, or alteration of applications, certificates, logbooks, reports, or records.
61.60 Change of address.

Subpart B——Aircraft Ratings and Special Certificates

61.61 Applicability.
61.63 Additional aircraft ratings (other than airline transport pilot).
61.65 Instrument rating requirements.
61.67 Category II pilot authorization requirements.
61.69 Glider towing: Experience and training requirements.
61.71 Graduates of an approved training program other than under this part: Special rules.
61.73 Military pilots or former military pilots: Special rules.
61.75 Private pilot certificate issued on basis of a foreign pilot license.
61.77 Special purpose pilot authorization: Operation of U.S.-registered civil aircraft leased by a person who is not a U.S. citizen.

Subpart C——Student Pilots

61.81 Applicability.
61.83 Eligibility requirements for student pilots.
61.85 Application.
61.87 Supervised pilot in command requirements for student pilots.
61.89 General limitations.
61.91 [Reserved.]
61.93 Supervised pilot in command cross-country flight requirements.
61.95 Operations in Class B airspace and at airports located within Class B airspace.

Subpart D——Recreational Pilots

61.96 Applicability
61.96a Eligibility requirements: General.
61.97 Aeronautical knowledge.
61.98 Flight proficiency.
61.99 Aeronautical experience.
61.100 Pilots based on small islands.
61.101 Recreational pilot privileges and limitations.

Subpart E——Private Pilots

61.102 Applicability.
61.103 Eligibility requirements: General.
61.105 Aeronautical knowledge.
61.107 Flight proficiency.
61.109 Aeronautical experience.
61.110 Night flying exceptions for private pilot certification.
61.111 Cross-country flights: Pilots based on small islands.
61.113 Private pilot privileges and limitations: Pilot in command.
61.115 Balloon rating: Limitations.
61.117 Private pilot privileges and limitations: Second in command of aircraft requiring more than one pilot.
61.118 through 61.120 [Reserved]

Subpart F——Commercial Pilots

61.121 Applicability.
61.123 Eligibility requirements: General.
61.125 Aeronautical knowledge.
61.127 Flight proficiency.
61.129 Aeronautical experience.
61.131 Exceptions to the night flying requirements for the commercial pilot certificate.
61.133 Commercial pilot privileges and limitations: General.
61.135 through 61.141 [Reserved.]

Subpart G——Airline Transport Pilots

61.151 Applicability.
61.153 Eligibility requirements: General.
61.155 Aeronautical knowledge.
61.157 Flight proficiency.
61.159 Aeronautical experience: Airplane category rating.
61.161 Aeronautical experience: Rotorcraft category and helicopter class rating with a type rating.
61.163 Aeronautical experience: Powered-lift category.
61.165 Additional aircraft category and class ratings.
61.167 General privileges and limitations.
61.169 [Reserved].
61.171 [Reserved].

Subpart H—Flight Instructors

61.181 Applicability.
61.183 Eligibility requirements.
61.185 Aeronautical knowledge.
61.187 Flight proficiency.
61.189 Flight instructor records.
61.191 Additional flight instructor ratings.
61.193 Flight instructor endorsements and authorizations.
61.195 Flight instructor limitations and qualifications.
61.197 Renewal of flight instructor certificates.
61.199 Expired flight instructor certificates and ratings.
61.201 Conversion to the current flight instructor ratings.

Subpart I—Ground Instructors

61.211 Applicability.
61.213 Eligibility requirements.
61.215 Aeronautical knowledge.
61.217 Ground instructor proficiency.
61.219 Ground instructor records.
61.221 Additional ground instructor ratings.
61.223 Ground instructor endorsements and authorizations.
61.225 Recency of experience for a holder of a ground instructor certificate.
61.227 Conversion to current ground instructor ratings.

Subpart A—General

§ 61.1 Applicability.

(a) This part prescribes the requirements for issuing pilot, flight instructor, and ground instructor certificates and ratings, the conditions under which those certificates and ratings are necessary, and the authorizations, privileges, and limitations of those certificates and ratings.

(b) This part prescribes the requirements for issuing pilot, flight instructor, and ground instructor certificates and ratings for persons who have taken courses approved by the Administrator under other parts of this chapter.

§ 61.1a Clarification of terms.

For the purposes of this part:

(a) *Aeronautical experience* means pilot time obtained in an aircraft, flight simulator, or flight training device for meeting the appropriate training and flight time for an airman certificate, rating, flight review, or recency of flight experience, of this part.

(b) *Airman certificate* means all pilot certificates (other than a student pilot certificate), flight instructor certificates, and ground instructor certificates issued under this part.

(c) *Authorized ground instructor* means—

(1) A person who holds a current ground instructor certificate issued under this part with ratings that apply to the training being given, and that person is authorized by the Administrator to give the training; or

(2) Any other person authorized by the Administrator to give ground training under this part in accordance with privileges and limitations specified by the Administrator.

(d) *Authorized flight instructor means*—

(1) A person who holds a current flight instructor certificate issued under this chapter with ratings that apply to the training being given, and that person is authorized by the Administrator to give the training; or

(2) Any other person authorized by the Administrator to give flight training under this part in accordance with privileges and limitations specified by the Administrator.

(e) *Cross-country time* means that time obtained in actual flight and, except as provided in paragraph (f)(3) of this section, each flight must include a landing at a point other than the point of departure, and—

(1) The person must—

(i) Hold a private, commercial pilot, or airline transport certificate issued under this part; and

(ii) Have used dead reckoning, pilotage, electronic navigation aids, or radio aids to navigate to the landing point.

(2) For the purpose of meeting the cross-country time eligibility requirements for a private or commercial pilot certificate or an instrument rating, the person must have obtained the time in actual flight, and—

(i) The point of landing must be at least a straight-line distance of more than 50 nautical miles from the point of departure; and

(ii) Dead reckoning, pilotage, electronic navigation aids, or radio aids were used to navigate to the landing point.

(3) For a military pilot, who holds or is qualified for a private or commercial pilot certificate under § 61.73 of this part, cross-country time is that time obtained—

(i) In actual flight in a military aircraft; and

(ii) On a flight that is at least a straight-line distance of more than 50 nautical miles from the point of departure, and dead reckoning, pilotage, electronic navigation aids, or radio aids were used for navigation.

(f) *Examiner* means any person who is authorized by the Administrator to conduct a practical test for an airman certificate or rating issued under this part, or a person who is authorized to conduct a knowledge test under this part.

(g) *Flight training* means that training, other than ground training, received from an authorized flight instructor in actual flight in an aircraft.

(h) *Ground training* means that training, other than flight training, received from an authorized ground or flight instructor.

(i) *Instrument approach* means an approach procedure, defined in part 97 of this chapter, that is conducted to an established minimum descent altitude (MDA) or decision height (DH), or if necessary, to a higher altitude selected by the air traffic control (ATC) facility with jurisdiction over that airspace for safety reasons.

(j) *Instrument Training* means that time in which instrument training is received from an authorized flight instructor under actual or simulated instrument flight conditions.

(k) *Knowledge Test* means a test on the aeronautical knowledge areas required for an airman certificate or rating that can be administered in a written form or by computer.

(l) *Pilot Time* means that time in which a person operates as a required pilot, receives training from an authorized instructor, gives training as an authorized flight instructor in an aircraft, or gives training as an authorized flight or ground instructor in an approved flight simulator, or approved flight training device.

(m) *Practical test* means a test on the approved areas of operations for an airman certificate, a rating, or an authorization that is conducted by having the applicant respond to questions and demonstrate maneuvers in actual flight, an approved flight simulator, or approved flight training device.

(n) *Supervised PIC time* is flight time in an aircraft that applies to either a student pilot or pilot who is not rated in the aircraft flown, but is under the supervision and authorization of an authorized flight instructor to conduct the flight. Depending on the crew compliment specifications set forth in the aircraft's flight manual, the flight

instructor may be onboard the aircraft in an assigned crewmember position. In those cases, the flight instructor shall act in the capacity of an assigned crew member and evaluate the person's ability to act as a pilot in command.

(o) *Training time* means training received in actual flight from an authorized flight instructor, on the ground from an authorized ground or flight instructor, or in a flight simulator or flight training device from an authorized ground or flight instructor.

§ 61.2 Certification of foreign pilots, flight instructors, and ground instructors.

(a) Except as provided for in paragraph (b) of this section, an airman certificate may not be issued to a person who is not a citizen of the United States or a resident alien of the United States unless that person satisfactorily accomplishes the appropriate knowledge or practical test within the United States.

(b) A person who is not a citizen of the United States or a resident alien of the United States may be issued an airman certificate, and the knowledge and practical test for that certificate may be administered outside the United States when:

(1) The Administrator determines the person needs a pilot certificate to operate as a required pilot crewmember of a civil aircraft of U.S. registry;

(2) The Administrator determines the person needs a flight instructor or ground instructor certificate to train persons who are citizens or resident aliens of the United States;

(3) The certificate is for an addition of a category, class, instrument, or type rating onto an existing U.S. pilot certificate, and provided the certificate is not one that was issued on the basis of a foreign pilot license;

(4) The certificate is for an addition, renewal, or reinstatement of a category, class, or instrument rating onto an existing U.S. flight instructor certificate; or

(5) The certificate is for an addition, renewal, or reinstatement of a category rating onto an existing U.S. ground instructor certificate.

§ 61.3 Requirement for certificates, ratings, and authorizations.

(a) *Pilot certificate.* Persons may not act as pilot in command or in any other capacity as a required pilot of a civil aircraft of U.S. registry, unless they have a valid airman certificate in their physical possession or readily accessible in the aircraft when exercising the privileges of their airman certificate.

(b) *Required pilot certificate for operating a foreign registered aircraft.* Persons may not act as pilot in command or in any other capacity as a required pilot of a civil aircraft of foreign registry within the United States, unless their airman certificate:

(1) Is valid and in their physical possession, or readily accessible in the aircraft when exercising the privileges of their airman certificate; and

(2) Has been issued under this part or by the country in which the aircraft is registered.

(c) *Medical certificate.*

(1) Except as provided for in paragraph (c)(2) of this section, a person who is serving as a required crewmember under any part of this chapter must have a:

(i) Current and appropriate medical certificate that has been issued under part 67 of this chapter; and

(ii) Medical certificate in the person's physical possession or readily accessible in the aircraft when exercising the privileges of that airman certificate.

(2) A person is not required to meet the requirements of paragraph (c)(1) of this section, if that person:

(i) Is holding a pilot or flight instructor certificate with a balloon or a glider rating and is piloting or training in a balloon or a glider as appropriate;

(ii) Is a student pilot who is seeking a recreational pilot certificate, or who is seeking a pilot certificate with a glider category rating or balloon class rating;

(iii) Is exercising the privileges of a recreational pilot certificate;

(iv) Is exercising the privileges of a flight instructor certificate, provided the person is not serving as a required crewmember or as the pilot-in-command;

(v) Is exercising the privileges of a ground instructor certificate;

(vi) Is operating an aircraft within a foreign country with a pilot certificate issued by that country and is using that foreign-issued pilot license and medical certificate; or

(vii) Is operating an aircraft with a U.S. pilot certificate issued on the basis of a foreign pilot license, issued under § 61.75 of this part, and holds a current medical certificate issued by the foreign country that issued the foreign pilot license.

(d) *Flight instructor certificate.*

(1) Persons who hold a flight instructor certificate must have that certificate in their physical possession or readily accessible in the aircraft when exercising the privileges of that flight instructor certificate.

(2) Except as provided in paragraphs (d) (3) and (4) of this section, no person other than the holder of a flight instructor certificate with the appropriate rating on that certificate or a person authorized by the Administrator may:

(i) Give training required to qualify a person for supervised PIC flight and supervised PIC cross-country flight;

(ii) Endorse on a pilot, flight instructor, or ground instructor certificate or rating issued under this part;

(iii) Endorse a pilot logbook to show training given; or

(iv) Endorse a student pilot certificate or logbook for supervised PIC operating privileges.

(3) A flight instructor certificate is not necessary if:

(i) The training is in accordance with a part 121 or part 135 air carrier approved training program;

(ii) The training is given by the holder of an airline transport pilot certificate under part 121 or 135 of this chapter; and

(iii) The person receiving the training and the person giving the training are employees of that air carrier.

(4) A flight instructor certificate is not necessary if the training is given by an instructor as prescribed in § 61.41 of this part.

(e) *Instrument rating.* Except as provided for in paragraph (k)(4) of this section, no person may act as pilot in command of a civil aircraft under IFR or in weather conditions less than the minimums prescribed for VFR flight unless that person holds:

(1) The appropriate aircraft category, class, type, if required, and instrument rating on that person's pilot certificate for the aircraft being flown;

(2) An airline transport pilot certificate with the appropriate aircraft category, class, and type rating, if required, for the aircraft being flown; or

(3) For a glider, the appropriate glider class rating on that person's pilot certificate and:

(i) An airplane single-engine class rating with an instrument-airplane single-engine rating; or

(ii) An airline transport pilot certificate with an airplane single-engine class rating.

(f) *Category II pilot authorization.* Except as provided in paragraph (f)(3) of this section, no person may act as a required pilot flight crewmember of a civil aircraft in a Category II operation unless that person meets the following requirements of this paragraph:

(1) The pilot in command must hold a current Category II pilot authorization for that type aircraft, and—

(i) Hold a private pilot or commercial pilot certificate with an instrument rating or an airline transport pilot certificate, appropriate to the category

and class of aircraft to be flown, and hold a current Category II pilot authorization for that type aircraft; or

(ii) For a civil aircraft of foreign registry, be authorized by the country where the aircraft is registered to conduct Category II operations.

(2) The second in command must—

(i) Hold a private pilot or commercial pilot certificate with an instrument rating, or an airline transport pilot certificate, appropriate to the category and class of aircraft to be flown.

(ii) For a civil aircraft of foreign registry, be authorized by the country where the aircraft is registered to conduct Category II operations as a second in command.

(3) paragraphs (f)(1) and (f)(2) of this section do not apply to pilots conducting Category II operations under part 121 or part 135 of this chapter.

(g) *Category A aircraft authorization.* The Administrator may issue a certificate of authorization for a Category II operation to the pilot of a small aircraft that is a Category A aircraft, as identified in § 97.3(b)(1) of this chapter if:

(1) The Administrator determines the Category II operation can be performed safely by that pilot under the terms of the certificate of authorization; and

(2) The Category II operation does not involve the carriage of persons or property for compensation or hire.

(h) *Ground instructor certificate.*

(1) Each person who holds a ground instructor certificate must have that certificate in their physical possession and immediately accessible when exercising the privileges of that certificate.

(2) Except as provided in paragraph (d) of this section, no person other than the holder of a ground instructor certificate with the appropriate rating on that certificate or a person authorized by the Administrator may:

(i) Give ground training required to qualify a person for supervised PIC flight and supervised PIC cross-country flight;

(ii) Give an endorsement on a pilot, flight instructor, or ground instructor certificate or rating, issued under this part; or

(iii) Endorse a pilot logbook to show training given.

(i) *Age limitation.* A person who is 60 years of age or older and who holds an airmen certificate, issued in accordance with this part, may not act as a required pilot crewmember while engaging in any scheduled international air services, non-scheduled international air transportation, or common carriage operation for compensation or hire in a civil aircraft having a:

(1) Passenger seating configuration of more than 30 seats, excluding any required crewmember seat; or

(2) Payload capacity of more than 7500 pounds (3400 kg).

(j) *Special purpose pilot authorization.* Persons that are required to hold a special purpose pilot authorization, issued in accordance with § 61.77 of this part, must have that authorization and their foreign pilot license in their physical possession or have it readily accessible in the aircraft, when exercising the privileges of that authorization.

(k) Until [insert date 2 years after the effective date of the final rule], a person with a commercial pilot certificate with a lighter-than-air category rating, which was issued prior to [insert effective date of the final rule], may:

(1) Give training in an airship or a balloon for the issuance of a certificate or rating;

(2) Give an endorsement on a pilot, flight instructor, or ground instructor certificate for an airship or balloon;

(3) Endorse a student pilot certificate or logbook for supervised PIC operating privileges in an airship or balloon; and

(4) Act as pilot in command of an airship under IFR or in weather conditions less than the minimum prescribed for VFR flight, if the person holds an airship class rating.

(l) *Inspection of certificate.* Each person who holds an airman certificate, medical certificate, authorization, or license required by this part must present it for inspection upon a request from:

(1) The Administrator;

(2) An authorized representative of the National Transportation Safety Board; or

(3) Any Federal, State, or local law enforcement officer.

§ 61.5 Certificates and ratings issued under this part.

(a) The following certificates are issued under this part to an applicant who satisfactorily accomplishes the training and certification requirements for the certificate sought:

(1) Pilot certificates—

(i) Student pilot.

(ii) Recreational pilot.

(iii) Private pilot.

(iv) Commercial pilot.

(v) Airline transport pilot.

(2) Flight instructor certificates.

(3) Ground instructor certificates.

(b) The following ratings are placed on a pilot certificate (other than student pilot) when an applicant satisfactorily accomplishes the training and certification requirements for the rating sought:

(1) Aircraft category ratings—

(i) Airplane.

(ii) Rotorcraft.

(iii) Glider.

(iv) Lighter-than-air.

(v) Powered lift.

(2) Airplane class ratings—

(i) Single-engine land.

(ii) Multiengine land.

(iii) Single-engine sea.

(iv) Multiengine sea.

(3) Rotorcraft class ratings—

(i) Helicopter.

(ii) Gyroplane.

(4) Glider class ratings—

(i) Powered.

(ii) Nonpowered.

(5) Lighter-than-air class ratings—

(i) Airship.

(ii) Balloon.

(6) Aircraft type ratings include the following—

(i) Large aircraft other than lighter-than-air.

(ii) Turbojet-powered airplanes.

(iii) Other aircraft type ratings specified by the Administrator through the aircraft type certification procedures.

(7) Instrument ratings (on private and commercial pilot certificates only) include the following—

(i) Instrument—airplane single-engine.

(ii) Instrument—airplane multiengine.

(iii) Instrument—helicopter.

(iv) Instrument—airship.

(v) Instrument—powered-lift.

(c) The following ratings are placed on a flight instructor certificate when an applicant satisfactorily accomplishes the training and certification requirements for the rating sought:

(1) Aircraft category ratings—

(i) Airplane.

(ii) Rotorcraft.

(iii) Glider.

(iv) Lighter-than-air.

(v) Powered-lift.

(2) Airplane class ratings—

(i) Single-engine.

(ii) Multiengine.

(3) Rotorcraft class ratings—

(i) Helicopter.

(ii) Gyroplane.

(4) Glider class ratings—

(i) Powered.

(ii) Nonpowered.

(5) Lighter-than-air class ratings—

(i) Airship.

(ii) Balloon.

(6) Instrument ratings—

(i) Instrument—airplane single-engine.

(ii) Instrument—airplane multiengine.

(iii) Instrument—helicopter.

(iv) Instrument—airship.

(v) Instrument—powered lift.

(d) The following ratings are placed on a ground instructor certificate when

an applicant satisfactorily accomplishes the training and certification requirements for the rating sought:

(1) Aircraft category ratings—

(i) Airplane.

(ii) Rotorcraft.

(iii) Glider.

(iv) Lighter-than-air.

(v) Powered lift.

(2) Instrument rating.

(e) Until [insert date 2 years from effective date of the final rule]:

(1) A person who holds a pilot certificate that does not bear the current ratings found in paragraphs (b)(4), (b)(7)(i), (b)(7)(ii), or (b)(7)(iv) of this section, may exchange that pilot certificate for a certificate with the new rating added by meeting the requirements of this paragraph.

(2) A person who holds a commercial pilot certificate with a lighter-than-air category and an airship class rating may exchange that certificate for a certificate with an instrument—airship rating, provided that person has—

(i) Received an endorsement from an authorized flight instructor who holds an instrument—airship rating on the flight instructor certificate, and that flight instructor has observed that person perform 10 hours of pilot-in-command time in an airship under IFR; or

(ii) Passed an instrument proficiency test in an airship given by an examiner and required by § 61.57(e) of this part.

(f) Until [insert date 2 years from effective date of the final rule], a person who holds a private or commercial pilot certificate with an airplane category rating and an instrument rating that does not bear the airplane instrument ratings of paragraph (b)(7)(i) or (b)(7)(ii) of this section may exchange that certificate for a private or commercial pilot certificate, as appropriate, with an:

(1) Instrument-airplane single engine rating, provided that person has an airplane single-engine class rating and has satisfactorily accomplished the practical test for an instrument rating in a single-engine or multiengine airplane; and

(2) Instrument-airplane multiengine rating, provided that person has an airplane multiengine class rating and has satisfactorily accomplished the practical test for an instrument rating in a—

(i) Multiengine airplane; or

(ii) Single-engine airplane and also demonstrated instrument proficiency during the practical test for the multiengine class rating such that the person's certificate does not bear the limitation ''Airplane Multiengine VFR Only.''

(g) A person who holds a commercial or private pilot certificate with a glider category rating may exchange that certificate for one with the current nonpowered glider class rating and without a further showing of proficiency, provided that person:

(1) Holds a glider category rating; and

(2) Has passed a practical test in a nonpowered glider.

(h) A person who holds a commercial or private pilot certificate may exchange that certificate for one with the current powered glider class rating and without a further showing of proficiency, provided that person:

(1) Holds a glider category rating; and

(2) Has passed a practical test in a powered glider.

§ 61.7 Obsolete certificates and ratings.

(a) The holder of a free balloon pilot certificate issued before November 1, 1973, may not exercise the privileges of that certificate.

(b) The holder of a pilot certificate that bears any of the following category ratings without an associated class rating, may not exercise the privileges of that category rating:

(1) Rotorcraft.

(2) Lighter-than-air.

(3) Helicopter.

(4) Autogiro.

(c) After [insert date 2 years from effective date of the final rule], the holder of the following certificates or ratings may not exercise the privileges of those certificates and ratings:

(1) Airplane—instrument rating.

(2) Glider category without a class rating.

(3) Basic ground instructor.

(4) Advanced ground instructor.

(5) Instrument ground instructor.

§ 61.9 Written syllabus for conducting training.

An authorized ground or flight instructor, as appropriate, who provides training for an airman certificate or rating issued under this part must:

(a) Use a written syllabus for conducting that training, and that syllabus must contain the following information—

(1) A summary of the total training time in the syllabus;

(2) A planned training time schedule for each lesson;

(3) A detailed description of the training to be covered in each lesson; and

(4) The aeronautical knowledge areas and approved areas of operation that are appropriate to the airman certificate and rating sought and required by this part.

(b) Ensure that the written syllabus contains all of the aeronautical knowledge areas and approved areas of operation that apply to the airman certificate and rating sought and required by this part;

(c) Furnish a copy of the written syllabus to the student before that student commences the training program;

(d) Ensure that the student has accomplished all lessons of the written syllabus before endorsing that student for the appropriate knowledge or practical test for a certificate or rating;

(e) Maintain a copy of the written syllabus and make it available for inspection by the Administrator upon request; and

(f) Provide the student with an itemized written record of the training accomplished when that student accomplishes the training syllabus or decides to terminate training.

§ 61.11 Expired pilot certificates and reissuance.

(a) No person who holds an expired pilot certificate or rating may act as a pilot and/or exercise the privileges of that pilot certificate and rating.

(b) The following pilot certificates and ratings have expired and may not be reissued:

(1) An airline transport pilot certificate issued before May 1, 1949, or an airline transport pilot certificate that contains a horsepower limitation;

(2) A private or commercial pilot certificate issued before July 1, 1945; or

(3) A pilot certificate with a lighter-than-air or free balloon rating issued before July 1, 1945.

(c) A pilot certificate, issued on the basis of a foreign pilot license will expire on the date the foreign license expires.

(d) An airline transport pilot certificate issued after April 30, 1949, that bears an expiration date but does not contain a horsepower limitation may be reissued without an expiration date.

(e) A private or commercial pilot certificate issued after June 30, 1945, that bears an expiration date may be reissued without an expiration date.

(f) A pilot certificate with a lighter-than-air or free balloon rating issued after June 30, 1945, that bears an expiration date may be reissued without an expiration date.

(g) A U.S. pilot certificate, issued on the basis of a foreign pilot license that does not have an expiration date, may be issued without an expiration date.

§ 61.13 Awarding of airman certificates, ratings, and authorizations.

(a) An applicant for an airman certificate or rating under this part must make that application on a form and in a manner acceptable to the Administrator.

(b) An applicant who is neither a United States citizen nor a resident alien of the United States:

(1) Must show evidence that the appropriate fee prescribed by part 187 of this chapter has been paid when that person applies for a—

(i) Student pilot certificate that is issued outside the United States; or

(ii) Knowledge or practical test for a U.S. airman certificate or rating issued under this part, if the test is administered outside the United States.

(2) May be refused issuance of any U.S. airman certificate and rating by the Administrator.

(c) Except for the provisions listed in paragraph (b) of this section, an applicant who satisfactorily accomplishes the training and certification requirements for the certificate and rating sought is entitled to receive that airman certificate and rating.

(d) *Limitations.*

(1) An applicant who cannot comply with certain approved areas of operation required on the practical test because of physical limitations may be issued an airman certificate and rating with the appropriate limitation placed on the applicant's airman certificate provided the:

(i) Applicant is able to meet all the other certification requirements for the airman certificate or rating sought;

(ii) Physical limitation has been recorded with the Federal Aviation Administration on the applicant's medical records; and

(iii) Administrator determines the applicant's inability to perform the particular area of operation will not adversely affect safety.

(2) A limitation placed on a person's airman certificate may be removed, provided that person demonstrates satisfactory proficiency:

(i) In the area of operation appropriate to the airman certificate level and rating sought; and

(ii) To an examiner.

(e) *Category II pilot authorization.*

(1) A Category II pilot authorization is:

(i) Issued as a part of a pilot's instrument rating or airline transport pilot certificate; and

(ii) Issued originally with a limitation of 1600 feet runway visual readout and a 150-foot decision height.

(2) The limitation in paragraph (e)(1)(ii) of this section may be removed when the person has, within the previous 6 calendar months from the month Category II pilot authorization is issued, performed and logged 3 Category II approaches to a landing under actual or simulated instrument conditions with a 150-foot decision height.

(f) Unless otherwise authorized by the Administrator, a person whose airman certificate has been suspended may not apply for any airman certificate or rating during the period of suspension.

(g) Unless otherwise authorized by the Administrator, a person whose pilot, flight instructor, or ground instructor certificate has been revoked may not apply for any airman certificate or rating for 1 year after the date of revocation.

§ 61.14 Refusal to submit to a drug test.

(a) This section applies to:

(1) An employee who performs a function listed in appendix I to part 121 of this chapter for a part 119 certificate holder operating under part 121 or part 135; and

(2) An employee who performs a function listed in appendix I to part 121 of this chapter for an operator as defined in § 135.1(c) of this chapter. An employee of a person conducting operations of foreign civil aircraft navigated within the United States pursuant to part 375 or emergency mail service operations pursuant to section 405(h) of the Federal Aviation Act of 1958 is excluded from the requirements of this section.

(b) Refusal by the holder of a certificate issued under this part to take a test for a drug specified in appendix I of part 121 of this chapter, when requested by an employer as defined in that appendix or an operator as defined in § 135.1(c) of this chapter, and under the circumstances specified in that appendix is grounds for:

(1) Denial of an application for any certificate or rating issued under this part for a period of up to 1 year after the date of that refusal; and

(2) Suspension or revocation of any certificate or rating issued under this part.

§ 61.15 Offenses involving alcohol or drugs.

(a) A conviction for the violation of any Federal or state statute relating to the growing, processing, manufacture, sale, disposition, possession, transportation, or importation of narcotic drugs, marijuana, or depressant or stimulant drugs or substances is grounds for:

(1) Denial of an application for any certificate or rating issued under this part for up to 1 year after the date of final conviction; or

(2) Suspension or revocation of any certificate or rating issued under this part.

(b) Committing an act prohibited by § 91.17(a) or § 91.19(a) of this chapter is grounds for:

(1) Denial of an application for a certificate or rating issued under this part for up to 1 year after the date of that act; or

(2) Suspension or revocation of any certificate or rating issued under this part.

(c) For the purposes of paragraphs (d) and (e) of this section, a motor vehicle action means:

(1) A conviction after November 29, 1990, for the violation of any Federal or state statute relating to the operation of a motor vehicle while intoxicated by alcohol or a drug, while impaired by alcohol or a drug, or while under the influence of alcohol or a drug;

(2) The cancellation, suspension, or revocation of a license to operate a motor vehicle by a state after November 29, 1990, for a cause related to the operation of a motor vehicle while intoxicated by alcohol or a drug, while impaired by alcohol or a drug, or while under the influence of alcohol or a drug; or

(3) The denial after November 29, 1990, of an application for a license to operate a motor vehicle by a state for a cause related to the operation of a motor vehicle while intoxicated by alcohol or a drug, while impaired by alcohol or a drug, or while under the influence of alcohol or a drug.

(d) Except for a motor vehicle action that results from the same incident or arises out of the same factual circumstances, a motor vehicle action occurring within 3 years of a previous motor vehicle action is grounds for:

(1) Denial of an application for any certificate or rating issued under this part for up to 1 year after the date of the last motor vehicle action; or

(2) Suspension or revocation of any certificate or rating issued under this part.

(e) Each person holding a certificate issued under this part shall provide a written report of each motor vehicle action to the FAA, Civil Aviation Security Division (AAC–700), P.O. Box 25810, Oklahoma City, OK 73125, not later that 60 days after the motor vehicle action. The report must include:

(1) The person's name, address, date of birth, and airman certificate number;

(2) The type of violation that resulted in the conviction or the administrative action;

(3) The date of the conviction or administrative action;

(4) The state that holds the record of conviction or administrative action; and

(5) A statement of whether the motor vehicle action resulted from the same incident or arose out of the same factual circumstances related to a previously reported motor vehicle action.

(f) Failure to comply with paragraph (e) of this section is grounds for:

(1) Denial of an application for any certificate or rating issued under this part for up to 1 year after the date of the motor vehicle action; or

(2) Suspension of revocation of any certificate or rating issued under this part.

§ 61.16 Refusal to submit to an alcohol test or to furnish test results.

A refusal to submit to a test to indicate the percentage by weight of alcohol in the blood, when requested by a law enforcement officer in accordance with § 91.17(c) of this chapter, or a refusal to furnish or authorize the release of the test results requested by the Administrator in accordance with § 91.17(c) or (d) of this chapter, is grounds for:

(a) Denial of an application for any certificate or rating issued under this part for up to 1 year after the date of that refusal; or

(b) Suspension or revocation of any certificate or rating issued under this part.

§ 61.17 Temporary certificate.

(a) A temporary pilot or flight instructor certificate, or rating, is issued for up to 120 days, at which time a permanent certificate will be issued to a person whom the Administrator finds qualified under this part.

(b) A temporary pilot or flight instructor certificate, or rating, expires:

(1) On the expiration date shown on the certificate;

(2) Upon receipt of the permanent certificate; or

(3) Upon receipt of a notice that the certificate or rating sought is denied or revoked.

§ 61.19 Duration of pilot and instructor certificates.

(a) *General.* The holder of a certificate with an expiration date may not, after that date, exercise the privileges of that certificate.

(b) *Student pilot certificate.* A student pilot certificate expires 24-calendar months from the month in which it is issued.

(c) *Other pilot certificates.* A pilot certificate (other than a student pilot certificate), issued under this part, is issued without a specific expiration date. The holder of a pilot certificate (issued on the basis of a foreign pilot license) may exercise the privileges of that certificate only while that person's foreign pilot license is effective.

(d) *Flight instructor certificate.* A flight instructor certificate:

(1) Is effective only while the holder has a current pilot certificate; and

(2) Expires 24-calendar months from the month in which it was issued or renewed.

(e) *Ground instructor certificate.* A ground instructor certificate, issued under this part, is issued without a specific expiration date.

(f) *Surrender, suspension, or revocation.* Any certificate issued under this part ceases to be effective if it is surrendered, suspended, revoked, or otherwise terminated.

(g) *Return of certificates.* The holder of any certificate, issued under this part, that has been suspended, revoked, or otherwise terminated must return that certificate to the FAA when requested to do so by the Administrator.

§ 61.21 Duration of a Category II pilot authorization.

(a) A Category II pilot authorization expires 6-calendar months from the month in which it was issued or renewed.

(b) Upon passing a practical test for a Category II pilot authorization, the authorization may be renewed for each type aircraft for the authorization held.

(c) A Category II pilot authorization for a specific type aircraft for which an authorization is held will not be renewed beyond 12-calendar months from the month the practical test was accomplished in that type aircraft.

(d) If the holder of a Category II pilot authorization satisfactorily accomplishes the practical test for a renewal in the month before the authorization expires, the holder is considered to have accomplished it during the month the authorization expired.

§ 61.23 Duration and requirement for a medical certificate.

(a) *Duration of a medical certificate.*

(1) A first-class medical certificate expires at the end of the last day of the 6th calendar month from the month of issuance shown on the medical certificate.

(2) A second-class medical certificate expires at the end of the last day of the 12th calendar month from the month of issuance shown on the medical certificate.

(3) A third-class medical certificate expires on the last day of the 24th calendar month from the month of issuance shown on the medical certificate.

(b) *Requirement for a medical certificate.* Except as provided in paragraph (b)(4) of this section, a person:

(1) Must hold at least a first-class medical certificate for flight operations requiring an airline transport pilot certificate;

(2) Must hold at least a second-class medical certificate for flight operations requiring a commercial pilot certificate;

(3) Must hold at least a third-class medical certificate—

(i) For flight operations requiring a private pilot certificate or a person who holds a student pilot certificate who is seeking a private pilot certificate or rating;

(ii) To be eligible for a student pilot certificate and that person is seeking a private pilot certificate, or a person who holds a private pilot certificate issued under this part; or

(iii) When exercising the privileges of a flight instructor certificate and the person is serving as a required crewmember or as the pilot-in-command.

(4) Does not need to hold a medical certificate—

(i) For a student pilot who is seeking a recreational pilot certificate, or who is seeking a pilot certificate with glider category rating or balloon class rating, but the person may not exercise the privileges of that student pilot certificate if the person has any known medical condition or deficiency that makes the person unable to pilot the aircraft;

(ii) When exercising the privileges of a recreational pilot certificate, but the person may not exercise the privileges of that pilot certificate if the person has any known medical condition or deficiency that makes the person unable to pilot the aircraft;

(iii) When exercising the privileges of a pilot certificate or flight instructor certificate with a glider category rating or balloon class rating, but the person may not exercise the privileges of that pilot certificate if the person has any known medical condition or deficiency that makes the person unable to pilot the aircraft;

(iv) When exercising the privileges of a flight instructor certificate, provided the person is not serving as a required crewmember or as the pilot-in-command; or

(v) When exercising the privileges of a ground instructor certificate.

§ 61.25 Change of name.

(a) An application to change the name on a certificate issued under this part must be accompanied by the applicant's:

(1) Current pilot certificate; and

(2) Copy of the marriage license, court order, or other document verifying the name change.

(b) The documents in paragraph (a) of this section will be returned to the applicant after inspection.

§ 61.27 Voluntary surrender or exchange of certificate.

(a) The holder of a certificate issued under this part may voluntarily surrender it for:

(1) Cancellation;

(2) Issuance of a lower grade certificate; or

(3) Another certificate with specific ratings deleted.

(b) Any request made under paragraph (a) of this section must include the following signed statement or its equivalent:

This request is made for my own reasons, with full knowledge that my (insert name of certificate or rating, as appropriate) may not be reissued to me unless I again pass the tests prescribed for its issuance.

§ 61.29 Replacement of a lost or destroyed airman or medical certificate or knowledge test report.

(a) A request for the replacement of a lost or destroyed airman certificate issued under this part shall be made by letter to the Department of Transportation, Federal Aviation Administration, Airman Certification Branch, P.O. Box 25082, Oklahoma City, OK 73125, and shall be accompanied by a check or money order for the appropriate fee and payable to the Federal Aviation Administration.

(b) A request for the replacement of a lost or destroyed medical certificate shall be made by letter to the Department of Transportation, Federal Aviation Administration, Aeromedical Certification Branch, P.O. Box 25082, Oklahoma City, OK 73125, and shall be accompanied by a check or money order for the appropriate fee and payable to the Federal Aviation Administration.

(c) A request for the replacement of a lost or destroyed knowledge test report shall be made by letter to the Department of Transportation, Federal Aviation Administration, Airman Certification Branch, P.O. Box 25082, Oklahoma City, OK 73125, and shall be accompanied by a check or money order for the appropriate fee and payable to the Federal Aviation Administration.

(d) The letter requesting replacement of a lost or destroyed airman certificate, medical certificate, or knowledge test report must state the:

(1) Name of the person;

(2) Permanent mailing address (including zip code);

(3) Social security number;

(4) Date and place of birth of the certificate holder;

(5) State any available information regarding the—

(i) Grade, number, date of issuance of the certificate, and the ratings;

(ii) Date of the medical examination; or

(iii) Date the knowledge test was taken.

(e) A person who has lost an airman certificate, medical certificate, or knowledge test report may obtain a facsimile from the FAA confirming that it was issued, and the:

(1) Facsimile may be carried as an airman certificate, medical certificate, or knowledge test report, as appropriate, for up to 60 days pending the person's receipt of a duplicate under paragraph (a), (b), or (c) of this section, unless the person has been notified that the certificate has been suspended or revoked.

(2) Request for such a facsimile must include the date on which a duplicate certificate or knowledge test report was previously requested, and a check or money order payable to the Federal Aviation Administration, for the cost of the duplicate.

§ 61.31 Type rating requirements, additional training, and authorization requirements.

(a) *Type ratings required.* A person who acts as a pilot in command of any of the following aircraft must hold a type rating for that aircraft:

(1) Large aircraft (except lighter-than-air).

(2) Turbojet-powered airplanes.

(3) Other aircraft specified by the Administrator through aircraft type certificate procedures.

(b) *Authorization in lieu of a type rating.* A person may be authorized to operate an aircraft requiring a type rating without a type rating for up to 60 days, provided:

(1) The Administrator has authorized the flight or series of flights;

(2) The Administrator has determined that an equivalent level of safety can be achieved through the operating limitations on the authorization;

(3) The person shows that compliance with paragraph (a) of this section is impracticable for the flight or series of flights; and

(4) The flight—

(i) Involves only a ferry flight, training flight, test flight, or practical test for a pilot certificate or rating;

(ii) Is within the United States;

(iii) Does not involve operations for compensation or hire unless the compensation or hire involves payment for the use of the aircraft for training or taking a practical test; and

(iv) Involves only the carriage of flight crewmembers considered essential for the flight.

(5) If the flight or series of flights cannot be accomplished within the time limit of the authorization, the Administrator may authorize an additional period of up to 60 days to accomplish the flight or series of flights.

(c) *Aircraft category, class, and type ratings: Limitations on the carriage of persons or operating for compensation or hire.* Unless a person holds a category, class rating, and type rating (if a class and type rating is required) that applies to the aircraft, that person may not act as pilot in command of an aircraft that is:

(1) Carrying another person; or

(2) Being operated for compensation or hire.

(d) *Aircraft category, class, and type ratings: Limitations on operating an aircraft as the pilot in command.* To serve as the pilot in command of an aircraft a person must hold the appropriate category, class, and type rating (if a class rating and type rating is required) for the aircraft to be flown, or that person must:

(1) Be enrolled in a course of training for the purpose of obtaining an additional pilot certificate and rating that are appropriate to that aircraft, and is under the supervision of an authorized flight instructor;

(2) Have received the required training of this part that are appropriate to the aircraft category, class, and type rating (if a class or type rating is required) for the aircraft to be flown; and

(3) Have received the required endorsement from an authorized flight instructor for supervised PIC flight in that aircraft.

(e) *Exceptions.*

(1) This section does not require a class rating for a powered-lift aircraft.

(2) This section does not require a category and class rating for aircraft not type certificated as airplanes, rotorcraft, gliders, powered-lift, or lighter-than-air aircraft.

(3) The rating limitations of this section do not apply to an applicant when taking a practical test given by an examiner; or

(4) The rating limitations of this section do not apply to the holder of a:

(i) Student pilot certificate;

(ii) Pilot certificate under the supervision of an authorized flight instructor when operating an aircraft for the purpose of obtaining an additional certificate or rating;

(iii) Pilot certificate when operating an aircraft under the authority of an experimental or provisional aircraft type certificate;

(iv) Pilot certificate with a lighter-than-air category rating when operating a balloon.

(f) *Additional training required for operating complex airplanes.* Except as provided in paragraph (f)(2) of this

section, no person may act as pilot in command of a complex airplane (an airplane that has a retractable landing gear, flaps, and controllable propeller), unless the person has met the requirements of this paragraph.

(1) The person must have—

(i) Received and logged ground and flight training from an authorized flight instructor in a complex airplane, or in a flight simulator or flight training device that is representative of a complex airplane, and has been found proficient on the operation and systems of the airplane; and

(ii) Received a one-time endorsement in the pilot's logbook from an authorized flight instructor who certifies the person is proficient to operate a complex airplane.

(2) The training and endorsement required by paragraph (f)(1) of this section is not required if the person has logged flight time as pilot in command of a complex airplane, or in a flight simulator or flight training device that is representative of a complex airplane prior to [insert effective date of the final rule].

(g) *Additional training required for operating high performance airplanes.* Except as provided in paragraph (g)(2) of this section, no person may act as pilot in command of a high performance airplane (an airplane with an engine of 200 horsepower or more), unless the person has met the requirements of this paragraph.

(1) The person must have—

(i) Received and logged ground and flight training from an authorized flight instructor in an high performance airplane, or in a flight simulator or flight training device that is representative of a high performance airplane, and has been found proficient on the operation and systems of the airplane; and

(ii) Received a one-time endorsement in the pilot's logbook from an authorized flight instructor who certifies the person is proficient to operate a high performance airplane.

(2) The training and endorsement required by paragraph (g)(1) of this section is not required if the person has logged flight time as pilot in command of a high performance airplane, or a flight simulator or flight training device that is representative of a high performance airplane prior to [insert effective date of the final rule].

(h) *Additional training required for operating pressurized aircraft capable of operating at high altitudes.*

(1) Except as provided in paragraph (h)(3) of this section, no person may act as pilot in command of a pressurized aircraft (an aircraft that has a service ceiling or maximum operating altitude, whichever is lower, above 25,000 feet MSL), unless that person has received and logged ground training from an authorized flight or ground instructor in at least the following subjects:

(i) High altitude aerodynamics and meteorology;

(ii) Respiration, effects, symptoms, and causes of hypoxia and any other high altitude sickness;

(iii) Duration of consciousness without supplemental oxygen;

(iv) Effects of prolonged usage of supplemental oxygen;

(v) Causes and effects of gas expansion and gas bubble formation;

(vi) Preventive measures for eliminating gas expansion, gas bubble formation, and high altitude sickness; and

(vii) Physical phenomena and incidents of decompression;

(2) Except as provided in paragraph (h)(3) of this section, no person may act as pilot in command of a pressurized aircraft (an aircraft that has a service ceiling or maximum operating altitude, whichever is lower, above 25,000 feet MSL), unless that person has received:

(i) Training in a pressurized aircraft, or in a flight simulator or flight training device that is representative of a pressurized aircraft, and the training must include flight at normal cruise while operating above 25,000 feet MSL, proper emergency procedures for simulated emergency rapid decompression and descent procedures; and

(ii) An endorsement in the person's logbook or training record from the instructor who gave the training and found the person proficient in a pressurized aircraft.

(3) The training and endorsement required by this paragraph is not required if a person can document satisfactory accomplishment of any of the following in a pressurized aircraft, or in a flight simulator or a flight training device that is representative of a pressurized aircraft:

(i) Serving as pilot in command before April 15, 1991;

(ii) Completing a practical test or rating before April 15, 1991;

(iii) Completing an official pilot-in-command check conducted by the military services of the United States; or

(iv) Completing a pilot-in-command proficiency check under parts 121, 125, or 135 of this chapter conducted by the Administrator or by an approved check pilot.

(i) *Additional training required by the aircraft's type certificate.* No person may serve as pilot in command of an aircraft that the Administrator has determined requires aircraft type specific training unless that person has received:

(1) Type specific training in the aircraft, or in a flight simulator or a flight training device that is representative of that type of aircraft, and has been found proficient on the operation and systems of the aircraft; and

(2) A logbook endorsement from an authorized flight instructor or ground instructor, as appropriate, who gave that person the training.

(j) *Additional training required for operating tailwheel airplanes.* Except as provided in paragraph (j)(4), no person may act as pilot in command of a tailwheel airplane unless that person has:

(1) Received and logged flight training from an authorized flight instructor in a tailwheel airplane on the maneuvers and procedures listed in this paragraph.

(2) Received an endorsement in the person's logbook from an authorized flight instructor who gave the training and found the person proficient in a tailwheel airplane.

(3) Received an endorsement in the person's logbook from an authorized flight instructor who gave the training and found the person proficient in at least normal and crosswind takeoffs and landings, wheel landings (unless the manufacturer has recommended against such landings), and go-arounds.

(4) The training and endorsement required by this paragraph is not required if the person logged pilot in command time of a tailwheel airplane before April 15, 1991.

§ 61.33 Tests: General procedure.

The Administrator shall designate the time, location, and examiner for conducting the tests prescribed by and under this part.

§ 61.35 Knowledge test: Prerequisites and passing grades.

(a) An applicant for a knowledge test must have:

(1) Received an endorsement from an authorized flight or ground instructor certifying that the applicant accomplished a ground training or a home study course required by this part for the certificate or rating sought and is prepared for the knowledge test; and

(2) Proper identification at the time of application that contains the applicant's—

(i) Photograph;

(ii) Signature;

(iii) Date of birth, which shows the applicant meets or will meet the age requirements of this part for the certificate sought before the expiration date of the airman knowledge test report; and

(iv) Actual residential address, if different from the applicant's mailing address.

(b) The Administrator shall specify the minimum passing grade for the knowledge test.

§ 61.37 Knowledge tests: Cheating or other unauthorized conduct.

(a) An applicant for a knowledge test may not:

(1) Copy or intentionally remove any knowledge test;

(2) Give to another applicant or receive from another applicant any part or copy of a knowledge test;

(3) Give assistance on, or receive assistance on, a knowledge test during the period that test is being given;

(4) Be represented by, or represent, another person for a knowledge test;

(5) Use any material or aid during the period that test is being given, unless specifically authorized to do so by the Administrator; and

(6) Intentionally cause, assist, or participate in any act prohibited by this paragraph.

(b) An applicant who the Administrator finds has committed an act prohibited by paragraph (a) of this section is prohibited, for 1 year after the date of committing that prohibited act, from:

(1) Applying for any certificate or rating under this chapter; and

(2) Applying for and taking any test under this chapter.

(c) Any certificate or rating held by an applicant who the Administrator finds has committed an act prohibited by paragraph (a) of this section may be suspended or revoked.

§ 61.39 Prerequisites for practical tests.

(a) Except as provided in paragraphs (b) and (c) of this section, to be eligible for a practical test for a certificate or rating issued under this part, an applicant must:

(1) Have satisfactorily accomplished the required knowledge test within the 24-calendar month period preceding the month the applicant accomplishes the practical test, if a knowledge test is required;

(2) Present the knowledge test report at the time of application for the practical test, if a knowledge test is required;

(3) Have satisfactorily accomplished the required training and attained the aeronautical experience prescribed by this part for the certificate or rating sought;

(4) Hold at least a current third-class medical certificate, if a medical certificate is required;

(5) Meet the prescribed age requirement of this part for the issuance of the certificate or rating sought;

(6) Except as provided in paragraph (c) of this section, an applicant must have an endorsement in the applicant's logbook or training record that has been signed by the applicant's authorized flight instructor who certifies that the applicant—

(i) Has received and logged training time within 60 days preceding the date of application in preparation for the practical test;

(ii) Is prepared for the required practical test; and

(iii) Has demonstrated satisfactory knowledge of the subject areas in which the applicant was deficient on the airman knowledge test.

(7) Have a completed and signed application form.

(b) Notwithstanding the provisions of paragraphs (a) (1) and (2) of this section, an applicant for an airline transport pilot certificate or an additional rating to an airline transport certificate may take the practical test for that certificate or rating with an expired knowledge test report, provided that applicant:

(1) Is employed as a flight crewmember by a U.S. air carrier or commercial operator under parts 121, 125, or 135 of this chapter and is employed by such a certificate holder at the time of the practical test and has satisfactorily accomplished that operator's approved—

(i) pilot-in-command aircraft qualification training program that is appropriate to the certificate and rating sought; and

(ii) requalification training requirements that is appropriate to the certificate and rating sought.

(2) Is employed as a flight crewmember by a U.S. scheduled military air transportation service operator at the time of the practical test, and has accomplished that operator's pilot-in-command aircraft qualification training program that is appropriate to the certificate and rating sought.

(c) An applicant for an airline transport pilot certificate or an additional rating to an airline transport pilot certificate in an aircraft that does not involve an aircraft type rating practical test need not comply with the provisions of paragraph (a)(6) of this section.

§ 61.41 Flight training received from flight instructors not certificated by the FAA.

(a) A person may credit flight training toward the requirements of a pilot certificate or rating issued under this part, if that person received the training from:

(1) A flight instructor of an Armed Force of either—

(i) The United States; or

(ii) A foreign member State to the International Civil Aviation Organization in a program for training military pilots.

(2) A flight instructor who is authorized to give such training by the licensing authority of a member State of International Civil Aviation Organization, and the flight training is given outside the United States.

(b) A flight instructor described in paragraph (a) of this section is not authorized to give any of the endorsements required by this part.

§ 61.43 Practical tests: General procedures.

(a) Except as provided in paragraph (b) of this section, the ability of an applicant for a certificate or rating to perform the required tasks on the practical test is based on that applicant's ability to safely:

(1) Perform the approved areas of operation for the certificate or rating sought within the approved standards;

(2) Demonstrate mastery of the aircraft with the successful outcome of each task performed never seriously in doubt;

(3) Demonstrate satisfactory proficiency and competency within the approved standards;

(4) Demonstrate sound judgment; and

(5) Demonstrate single-pilot competence if the aircraft is type certificated for single-pilot operations.

(b) If an applicant does not demonstrate single pilot proficiency, as required in paragraph (a)(5) of this section, the following limitation will apply:

(1) A limitation of ''Second in Command Required'' will be placed on the applicant's airman certificate.

(2) The limitation may be removed if the applicant satisfactorily accomplishes the appropriate practical test by demonstrating single-pilot competence in the aircraft in which single-pilot privileges are sought.

(c) If an applicant fails any of the approved areas of operation, that applicant fails the practical test.

(d) An applicant is not eligible for a certificate or rating sought until all the approved areas of operation are satisfactorily accomplished.

(e) The examiner or the applicant may discontinue a practical test at any time:

(1) When the applicant fails one or more of the approved areas of operation; or

(2) Due to inclement weather conditions, aircraft airworthiness, or any other safety of flight concern.

(f) If a practical test is discontinued, the applicant is entitled to credit those

approved areas of operation that were satisfactorily accomplished, but only if the applicant:

(1) Satisfactorily accomplishes the remainder of the practical test within the 60-day period after the date the practical test was discontinued;

(2) Presents to the examiner for the retest the original notice of disapproval form or the letter of discontinuance form, as appropriate;

(3) Satisfactorily accomplishes any additional training needed and obtains the appropriate instructor endorsements, if additional training is required; and

(4) Presents to the examiner for the retest a properly completed and signed application.

§ 61.45 Practical tests: Required aircraft and equipment.

(a) *General.* An applicant for a certificate or rating under this part must furnish:

(1) An aircraft for the practical test that is of U.S. registry with a current standard, limited, or primary airworthiness certificate;

(2) An aircraft of U.S. registry with a current airworthiness certificate, other than standard, limited, or primary, provided the examiner conducting the test agrees;

(3) An aircraft of foreign registry that is properly certificated by the country of registry, provided the examiner conducting the test agrees; or

(4) A military aircraft that is in a safe operational status and is approved for use on the practical test by the appropriate military authority, provided the examiner conducting the test agrees.

(b) *Required equipment (other than controls).* Except for a practical test in a balloon and, as provided in paragraph (e) of this section, an aircraft used for a practical test must have:

(1) The equipment for each area of operation required for the practical test;

(2) No prescribed operating limitations that prohibit its use in any of the approved areas of operation required for the practical test;

(3) At least two pilot seats with adequate visibility for each person to operate the aircraft safely; and

(4) Cockpit and outside visibility adequate to evaluate the performance of the applicant, where an additional jump seat is provided for the examiner.

(c) *Required controls.* An aircraft used for a practical test:

(1) Must have engine power controls and flight controls that are easily reached and operable in a normal manner by both pilots, unless the examiner determines that the practical test can be conducted safely without them.

(2) May be used even if the engine power controls and flight controls are not easily reached and operable in a normal manner by both pilots, provided the examiner determines the flight can be conducted safely.

(3) Must have flight controls that are easily reached and operable in a normal manner by both pilots, for a rating in lighter-than-air aircraft, unless the examiner determines that the practical test can be conducted safely without them.

(d) *Simulated instrument flight equipment.* An applicant for a practical test that involves maneuvering an aircraft solely by reference to instruments must furnish:

(1) Equipment aboard the aircraft that permits the applicant to accomplish the approved areas of operation that apply to the rating sought; and

(2) A device that prevents the applicant from having visual reference outside the aircraft, but does not prevent the examiner from having visual reference outside the aircraft.

(e) *Aircraft with single controls.* A practical test may be conducted in an aircraft having a single set of controls, provided the:

(1) Examiner agrees to conduct the test;

(2) Test does not involve a demonstration of instrument skills; and

(3) Proficiency of the applicant can be observed by an examiner, who is in a position to observe the applicant.

§ 61.47 Status of an examiner who is authorized by the Administrator to conduct practical tests.

(a) An examiner represents the Administrator for the purpose of conducting practical tests for certificates and ratings issued under this part and to observe an applicant's ability to perform the approved areas of operation on the practical test.

(b) The student is the pilot in command of the aircraft during the practical test unless the examiner or another person has been so designated before the flight.

(c) Notwithstanding the type of aircraft used during the practical test, the applicant and the examiner (and any other occupants authorized to be on board by the examiner) are not subject to the requirements or limitations on the carriage of passengers that are specified in this chapter.

§ 61.49 Retesting after failure.

(a) An applicant for a knowledge or practical test who fails that test may only reapply for the test after the applicant has received:

(1) The necessary training from an authorized flight or ground instructor, as appropriate, who has determined that the applicant is now proficient to pass the test; and

(2) An endorsement from an authorized flight or ground instructor, as appropriate, who gave the applicant the additional training.

(b) An applicant for a flight instructor certificate with an airplane category rating, or for a flight instructor certificate with a glider category rating, who has failed the practical test due to deficiencies in instructional proficiency on stall awareness, spin entry, spins, and spin recovery must:

(1) Comply with the requirements of paragraph (a) of this section before being retested;

(2) Bring an aircraft to the retest that is of the appropriate aircraft category for the rating sought and is certificated for spins; and

(3) Demonstrate satisfactory instructional proficiency on stall awareness, spin entry, spins, and spin recovery to an examiner during the retest.

§ 61.51 Pilot logbooks.

(a) *Training time and aeronautical experience.* Each person must document and record the following time in a manner acceptable to the Administrator:

(1) Training and aeronautical experience used to meet the requirements for a certificate, rating, or flight review of this part.

(2) The aeronautical experience required for meeting the recency of flight experience requirements of this part.

(b) *Logbook entries.* For the purposes of meeting the requirements of paragraph (a) of this section, each person must enter the following information for each flight or lesson logged:

(1) General:

(i) Date.

(ii) Total time of flight.

(iii) Locations where the aircraft departed and arrived.

(iv) Type and identification of aircraft.

(v) The name and certificate number of a safety pilot, if required by § 91.109(b) of this chapter.

(2) Type of pilot experience or training:

(i) Pilot in command.

(ii) Second in command.

(iii) Flight and ground training received from an authorized flight instructor.

(iv) Training received in an approved flight training device or flight simulator from authorized flight or ground instructor.

(3) Conditions of flight:

(i) Day or night.

(ii) Actual instrument.

(iii) Simulated instrument.

(c) *Logging of pilot time.* The pilot time described in this section may be used to:

(1) Apply for a certificate or rating issued under this part; or

(2) Satisfy the recent flight experience requirements of this part.

(d) *Logging of pilot-in-command flight time.* Except as provided in paragraph (e) of this section, only one person may log pilot-in-command flight time, provided the:

(1) Person has final authority and responsibility for the operation and safety of the flight;

(2) Person holds the appropriate category, class, and type rating, if appropriate;

(3) Person has been designated as pilot in command before or during the flight; and

(4) Flight time occurs in actual flight conditions in an aircraft.

(e) *Two people logging pilot-in-command flight time.* If a certificated pilot and an authorized flight instructor are on board an aircraft at the same time, and each holds the appropriate category, class, and type rating (if a type rating is required) for that aircraft, then both the pilot and the flight instructor may log pilot-in-command time provided:

(1) The flight instructor—

(i) Is authorized by this chapter to conduct the training and is conducting training during the flight;

(ii) Holds at least a third-class medical certificate issued under part 67 of this chapter; and

(iii) Occupies a pilot station in the aircraft that has functioning flight controls.

(2) The pilot—

(i) Is receiving training from the flight instructor in a course of training for the issuance of a certificate or rating or to obtain the recency of experience requirements of this part;

(ii) Is qualified to conduct the flight in accordance with the operating rule under which the flight is being conducted; and

(iii) Is manipulating the controls of the aircraft.

(3) The aircraft has dual functioning flight controls and the engine controls can be reached from either pilot station.

(f) *Student pilots logging pilot-in-command flight time.* The holder of a student pilot certificate may log pilot in command time when the student pilot:

(1) Is the sole occupant of the aircraft;

(2) Has a current pilot-in-command flight endorsement as required under § 61.87 of this part; and

(3) Is undergoing a course of training for a pilot certificate or rating or is logging pilot-in-command flight time to obtain the pilot-in-command flight experience requirements for a pilot certificate or aircraft rating.

(g) *Logging second-in-command flight time.* A person may log second-in-command flight time, provided the person:

(1) Is qualified in accordance with the second-in-command requirements of § 61.55 of this part, and occupies a crewmember seat in an aircraft that requires more than one pilot by the aircraft's type certificate; or

(2) The person holds the appropriate category, class, and instrument rating (if an instrument rating is required for the flight) for the aircraft being flown, and the regulations under which the flight is being conducted requires a second-in-command pilot.

(h) *Logging instrument flight time.*

(1) A person may log instrument flight time when the person operates the aircraft solely by reference to instruments under actual or simulated instrument flight conditions.

(2) A person may log instrument flight time when the person is appropriately qualified for and is serving as an instrument flight instructor under actual instrument flight conditions.

(3) For the purposes of logging instrument flight time, to meet the instrument currency requirements of § 61.57(e) of this part, the following information must be recorded in the person's logbook—

(i) The location, number, and kind of instrument approaches accomplished; and

(ii) The name and pilot certificate number of the safety pilot, if required.

(i) *Logging training time.*

(1) A person may log training time when the person receives training from an authorized flight instructor in an aircraft, flight simulator, or flight training device for the purpose of obtaining a certificate, rating, or recency of experience requirements of this part.

(2) A person may log training time when the person receives training from an authorized ground instructor in a flight simulator or flight training device for the purpose of obtaining a certificate, rating, or recency of experience requirements, of this part.

(3) The training time must be logged in a logbook or training record, and must:

(i) Be certified in a legible manner by the authorized flight or ground instructor, as appropriate; and

(ii) Include a description of the training given, the length of the training lesson, and the instructor's signature, certificate number, and certificate expiration date.

(j) *Presentation of logbook.*

(1) Persons must present their pilot certificate, medical certificate, logbook, or any other record required by this part for inspection upon a request by:

(i) The Administrator;

(ii) An authorized representative from the National Transportation Safety Board; or

(iii) Any Federal, State, or local law enforcement officer.

(2) Student pilots must carry the following items in the aircraft when exercising the privileges of their student pilot certificate:

(i) Pilot logbook; and

(ii) Student pilot certificate.

(3) Recreational pilots must carry their logbook with the required instructor endorsements on all flights when serving as pilot-in-command or as a required flight crewmember for flights:

(i) Of more than 50 nautical miles from an airport where training was received;

(ii) In airspace in which communication with air traffic control is required;

(iii) Between sunset and sunrise; and

(iv) In an aircraft for which the pilot is not rated.

§ 61.53 Operations during medical deficiency.

(a) Operations that require a medical certificate. Except as provided for in paragraph (b) of this section, a person who holds a current medical certificate issued under part 67 of this chapter shall not act as pilot in command, or in any other capacity as a required pilot flight crewmember, while that person:

(1) Knows or has reason to know of any medical condition that would make the person unable to meet the requirements for the medical certificate held; or

(2) Is taking medication or receiving other treatment for a medical condition that results in the person being unable to meet the requirements for the medical certificate held.

(b) Operations that do not require a medical certificate. For operations provided for in § 61.23(b)(4) of this part without a medical certificate, a person shall not act as pilot in command while that person:

(1) Knows or has reason to know of any medical condition that would make them unable to operate the aircraft in a safe manner; or

(2) Is taking medication or receiving other treatment for a medical condition that would make them unable to operate the aircraft in a safe manner.

§ 61.55 Second-in-command qualifications.

(a) Except as provided in paragraph (d) of this section, no person may serve as a second in command of an aircraft type certificated for more than one required pilot flight crewmember or in operations requiring a second in command unless that person holds:

(1) At least a current private pilot certificate with the appropriate category and class rating; and

(2) An instrument rating that applies to the aircraft being flown if the flight is under IFR.

(b) No person may serve as a second in command of an aircraft type certificated for more than one required pilot flight crewmember or in operations requiring a second in command unless that person has within the previous 12 calendar months:

(1) Reviewed on the specific type aircraft, for which second-in-command privileges are requested, and that review must include becoming familiar with the aircraft's—

(i) Operational procedures on the powerplant, equipment, and systems;

(ii) Performance specifications and limitations;

(iii) Normal, abnormal, and emergency operating procedures;

(iv) Flight manual; and

(v) Placards and markings.

(2) Performed and logged practice in the type aircraft or in an approved flight simulator or approved flight training device that represents the type of aircraft for which second-in-command privileges are requested, and the practice must include at least—

(i) Three takeoffs and landings to a full stop as the sole manipulator of the flight controls;

(ii) Engine-out procedures and maneuvering with an engine out while executing the duties of a pilot in command; and

(iii) Flight deck resource management training.

(c) If a person complies with the requirements in paragraph (b) of this section in the calendar month before or the calendar month after the month in which compliance with this section is required, then that person is considered to have accomplished the training and practice requirements of paragraph (b) of this section in the month it is due.

(d) This section does not apply to a person who is:

(1) Designated and qualified as a pilot in command, under part 121, 125, or 135 of this chapter in that specific type of aircraft;

(2) Designated as the second in command, under part 121, 125, or 135 of this chapter in that specific type of aircraft; or

(3) Designated as the second in command in that specific type of aircraft for the purpose of receiving flight training required by this section and no passengers or cargo are carried on the aircraft.

(e) A person who holds a commercial or airline transport pilot certificate with the appropriate category and class rating need not meet the requirements of paragraph (b)(2) of this section, provided that pilot:

(1) Is conducting ferry flights, aircraft flight tests, or evaluation flights of an aircraft's equipment; and

(2) Does not carry any person or cargo aboard the aircraft, unless the person or cargo is considered necessary for the flight.

(f) To meet the requirements of paragraph (b)(2) of this section, a person may serve as a second in command in that specific type of aircraft, if:

(1) The flight occurs under day VFR or day IFR; and

(2) No person or cargo are carried aboard the aircraft, unless the person or cargo is considered necessary for the flight.

§ 61.56 Flight review.

(a) A flight review consists of a minimum of 1 hour of flight instruction and 1 hour of ground instruction. The review must include—

(1) A review of the current general operating and flight rules of part 91 of this chapter; and

(2) A review of those maneuvers and procedures which, at the discretion of the person giving the review, are necessary for the pilot to demonstrate the safe exercise of the privileges of the pilot certificate.

(b) Glider pilots may substitute a minimum of three instructional flights in a glider, each of which includes a 360 degree turn, in lieu of the 1 hour of flight instruction required in paragraph (a).

(c) Except as provided in paragraphs (d) and (e) of this section, no person may act as pilot in command of an aircraft unless, since the beginning of the 24th calendar month before the month in which that pilot acts as pilot in command, that person has—

(1) Accomplished a flight review given in an aircraft for which that pilot is rated by an appropriately rated instructor certificated under this part or other person designated by the Administrator; and

(2) A logbook endorsed by the person who gave the review certifying that the person has satisfactorily completed the review.

(d) A person who has, within the period specified in paragraph (c) of this section, satisfactorily completed a pilot proficiency check conducted by the FAA, an approved pilot check airman, or a U.S. Armed Force, for a pilot certificate, rating, or operating privilege, need not accomplish the flight review required by this section.

(e) A person who has, within the period specified in paragraph (c) of this section, satisfactorily completed one or more phases of an FAA-sponsored pilot proficiency award program need not accomplish the flight review required by this section.

(f) A person who holds a current flight instructor certificate who has, within the period specified in paragraph (c) of this section, satisfactorily completed a renewal of a flight instructor certificate under the provisions on 61.197(c), need not accomplish the 1 hour of ground instruction specified in subparagraph (a)(1) of this section.

(g) The requirements of this section may be accomplished in combination with the requirements of § 61.57 and other applicable recency requirements at the discretion of the instructor.

§ 61.57 Recent flight experience: Pilot-in-command.

(a) *General experience.*

(1) Except as provided by paragraph (e) of this section, no person may act as a pilot in command of an aircraft carrying passengers or as required pilot aboard an aircraft that requires more than one pilot crewmember unless that person has made at least three takeoffs and three landings to a full stop within the preceding 90 days, and:

(i) The person acted as sole manipulator of the flight controls;

(ii) The required takeoffs and landings were performed in an aircraft of the same category, class, and type (if a type rating is required), and if the aircraft to be flown is an airplane with a tailwheel landing gear, the takeoffs and landings must have been in a tailwheel airplane; and

(iii) Each required takeoff and landing involved a flight in the traffic pattern at the recommended traffic pattern altitude for the airport.

(2) A person may act as a pilot in command or as required pilot and sole manipulator of the controls for an aircraft that requires more than one pilot under day VFR or day IFR, provided no persons or property, other than that necessary for compliance with paragraph (a) of this section, are carried.

(b) *Night experience.* Except as provided by paragraph (e) of this section, no person may act as pilot in command of an aircraft carrying passengers at night, nor as a required pilot aboard an aircraft requiring more

than one pilot crewmember at night, unless that person has complied with the requirements of paragraph (a) of this section at night.

(c) *Recent instrument experience.* Except as provided in paragraph (e) of this section, no person may act as pilot in command under IFR or in weather conditions less than the minimums prescribed for VFR, unless that person has met the following requirements within the preceding 6 calendar months:

(1) To obtain instrument experience in an aircraft (other than a glider), that person has performed and logged—

(i) At least six instrument approaches;

(ii) Holding procedures;

(iii) Intercepting and tracking VOR radials and NDB bearings;

(iv) Recovery from unusual flight altitudes; and

(v) Flight by reference to instruments.

(2) The instrument experience requirements of paragraph (d)(1) of this section must have been logged in an aircraft that is not a glider, and performed in—

(i) Actual flight, appropriate to the category of aircraft for the instrument privileges sought; or

(ii) An approved flight simulator or flight training device that is representative of the aircraft category for the instrument privileges sought.

(3) If the person does not carry passengers and if the instrument recency experience is in a glider, that person must have performed and logged at least—

(i) Three hours of instrument time in actual flight of which 1.5 hours may be acquired in a single-engine airplane or a glider; or

(ii) Three hours of instrument time must have been in a glider.

(d) *Instrument proficiency check.* Except as provided by paragraph (e) of this section, a person who does not meet the recent instrument requirements of paragraph (d) of this section within the prescribed time or within 6 calendar months after the prescribed time, may not serve as pilot in command under IFR or in weather conditions less than the minimums prescribed for VFR until that person satisfactorily accomplishes an instrument proficiency check:

(1) Consisting of a representative number of tasks required by the instrument rating practical test, and the check must be—

(i) In an aircraft that is appropriate to the aircraft category and instrument privileges sought;

(ii) In an approved flight simulator or flight training device that is representative of the aircraft category (other than a glider) for which instrument privileges sought; or

(iii) For a glider, in a single-engine airplane or a glider.

(2) Given by one of the following persons—

(i) An examiner;

(ii) A person authorized by the U.S. Armed Forces to conduct instrument flight tests, provided the person being tested is a member of the U.S. Armed Forces;

(iii) A company check pilot who is authorized to conduct instrument flight tests under part 121, 125, or 135 of this chapter, and provided that both the check pilot and the pilot being tested are employees of that operator;

(iv) An instrument flight instructor who holds the appropriate instrument instructor rating for the class of aircraft in which the check is being conducted; or

(v) A person approved by the Administrator to conduct instrument practical tests.

(e) *Exceptions.*

(1) Paragraphs (a) and (b) of this section do not apply to a pilot in command that is employed by a part 125 operator and is engaged in a flight operation for that certificate holder.

(2) This section does not apply to a pilot in command that is employed by a part 121 or part 135 operator and is engaged in a flight operation for that certificate holder.

§ 61.58 Pilot-in-command proficiency check: Operation of aircraft requiring more than one required pilot.

(a) Except as provided in paragraph (e) of this section, no person may act as pilot in command of an aircraft that is type certificated for more than one required pilot crewmember unless the proficiency checks prescribed in paragraphs (b) and (c) of this section are satisfactorily accomplished.

(b) Within 12-calendar months preceding the month the person acts as pilot in command of an aircraft that is type certificated for more than one required pilot crewmember that person must have accomplished one of the following:

(1) For an airplane, a proficiency check—

(i) In that airplane type, or in a flight simulator or flight training device that is representative of that type of airplane;

(ii) Given to that person by an examiner; and

(iii) Consisting of those areas of operations that are appropriate to the standards required of an airline transport pilot certificate for that airplane class rating.

(2) For other aircraft, a proficiency checks—

(i) In that aircraft type, or in a flight simulator or flight training device that is representative of that type of aircraft;

(ii) Given to that person by an examiner; and

(iii) Consisting of those areas of operations that are appropriate to the standards required of an airline transport pilot certificate for that aircraft category and class rating.

(3) A pilot in command proficiency check given to that person in accordance with part 121, 123, 125, or 135 of this chapter.

(4) A practical test required for an aircraft type rating.

(5) An initial or periodic proficiency check for the issuance of an examiner or check airman designation.

(6) A military proficiency check required for pilot in command and instrument privileges in an aircraft which the military requires to be operated by more than one pilot.

(c) Except as provided in paragraph (d) of this section, within 24-calendar months preceding the month the person acts as pilot in command of an aircraft that is type certificated for more than one required pilot crewmember, that person must have accomplished one of the following proficiency checks in the particular type of aircraft in which the person is to serve as pilot in command:

(1) A proficiency check—

(i) In that aircraft type, or in a flight simulator or flight training device that is representative of that type of aircraft;

(ii) Given to that person by an examiner; and

(iii) Consisting of those areas of operations that are appropriate to the standards required of an airline transport pilot certificate for that aircraft category and class rating.

(2) A pilot in command proficiency check given to that person in accordance with part 121, 123, 125, or 135 of this chapter;

(3) A practical test required for an aircraft type rating;

(4) An initial or periodic proficiency check for the issuance of a pilot examiner or check airman designation; or

(5) A military proficiency check required for pilot in command and instrument privileges in an aircraft which the military requires to be operated by more than one pilot.

(d) For airplanes, the maneuvers and procedures required for the checks and test prescribed in paragraphs (c) (1), (2), (4), and (5) of this section, and paragraph (c)(3) of this section for type ratings obtained in conjunction with part 121 of this chapter, training programs may be performed in a flight simulator or flight training device if the:

(1) Maneuver or procedure can be performed in a flight simulator or flight training device as set forth in appendix F to part 121 of this chapter; and

(2) Flight simulator or flight training device is one that is approved for the particular maneuver or procedure.

(e) This section does not apply to persons conducting operations subject to parts 121, 123, 125, 133, 135, and 137 of this chapter.

(f) For the purpose of meeting the proficiency check requirements of paragraphs (b) and (c) of this section, a person may act as pilot in command of a flight under day VFR or day IFR if no persons or property, other than as necessary for compliance thereunder, are carried.

(g) If a person takes the proficiency check required by paragraph (a) of this section in the calendar month before, or the calendar month after the month in which it is due, that person is considered to have taken it in the month it is due.

§ 61.59 Falsification, reproduction, or alteration of applications, certificates, logbooks, reports, or records.

(a) No person may make or cause to be made:

(1) Any fraudulent or intentionally false statement on any application for a certificate, rating, or duplicate thereof, issued under this part;

(2) Any fraudulent or intentionally false entry in any logbook, record, or report that is required to be kept, made, or used, to show compliance with any requirement for the issuance, or exercise of the privileges of any certificate or rating under this part;

(3) Any reproduction, for fraudulent purpose, of any certificate or rating under this part; or

(4) Any alteration of any certificate or rating under this part.

(b) The commission of an act prohibited under paragraph (a) of this section is a basis for suspending or revoking any airman or ground instructor certificate or rating held by that person.

§ 61.60 Change of address.

Persons who hold an airman certificate, and who have a change in their permanent mailing address, may not exercise the privileges of their certificate unless they notify the Federal Aviation Administration, Airman Certification Branch, Box 25082, Oklahoma City, Oklahoma 73125, in writing of the new address within 30 days from the date the person moved.

Subpart B—Aircraft Ratings and Special Certificates

§ 61.61 Applicability.

This subpart prescribes the requirements for the issuance of additional aircraft ratings after a pilot certificate is issued, and the requirements and limitations for special purpose pilot authorizations issued by the Administrator.

§ 61.63 Additional aircraft ratings (other than airline transport pilot).

(a) *Additional category rating.* Persons who apply for an additional aircraft category rating to be added to their current pilot certificate:

(1) Must have received the required training and aeronautical experience time prescribed by this part that applies to the pilot certificate for the aircraft category and class rating sought;

(2) Must have an endorsement in their logbook or training record from an authorized flight instructor or ground instructor, and that endorsement must attest that they have been found competent on the aeronautical knowledge areas that are appropriate to the pilot certificate for the aircraft category or class rating sought;

(3) Must have an endorsement in their logbook or training record from an authorized flight instructor, and that endorsement must attest that they have been found proficient on the areas of operation that are appropriate to the pilot certificate for the aircraft category or class rating sought;

(4) Must have satisfactorily accomplished the required practical test that is appropriate to the pilot certificate for the aircraft category or class rating sought;

(5) Need not accomplish the supervised pilot in command time prescribed by this part that applies to the pilot certificate for the aircraft category or class rating sought; and

(6) Need not accomplish another knowledge test, provided they hold an airplane, rotorcraft, powered-lift, or airship rating at that pilot certificate level.

(b) *Additional class rating.* Persons who apply for an additional class rating to be added on their pilot certificate:

(1) Must have an endorsement in their logbook or training record from an authorized flight instructor, and that endorsement must attest they have been found competent on the aeronautical knowledge areas that are appropriate to the pilot certificate for the aircraft class rating sought;

(2) Must have an endorsement in their logbook or training record from an authorized flight instructor, and that endorsement must attest they have been found proficient on the areas of operation that are appropriate to the pilot certificate for the aircraft class rating sought;

(3) Must have satisfactorily accomplished the required practical test that is appropriate to the pilot certificate for the aircraft class rating sought;

(4) Need not meet the specified training time and aeronautical experience time prescribed by this part that applies to the pilot certificate for the aircraft class rating sought; and

(5) Need not accomplish another knowledge test, provided they hold an airplane, rotorcraft, powered-lift, or airship rating at that pilot certificate level.

(c) *Additional type rating or an addition of an aircraft type rating that is accomplished concurrently with an additional aircraft category or class rating.* Persons who apply for an additional aircraft type rating to be added on their pilot certificate, or an addition of aircraft type rating that is accomplished concurrently with an additional aircraft category or class rating:

(1) Must hold or concurrently obtain an instrument rating that is appropriate to the aircraft's category, class, or type rating sought;

(2) Must have an endorsement in their logbook or training record from an authorized flight instructor, and that endorsement must attest that they have been found competent on the aeronautical knowledge areas that are appropriate to the pilot certificate for the aircraft category, class, or type rating sought;

(3) Must have an endorsement in their logbook or training record from an authorized flight instructor, and that endorsement must attest that they have been found proficient on the areas of operation that are appropriate to the standards of an airline transport pilot certificate for the aircraft category, class, or type rating sought;

(4) Must have satisfactorily accomplished the required practical test that is appropriate to the airline transport pilot certificate for the aircraft category, class, or type rating sought;

(5) Need not meet the specified training time and aeronautical experience time prescribed by this part that applies to the pilot certificate for the aircraft category or class rating sought;

(6) Must perform the practical test under instrument flight rules, unless the practical test cannot be accomplished under instrument flight rules because the aircraft's type certificate makes the

aircraft incapable of operating under instrument flight rules, then—

(i) The person may obtain a type rating limited to ''VFR only;'' and

(ii) The ''VFR only'' limitation may be removed for that aircraft type when the person satisfactorily accomplishes the practical test under instrument flight rules.

(7) When an instrument rating is issued to persons who hold one or more type ratings, the type ratings on the amended pilot certificate shall bear the ''VFR only'' limitation for each aircraft type rating for which they have not shown the instrument competency; and

(8) Need not accomplish another knowledge test, provided they hold an airplane, rotorcraft, powered-lift, or airship rating on their pilot certificate.

§ 61.65 Instrument rating requirements.

(a) *General.* A person who applies for an instrument rating must:

(1) Hold at least a private pilot certificate with an aircraft category and class rating that applies to the instrument rating sought;

(2) Be able to read, speak, write, and understand the English language;

(3) Hold at least a current third-class medical certificate issued under part 67 of this chapter;

(4) Present documentation of having—

(i) Received and logged ground training from an authorized instructor, or accomplished a home study course of training on the approved aeronautical knowledge areas of paragraph (b) of this section that apply to the instrument rating sought;

(ii) Received a logbook or training record endorsement from the authorized instructor, who gave that person training or reviewed that person's home study course, certifying that the person is prepared to satisfactorily accomplish the required knowledge test;

(iii) Received and logged training from an authorized flight instructor in the aircraft, or from an authorized instructor in a flight simulator or training device that represents that class of aircraft for the instrument rating sought on the approved areas of operation of paragraph (c) of this section; and

(iv) Received a logbook or training record endorsement from the authorized instructor who gave that person the training and certified that the person is prepared to satisfactorily accomplish the required practical test.

(5) Satisfactorily accomplish the required knowledge test on the approved aeronautical knowledge areas of paragraph (b) of this section;

(6) Satisfactorily accomplish the required practical test on the approved areas of operation of paragraph (c) of this section;

(7) Satisfactorily accomplish an instrument rating practical test in a multiengine airplane, and who holds an airplane category and single-engine class rating on the person's pilot certificate will also have met the requirements for issuance of an instrument rating-airplane single engine;

(8) Is not required to accomplish another knowledge test, when that person already holds an instrument rating on the person's pilot certificate; and

(9) Comply with the applicable requirements of this section.

(b) *Aeronautical knowledge.* A person who applies for an instrument rating must have received and logged ground training from authorized instructor, or accomplished a home study course on the following aeronautical knowledge areas that apply to the instrument rating sought:

(1) The Federal Aviation Regulations of this chapter that apply to flight operations under IFR;

(2) The appropriate information that apply to flight operations under IFR in the ''Airman's Information Manual;''

(3) The air traffic control system and procedures for instrument flight operations;

(4) IFR navigation and approaches by use of radio aids;

(5) The use of IFR enroute and instrument approach procedure charts;

(6) The procurement and use of aviation weather reports and forecasts and the elements of forecasting weather trends based on that information and personal observation of weather conditions;

(7) The safe and efficient operation of aircraft under IFR and conditions that apply to the instrument rating sought;

(8) The recognition of critical weather situations and windshear avoidance;

(9) Aeronautical decision making and judgment; and

(10) Flight deck resource management, including crew communications and coordination.

(c) *Areas of operation.* A person who applies for an instrument rating must receive and log training from an authorized flight instructor in an aircraft, or from an authorized instructor in an approved flight simulator or training device (or any combination thereof) that includes the following approved areas of operation:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Air traffic control clearances and procedures;

(4) Flight by reference to instruments;

(5) Navigation aids;

(6) Instrument approach procedures;

(7) Emergency operations; and

(8) Postflight procedures.

(d) *Aeronautical experience.* A person who applies for an instrument rating must have received and logged the following training:

(1) At least 40 hours of instrument training from an authorized flight instructor-instrument or ground instructor-instrument on the approved areas of operation of this section;

(2) Not more than 20 hours of the instrument training prescribed in paragraph (d)(1) of this section may be met by training received from an authorized flight instructor-instrument or ground instructor-instrument in a flight simulator or flight training device;

(3) At least 5 hours of instrument flight training from an authorized instrument flight instructor in the category and class aircraft for the instrument rating sought;

(4) At least 3 hours of instrument training that is appropriate to the instrument-aircraft class rating sought and from an authorized instructor in preparation for the practical test within the 60-days preceding the date of the test;

(5) For an instrument-airplane rating, instrument training specific to airplanes on cross-country flight procedures that includes at least one cross-country flight in the class airplane for the instrument rating sought, is performed under IFR, and consists of—

(i) A distance of at least 250 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 100 nautical miles between airports;

(ii) An instrument approach at each airport; and

(iii) Three different kinds of approaches with the use of navigation aids.

(6) For an instrument-helicopter rating, instrument training specific to helicopters on cross-country flight procedures that includes at least one cross-country flight in a helicopter, is performed under IFR, and consists of—

(i) A distance of at least 100 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 50 nautical miles between airports;

(ii) An instrument approach at each airport; and

(iii) Three different kinds of approaches with the use of navigation aids.

(7) For an instrument-airship rating, instrument training specific to airships on cross-country flight procedures that includes at least one cross-country flight

in an airship, is performed under IFR, and consists of—

(i) A distance of at least 50 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 25 nautical miles between airports;

(ii) An instrument approach at each airport; and

(iii) Three different kinds of approaches with the use of navigation aids.

(8) For an instrument-powered-lift rating, instrument training specific to powered-lift on cross-country flight procedures that includes at least one cross-country flight in a powered-lift, is performed under IFR, and consists of—

(i) A distance of at least 250 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 100 nautical miles between airports;

(ii) An instrument approach at each airport; and

(iii) Three different kinds of approaches with the use of navigation aids.

§ 61.67 Category II pilot authorization requirements.

(a) *General.* A person who applies for a Category II pilot authorization must hold:

(1) At least a private or commercial pilot certificate with an instrument rating or an airline transport pilot certificate; and

(2) A type rating for the aircraft type if the authorization is requested for a large aircraft or a small turbojet aircraft.

(b) *Experience requirements.* Except for a person who holds an airline transport pilot certificate, a person who applies for a Category II authorization must have at least:

(1) Fifty hours of night flight time under VFR conditions as pilot in command.

(2) Seventy-five hours of instrument time under actual or simulated conditions that may include 25 hours in an approved flight simulator or training device.

(3) Two hundred-fifty hours of cross-country flight time as pilot in command.

(4) The night flight and instrument flight time used to meet the requirements of paragraphs (b) (1) and (2) of this section may also be used to meet the requirements of paragraph (b)(3) of this section.

(c) *Practical test requirements.*

(1) A practical test must be satisfactorily accomplished by a person who applies for:

(i) Issuance or renewal of an authorization; and

(ii) The addition of another type aircraft to the applicant's Category II authorization.

(2) To be eligible for the practical test for an authorization under this section, the person must meet the requirements of paragraph (a) of this section and, if the practical test has not been accomplished during the 12-calendar months preceding the month of the test, then that person must meet the following recent experience requirements:

(i) The requirements of § 61.57(e);

(ii) At least six ILS approaches during the 6-calendar months preceding the month of the test of which at least three of the approaches must have been conducted without the use of an approach coupler, and these approaches—

(A) Must be under actual or simulated instrument flight conditions to the decision height of the approach, and in the type aircraft in which the practical test is to be performed; and

(B) Need not be conducted down to the decision heights authorized for Category II operations.

(iii) The flight time acquired in meeting the requirements of paragraph (c)(2)(ii) of this section may be used to meet the requirements of paragraph (c)(2)(i) of this section.

(d) *Practical test procedures.* The practical test consists of two phases:

(1) *Phase I-knowledge test.* The person must demonstrate knowledge of the following—

(i) Required landing distance;

(ii) Recognition of the decision height;

(iii) Missed approach procedures and techniques utilizing computed or fixed attitude guidance displays;

(iv) RVR, its use and limitations;

(v) Use of visual clues, their availability or limitations, and altitude at which they are normally discernible at reduced RVR readings;

(vi) Procedures and techniques related to transition from nonvisual to visual flight during a final approach under reduced RVR;

(vii) Effects of vertical and horizontal windshear;

(viii) Characteristics and limitations of the ILS and runway lighting system;

(ix) Characteristics and limitations of the flight director system, auto approach coupler (including split axis type if equipped), auto throttle system (if equipped), and other required Category II equipment;

(x) Assigned duties of the second in command during Category II approaches; and

(xi) Instrument and equipment failure warning systems.

(2) *Phase II-proficiency test.* The test must—

(i) Be taken in an aircraft that meets the requirements of part 91 of this chapter for Category II operations;

(ii) Consist of at least two ILS approaches to 100 feet including at least one landing and one missed approach;

(iii) Be performed with all approaches made with the use of an approved flight control guidance system;

(iv) Include at least one manual approach if an approved automatic approach coupler is installed;

(v) Include a missed approach that is executed with one engine set in idle or zero thrust position before reaching the middle marker for a multiengine aircraft that has performance capability to execute a missed approach with an engine out; and

(vi) Include flight maneuvers performed solely by reference to instruments and in coordination with a second in command who holds a class rating and, in the case of a large aircraft or a small turbojet aircraft, a type rating for that aircraft.

§ 61.69 Glider towing: Experience and training requirements.

(a) No person may act as pilot in command for towing a glider unless that person:

(1) Holds at least a private pilot certificate with an airplane category and a single engine class rating;

(2) Has logged at least 100 hours of pilot-in-command time in single engine airplanes;

(3) Has a logbook endorsement from an authorized glider flight instructor who certifies that the person has received ground and flight training in gliders and is proficient in—

(i) The techniques and procedures essential to the safe towing of gliders, including airspeed limitations;

(ii) Emergency procedures;

(iii) Signals used; and

(iv) Maximum angles of bank.

(4) Has made at least three flights as the sole manipulator of the controls of an aircraft towing a glider while accompanied by a pilot who meets the requirements of this section; and

(5) Has received a logbook endorsement from the pilot described in paragraph (a)(4) of this section, and that endorsement must certify that the person has accomplished at least 3 flights in a single engine airplane while towing a glider.

(b) The pilot, described in paragraph (a)(4) of this section, who accompanies and endorses the logbook of persons seeking glider towing privileges:

(1) Must have met the requirements of this section prior to accompanying or endorsing the logbook of persons seeking glider towing privileges;

(2) Must have logged at least 10 flights as pilot in command of a single engine airplane while towing a glider; and

(3) Holds only a private pilot certificate, then that pilot—

(i) Must also have logged at least 100 hours of pilot-in-command time in airplanes, or 200 hours of pilot-in-command time in a combination of powered and other than powered aircraft; and

(ii) Must have performed and logged at least three flights within the 12-calendar months preceding the month that pilot accompanies or endorses the logbook of persons seeking glider towing privileges—

(A) In a single-engine airplane while towing a glider and be accompanied by another pilot who meets the requirements of this section; or

(B) As pilot in command of a glider being towed by a single-engine airplane.

§ 61.71 Graduates of an approved training program, other than under this part: Special rules.

(a) A person who graduates from an approved training program under parts 141 or 142 of this chapter, is considered to have met the applicable aeronautical experience, aeronautical knowledge, and approved areas of operation requirements of this part, if that person presents the graduation certificate and satisfactorily accomplishes the required practical test within the 60-day period after the date of graduation.

(b) A person may apply for an airline transport pilot certificate, type rating, or both under this part, and will be considered to have met the applicable requirements of § 61.157 of this part for that certificate and rating, if that person has—

(1) Satisfactorily accomplished an approved training program and the pilot-in-command proficiency check for that airplane type, in accordance with the pilot in command requirements of subparts N and O of part 121 of this chapter; and

(2) Made application for that airline transport pilot certificate, type rating, or both within the 60-day period from the date the person satisfactorily accomplished the approved training program and pilot-in-command proficiency check for that airplane type.

§ 61.73 Military pilots or former military pilots: Special rules.

(a) *General.* Military pilots or former military pilots who have graduated from a U.S. military pilot training course, have received official military aeronautical orders, and meet the applicable requirements of this section may apply, on the basis of their military training, for:

(1) A commercial pilot certificate.

(2) An aircraft rating in the category and class of aircraft for which that military pilot is qualified.

(3) An instrument rating with the appropriate aircraft rating for which that military pilot is qualified.

(4) A type rating, if appropriate.

(5) This section does not apply to a military pilot or a former military pilot who has been removed from flying status for lack of proficiency or because of disciplinary action.

(b) *Military pilots on active flying status within the past 12 months.* A rated military pilot or former rated military pilot who has been on active flying status within the 12 months before applying must:

(1) Satisfactorily accomplishes a knowledge test on the appropriate parts of this chapter that apply to pilot privileges and limitations, air traffic and general operating rules, and accident reporting rules;

(2) Present documents showing that the requirements of paragraph (d) of this section are met for at least one aircraft rating; and

(3) Present documents showing that the military pilot, is or was, at any time during the 12-calendar months before the month of application—

(i) A rated military pilot on active flying status in an armed force of the United States; or

(ii) A rated military pilot of an armed force of a member State to the International Civil Aviation Organization, assigned to pilot duties (other than flight training) with an armed force of the United States who holds, at the time of application, a current civil pilot license issued by that member State authorizing at least the privileges of the pilot certificate sought.

(c) *Military pilots not on active flying status during the 12 calendar months before the month of application.* A rated military pilot or former military pilot who has not been on active flying status during the 12 calendar months before the month of application must:

(1) Satisfactorily accomplishes the appropriate knowledge and practical tests prescribed in this part for the certificate or rating sought;

(2) Hold at least a third class medical certificate issued under part 67 of this chapter; and

(3) Present documents showing that the applicant, was or is, during the 12 calendar months before the month of application, a rated military pilot as prescribed by paragraph (b)(3) of this section.

(d) *Aircraft category, class, and type ratings.* A military pilot who applies for additional aircraft category, class, or type rating is issued that rating at the commercial pilot certificate level if the pilot presents documentary evidence that shows satisfactory accomplishment of:

(1) An official U.S. military checkout and instrument proficiency checkout in the aircraft as pilot in command during the 12 calendar months before the month of application;

(2) At least 10 hours of pilot in command time in the aircraft during the 12 calendar months before the month of application;

(3) An FAA practical test in that aircraft after first—

(i) Meeting the requirements of paragraph (b)(1) and (2) of this section; and

(ii) Having received an endorsment from an authorized flight instructor who certifies that the pilot is proficient to accomplish the required practical test, and that endorsement is dated within the 60-day period preceding the date of the practical test.

(e) *Instrument rating.* Military pilots who apply for an airplane instrument rating, a helicopter instrument rating, or a powered-lift instrument rating to be added on their commercial pilot certificate, are entitled to that instrument rating if the pilots have, within the 12 calendar months preceding the month of application:

(1) Satisfactorily accomplished an instrument proficiency checkout of a U.S. Armed Force in the aircraft category and class for the instrument rating sought; and

(2) Is authorized by the U.S. Armed Force to conduct IFR flights on Federal airways in that aircraft category and class for the instrument rating sought.

(f) *Aircraft type rating.* An aircraft type rating is issued only for aircraft types that the Administrator has certificated for civil operations.

(g) *Aircraft type rating placed on an airline transport pilot certificate.* A military pilot who holds an airline transport pilot certificate and who requests an aircraft type rating to be placed on their airline transport pilot certificate may be issued that aircraft type rating at the airline transport pilot certificate level, provided that person—

(1) Holds a category and class rating for that type of aircraft at the airline transport pilot certificate level; and

(2) Satisfactorily accomplishes an official U.S. military checkout and instrument proficiency checkout in that type of aircraft as pilot in command during the 12 calendar months before the month of application.

(h) *Evidentiary documents.* The following documents are satisfactory

evidence for meeting the requirements of this section to show:

(1) Membership of the armed forces, an official identification card issued to the pilot by an armed force may be used.

(2) The military pilot's discharge or release from an armed force or former membership of an armed force, an original or a copy of a certificate of discharge or release may be used.

(3) Current or previous status as a rated military pilot with a U.S. Armed Force, for which one of the following may be used, as appropriate:

(i) An official U.S. Armed Force order to flight duty as a military pilot;

(ii) An official U.S. Armed Force form or logbook showing military pilot status; or

(iii) An official order showing that the military pilot graduated from a U.S. military pilot school and is rated as a military pilot.

(4) Flight time in military aircraft as a member of a U.S. Armed Force, an appropriate official U.S. Armed Force form or summary, or a certified U.S. Armed Force logbook may be used.

(5) Pilot-in-command status, an official U.S. armed force record of a military checkout as pilot in command may be used.

(6) Instrument pilot qualification, a current instrument grade slip that is issued by a U.S. Armed Force, or an official record of satisfactorily accomplishment of an instrument proficiency check during the 12 calendar months preceding the month of the application may be used.

§ 61.75 Private pilot certificate issued on basis of a foreign pilot license.

(a) *General.* A person who holds a current foreign pilot license, issued by a member State to the International Civil Aviation Organization (ICAO), may apply for and may be issued only a private pilot certificate with the appropriate ratings when the application is based on the foreign pilot license and meets the requirements of this section.

(b) *Certificate issued.* A U.S. private pilot certificate that is issued under this section shall specify the person's foreign license number and country of issuance. A person who holds a current pilot license, issued by a member State to ICAO, may be issued a private pilot certificate based on the foreign pilot license without any further showing of proficiency, and provided that person:

(1) Meets the requirements of this section;

(2) Holds a foreign pilot license that—

(i) Is not under an order of revocation or suspension by the foreign country that issued the foreign pilot license; and

(ii) Does not contain an endorsement stating that the person has not met all of the standards of ICAO;

(3) Does not currently hold a U.S. pilot certificate;

(4) Holds a current medical certificate issued under part 67 of this chapter or a current medical certificate issued by the country that issued the person's foreign pilot license; and

(5) Is able to read, speak, write, and understand the English language.

(c) *Aircraft ratings issued.* Aircraft ratings listed on a person's foreign pilot license, in addition to any issued after testing under the provisions of this part, may be placed on that person's U.S. pilot certificate.

(d) *Instrument ratings issued.* A person who holds an instrument rating on the foreign pilot license, issued by a member State to ICAO, may be issued an instrument rating on the U.S. private pilot certificate provided:

(1) The person's foreign pilot license authorizes instrument privileges;

(2) Upon application for the instrument rating privileges, the person satisfactorily accomplishes the appropriate knowledge test; and

(3) The person is able to read, speak, write, and understand the English language.

(e) *Operating privileges and limitations.* A person who receives a U.S. private pilot certificate that has been issued under the provisions of this section:

(1) May act as a pilot of a civil aircraft of U.S. registry in accordance with the private pilot privileges authorized by this part;

(2) Is limited to the privileges placed on the certificate by the Administrator;

(3) Is subject to the limitations and restrictions on the person's U.S. certificate and foreign pilot certificate when exercising the privileges of that U.S. pilot certificate in an aircraft of U.S. registry operating within or outside the United States; and

(4) Shall not exercise the privileges of that U.S. private pilot certificate when the person's foreign pilot license has been revoked or suspended.

(f) *Limitation on licenses used as basis for U.S. certificate.* Only one foreign pilot license may be used as a basis for issuing a U.S. private pilot certificate. The foreign pilot license and medical certificate used as a basis for issuing a U.S. private pilot certificate under this section must be in the English language or accompanied by an English language transcription that has been signed by an official or representative of the foreign aviation authority that issued the foreign pilot license.

(g) *Limitation placed on U.S. private pilot certificate.* The U.S. private pilot certificate issued under this section is valid only when that person has their foreign pilot license in their personal possession or readily accessible in the aircraft.

§ 61.77 Special purpose pilot authorization: Operation of U.S.-registered civil aircraft leased by a person who is not a U.S. citizen.

(a) *General.* After meeting the requirements of this section, a holder of a foreign pilot certificate or license issued by a member State of the International Civil Aviation Organization (ICAO) may be issued a special purpose pilot authorization by the Administrator for the purpose of performing pilot duties:

(1) On a civil aircraft of U.S. registry that is leased to a person who is not a citizen of the United States; and

(2) For carrying persons or property for compensation or hire on that aircraft.

(b) *Eligibility.* To be eligible for the issuance or renewal of a special purpose pilot authorization, a person must meet the following eligibility prerequisites:

(1) Hold a current foreign pilot certificate that has been issued by the aeronautical authority of a member State to ICAO from where the person holds citizenship or resident status;

(2) The person's foreign pilot certificate must contain the appropriate aircraft category, class, instrument rating, and type rating, if appropriate, for the aircraft to be flown;

(3) Hold a medical certificate from the aeronautical authority of a member State to ICAO from where the person holds citizenship or resident status;

(4) Must not already hold a special purpose pilot authorization, but if the person already holds a special purpose pilot authorization, then that special purpose pilot authorization must either be surrendered to the FAA Flight Standards District Office that issued it, or to the FAA Flight Standards District Office processing the application for the authorization prior to being issued another special purpose pilot authorization;

(5) Meet the currency requirements of this part and must present a logbook/flight record showing compliance with the currency requirements of this part;

(6) Show that the person will not reach the age of 60 years prior to the expiration date of the special purpose pilot authorization a birth certificate or some other official documentation; and

(7) Present a copy of the person's foreign pilot certificate and a letter to an FAA Flight Standards District Office from the lessee of the aircraft that—

(i) Acknowledges the person is employed by the lessee;

(ii) Specifies the aircraft type in which the person will be performing pilot duties; and

(iii) States that the person is currently qualified to exercise the privileges listed on that person's pilot certificate or license for the aircraft to be flown and that the person has satisfactorily accomplished the applicable ground and flight training in the aircraft type in which the person will be performing pilot duties.

(c) *Privileges.* A person who meets the general and eligibility requirements of, and is issued a special purpose pilot authorization under, this section:

(1) May exercise the privileges prescribed on the special purpose pilot authorization; and

(2) Must comply with the limitations specified in this section and any additional limitations specified on the special purpose pilot authorization.

(d) *Limitations.* Anytime persons are exercising the privileges of a special purpose pilot authorization those persons are subject to the following limitations:

(1) May apply for 60-calendar months extension of their authorization, provided they—

(i) Continue to meet the eligibility prerequisites and other requirements of this section; and

(ii) Surrender the expired special purpose pilot authorization upon receipt of the new authorization.

(2) May only hold one special purpose pilot authorization;

(3) May only conduct a flight or series of flights between foreign countries in foreign air commerce within the time period allotted on the authorization;

(4) Must carry their foreign pilot license, medical certificate, and special purpose pilot authorizationin in their physical possession or immediately available in the aircraft, while exercising the privileges of that special purpose pilot authorization; and

(5) Persons, who are 60 years of age or older, may not request nor may they be issued a special purpose pilot authorization, when the purpose of that authorization is for those persons to serve as a required pilot crewmember for a foreign air carrier in—

(i) Scheduled international air services in a U.S.-registered civil aircraft with more than 30 passenger seats, excluding any required crewmember seat, or 7500 pounds payload capacity; or

(ii) Non-scheduled international air transport operationsin a U.S.-registered civil aircraft with more than 30 passenger seats, excluding any required crewmember seat, or 7500 pounds payload capacity.

(e) *Expiration date.* Each special purpose pilot authorization, issued under this section, expires—

(1) Sixty-calendar months from the month it was issued, unless sooner suspended or revoked;

(2) When the lease agreement for the aircraft expires or the lessee terminates the employment of the person who holds the special purpose pilot authorization;

(3) Whenever the person's pilot or medical certificate has been suspended, revoked, or is no longer valid; or

(4) Whenever the person reaches the age of 60.

Subpart C—Student Pilots

§ 61.81 Applicability.

This subpart prescribes the requirements for the issuance of student pilot certificates, the conditions under which those certificates are necessary, and the general operating rules and limitations for the holders of those certificates.

§ 61.83 Eligibility requirements for student pilots.

To be eligible for a student pilot certificate, an applicant must:

(a) Be at least 16 years of age for other than a rating in a glider or balloon.

(b) Be at least 14 years of age for a rating in a glider or balloon.

(c) Be able to read, speak, write, and understand the English language.

(d) Hold at least a current third-class medical certificate issued under part 67 of this chapter for other than a rating in glider or balloon, or a student pilot who is seeking a recreational pilot certificate.

(e) Affix a signed and dated statement to the application certifying that no known medical defect exists that would make the applicant unable to pilot the aircraft for training for a rating in a glider or balloon, or a student pilot who is seeking a recreational pilot certificate.

§ 61.85 Application.

An application for a student pilot certificate is made on a form and in a manner provided by the Administrator and is submitted to:

(a) A designated aviation medical examiner when applying for an FAA medical certificate in the United States; or

(b) An examiner, accompanied by a current FAA medical certificate, or in the case of an application for a pilot certificate with a glider or balloon rating, it may be accompanied by the applicant's certification that no known medical defect makes the applicant unable to pilot a glider or balloon.

§ 61.87 Supervised pilot-in-command requirements for student pilots.

(a) *General.* A student pilot may not operate an aircraft in supervised pilot-in-command (PIC) flight unless that student has met the requirements of this section.

(b) *Aeronautical knowledge.* A student pilot must demonstrate satisfactory aeronautical knowledge on a test that meets the requirements of this paragraph:

(1) The test must address the student pilot's knowledge of—

(i) Applicable sections of parts 61 and 91 of this chapter;

(ii) Airspace rules and procedures for the airport where the supervised PIC flight will be performed; and

(iii) Flight characteristics and operational limitations for the make and model of aircraft to be flown.

(2) The student's flight instructor must—

(i) Administer the test; and

(ii) At the conclusion of the test, review all incorrect answers with the student before authorizing that student to conduct a supervised PIC flight.

(c) *Supervised PIC flight training.* In order to perform supervised PIC flight training, a student pilot must have:

(1) Received and logged flight training on the maneuvers and procedures of this section that are appropriate to the make and model of aircraft to be flown; and

(2) Demonstrated satisfactory proficiency and safety, as judged by an authorized flight instructor, on the maneuvers and procedures required by this section in the make and model of aircraft to be flown.

(d) *Maneuvers and procedures for supervised PIC flight training in a single engine airplane.* A student pilot who is receiving training in a single engine airplane rating must receive and log supervised PIC flight training on the following maneuvers and procedures:

(1) Proper flight preparation procedures, including preflight planning and preparation, powerplant operation, and aircraft systems;

(2) Taxiing or surface operations including runups;

(3) Takeoffs and landings including normal and crosswind;

(4) Straight and level flight and turns in both directions;

(5) Climbs and climbing turns;

(6) Airport traffic patterns including entry and departure procedures;

(7) Collision avoidance, windshear avoidance, and wake turbulence avoidance;

(8) Descents with and without turns using high and low drag configurations;

(9) Flight at various airspeeds from cruise to slow flight;

(10) Emergency procedures and equipment malfunctions;
(11) Ground reference maneuvers;
(12) Approaches to a landing area with simulated engine malfunctions;
(13) Slips to a landing; and
(14) Go-arounds.

(e) *Maneuvers and procedures for supervised PIC flight training in a multiengine airplane.* A student pilot who is receiving training in a multiengine airplane, must receive and log supervised PIC flight training on the following maneuvers and procedures:
(1) Proper flight preparation procedures including preflight planning and preparation, powerplant operation, and aircraft systems;
(2) Taxiing or surface operations including runups;
(3) Takeoffs and landings including normal and crosswind;
(4) Straight and level flight and turns in both directions;
(5) Climbs and climbing turns;
(6) Airport traffic patterns including entry and departure procedures;
(7) Collision avoidance, windshear avoidance, and wake turbulence avoidance;
(8) Descents with and without turns using high and low drag configurations;
(9) Flight at various airspeeds from cruise to slow flight;
(10) Emergency procedures and equipment malfunctions;
(11) Ground reference maneuvers;
(12) Approaches to a landing area with simulated engine malfunctions; and
(13) Go-arounds.

(f) *Maneuvers and procedures for supervised PIC flight training in a helicopter.* A student pilot who is receiving training in a helicopter must receive and log supervised PIC flight training on the following maneuvers and procedures:
(1) Proper flight preparation procedures including preflight planning and preparation, powerplant operation, and aircraft systems;
(2) Taxiing or surface operations including runups;
(3) Takeoffs and landings including normal and crosswind;
(4) Straight and level flight and turns in both directions;
(5) Climbs and climbing turns;
(6) Airport traffic patterns including entry and departure procedures;
(7) Collision avoidance, windshear avoidance, and wake turbulence avoidance;
(8) Descents with and without turns;
(9) Flight at various airspeeds;
(10) Emergency procedures and equipment malfunctions;
(11) Ground reference maneuvers;
(12) Approaches to the landing area;
(13) Hovering and hovering turns;
(14) Go-arounds;
(15) Simulated emergency procedures, including autorotational descents with a power recovery and power recovery to a hover;
(16) Rapid decelerations; and
(17) Simulated one engine inoperative approaches and landings for multiengine helicopters.

(g) *Maneuvers and procedures for supervised PIC flight training in a gyroplane.* A student pilot who is receiving training in a gyroplane must receive and log supervised PIC flight training on the following maneuvers and procedures:
(1) Proper flight preparation procedures including preflight planning and preparation, powerplant operation, and aircraft systems;
(2) Taxiing or surface operations including runups;
(3) Takeoffs and landings including normal and crosswind;
(4) Straight and level flight and turns in both directions;
(5) Climbs and climbing turns;
(6) Airport traffic patterns including entry and departure procedures;
(7) Collision avoidance, windshear avoidance, and wake turbulence avoidance;
(8) Descents with and without turns;
(9) Flight at various airspeeds;
(10) Emergency procedures and equipment malfunctions;
(11) Ground reference maneuvers;
(12) Approaches to the landing area;
(13) High rates of descents with power on and with simulated power-off and recovery from those flight configurations;
(14) Go-arounds; and
(15) Simulated emergency procedures, including simulated power-off landings and simulated power failure during departures.

(h) *Maneuvers and procedures for supervised PIC flight training in a powered-lift.* A student pilot who is receiving training in a powered-lift must receive and log supervised PIC flight training on the following maneuvers and procedures:
(1) Proper flight preparation procedures, including preflight planning and preparation, powerplant operation, and aircraft systems;
(2) Taxiing or surface operations including runups;
(3) Takeoffs and landings including normal and crosswind;
(4) Straight and level flight and turns in both directions;
(5) Climbs and climbing turns;
(6) Airport traffic patterns including entry and departure procedures;
(7) Collision avoidance, windshear avoidance, and wake turbulence avoidance;
(8) Descents with and without turns;
(9) Flight at various airspeeds from cruise to slow flight;
(10) Emergency procedures and equipment malfunctions;
(11) Ground reference maneuvers;
(12) Approaches to a landing with simulated engine malfunctions;
(13) Go-arounds;
(14) Approaches to the landing area;
(15) Hovering and hovering turns; and
(16) For multiengine powered-lifts, simulated one engine inoperative approaches and landings.

(i) *Maneuvers and procedures for supervised PIC flight training in a nonpowered glider.* A student pilot who is receiving training in a nonpowered glider must receive and log supervised PIC flight training on the following maneuvers and procedures:
(1) Proper flight preparation procedures, including preflight planning, preparation, and aircraft systems;
(2) Launches, including normal and crosswind;
(3) Straight and level flight and turns in both directions;
(4) Airport traffic patterns including entry procedures;
(5) Collision avoidance, windshear avoidance, and wake turbulence avoidance;
(6) Descents with and without turns using high and low drag configurations;
(7) Flight at various airspeeds;
(8) Emergency procedures and equipment malfunctions;
(9) Ground reference maneuvers;
(10) Inspection of towline rigging and the review of signals and release procedures;
(11) Aerotows or ground tows;
(12) Procedures for disassembly and assembly of the glider;
(13) Stall entry, stall, and stall recovery;
(14) Straight glides, turns, and spirals;
(15) Landings, including normal and crosswind;
(16) Slips to a landing;
(17) Procedures and techniques for thermalling; and
(18) Emergency operations including towline break procedures.

(j) *Maneuvers and procedures for supervised PIC flight training in a powered glider.* A student pilot who is receiving training in a powered glider must receive and log supervised PIC flight training on the following maneuvers and procedures:
(1) Proper flight preparation procedures including preflight planning and preparation, powerplant operation, and aircraft systems;

(2) Taxiing or surface operations including runups;
(3) Takeoffs and landings including normal and crosswind;
(4) Straight and level flight and turns in both directions;
(5) Climbs and climbing turns;
(6) Airport traffic patterns including entry and departure procedures;
(7) Collision avoidance, windshear avoidance, and wake turbulence avoidance;
(8) Descents with and without turns using high and low drag configurations;
(9) Flight at various airspeeds;
(10) Emergency procedures and equipment malfunctions;
(11) Ground reference maneuvers;
(12) Inspection of towline rigging and the review of signals and release procedures;
(13) Aerotows or ground tows;
(14) Procedures for disassembly and assembly of the glider;
(15) Stall entry, stall, and stall recovery;
(16) Straight glides, turns, and spirals;
(17) Slips to a landing;
(18) Procedures and techniques for thermalling; and
(19) Emergency operations including towline break procedures.

(k) *Maneuvers and procedures for supervised PIC flight training in an airship.* A student pilot who is receiving training in an airship must receive and log supervised PIC flight training on the following maneuvers and procedures:
(1) Proper flight preparation procedures including preflight planning and preparation, powerplant operation, and aircraft systems;
(2) Taxiing or surface operations including runups;
(3) Takeoffs and landings including normal and crosswind;
(4) Straight and level flight and turns in both directions;
(5) Climbs and climbing turns;
(6) Airport traffic patterns including entry and departure procedures;
(7) Collision avoidance, windshear avoidance, and wake turbulence avoidance;
(8) Descents with and without turns;
(9) Flight at various airspeeds from cruise to slow flight;
(10) Emergency procedures and equipment malfunctions;
(11) Ground reference maneuvers;
(12) Rigging, ballasting, controlling pressure in the ballonets, and superheating; and
(13) Landings with positive and with negative static trim.

(l) *Maneuvers and procedures for supervised PIC flight training in a balloon.* A student pilot who is receiving training in a balloon, must receive and log supervised PIC flight training on the following maneuvers and procedures:
(1) Layout and assembly procedures;
(2) Proper flight preparation procedures including preflight planning and preparation and aircraft systems;
(3) Ascents and descents;
(4) Landing and recovery procedures;
(5) Emergency procedures and equipment malfunctions;
(6) Operation of hot air or gas source, ballast, valves, and rip panels, as appropriate;
(7) Use of rip panel for simulating an emergency;
(8) The effects of wind on climb and approach angles; and
(9) Obstruction detection and avoidance techniques.

(m) *Limitations on student pilots operating an aircraft in supervised PIC flight at night.* A student pilot may not operate an aircraft in supervised PIC flight at night unless that student pilot has received:
(1) Flight training at night on night flying procedures that includes takeoffs, approaches, landings, and go-arounds at night at the airport where the supervised PIC flight will be conducted;
(2) Navigation training at night in the vicinity of the airport where the supervised PIC flight will be conducted;
(3) An endorsement in the student's logbook for the specific make and model aircraft to be flown for night supervised PIC flight, by the flight instructor who gave the training; and
(4) An endorsement in the student's logbook, for the specific make and model aircraft to be flown for night supervised PIC flight, by the flight instructor who gave the training within the 90-day period preceding the date of the flight.

(n) *Limitations on student pilots operating an aircraft in supervised PIC flight.* Student pilots may not operate an aircraft in supervised PIC flight unless they have:
(1) Had their student pilot certificate endorsed, for the specific make and model aircraft to be flown, by the flight instructor who gave the training; and
(2) Received a logbook endorsement, for the specific make and model aircraft to be flown, by the flight instructor who gave the training within the 90 days preceding the date of the flight had.

(o) *Limitations on flight instructors authorizing supervised PIC flight.*
(1) No flight instructor may authorize a student pilot to perform a supervised PIC flight unless that flight instructor has:
(i) Given that student pilot training in the aircraft in which the supervised PIC flight is to be flown;
(ii) Determined the student pilot is proficient on the maneuvers and procedures prescribed in this section;
(iii) Determined the student pilot is proficient in the make and model of aircraft to be flown;
(iv) Endorsed the student pilot's certificate for the specific make and model aircraft to be flown; and
(iv) Endorsed the student pilot's logbook for the specific make and model aircraft to be flown, and that endorsement remains current for supervised PIC flight privileges, provided the flight instructor updates the student's logbook every 90 days thereafter.
(2) The flight training required by this section must be given by an authorized flight instructor who is appropriately rated and current.

§ 61.89 General limitations.

(a) A student pilot may not act as pilot in command of an aircraft:
(1) That is carrying a passenger;
(2) That is carrying property for compensation or hire;
(3) For compensation or hire;
(4) In furtherance of a business;
(5) On an international flight, except a student pilot may make supervised PIC training flights from Haines, Gustavus, or Juneau, Alaska to White Horse, Yukon, Canada and return, over the province of British Columbia;
(6) With a flight or surface visibility of less than 3 statute miles during daylight hours or 5 statute miles at night;
(7) When the flight cannot be made with visual reference to the surface; and
(8) In a manner contrary to any limitations placed in the pilot's logbook by the instructor.

(b) A student pilot may not act as a required pilot flight crewmember on any aircraft for which more than one pilot is required by the type certificate of the aircraft or regulations under which the flight is conducted, except when receiving flight training from an authorized flight instructor on board an airship and no person other than a required flight crewmember is carried on the aircraft.

§ 61.91 [Reserved.]

§ 61.93 Supervised pilot in command cross-country flight requirements.

(a) *General.*
(1) Except as provided in paragraph (b) of this section, a student pilot must meet the requirements of this section before:
(i) Conducting a supervised PIC cross-country flight, or any flight, greater than 25 nautical miles from the airport from where the flight originated.

(ii) Making a supervised PIC flight and landing at any location other than the airport of origination.

(2) Except as provided in paragraph (b) of this section, a student pilot who seeks supervised PIC cross-country flight privileges must:

(i) Have received flight training from an authorized flight instructor on the maneuvers and procedures of this section that are appropriate to the make and model aircraft for which supervised PIC cross-country privileges are sought;

(ii) Have demonstrated cross country proficiency on the appropriate maneuvers and procedures of this section and to an authorized flight instructor;

(iii) Have satisfactorily accomplished the supervised PIC flight maneuvers and procedures, required by § 61.87 of this part, in the make and model aircraft for which supervised PIC cross-country privileges are sought; and

(iv) Comply with any limitations included in the flight instructor's endorsement that is required by paragraph (c) of this section.

(3) A student pilot who seeks supervised PIC cross-country flight privileges must have received ground training from an authorized ground or flight instructor and flight training from an authorized flight instructor on the cross-country maneuvers and procedures listed in this section that are appropriate to the aircraft to be flown.

(4) A student pilot who seeks supervised PIC cross-country flight privileges must have demonstrated the cross-country maneuvers and procedures of this section to an acceptable level of proficiency to an authorized flight instructor.

(b) *Authorization to perform certain supervised PIC flights and cross-country flights.* A student pilot may receive an endorsement from an authorized flight instructor to make supervised PIC flights from the airport where the student pilot normally receives training to another location, if that student pilot complies with this paragraph.

(1) Supervised PIC flights may be made to another airport that is within 25 nautical miles from the airport where the student pilot normally receives training, provided—

(i) An authorized flight instructor has given the student pilot flight training at the other airport, and that training includes flight in both directions over the route, entering and exiting the traffic pattern, and takeoffs and landings at the other airport;

(ii) The flight instructor endorses that student pilot's logbook authorizing the flight;

(iii) The student pilot has a current supervised PIC flight endorsement in accordance with § 61.87 of this part;

(iv) The flight instructor has determined that the student pilot is proficient to make the flight; and

(v) The purpose of the flight is to practice takeoffs and landings at that other airport.

(2) Repeated specific supervised PIC cross-country flights may be made to another airport that is within 50 nautical miles of the airport from which the flight originated, provided—

(i) The flight instructor has given the student flight training in both directions over the route, including entry and exiting the traffic patterns, takeoffs, and landings at the airports to be used;

(ii) The flight instructor who gave the training has endorsed the student's logbook certifying that the student is proficient to make such flights;

(iii) The student has a current supervised PIC endorsement in accordance with § 61.87 of this part; and

(iv) The student has a current supervised PIC cross country flight endorsement in accordance with § 61.93 of this part.

(c) *Endorsements for supervised PIC cross country flights.* A student pilot must have the endorsements prescribed in this paragraph for each cross-country flight:

(1) *Student pilot certificate endorsement.* A student pilot must have a supervised PIC cross-country endorsement from the flight instructor who conducted the training, and that endorsement must be placed on that person's student pilot certificate for the specific make and model of aircraft to be flown.

(2) *Logbook endorsement.*

(i) A student pilot must have a supervised PIC cross-country endorsement from the flight instructor, who conducted the training, and that endorsement must be placed in that person's logbook for the specific make and model of aircraft to be flown.

(ii) A certificated pilot who is receiving training for an additional aircraft category and class rating must have an endorsement from the flight instructor who conducted the training, and that endorsement must be placed in that person's logbook for the specific make and model of aircraft to be flown.

(iii) For each cross-country flight, the flight instructor who reviews the cross-country planning must make an endorsement in the person's logbook after reviewing that person's cross-country planning. The endorsement must—

(A) Specify the make and model of aircraft to be flown;

(B) State that the student's preflight planning and preparation is correct and that the student is prepared to make the flight safely under the known circumstances; and

(C) State that any limitations required by the student's instructor are met.

(d) *Maneuvers and procedures for supervised PIC cross-country flight training in a single engine airplane.* A student pilot, who is receiving training for supervised PIC cross country flight training in a single engine airplane, must receive and log supervised PIC cross country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency procedures;

(5) Traffic pattern procedures that include area departure, area arrival, entry into the traffic pattern, and approach;

(6) Procedures and operating practices for collision avoidance, wake turbulence precautions, and windshear avoidance;

(7) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(8) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(9) Use of radios for VFR navigation and two-way communications;

(10) Takeoff, approach, and landing procedures, including short field, soft field, and crosswind takeoffs, approaches, and landings;

(11) Climbs at best angle and best rate; and

(12) Control and maneuvering solely by reference to flight instruments, including straight and level flight, turns, descents, climbs, use of radio aids, and ATC directives.

(e) *Maneuvers and procedures for supervised PIC cross-country flight training in a multiengine airplane.* A student pilot who is receiving training for supervised PIC cross country flight training in a multiengine airplane must receive and log supervised PIC cross country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead

reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency procedures;

(5) Traffic pattern procedures that include area departure, area arrival, entry into the traffic pattern, and approach;

(6) Procedures and operating practices for collision avoidance, wake turbulence precautions, and windshear avoidance;

(7) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(8) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(9) Use of radios for VFR navigation and two-way communications;

(10) Takeoff, approach, and landing procedures, including short field, soft field, and crosswind takeoffs, approaches, and landings;

(11) Climbs at best angle and best rate; and

(12) Control and maneuvering solely by reference to flight instruments, including straight and level flight, turns, descents, climbs, use of radio aids, and ATC directives.

(f) *Maneuvers and procedures for supervised PIC cross-country flight training in a helicopter.* A student pilot who is receiving training for supervised PIC cross country flight training in a helicopter must receive and log supervised PIC cross country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency procedures;

(5) Traffic pattern procedures that include area departure, area arrival, entry into the traffic pattern, and approach;

(6) Procedures and operating practices for collision avoidance, wake turbulence precautions, and windshear avoidance;

(7) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(8) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(9) Use of radios for VFR navigation and two-way communications; and

(10) Takeoff, approach, and landing procedures.

(g) *Maneuvers and procedures for supervised PIC cross-country flight training in a gyroplane.* A student pilot who is receiving training for supervised PIC cross country flight training in a gyroplane must receive and log supervised PIC cross country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency procedures;

(5) Traffic pattern procedures that include area departure, area arrival, entry into the traffic pattern, and approach;

(6) Procedures and operating practices for collision avoidance, wake turbulence precautions, and windshear avoidance;

(7) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(8) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(9) Use of radios for VFR navigation and two-way communications; and

(10) Takeoff, approach, and landing procedures, including short field and soft field takeoffs, approaches, and landings.

(h) *Maneuvers and procedures for supervised PIC cross-country flight training in a powered-lift.* A student pilot who is receiving training for supervised PIC cross country flight training in a powered-lift must receive and log supervised PIC cross country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency procedures;

(5) Traffic pattern procedures that include area departure, area arrival, entry into the traffic pattern, and approach;

(6) Procedures and operating practices for collision avoidance, wake turbulence precautions, and windshear avoidance;

(7) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(8) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(9) Use of radios for VFR navigation and two-way communications;

(10) Takeoff, approach, and landing procedures that include high altitude, steep, and shallow takeoffs, high altitude, steep, and shallow approaches and landings; and

(11) Control and maneuvering solely by reference to flight instruments, including straight and level flight, turns, descents, climbs, use of radio aids, and radar directives.

(i) *Maneuvers and procedures for supervised PIC cross-country flight training in a nonpowered glider.* A student pilot who is receiving training for supervised PIC cross country flight training in a nonpowered glider must receive and log supervised PIC cross country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency situations procedures;

(5) Traffic pattern procedures that include area departure, area arrival, entry into the traffic pattern, and approach;

(6) Procedures and operating practices for collision avoidance, wake turbulence precautions, and windshear avoidance;

(7) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(8) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(9) Landings accomplished without the use of the altimeter from at least 2,000 feet above the surface; and

(10) Recognition of weather and upper air conditions favorable for cross-country soaring, ascending and descending flight, and altitude control.

(j) *Maneuvers and procedures for supervised PIC cross-country flight training in a powered glider.* A student pilot who is receiving training for supervised PIC cross country flight training in a powered glider must receive and log supervised PIC cross country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency procedures;

(5) Traffic pattern procedures that include area departure, area arrival, entry into the traffic pattern, and approach;

(6) Procedures and operating practices for collision avoidance, wake turbulence precautions, and windshear avoidance;

(7) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(8) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(9) Landings accomplished without the use of the altimeter from at least 2,000 feet above the surface; and

(10) Recognition of weather and upper air conditions favorable for cross-country soaring, ascending and descending flight, and altitude control.

(k) *Maneuvers and procedures for supervised PIC cross-country flight training in an airship.* A student pilot who is receiving training for supervised PIC cross country flight training in an airship must receive and log supervised PIC cross country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency procedures;

(5) Traffic pattern procedures that include area departure, area arrival, entry into the traffic pattern, and approach;

(6) Procedures and operating practices for collision avoidance, wake turbulence precautions, and windshear avoidance;

(7) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(8) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(9) Use of radios for VFR navigation and two-way communications;

(10) Control of air pressure with regard to ascending and descending flight and altitude control;

(11) Control of airship solely by reference to flight instruments; and

(12) Recognition of weather and upper air conditions conducive for the direction of cross-country flight.

(l) *Maneuvers and procedures for supervised PIC cross-country flight training in a balloon.* A student pilot who is receiving training for supervised PIC-cross country flight training in a balloon must receive and log supervised PIC cross-country flight training on the following maneuvers and procedures:

(1) Use of aeronautical charts for VFR navigation using pilotage and dead reckoning with the aid of a magnetic compass;

(2) Use of aircraft performance charts pertaining to cross-country flight;

(3) Procurement and analysis of aeronautical weather reports and forecasts, including recognition of critical weather situations and estimating visibility while in flight;

(4) Emergency procedures;

(5) Recognition, avoidance, and operational restrictions of hazardous terrain features in the geographical area where the cross-country flight will be flown;

(6) Procedures for operating the instruments and equipment installed in the aircraft to be flown, including recognition and use of the proper operational procedures and indications;

(7) Control of gas pressure or burner, as appropriate, in relation to ascending and descending flight and altitude control; and

(8) Recognition of weather and upper air conditions conducive for the direction of cross-country flight.

(m) *Limitations on flight instructors authorizing supervised PIC cross-country flights.* A flight instructor may not authorize a student pilot to conduct a supervised PIC cross-country flight unless that instructor has:

(1) Determined that the student's cross country planning is correct for the flight;

(2) Reviewed the current and forecast weather conditions and has determined that the flight can be completed under VFR;

(3) Determined that the student is proficient to conduct the flight safely;

(4) Determined that the student has the appropriate supervised PIC cross-country endorsement for the make and model of aircraft to be flown; and

(5) Determined that the student's supervised PIC flight endorsement is current for the make and model aircraft to be flown.

§ 61.95 Operations in Class B airspace and at airports located within Class B airspace.

(a) A student pilot may not operate an aircraft on a supervised PIC flight in Class B airspace unless the:

(1) Student pilot has received both ground and flight training from an authorized instructor on that Class B airspace area and the flight training was received in the specific Class B airspace area for which supervised PIC flight is authorized;

(2) Logbook of that student pilot has been endorsed by the flight instructor who gave the student pilot flight training, and the endorsement must be dated within the 90-day period preceding the date of the flight in that Class B airspace area; and

(3) Logbook endorsement specifies that the student pilot has received the required ground and flight training and has been found proficient to conduct supervised PIC flight in that specific Class B airspace area.

(b) A student pilot may not operate an aircraft on a supervised PIC flight to, from, or at an airport located within Class B airspace listed in § 91.131(b) of this chapter unless the:

(1) Student pilot has received both ground and flight training from an authorized instructor to operate at that airport and the flight and ground training has been received at the specific airport for which the supervised PIC flight is authorized;

(2) Logbook of that student pilot has been endorsed by the flight instructor who gave the student pilot flight training, and the endorsement must be dated within the 90-day period

preceding the date of the flight at that airport; and

(3) Logbook endorsement specifies that the student pilot has received the required ground and flight training and has been found proficient to conduct supervised PIC flight operations at that specific airport.

Subpart D—Recreational Pilots

§ 61.96 Applicability.

This subpart prescribes the requirement for the issuance of recreational pilot certificates and ratings, the conditions under which those certificates and ratings are necessary, and the general operating rules for persons who hold those certificates and ratings.

§ 61.96a Eligibility requirements: General.

To be eligible for a recreational pilot certificate, a person who applies for that certificate must:

(a) Be at least 17 years of age;

(b) Be able to read, speak, write, and understand the English language;

(c) Affix a signed and dated statement to the application certifying the person does not have any known medical limitations that prevents the person from operating the aircraft, for the aircraft category and class rating sought;

(d) Receive a logbook endorsement from an authorized flight or ground instructor who—

(1) Conducted the training or reviewed the applicant's home study on the aeronautical knowledge areas listed in § 61.97(b) of this part that apply to the aircraft category and class rating sought; and

(2) Certified that the applicant is prepared for the required knowledge test.

(e) Satisfactorily accomplish the required knowledge test on the aeronautical knowledge areas listed in § 61.97(b) of this part;

(f) Receive flight training and a logbook endorsement from the authorized flight instructor who—

(1) Conducted the training on the approved areas of operation listed in § 61.98(b) of this part that apply to the aircraft category and class rating sought; and

(2) Certified that the applicant is prepared for the required practical test.

(g) Meet the aeronautical experience requirements of § 61.99 of this part that apply to the aircraft category and class rating sought;

(h) Satisfactorily accomplish the required practical test on the approved areas of operation listed in § 61.98(b) of this part that apply to the aircraft category and class rating sought; and

(i) Comply with the sections of this part that apply to the aircraft category and class rating sought.

§ 61.97 Aeronautical knowledge.

(a) *General.* A person who applies for a recreational pilot certificate must receive and log ground training from an authorized flight or ground instructor, or complete a home study course on the aeronautical knowledge areas of paragraph (b) of this section that apply to the aircraft category and class rating sought.

(b) *Aeronautical knowledge areas.*

(1) The applicable Federal Aviation Regulations for recreational pilot privileges, limitations, and flight operations that apply to the aircraft rating sought;

(2) Accident reporting requirements of the National Transportation Safety Board;

(3) Use of the applicable portions of the ''Airman's Information Manual'' and FAA advisory circulars;

(4) The use of aeronautical charts for VFR navigation using pilotage with the aid of a magnetic compass;

(5) The recognition of critical weather situations from the ground and in flight, windshear avoidance, and the procurement and use of aeronautical weather reports and forecasts;

(6) The safe and efficient operation of aircraft, including collision avoidance, and recognition and avoidance of wake turbulence;

(7) The effects of density altitude on takeoff and climb performance;

(8) Weight and balance computations;

(9) Principles of aerodynamics, powerplants, and aircraft systems;

(10) Stall awareness, spin entry, spins, and spin recovery techniques, if applying for an airplane-single engine rating;

(11) Aeronautical decision making and judgment; and

(12) Preflight action that includes:

(i) How to obtain information on runway lengths at airports of intended use, data on takeoff and landing distances, weather reports and forecasts, and fuel requirements;

(ii) How to plan for alternatives if the planned flight cannot be completed; and

(iii) Proper planning procedures for possible traffic delays.

§ 61.98 Flight proficiency.

(a) *General.* A person who applies for a recreational pilot certificate must have received and logged ground training from authorized ground or flight instructor, and flight training from an authorized flight instructor on the approved areas of operation of this section that apply to the aircraft class rating sought.

(b) *For an single engine airplane rating.* Areas of operation for an airplane category rating with a single engine class rating are the following:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Ground reference maneuvers;

(7) Navigation;

(8) Stalls and slow flight;

(9) Emergency operations; and

(10) Postflight procedures.

(c) *For a helicopter rating.* Areas of operation for a rotorcraft category rating with a helicopter class rating are the following:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and heliport operations;

(4) Hovering maneuvers;

(5) Takeoffs, landings, and go-arounds;

(6) Performance maneuvers;

(7) Ground reference maneuvers;

(8) Navigation;

(9) Emergency operations; and

(10) Postflight procedures.

(d) *For a gyroplane rating.* Areas of operation for a rotorcraft category rating with a gyroplane class rating are the following:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Ground reference maneuvers;

(7) Navigation;

(8) Flight at slow airspeeds;

(9) Emergency operations; and

(10) Postflight procedures.

§ 61.99 Aeronautical experience.

A person who applies for a recreational pilot certificate must accomplish and log at least 30 hours of flight training time that includes at least:

(a) Fifteen hours of flight training from an authorized flight instructor on the approved areas of operation listed in § 61.98 of this part that consists of at least—

(1) Except as provided in § 61.100 of this part, 2 hours of flight training to and at an airport that is located more than 25 nautical miles from the airport where the applicant normally trains, which includes at least 3 takeoffs and 3 landings; and

(2) Three hours of flight training in the aircraft for the rating sought in preparation for the practical test within the 60 days preceding the date of the practical test.

(b) Three hours of supervised PIC flying in the aircraft for the rating sought, on the approved areas of operation listed in § 61.98 of this part that apply to the aircraft category and class rating sought.

§ 61.100 Pilots based on small islands.

A person who applies for a recreational pilot certificate, is based and receives training on a small island that has only one airport, and who cannot comply with the distance requirements of § 61.99(a)(1) of this part without flying over water for more than 10 nautical miles from the nearest shoreline is subject to the following limitations and conditions:

(a) The applicant's pilot certificate will be issued with the limitation, ''Passenger carrying prohibited in flights more than 10 nautical miles from the (appropriate island).''

(b) Upon meeting the distance requirements of § 61.99(a)(1) of this part, the applicant may have the limitation in paragraph (a) of this section removed.

§ 61.101 Recreational pilot privileges and limitations.

(a) A person who holds a recreational pilot certificate may:

(1) Carry no more than one passenger; and

(2) Share equally the operating expenses of a flight with a passenger, provided the expenses involve only fuel, oil, and airport expenses.

(b) A person who holds a recreational pilot certificate may act as pilot in command of an aircraft on a flight that is within 50 nautical miles from the departure airport, provided that person:

(1) Received ground and flight training on takeoff, departure, arrival, and landing procedures at the departure airport;

(2) Received ground and flight training on the area, terrain, and aids to navigation that are in the vicinity of the departure airport;

(3) Has been found proficient to operate the airplane at the departure airport and the area within 50 nautical miles from that airport, and has received a logbook endorsement from the authorized flight instructor who gave the person the training prescribed by this paragraph; and

(4) Received a logbook endorsement that authorizes flight, which is carried in the person's possession in the aircraft.

(c) A person who holds a recreational pilot certificate may act as pilot in command of an aircraft on a flight that exceeds 50 nautical miles from the departure airport, provided that person:

(1) Has received ground and flight training from an authorized flight instructor on the cross country training requirements of subpart E of this part that apply to the aircraft rating held;

(2) Has been found proficient in cross country flying, and has received a logbook endorsement from the authorized flight instructor, who gave the person the cross country training prescribed by subpart E of this part that apply to the aircraft rating held; and

(3) Received a logbook endorsement, which is carried in the person's possession in the aircraft, that certifies the person has received and been found proficient on the cross training requirements of subpart E of this part that apply to the aircraft rating held.

(d) Except as provided in paragraph (h) of this section, a recreational pilot may not act as pilot in command of an aircraft:

(1) That is certificated for more than four occupants, with more than one powerplant, with a powerplant of more than 180 horsepower, or with retractable landing gear.

(2) That is classified as a multiengine airplane, powered-lift, glider, airship, or balloon;

(3) That is carrying a passenger or property for compensation or hire;

(4) For compensation or hire;

(5) In furtherance of a business;

(6) Between sunset and sunrise;

(7) In airspace in which communication with air traffic control is required;

(8) At an altitude of more than 10,000 feet MSL or 2,000 feet AGL, whichever is higher;

(9) When the flight or surface visibility is less than 3 statute miles;

(10) Without visual reference to the surface;

(11) On a flight outside the United States;

(12) To demonstrate that aircraft in flight to a prospective buyer;

(13) That is used in a passenger-carrying airlift and sponsored by a charitable organization; and

(14) That is towing any object.

(e) A recreational pilot may not act as a required pilot flight crewmember on any aircraft for which more than one pilot is required by the type certificate of the aircraft or the regulations under which the flight is conducted, except when:

(1) Receiving flight training from an authorized flight instructor on board an airship; or

(2) The other person on the aircraft is a required flight crewmember.

(f) A person who holds a recreational pilot certificate and has logged fewer than 400 flight hours and has not logged pilot-in-command time in an aircraft within the 180 days preceding the flight shall not act as pilot in command of an aircraft:

(1) Until the pilot received flight training and a logbook endorsement from an authorized flight instructor who gave that person the flight training, and the instructor certified that the person is proficient to act as pilot in command of the aircraft; or

(2) Unless the pilot has satisfactorily accomplished a combination of the requirements of §§ 61.56 and 61.57 of this part, which meet the requirements of this paragraph.

(g) The recreational pilot certificate issued under this part will carry the notation on the person's pilot certificate, ''Holder does not meet ICAO requirements.''

(h) A recreational pilot may operate an aircraft as the sole occupant in the conditions and in an aircraft described in paragraph (d) of this section, provided the pilot:

(1) Is under the supervision of an authorized flight instructor for the purpose of obtaining an additional certificate or rating;

(2) Has received, within the 90-day period preceding the date of the flight, a logbook endorsement from an authorized flight instructor and that endorsement must certify the pilot has met the appropriate aeronautical knowledge and flight training requirements listed in § 61.87 of this part for the aircraft to be flown;

(3) Received within the 90 days preceding the date of the flight a logbook endorsement from an authorized flight instructor and that endorsement must certify the pilot is proficient to operate in that airspace, for operating an aircraft in airspace that requires communication with air traffic control;

(4) Received within the 90 days preceding the date of the flight, a logbook endorsement from an authorized flight instructor and that endorsement must certify the pilot is proficient to operate the aircraft in those flight conditions, for an operating an aircraft between sunset and sunrise, and provided the flight or surface visibility conditions are at least 5 statute miles; and

(5) Received a logbook endorsement described in this paragraph and carried in the pilot's physical possession in the aircraft.

Subpart E—Private Pilots

§ 61.102 Applicability.

This subpart prescribes the requirements for the issuance of private pilot certificates and ratings, the conditions under which those

certificates and ratings are necessary, and the general operating rules for persons who hold those certificates and ratings.

§ 61.103 Eligibility requirements: General.

To be eligible for a private pilot certificate, a person must:

(a) Be at least 17 years of age, or for a rating in a glider or balloon be at least 16 years of age.

(b) Be able to read, speak, write, and understand the English language.

(c) Hold at least a current third-class medical certificate issued under part 67 of this chapter, or for a rating in a glider or balloon affix a signed and dated statement to the application certifying that no known medical defect exists that would make the person unable to pilot a glider or balloon, as appropriate.

(d) Receive a logbook endorsement from an authorized instructor who—

(1) Conducted the training or reviewed the person's home study on the aeronautical knowledge areas listed in § 61.105(b) of this part that apply to the aircraft rating sought; and

(2) Certified that the person is prepared for the required knowledge test.

(e) Satisfactorily accomplish the required knowledge test on the aeronautical knowledge areas listed in § 61.105(b) of this part.

(f) Receive flight training and a logbook endorsement from the authorized instructor who—

(1) Conducted the training on the approved areas of operation listed in § 61.107 of this part that apply to the aircraft rating sought; and

(2) Certified that the person is prepared for the required practical test.

(g) Meet the aeronautical experience requirements of this part that apply to the aircraft rating sought before applying for the practical test.

(h) Satisfactorily accomplishes a practical test on the approved areas of operation listed in § 61.107 of this part that apply to the aircraft rating sought.

(i) Comply with the appropriate sections of this part that apply to the aircraft rating sought.

§ 61.105 Aeronautical knowledge.

(a) *General.* A person who is applying for a private pilot certificate must receive and log ground training from an authorized flight or ground instructor, or complete a home study course on the aeronautical knowledge areas of paragraph (b) of this section that apply to the aircraft rating sought.

(b) *Aeronautical knowledge areas.*

(1) The applicable Federal Aviation Regulations for private pilot privileges, limitations, and flight operations;

(2) Accident reporting requirements of the National Transportation Safety Board;

(3) Use of the applicable portions of the ''Airman's Information Manual'' and FAA advisory circulars;

(4) The use of aeronautical charts for VFR navigation using pilotage, dead reckoning, and radio aids;

(5) Radio communication procedures;

(6) The recognition of critical weather situations from the ground and in flight, windshear avoidance, and the procurement and use of aeronautical weather reports and forecasts;

(7) The safe and efficient operation of aircraft, including collision avoidance, and recognition and avoidance of wake turbulence;

(8) The effects of density altitude on takeoff and climb performance;

(9) Weight and balance computations;

(10) Principles of aerodynamics, powerplants, and aircraft systems;

(11) Stall awareness, spin entry, spins, and spin recovery techniques for the airplane and glider category and class ratings;

(12) Aeronautical decision making and judgment; and

(13) Preflight action that includes:

(i) How to obtain information on runway lengths at airports of intended use, data on takeoff and landing distances, weather reports and forecasts, and fuel requirements;

(ii) How to plan for alternatives if the planned flight cannot be completed; and

(iii) How to plan procedures for possible traffic delays.

§ 61.107 Flight proficiency.

(a) *General.* A person who applies for a private pilot certificate must receive and log ground training from an authorized ground or flight instructor and flight training from an authorized flight instructor on the approved areas of operation of this section that apply to the aircraft rating sought.

(b) *Areas of operation for an airplane category rating with a single engine class rating.* Areas of operation for an airplane category rating with a single engine class rating are the following:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and seaplane base operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Ground reference maneuvers;

(7) Navigation;

(8) Stalls and slow flight;

(9) Basic instrument maneuvers;

(10) Emergency operations;

(11) Night operations, except as provided in § 61.110 of this part; and

(12) Postflight procedures.

(c) *Areas of operation for an airplane category rating with a multiengine class rating.* Areas of operation for an airplane category rating with a multiengine class rating are the following:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and seaplane base operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Ground reference maneuvers;

(7) Navigation;

(8) Stalls and slow flight;

(9) Basic instrument maneuvers;

(10) Emergency operations;

(11) Multiengine operations;

(12) Night operations, except as provided in § 61.110 of this part; and

(13) Postflight procedures.

(d) *Areas of operation for a rotorcraft category rating with a helicopter class rating.* Areas of operation for a rotorcraft category rating with a helicopter class rating are the following:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and heliport operations;

(4) Hovering maneuvers;

(5) Takeoffs, landings, and go-arounds;

(6) Performance maneuvers;

(7) Navigation;

(8) Emergency operations;

(9) Night operations, except as provided in § 61.110 of this part; and

(10) Postflight procedures.

(e) *Areas of operation for a rotorcraft category rating with a gyroplane class rating.* Areas of operation for a rotorcraft category rating with a gyroplane class rating are the following:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Ground reference maneuvers;

(7) Navigation;

(8) Flight at slow airspeeds;

(9) Emergency operations;

(10) Night operations, except as provided in § 61.110 of this part; and

(11) Postflight procedures.

(f) *Areas of operation for a powered-lift category rating.* Areas of operation for a powered-lift category rating are the following:

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and heliport operations;

(4) Hovering maneuvers;

(5) Takeoffs, landings, and go-arounds;

(6) Performance maneuvers;

(7) Ground reference maneuvers;
(8) Navigation;
(9) Stalls and slow flight;
(10) Basic instrument maneuvers;
(11) Emergency operations;
(12) Night operations, except as provided in § 61.110 of this part; and
(13) Postflight procedures.

(g) *Areas of operation for a glider category rating with a non-powered class rating.* Areas of operation for a glider category rating with a non-powered class rating are the following:
(1) Preflight preparation;
(2) Preflight procedures;
(3) Airport and gliderport operations;
(4) Launches and landings;
(5) Performance speeds;
(6) Soaring techniques;
(7) Performance maneuvers;
(8) Navigation;
(9) Stalls and slow flight;
(10) Emergency operations; and
(11) Postflight procedures.

(h) *Areas of operation for a glider category rating with a powered class rating.* Areas of operation for a glider category rating with a powered class rating are the following:
(1) Preflight preparation;
(2) Preflight procedures;
(3) Airport and gliderport operations;
(4) Takeoffs, landings, and go-arounds;
(5) Performance speeds;
(6) Soaring techniques;
(7) Performance maneuvers;
(8) Navigation;
(9) Stalls and slow flight;
(10) Emergency operations; and
(11) Postflight procedures.

(i) *Areas of operation for a lighter-than-air category rating with an airship class rating.* Areas of operation for a lighter-than-air category rating with an airship class rating are the following:
(1) Preflight preparation;
(2) Preflight procedures;
(3) Airport operations;
(4) Takeoffs, landings, and go-arounds;
(5) Performance maneuvers;
(6) Ground reference maneuvers;
(7) Navigation;
(8) Emergency operations; and
(9) Postflight procedures.

(j) *Areas of operation for a lighter-than-air category rating with a balloon class rating.* Areas of operation for a lighter-than-air category rating with a balloon class rating are the following:
(1) Preflight preparation;
(2) Preflight procedures;
(3) Balloonport operations;
(4) Lift-offs and landings;
(5) Performance maneuvers;
(6) Navigation;
(7) Emergency operations; and
(8) Postflight procedures.

§ 61.109 Aeronautical experience.

(a) A person who applies for a private pilot certificate with an airplane, rotorcraft, or powered-lift category rating must accomplish and log at least 40 hours of flight time that includes at least 20 hours of flight training time from an authorized flight instructor and 5 hours of supervised PIC flight time, on the approved areas of operation listed in § 61.107 of this part, and the training must include at least:

(1) *For an airplane single engine rating.*
(i) Three hours of cross-country flight training in a single engine airplane;
(ii) Except as provided in § 61.110 of this part, 3 hours of night flight training in a single engine airplane that includes—
(A) One cross country flight of over 100 nautical miles duration; and
(B) Ten takeoffs and 10 landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.
(iii) Three hours of instrument flight training in a single engine airplane;
(iv) Three hours of flight training in preparation for the practical test in a single engine airplane, and must have been performed within 60 days preceding the date of the test; and
(v) Supervised PIC flying in a single engine airplane, consisting of at least—
(A) One supervised PIC cross-country flight of over 100 nautical miles, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and
(B) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(2) *For an airplane multiengine rating.*
(i) Three hours of cross-country flight training in a multiengine airplane;
(ii) Except as provided in § 61.110 of this part, 3 hours of night flight training in a multiengine airplane that includes—
(A) One cross country flight of over 100 nautical miles duration; and
(B) Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.
(iii) Three hours of instrument flight training in a multiengine airplane;
(iv) Three hours of flight training in preparation for the practical test in a multiengine airplane, and must have been performed within the 60-day period preceding the date of the test; and
(v) Supervised PIC flying in a multiengine airplane, consisting of at least—
(A) One supervised PIC cross-country flight of over 100 nautical miles, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and
(B) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(3) *For a rotorcraft-helicopter rating.*
(i) Three hours of cross-country flight training in a helicopter;
(ii) Except as provided in § 61.110 of this part, 3 hours of night flight training in a helicopter that includes—
(A) One cross country flight of over 50 nautical miles duration; and
(B) Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.
(iii) Three hours of flight training in preparation for the practical test in a helicopter, and must have been performed within 60 days preceding the date of the test; and
(iv) Supervised PIC flying in a helicopter, consisting of at least—
(A) One supervised PIC cross-country flight of over 50 nautical miles, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 25 nautical miles between the takeoff and landing locations; and
(B) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(4) *For a rotorcraft-gyroplane rating.*
(i) Three hours of cross-country flight training in a gyroplane;
(ii) Except as provided in § 61.110 of this part, 3 hours of night flight training in a gyroplane that includes—
(A) One cross country flight of over 50 nautical miles duration; and
(B) Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.
(iii) Three hours of flight training in preparation for the practical test in a gyroplane, and must have been performed within the 60-day period preceding the date of the test; and
(iv) Supervised PIC flying in a gyroplane, and consisting of at least—
(A) One supervised PIC cross-country flight of over 50 nautical miles, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 25 nautical miles between the takeoff and landing locations; and
(B) Three takeoffs and three landings to a full stop (with each landing

involving a flight in the traffic pattern) at an airport with an operating control tower.

(5) *For a powered-lift rating.*

(i) Three hours of cross-country flight training in a powered-lift;

(ii) Except as provided in § 61.110 of this part, 3 hours of night flight training in a powered-lift that includes—

(A) One cross country flight of over 100 nautical miles duration; and

(B) Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of instrument flight training in a powered-lift;

(iv) Three hours of flight training in preparation for the practical test in a powered-lift, and must have been performed within the 60-day period preceding the date of the test; and

(v) Supervised PIC flying in a powered-lift, consisting of at least—

(A) One supervised PIC cross-country flight of over 100 nautical miles, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and

(B) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(b) *For a glider rating.* A person who applies for a private pilot certificate with a glider category and class rating must accomplish and log the following flight time and training requirements:

(1) At least 10 hours of flight training and 20 flights on the approved areas of operation listed in § 61.107 of this part that apply to the glider class rating sought; or

(2) A person who has logged at least 40 hours of flight time in heavier-than-air aircraft or who already holds a category and class rating in a glider, must perform at least 5 hours of flight training and 10 flights, on the approved areas of operation listed in § 61.107 of this part that apply to the glider class rating sought.

(3) At least two supervised PIC flights on the approved areas of operation listed in § 61.107 that apply to the glider class rating sought.

(4) The flight training requirements in paragraphs (c) (1) or (2) of this section must include at least 3 flights of flight training in preparation for the practical test within the 60-day period preceding the test and in the class of glider for the rating sought.

(5) A person applying for a glider category rating with a nonpowered class rating seeks privileges for ground launch procedures, in addition to complying with the requirements of paragraphs (c) (1) through (4), as appropriate, must log and receive at least 5 flights of flight training and 2 supervised PIC flights in a nonpowered glider using a winch or auto tow on the appropriate approved areas of operation listed in § 61.107(g) of this part.

(c) *For an airship rating.* A person who applies for a private pilot certificate with a lighter-than-air category and airship class rating must receive and log at least 25 hours of flight training in airships on the approved areas of operation listed in § 61.107(i) of this part, which consists of at least:

(1) Three hours of cross-country flight training in an airship;

(2) Except as provided in § 61.110 of this part, 3 hours of night flight training in an airship that includes—

(i) A cross country flight of over 25 nautical miles; and

(ii) Five takeoffs and 5 landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(3) Three hours of instrument flight training in an airship;

(4) Three hours of flight training in an airship in preparation for the practical test within the 60 days preceding the date of the test; and

(5) Five hours of supervised PIC flight training in an airship and with an authorized flight instructor.

(d) *For a balloon rating.* A person who applies for a private pilot certificate with a lighter-than-air category and balloon class rating must receive and log at least 10 hours of flight training that includes at least 6 training flights, on the approved areas of operation listed in § 61.107(j) of this part, that includes:

(1) *Gas balloon.* If the training is being performed in a gas balloon, the training must include at least two flights of 2 hours each that consists of—

(i) At least one training flight that covers the approved areas of operation appropriate to a gas balloon within 60 days prior to application for the rating; and

(ii) At least one supervised PIC flight in a gas balloon.

(2) *Balloon with an airborne heater.* If the training is being performed in a balloon with an airborne heater, the training must include at least—

(i) Two training flights of one hour each that covers the approved areas of operation appropriate to a balloon with an airborne heater within 60 days prior to application for the rating; and

(ii) One supervised PIC flight in a balloon with an airborne heater.

§ 61.110 Night flying exceptions for private pilot certification.

A person is not required to comply with the night flying requirements of this subpart:

(a) If that person has a medical restriction from operating an aircraft at night, then that person may—

(1) Be issued a permanent private pilot certificate with the limitation ''Night flying prohibited;'' and

(2) Have that limitation removed if the condition which was the basis for the medical restriction is corrected, and the person accomplishes the appropriate night flying requirements of this subpart.

(b) If that person receives flight training in the State of Alaska and is not able to accomplish the training, then that person—

(1) May be issued a temporary pilot certificate for only 12 calendar months, with a limitation ''Night flying prohibited;''

(2) Must comply with the appropriate night flying requirements of this subpart within the 12-calendar month period following issuance of the temporary private pilot certificate, or the certificate will be suspended until the person complies with the appropriate night flying requirements of this subpart; and

(3) May have the ''Night flying prohibited'' limitation of this section removed if the person—

(i) Accomplishes the appropriate night flight training requirements of this subpart in the category and class of aircraft for which night flying privileges are sought;

(ii) Presents to an examiner, a logbook or training record endorsement from an authorized flight instructor that verifies accomplishment of the night flying requirements of this subpart that are appropriate to the category and class aircraft for which night flying privileges are sought; and

(iii) Satisfactorily accomplishes the night operations portion of the practical test that are appropriate to the category and class of aircraft for which night flying privileges are sought.

§ 61.111 Cross-country flights: Pilots based on small islands.

A person who applies for a private pilot certificate and who cannot comply with the cross-country distance requirements of this subpart without flying over water for more than 10 nautical miles from the nearest shoreline, is not required to comply with the cross-country distance requirements of this subpart for cross-country flight. The person is subject to the following limitations and conditions:

(a) The person's pilot certificate will be issued with the limitation noted, ''Passenger carrying prohibited in flights more than 10 nautical miles from the (appropriate island).''

(b) Upon meeting the cross-country distance requirements in this subpart, the person may have the limitation in paragraph (a) of this section removed.

§ 61.113 Private pilot privileges and limitations: Pilot in command.

(a) Except as provided in paragraphs (b) through (f) of this section, no person who holds a private pilot certificate may act as pilot in command of an aircraft that is carrying passengers or property for compensation or hire; nor may that person, for compensation or hire, act as pilot in command of an aircraft.

(b) A private pilot may, for compensation or hire, act as pilot in command of an aircraft in connection with any business or employment if:

(1) The flight is only incidental to that business or employment; and

(2) The aircraft does not carry passengers or property for compensation or hire.

(c) A private pilot may share equally the operating expenses of a flight with passengers, provided the expenses involve only fuel, oil, and airport expenditures.

(d) No person who holds a private pilot certificate may act as pilot in command of an aircraft for a passenger-carrying airlift that is sponsored by a charitable organization described in paragraph (d)(7) of this section, for which the passengers are only making a donation to the organization, unless the following requirements are met:

(1) The sponsor of the airlift notifies the FAA Flight Standards District Office with jurisdiction over the area concerned at least 7 days before the event and furnishes—

(i) A signed letter from the sponsor that shows the name of the sponsor, the purpose of the charitable event, the date and time of the event, and the location of the event; and

(ii) A photocopy of each pilot in command's pilot certificate, medical certificate, and logbook entries that show the pilot is current in accordance with §§ 61.56 and 61.57 of this part and has logged at least 200 hours of flight time.

(2) The charitable event takes place at a public airport that is adequate for the aircraft to be used or at an airport that has been approved by the FAA for the operation.

(3) No acrobatic or formation flights are conducted.

(4) Each aircraft used for the charitable event holds a standard airworthiness certificate.

(5) Each aircraft used for the charitable event is airworthy, in accordance with the applicable sections of subpart E of part 91 of this chapter.

(6) Each flight for the charitable event is made during day-VFR conditions.

(7) The charitable organization is an organization identified as such by the U.S. Department of Treasury regulations.

(e) A private pilot may be reimbursed for aircraft operating expenses that are directly related to and for search and location operations, provided the operation is sanctioned and under the direction and control of:

(1) A local, state, or Federal law enforcement agency; or

(2) An organization that conducts search and location operations.

(f) A private pilot who meets the requirements of § 61.69 of this part may act as pilot in command of an aircraft towing a glider.

§ 61.115 Balloon rating: Limitations.

(a) If a person who applies for private pilot certificate with a balloon rating takes a practical test in a balloon with an airborne heater:

(1) The pilot certificate will contain a limitation restricting the exercise of the privilege of that certificate to a balloon with an airborne heater; and

(2) The limitation may be removed when the person obtains the required aeronautical experience in a gas balloon and receives a logbook endorsement from an authorized instructor who attests to the person's accomplishment of the required aeronautical experience and ability to satisfactorily operate a gas balloon.

(b) If a person who applies for a private pilot certificate with a balloon rating takes a practical test in a gas balloon:

(1) The pilot certificate will contain a limitation restricting the exercise of the privilege of that certificate to a gas balloon; and

(2) The limitation may be removed when the person obtains the required aeronautical experience in a balloon with an airborne heater and receives a logbook endorsement from an authorized instructor who attests to the person's accomplishment of the required aeronautical experience and ability to satisfactorily operate a balloon with an airborne heater.

§ 61.117 Private pilot privileges and limitations: Second in command of aircraft requiring more than one pilot.

Except as provided in § 61.113 of this part, no private pilot may, for compensation or hire, act as second in command of an aircraft that is type certificated for more than one pilot, nor may that pilot act as second in command of such an aircraft that is carrying passengers or property for compensation or hire.

§§ 61.118 through 61.120 [Reserved]

Subpart F—Commercial Pilots

§ 61.121 Applicability.

This subpart prescribes the requirements for the issuance of commercial pilot certificates and ratings, the conditions under which those certificates and ratings are necessary, and the general operating rules for persons who hold those certificates and ratings.

§ 61.123 Eligibility requirements: General.

To be eligible for a commercial pilot certificate, a person must:

(a) Be at least 18 years of age;

(b) Be able to read, speak, write, and understand the English language;

(c) Hold at least a current third-class medical certificate issued under part 67 of this chapter, or for a rating in a glider or balloon affix a signed and dated statement to the application certifying that no known medical defect exists that would make the person unable to pilot a glider or balloon, as appropriate;

(d) Receive a logbook endorsement from an authorized instructor who—

(1) Conducted the required ground training or reviewed the person's home study on the aeronautical knowledge areas listed in § 61.125 of this part that apply to the aircraft category and class rating sought; and

(2) Certified that the person is prepared for the required knowledge test that apply to the aircraft category and class rating sought.

(e) Satisfactorily accomplish the required knowledge test on the aeronautical knowledge areas listed in § 61.125 of this part;

(f) Received the required training and a logbook endorsement from the authorized instructor who—

(1) Conducted the training on the approved areas of operation listed in § 61.127 of this part that apply to the aircraft category and class rating sought; and

(2) Certified that the person is prepared for the required practical test.

(g) Meet the aeronautical experience requirements of this subpart that apply to the aircraft category and class rating sought before applying for the practical test;

(h) Satisfactorily accomplish the required practical test on the approved areas of operation listed in § 61.127 of this part that apply to the aircraft category and class rating sought; and

(i) Hold at least a private pilot certificate.

§ 61.125 Aeronautical knowledge.

(a) *General.* A person who applies for a commercial pilot certificate must receive and log ground training, or accomplish a home study course, on the aeronautical knowledge areas of this section that apply to the aircraft category and class rating sought.

(b) *Aeronautical knowledge areas.*

(1) The Federal Aviation Regulations that apply to commercial pilot privileges, limitations, and flight operations;

(2) Accident reporting requirements of the National Transportation Safety Board;

(3) Basic aerodynamics and the principles of flight;

(4) Meteorology to include recognition of critical weather situations, windshear recognition and avoidance, and the use of aeronautical weather reports and forecasts;

(5) The safe and efficient operation of aircraft;

(6) Weight and balance computations;

(7) Use of performance charts;

(8) Significance and effects of exceeding aircraft performance limitations;

(9) Use of aeronautical charts and magnetic compass for pilotage and dead reckoning;

(10) Use of air navigation facilities;

(11) Aeronautical decision making and judgment;

(12) Principles and functions of aircraft systems;

(13) Maneuvers, procedures, and emergency operations appropriate to the aircraft;

(14) Night and high altitude operations; and

(15) Descriptions of and procedures for operating within the National Airspace System.

§ 61.127 Flight proficiency.

(a) *General.* A person who applies for a commercial pilot certificate must receive and log ground and flight training on the approved areas of operation of this section that apply to the aircraft category and class rating sought.

(b) *Areas of operation for an airplane category rating with a single engine class rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and seaplane base operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Ground reference maneuvers;

(7) Navigation;

(8) Stalls and slow flight;

(9) Emergency operations;

(10) High altitude operations; and

(11) Postflight procedures.

(c) *Areas of operation for an airplane category rating with a multiengine class rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and seaplane base operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Navigation;

(7) Stalls and slow flight;

(8) Emergency operations;

(9) Multiengine operations;

(10) High altitude operations; and

(11) Postflight procedures.

(d) *Areas of operation for a rotorcraft category rating with a helicopter class rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and heliport operations;

(4) Hovering maneuvers;

(5) Takeoffs, landings, and go-arounds;

(6) Performance maneuvers;

(7) Navigation;

(8) Emergency operations;

(9) Special operations; and

(10) Postflight procedures.

(e) *Areas of operation for a rotorcraft category rating with a gyroplane class rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Ground reference maneuvers;

(7) Navigation;

(8) Flight at slow airspeeds;

(9) Emergency operations; and

(10) Postflight procedures.

(f) *Areas of operation for a powered-lift category rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and heliport operations;

(4) Hovering maneuvers;

(5) Takeoffs, landings, and go-arounds;

(6) Performance maneuvers;

(7) Ground reference maneuvers;

(8) Navigation;

(9) Stalls and slow flight;

(10) Emergency operations;

(11) High altitude operations;

(12) Special operations; and

(13) Postflight procedures.

(g) *Areas of operation for a glider category rating with a non-powered class rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and gliderport operations;

(4) Launches and landings;

(5) Performance speeds;

(6) Soaring techniques;

(7) Performance maneuvers;

(8) Navigation;

(9) Stalls and slow flight;

(10) Emergency operations; and

(11) Postflight procedures.

(h) *Areas of operation for a glider category rating with a powered class rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport and gliderport operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance speeds;

(6) Soaring techniques;

(7) Performance maneuvers;

(8) Navigation;

(9) Stalls and slow flight;

(10) Emergency operations; and

(11) Postflight procedures.

(i) *Areas of operation for a lighter-than-air category rating with an airship class rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Airport operations;

(4) Takeoffs, landings, and go-arounds;

(5) Performance maneuvers;

(6) Ground reference maneuvers;

(7) Navigation;

(8) Emergency operations; and

(9) Postflight procedures.

(j) *Areas of operation for a lighter-than-air category rating with a balloon class rating.*

(1) Preflight preparation;

(2) Preflight procedures;

(3) Balloonport operations;

(4) Lift-offs and landings;

(5) Performance maneuvers;

(6) Navigation;

(7) Emergency operations; and

(8) Postflight procedures.

§ 61.129 Aeronautical experience.

(a) *For an airplane single engine rating.* A person who applies for a commercial pilot certificate with an airplane category and single engine class rating must accomplish and log at least 250 hours of flight time as a pilot (of which 50 hours may have been accomplished in an approved flight simulator or flight training device that is representative of a single engine airplane) that consists of at least:

(1) One hundred hours in powered aircraft, of which 50 hours must be in airplanes;

(2) One hundred hours of pilot-in-command flight time, which includes at least—

(i) Fifty hours in airplanes; and

(ii) Fifty hours in cross-country flight in airplanes.

(3) Twenty hours of training on the approved areas of operation listed in § 61.127(b) of this part that includes at least—

(i) Five hours of instrument training in a single engine airplane;

(ii) Ten hours of training in a single engine airplane that has a retractable landing gear, flaps, and a controllable pitch propeller, or is turbine-powered;

(iii) One cross-country flight in a single engine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iv) One cross-country flight in a single engine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(v) Three hours in a single engine airplane in preparation for the practical test within the 60-day period preceding the date of the test.

(4) Ten hours of supervised PIC flying in a single engine airplane on the approved areas of operation listed in § 61.127(b) of this part, which includes at least—

(i) One cross-country flight, if the training is being performed in the state of Hawaii, then that cross-country flight must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(ii) One cross-country flight, if the training is being performed in a State other than Hawaii, then that cross-country flight must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(iii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower.

(b) *For an airplane multiengine rating.* A person who applies for a commercial pilot certificate with an airplane category and multiengine class rating must accomplish and log at least 250 hours of flight time as a pilot (of which 50 hours may have been accomplished in an approved flight simulator or flight training device that is representative of a multiengine airplane) that consists of at least:

(1) One hundred hours in powered aircraft, of which 50 hours must be in airplanes;

(2) One hundred hours of pilot-in-command flight time, which includes at least—

(i) Fifty hours in airplanes; and

(ii) Fifty hours in cross-country flight in airplanes.

(3) Twenty hours of training on the approved areas of operation listed in § 61.127(c) of this part that includes at least—

(i) Five hours of instrument training in a multiengine airplane;

(ii) Ten hours of training in a multiengine airplane that has a retractable landing gear, flaps, and a controllable pitch propeller, or is turbine-powered;

(iii) One cross-country flight in a multiengine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iv) One cross-country flight in a multiengine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(v) Three hours in a multiengine airplane in preparation for the practical test within the 60-day period preceding the date of the test.

(4) Ten hours of supervised PIC flying in a multiengine airplane on the approved areas of operation listed in § 61.127(c) of this part, which includes at least—

(i) One cross-country flight, if the training is being performed in the state of Hawaii, then that cross-country flight must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(ii) One cross-country flight, if the training is being performed in a State other than Hawaii, then that cross-country flight must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(iii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower.

(c) *For a helicopter rating.* A person who applies for a commercial pilot certificate with a rotorcraft category and helicopter class rating must accomplish and log at least 150 hours of flight time as a pilot (of which 25 hours may have been accomplished in an approved flight simulator or flight training device that is representative of a helicopter) that consists of at least:

(1) One hundred hours in powered aircraft, of which 50 hours must be in helicopters;

(2) One hundred hours of pilot-in-command flight time, which includes at least—

(i) Thirty-five hours in helicopters; and

(ii) Ten hours in cross-country flight in helicopters.

(3) Twenty hours of training on the approved areas of operation listed in § 61.127(d) of this part that includes at least—

(i) Five hours of instrument training in a helicopter;

(ii) One cross-country flight in a helicopter of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iii) One cross-country flight in a helicopter of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(iv) Three hours in a helicopter in preparation for the practical test within the 60-day period preceding the date of the test.

(4) Ten hours of supervised PIC flying in a helicopter on the approved areas of operation listed in § 61.127(d) of this part, which includes at least—

(i) One cross-country flight with landings at a minimum of three points, and one of the routes having a straight-line distance of at least 50 nautical miles from the original point of departure; and

(ii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern).

(d) *For a gyroplane rating.* A person who applies for a commercial pilot certificate with a rotorcraft category and gyroplane class rating must accomplish and log at least 150 hours of flight time as a pilot (of which 5 hours may have been accomplished in an approved flight simulator or flight training device that is representative of a gyroplane) that consists of at least:

(1) One hundred hours in powered aircraft, of which 25 hours must be in gyroplanes;

(2) One hundred hours of pilot-in-command flight time, which includes at least—

(i) Ten hours in gyroplanes; and

(ii) Three hours in cross-country flight in gyroplanes.

(3) Twenty hours of training on the approved areas of operation listed in § 61.127(d) of this part that includes at least—

(i) Five hours of instrument training in a gyroplane;

(ii) One cross-country flight in a gyroplane of at least 2 hours in duration,

a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iii) One cross-country flight in a gyroplane of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(iv) Three hours in a gyroplane in preparation for the practical test within the 60-day period preceding the date of the test.

(4) Ten hours of supervised PIC flying in a gyroplane on the approved areas of operation listed in § 61.127(e) of this part, which includes at least—

(i) One cross-country flight with landings at a minimum of three points, and one of the routes having a straight-line distance of at least 50 nautical miles from the original point of departure; and

(ii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern).

(e) *For a powered-lift rating.* A person who applies for a commercial pilot certificate with a powered-lift category rating must accomplish and log at least 250 hours of flight time as a pilot (of which 50 hours may have been accomplished in an approved flight simulator or flight training device that is representative of a powered-lift) that consists of at least:

(1) One hundred hours in powered aircraft, of which 50 hours must be in a powered-lift;

(2) One hundred hours of pilot-in-command flight time, which includes at least—

(i) Fifty hours in a powered-lift; and

(ii) Fifty hours in cross-country flight in a powered-lift.

(3) Twenty hours of training on the approved areas of operation listed in § 61.127(e) of this part that includes at least—

(i) Five hours of instrument training in a powered-lift;

(ii) One cross-country flight in a powered-lift of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iv) One cross-country flight in a powered-lift of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(v) Three hours in a powered-lift in preparation for the practical test within the 60-day period preceding the date of the test.

(4) Ten hours of supervised PIC flying in a powered-lift on the approved areas of operation listed in § 61.127(e) of this part, which includes at least—

(i) One cross-country flight, if the training is being performed in the state of Hawaii, then that cross-country flight must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(ii) One cross-country flight, if the training is being performed in a State other than Hawaii, then that cross-country flight must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(iii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower.

(f) *For a glider-nonpowered rating.* A person who applies for a commercial certificate with a glider category and nonpowered class rating must accomplish and log at least:

(1) Twenty-five hours and 100 flights in gliders as pilot in command, which includes at least 10 flights in a nonpowered glider; or

(2) Two hundred hours in heavier-than-air aircraft, and 20 flights in gliders as pilot in command, which includes at least 10 flights in a nonpowered glider.

(3) The flight time requirements in paragraph (f) (1) or (2) of this section must consist of at least the following flight training in a nonpowered glider—

(i) Five hours of flight training or 10 training flights on the approved areas of operation listed in § 61.127(g) of this part; and

(ii) Three flights in preparation for the practical test within the 60-day period preceding the date of the test.

(4) Five supervised PIC flights in a nonpowered glider on the approved areas of operation listed in § 61.127(g) of this part.

(5) If an applicant with a glider category rating and a nonpowered class rating seeks privileges for ground launch procedures, that person must accomplish and log at least five training flights and two supervised PIC flights in a nonpowered glider using a winch or auto tow on the applicable areas of operation listed in § 61.127(g) of this part.

(g) *For a glider-powered rating.* A person who applies for a commercial certificate with a glider category and powered class rating must accomplish and log at least:

(1) Twenty-five hours and 100 flights in gliders as pilot in command, which includes at least 10 flights in a powered glider; or

(2) Two hundred hours in heavier-than-air aircraft, and 20 flights in gliders as pilot in command, which includes at least 10 flights in a powered glider.

(3) The flight time requirements in paragraph (f)(1) or (2) of this section must consist of at least the following flight training in a powered glider—

(i) Five hours of flight training or 10 training flights on the approved areas of operation listed in § 61.127(h) of this part; and

(ii) Three flights in preparation for the practical test within the 60-day period preceding the date of the test.

(4) Five supervised PIC flights in a powered glider on the approved areas of operation listed in § 61.127(h) of this part.

(h) *For an airship rating.* A person who applies for a commercial pilot certificate with a lighter-than-air category and airship class rating must accomplish and log at least 200 hours of flight time as a pilot, which includes at least the following hours:

(1) Fifty hours in airships;

(2) Thirty hours of pilot in command time in airships, which consists of at least—

(i) Ten hours of cross-country flight time in airships; and

(ii) Ten hours of night flight time in airships.

(3) Twenty hours of training in airships on the approved areas of operation listed in § 61.127(i) of this part, which includes at least—

(i) Three hours in an airship in preparation for the practical test within the 60-day period preceding the date of the test;

(ii) Five hours of instrument training in airships;

(iii) One cross-country flight in an airship of at least 1 hour in duration, a total straight-line distance of more than 25 nautical miles from the original point of departure, and occurring in day-VFR conditions; and

(iv) One cross-country flight in an airship of at least 1 hour in duration, a total straight-line distance of more than 25 nautical miles from the original point of departure, and occurring in night-VFR conditions.

(4) Ten hours of pilot in command flight training with an authorized flight instructor in airships, on the approved areas of operation listed in § 61.127(i) of this part, which includes at least—

(i) One cross-country flight with landings at a minimum of three points, and one of the routes having a straight-line distance of at least 25 nautical miles from the original point of departure; and

(ii) Five hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern).

(i) *For a balloon rating.* A person who applies for a commercial pilot certificate with a lighter-than-air category and a balloon class rating must accomplish and log at least 35 hours of flight time as a pilot, which includes at least the following requirements:

(1) Twenty hours in balloons;

(2) Ten flights in balloons;

(3) Two flights in balloons as the pilot in command; and

(4) Ten hours of flight training that includes at least 10 training flights in balloons on the approved areas of operation listed in § 61.127(j) of this part, which consist of at least—

(i) If the training is received in a gas balloon, the training must include at least—

(A) Two training flights of 2 hours each in a gas balloon that covers the approved areas of operation appropriate to a gas balloon within 60 days prior to application for the rating; and

(B) Two supervised PIC flights in a gas balloon on the approved areas of operation.

(ii) If the training is received in a balloon with an airborne heater, the training must include at least—

(A) Two training flights of 1 hour each in a balloon with an airborne heater that covers the approved areas of operation appropriate to a balloon with an airborne heater within 60 days prior to application for the rating; and

(B) Two supervised PIC flights in a balloon with an airborne heater on the approved areas of operation.

§ 61.131 Exceptions to the night flying requirements for the commercial pilot certificate.

A person is not required to comply with the night flying requirements of this subpart:

(a) If that person has a medical restriction from operating an aircraft at night, then that person may—

(1) Be issued a permanent commercial pilot certificate with the limitation ''Night flying prohibited;'' and

(2) Have that limitation removed if the condition which was the basis for the medical restriction is corrected, and the person accomplishes the appropriate night flying requirements of this subpart.

(b) If that person receives flight training in the State of Alaska and is not able to accomplish the training, then that person—

(1) May be issued a temporary pilot certificate for only 12 calendar months, with a limitation ''Night flying prohibited;'' and

(2) Must comply with the appropriate night flying requirements of this subpart within 12 calendar months following issuance of the temporary commercial pilot certificate, or the certificate will be suspended until the person complies with the appropriate night flying requirements of this subpart.

(3) May have the ''Night flying prohibited'' limitation of this section removed if the person—

(i) Accomplishes the appropriate night flight training requirements of this subpart in the category and class of aircraft for which night flying privileges are sought;

(ii) Presents to an examiner, a logbook or training record endorsement from an authorized flight instructor that verifies accomplishment of the night flying requirements of this subpart that are appropriate to the category and class aircraft for which night flying privileges are sought; and

(iii) Accomplishes the night operations portion of the practical test that are appropriate to the category and class of aircraft for which night flying privileges are sought.

§ 61.133 Commercial pilot privileges and limitations: General.

(a) *Privileges.* A person who holds a commercial pilot certificate may act as pilot in command of an aircraft for:

(1) Carrying persons or property for compensation or hire, provided the person is qualified in accordance with this part and with the applicable other parts of this chapter that apply to the operation; and

(2) Compensation or hire, provided the person is qualified in accordance with this part and with the applicable other parts of this chapter, that apply to the operation.

(b) *Limitations.*

(1) A person who applies for a commercial pilot certificate with an airplane category, airship class, or powered-lift category rating, and does not hold an instrument rating in the same category and class will be issued a commercial pilot certificate that contains the limitation, ''The carriage of passengers for hire in (airplanes) (airships) (powered lifts) on cross-country flights in excess of 50 nautical miles or at night is prohibited.'' The limitation may be removed when the person satisfactorily accomplishes the requirements listed in § 61.65 of this part for an instrument rating in the same category and class of aircraft listed on the person's commercial pilot certificate.

(2) If a person who applies for commercial pilot certificate with a balloon rating takes a practical test in a balloon with an airborne heater:

(i) The pilot certificate will contain a limitation restricting the exercise of the privilege of that certificate to a balloon with an airborne heater; and

(ii) The limitation may be removed when the person obtains the required aeronautical experience in a gas balloon and receives a logbook endorsement from an authorized instructor who attests to the person's accomplishment of the required aeronautical experience and ability to satisfactorily operate a gas balloon.

(3) If a person who applies for a commercial pilot certificate with a balloon rating takes a practical test in a gas balloon:

(i) The pilot certificate will contain a limitation restricting the exercise of the privilege of that certificate to a gas balloon; and

(ii) The limitation may be removed when the person obtains the required aeronautical experience in a balloon with an airborne heater and receives a logbook endorsement from an authorized instructor who attests to the person's accomplishment of the required aeronautical experience and ability to satisfactorily operate a balloon with an airborne heater.

§ 61.135 through 61.141 [Reserved]

Subpart G—Airline Transport Pilots

§ 61.151 Applicability.

This subpart prescribes the requirements for the issuance of airline transport pilot certificates and ratings, the conditions under which those certificates and ratings are necessary, and the general operating rules for persons who hold those certificates and ratings.

§ 61.153 Eligibility requirements: General.

To be eligible for an airline transport pilot certificate, a person must:

(a) Be at least 23 years of age;

(b) Be able to read, speak, write, and understand the English language;

(c) Be of good moral character;

(d) Hold at least a current third-class medical certificate issued under part 67 of this chapter;

(e) Meet at least one of the following requirements—

(1) Hold at least a commercial pilot certificate and an instrument rating;

(2) Meet the requirements of § 61.73 of this part to qualify for a commercial pilot certificate and an instrument rating if the person is a rated pilot in the U.S. military; or

(3) Hold either a foreign airline transport pilot or foreign commercial pilot license and an instrument rating if

the person holds a pilot license issued by a member State to the International Civil Aviation Organization.

(f) Meet the aeronautical experience requirements of this subpart that apply to the aircraft category and class rating sought before applying for the practical test;

(g) Satisfactorily accomplish the knowledge test on the aeronautical knowledge areas of § 61.155(c) of this part that apply to the aircraft category and class rating sought;

(h) Satisfactorily accomplish the practical test on the applicable approved areas of operation listed in § 61.157(d) of this part that apply to the aircraft category and class rating sought; and

(i) Comply with the sections of this part that apply to the aircraft category and class rating sought.

§ 61.155 Aeronautical knowledge.

(a) *General.* The knowledge test for an airline transport pilot certificate is based on the aeronautical knowledge areas listed in paragraph (c) of this section.

(b) *Aircraft type rating.* A person who is applying for an additional aircraft type rating to be added to their airline transport certificate is not required to accomplish a knowledge test if that person's airline transport pilot certificate lists the aircraft category and class rating that is appropriate to the type rating sought.

(c) *Aeronautical knowledge areas.*

(1) The applicable Federal Aviation Regulations of this chapter that relate to airline transport pilot privileges, limitations, and flight operations appropriate to the aircraft category and class rating sought;

(2) Meteorology including knowledge of and effects of fronts, frontal characteristics, cloud formations, icing, and upper air-data;

(3) The general system of weather and NOTAM collection, dissemination, interpretation, and use;

(4) Interpretation of weather charts, maps, forecasts, sequences, abbreviations, symbols, and use;

(5) The National Weather Service function as it pertains to operation in the National Airspace System;

(6) Windshear and microburst awareness, identification, and avoidance;

(7) Principles of air navigation under instrument meteorological conditions in the National Airspace System;

(8) Air traffic control procedures and pilot responsibilities as they relate to en route operations, terminal area and radar operations, and instrument departure and approach procedures;

(9) Aircraft loading, weight and balance, use of charts, graphs, tables, formulas, and computations, and the effects on aircraft performance that apply to the aircraft category and class rating sought;

(10) Aircraft aerodynamics relating to the aircraft's flight characteristics, performance, and normal and abnormal flight regimes and characteristics that apply to the aircraft category and class rating sought;

(11) Flight crewmember physiological factors;

(12) Aeronautical decision making and judgment; and

(13) Flight deck resource management to include crew communications and coordination.

§ 61.157 Flight proficiency.

(a) *General.*

(1) The practical test for an airline transport pilot certificate is given for:

(i) An airplane category and single-engine class rating with an airplane type rating if a type rating is required;

(ii) An airplane category and multiengine class rating with an airplane type rating if a type rating is required;

(iii) A rotorcraft category and helicopter class rating with a type rating if a type rating is required;

(iv) A powered-lift category rating with a type rating, if a type rating is required; and

(v) An aircraft type rating.

(2) A person who is applying for an airline transport pilot practical test must meet—

(i) The eligibility requirements of § 61.153 of this part; and

(ii) The aeronautical knowledge and aeronautical experience requirements of this subpart that apply to the aircraft category and class rating sought.

(b) *Aircraft type rating.* Except as provided in paragraph (c) of this section, a person who is applying for an aircraft type rating to be added to an airline transport pilot or an aircraft type rating associated with an airline transport pilot certificate:

(1) Must receive and log ground training from an authorized ground or flight instructor and flight training from an authorized flight instructor on the approved areas of operation in this section that apply to the aircraft type rating sought; and

(2) Must receive a logbook endorsement from the instructor who conducted the training, certifying the applicant completed the training on the appropriate approved areas of operation listed in paragraph (e) of this section that apply to the aircraft type rating sought.

(c) A person who is applying for an aircraft type rating to be added to an airline transport pilot certificate or an aircraft type rating concurrently with an airline transport pilot certificate, and who is an employee of a part 119 certificate holder operating under part 121 or part 135, may present a training record that shows satisfactory completion of that certificate holder's approved pilot-in-command training program for the aircraft type rating sought, instead of complying with the requirements of paragraph (b) of this section.

(d) A person who successfully completes an airline transport pilot practical test, the type rating(s), if appropriate, on the superseded pilot certificate shall be brought forward to the airline transport pilot certificate level provided the practical test was accomplished in that category and class of aircraft. If the type rating(s) for that category and class of aircraft on the superseded pilot certificate is limited to VFR, that limitation shall be carried forward to the person's airline transport pilot certificate level.

(e) *Areas of operation.*

(1) The areas of operation for an airplane category-single engine class rating with a type rating, if a type rating is required, are as follows:

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Takeoff and departure phase;

(iv) Inflight maneuvers;

(v) Instrument procedures;

(vi) Landings and approaches to landings;

(vii) Normal and abnormal procedures;

(viii) Emergency procedures; and

(ix) Postflight procedures.

(2) The areas of operation for an airplane category-multiengine class rating with a type rating, if a type rating is required, are as follows:

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Takeoff and departure phase;

(iv) Inflight maneuvers;

(v) Instrument procedures;

(vi) Landings and approaches to landings;

(vii) Normal and abnormal procedures;

(viii) Emergency procedures; and

(ix) Postflight procedures.

(3) The areas of operation for a powered-lift category rating with a type rating, if a type rating is required, are as follows:

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Takeoff and departure phase;

(iv) Inflight maneuvers;

(v) Instrument procedures;

(vi) Landings and approaches to landings;

(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.
(4) The areas of operation for a rotorcraft category-helicopter class rating with a type rating, if a type rating is required, are as follows:
(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

§ 61.159 Aeronautical experience: Airplane category rating.

(a) Except as provided in paragraph (d) of this section, a person who is applying for an airline transport pilot certificate with an airplane category and class rating must have at least 1,500 hours of total time as a pilot that includes at least:
(1) 500 hours of cross-country flight time;
(2) 100 hours of night flight time;
(3) 75 hours of instrument time in actual or simulated instrument meteorological conditions, of which at least 50 hours are obtained in actual flight; and
(4) 250 hours of flight time in an airplane as a pilot in command or as a second in command performing the duties and functions of a pilot in command under the supervision of a pilot in command, or any combination thereof, which includes at least—
(i) 100 hours of cross-country flight time; and
(ii) 25 hours of night flight time.
(b) A person who has performed at least 20 night takeoffs and landings to a full stop may substitute each additional night takeoff and landing to a full stop in excess of the minimum 20 accomplished takeoffs for 1 hour of night flight time to satisfy the requirements of paragraph (a)(2) of this section for a total credited time of no more than 25 hours.
(c) A commercial pilot may credit the following second-in-command and flight engineer flight time (or a combination of either crewmember position flight time) toward the 1,500 hours of total time as a pilot required by paragraph (a) of this section:
(1) Second-in-command time acquired in an airplane required to have more than one pilot by the airplane's flight manual or type certificate;
(2) Second-in-command time acquired in an airplane for a part 119 certificate holder operating under part 121 or part 135 for which a second in command is required; and
(3) Flight engineer time, provided the time—
(i) Is acquired while operating under part 121 of this chapter;
(ii) Is acquired in an airplane that is required to have a flight engineer by the airplane's flight manual or type certificate;
(iii) Is acquired while the person is participating in a pilot training program approved under part 121 of this chapter; and
(iv) Does not exceed more than 1 hour of flight time to be credited for each 3 hours of flight engineer time for a total credited time of no more than 500 hours.
(d) A person who does not meet the aeronautical experience requirements of this section may be issued an airline transport pilot certificate with the limitation ''Holder does not meet the pilot-in-command aeronautical experience requirements of ICAO'' as prescribed by Article 39 of the Convention on International Civil Aviation, as provided in § 61.167(b) of this part.

§ 61.161 Aeronautical experience: Rotorcraft category and helicopter class rating.

A person who is applying for an airline transport pilot certificate with a rotorcraft category and helicopter class rating, must have at least 1,200 hours of total time as a pilot that includes at least:
(a) 500 hours of cross-country flight time;
(b) 100 hours of night flight time, of which 15 hours are in helicopters;
(c) 200 hours of flight time in helicopters, which includes at least 75 hours as a pilot in command or as second in command performing the duties and functions of a pilot in command under the supervision of a pilot in command, or any combination of either crewmember position flight time; and
(d) 75 hours of instrument time in actual or simulated instrument meteorological conditions, of which at least 50 hours are obtained in actual flight with at least 25 hours in helicopters as a pilot in command or as second in command performing the duties and functions of a pilot in command under the supervision of a pilot in command, or any combination of either crewmember position flight time.

§ 61.163 Aeronautical experience: Powered-lift category rating.

A person who is applying for an airline transport pilot certificate with a powered-lift category rating must have at least 1,500 hours of total time as a pilot that includes at least:
(a) 500 hours of cross-country flight time;
(b) 100 hours of night flight time;
(c) 75 hours of instrument time in actual or simulated instrument meteorological conditions, of which at least 50 hours are obtained in actual flight; and
(d) 250 hours in a powered-lift as a pilot in command or as a second in command performing the duties and functions of a pilot in command under the supervision of a pilot in command, or any combination thereof, which includes at least—
(1) 100 hours of cross-country flight time; and
(2) 25 hours of night flight time.

§ 61.165 Additional aircraft category and class ratings.

(a) *Rotorcraft category and helicopter class rating.* A person who is applying for an airline transport certificate with a rotorcraft category and helicopter class rating who holds an airline transport certificate with another aircraft category rating must:
(1) Meet the eligibility requirements of § 61.153 of this part;
(2) Satisfactorily accomplish the knowledge test on the aeronautical knowledge areas of § 61.155 of this part that apply to the rotorcraft category and helicopter class rating sought;
(3) Comply with the requirements in § 61.157(b) of this part, if appropriate;
(4) Meet the applicable aeronautical experience requirements of § 61.161 of this part that apply to helicopter total time; and
(5) Satisfactorily accomplish the practical test on the approved areas of operations of § 61.157(e)(4) of this part that apply to the rotorcraft category and helicopter class rating sought.
(b) *Airplane category rating with a single-engine class rating.* A person who is applying for an airline transport certificate with an airplane category and single engine class rating and holds an airline transport certificate with another aircraft category or class rating must:
(1) Meet the eligibility requirements of § 61.153 of this part;
(2) Accomplish the knowledge test on the aeronautical knowledge areas of § 61.155 of this part that apply to the airplane category and single-engine class rating sought;
(3) Comply with the requirements in § 61.157(b) of this part, if appropriate;

(4) Meet the applicable aeronautical experience requirements of § 61.159 of this part that apply to airplane total time; and

(5) Accomplish the practical test on the approved areas of operations of § 61.157(e)(1) of this part that apply to the airplane category and single-engine class rating sought.

(c) *Airplane category rating with a multiengine class rating.* A person who is applying for an airline transport certificate with an airplane category and multiengine class rating and holds an airline transport certificate with another aircraft category or class rating must:

(1) Meet the eligibility requirements of § 61.153 of this part;

(2) Accomplish the knowledge test on the aeronautical knowledge areas of § 61.155 of this part that apply to the airplane category and multiengine class rating sought;

(3) Comply with the requirements in § 61.157(b) of this part, if appropriate;

(4) Meet the applicable aeronautical experience requirements of § 61.159 of this part that apply to airplane total time; and

(5) Accomplish the practical test on the approved areas of operations of § 61.157(e)(2) of this part that apply to the airplane category and multiengine class rating sought.

(d) *Powered-lift category.* A person who is applying for an airline transport certificate with a powered-lift category rating, and holds an airline transport certificate with another aircraft category rating must:

(1) Meet the eligibility requirements of § 61.153 of this part;

(2) Accomplish the required knowledge test on the aeronautical knowledge areas of § 61.155 of this part that apply to the powered-lift category rating sought;

(3) Comply with the requirements in § 61.157(b) of this part, if appropriate;

(4) Meet the applicable aeronautical experience requirements of § 61.163 of this part that apply to powered-lift total time; and

(5) Accomplish the required practical test on the approved areas of operations of § 61.157(e)(3) of this part that apply to the powered-lift category rating sought.

§ 61.167 General privileges and limitations.

(a) *Privileges.* A person who holds an airline transport pilot certificate is entitled to the same privileges as those afforded a person who holds a commercial pilot certificate with an instrument rating.

(b) *Limitations.* A person who applies for an airline transport pilot will be issued an airline transport certificate with the limitation, ''Holder does not meet the pilot-in-command aeronautical experience requirements of ICAO,'' for the following circumstances:

(1) The person—

(i) Credits second-in-command or flight engineer time under § 61.159(c) of this part toward the minimum 1,500 hours of total flight time as a pilot that is required by § 61.159(a) of this part; and

(ii) Lacks at least 1,200 hours of total flight time as a pilot, but otherwise meets the other aeronautical experience requirements of this subpart, appropriate to the aircraft rating sought.

(2) The person does not have at least 150 hours of pilot-in-command time in an aircraft that is appropriate to the aircraft rating sought, but otherwise meets the aeronautical experience requirements of this subpart.

(c) *Removal of limitations.* The limitation required by paragraph (b) of this section may be removed when the person:

(1) Meets the aeronautical experience requirements for the aircraft rating sought; and

(2) Presents evidence within a logbook of having accomplished the required appropriate aeronautical experience.

§ 61.169 [Reserved]

§ 61.171 [Reserved]

Subpart H—Flight Instructors

§ 61.181 Applicability.

This subpart prescribes the requirements for the issuance of flight instructor certificates and ratings, the conditions under which those certificates and ratings are necessary, and the limitations on those certificates and ratings.

§ 61.183 Eligibility requirements.

To be eligible for a flight instructor certificate or rating a person must:

(a) Be at least 18 years of age;

(b) Be able to read, speak, write, and understand the English language;

(c) Hold either a commercial pilot or airline transport pilot certificate—

(1) With an aircraft category and class rating that is appropriate to the flight instructor rating sought;

(2) With an instrument rating, if the person holds a commercial pilot certificate, that is appropriate to the flight instructor rating sought, if applying for—

(i) A flight instructor certificate with an airplane category and single-engine class rating;

(ii) A flight instructor certificate with an airplane category and multiengine class rating;

(iii) A flight instructor certificate with a rotorcraft category and helicopter class rating;

(iv) A flight instructor certificate with an airship rating;

(v) A flight instructor certificate with a powered-lift rating; or

(vi) A flight instructor certificate-instrument rating (aircraft category and class).

(d) Receive a logbook endorsement from an authorized instructor who gave the ground training on the aeronautical knowledge areas listed in § 61.185 of this part appropriate to the required knowledge test.

(e) Accomplish a knowledge test on the aeronautical knowledge areas listed in § 61.185(a) of this part;

(f) Accomplish a knowledge test on the aeronautical knowledge areas listed in § 61.185(b) of this part that are appropriate to the flight instructor rating sought;

(g) Receive a logbook endorsement from an authorized flight instructor who gave the flight training on the approved areas of operation listed in § 61.187 of this part, appropriate to the flight instructor rating sought and prior to applying for the practical test;

(h) Accomplish the required practical test that is appropriate to the flight instructor rating sought;

(i) Accomplish the following for a flight instructor certificate with an airplane rating or with a glider rating—

(1) Must have received a one time logbook endorsement from an authorized flight instructor on ground and flight training on instructional procedures for stall awareness, spin entry, spins, and spin recovery procedures in an airplane or glider that is certificated for spins;

(2) Must have demonstrated instructional proficiency in stall awareness, spin entry, spins, and spin recovery procedures; and

(3) May present the person's spin training endorsement to an examiner, and that examiner may accept that endorsement as satisfactory accomplishment of the required knowledge and skill of stall awareness, spin entry, spins, or spin recovery instructional procedures for the practical test, provided that the practical test is not a retest as a result of the person failing the previous test for deficiencies in the knowledge or skill of stall awareness, spin entry, spins, or spin recovery instructional procedures. If the retest is a result of deficiencies in the knowledge or skill of stall awareness, spin entry, spins, or spin

recovery instructional procedures, the examiner must test the person on stall awareness, spin entry, spins, and spin recovery instructional procedures in an airplane or glider that is certificated for spins.

(j) Log at least 15 hours as pilot in command in the category and class of aircraft that is appropriate to the flight instructor rating sought; and

(k) Comply with the appropriate sections of this part that apply to the flight instructor rating sought.

§ 61.185 Aeronautical knowledge.

A person who is applying for a flight instructor certificate must receive and log ground training from an authorized ground or flight instructor on the aeronautical knowledge areas of this section:

(a) *Aeronautical knowledge areas.*

(1) The learning process;

(2) Elements of effective teaching;

(3) Student evaluation, quizzing, and testing;

(4) Course development;

(5) Lesson planning; and

(6) Classroom training techniques.

(b) A person who is applying for a flight instructor certificate must receive and log ground training on the aeronautical knowledge areas in which ground training is required for—

(1) A recreational, private, and commercial pilot certificate that is appropriate to the flight instructor rating sought; and

(2) An instrument rating, if that person is applying for—

(i) A flight instructor certificate—airplane category and single-engine class rating;

(ii) A flight instructor certificate—airplane category with an multiengine class rating;

(iii) A flight instructor certificate—rotorcraft category with a helicopter class rating;

(iv) A flight instructor certificate—lighter-than-air category with an airship class rating;

(v) A flight instructor certificate—powered-lift category rating; or

(vi) A flight instructor certificate—instrument (with the appropriate aircraft category and class rating).

§ 61.187 Flight proficiency.

(a) *General.* A person who is applying for a flight instructor certificate must receive ground training from an authorized ground or flight instructor, and flight training from an authorized flight instructor on the approved areas of operation listed in this section that apply to the flight instructor rating sought, and the person's logbook must contain an endorsement from an authorized flight instructor certifying that the person is proficient to pass a practical test on those areas of operation.

(b) *Areas of operation for an airplane category rating with a single engine class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Airport and seaplane base operations;

(7) Takeoffs, landings, and go-arounds;

(8) Fundamentals of flight;

(9) Performance maneuvers;

(10) Ground reference maneuvers;

(11) Stalls, spins, and slow flight;

(12) Basic instrument maneuvers;

(13) Emergency operations; and

(14) Postflight procedures.

(c) *Areas of operation for an airplane category rating with a multiengine class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Airport and seaplane base operations;

(7) Takeoffs, landings, and go-arounds;

(8) Fundamentals of flight;

(9) Performance maneuvers;

(10) Ground reference maneuvers;

(11) Stalls and slow flight;

(12) Basic instrument maneuvers;

(13) Emergency operations;

(14) Multiengine operations; and

(15) Postflight procedures.

(d) *Areas of operation for a rotorcraft category rating with a helicopter class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Airport and heliport operations;

(7) Hovering maneuvers;

(8) Takeoffs, landings, and go-arounds;

(9) Fundamentals of flight;

(10) Performance maneuvers;

(11) Emergency operations;

(12) Special operations; and

(13) Postflight procedures.

(e) *Areas of operation for a rotorcraft category rating with a gyroplane class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Airport operations;

(7) Takeoffs, landings, and go-arounds;

(8) Fundamentals of flight;

(9) Performance maneuvers;

(10) Flight at slow airspeeds;

(11) Ground reference maneuvers;

(12) Emergency operations; and

(13) Postflight procedures.

(f) *Areas of operation for a powered-lift category rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Airport and heliport operations;

(7) Hovering maneuvers;

(8) Takeoffs, landings, and go-arounds;

(9) Fundamentals of flight;

(10) Performance maneuvers;

(11) Ground reference maneuvers;

(12) Stalls and slow flight;

(13) Basic instrument maneuvers;

(14) Emergency operations;

(15) Special operations; and

(16) Postflight procedures.

(g) *Areas of operation for a glider category rating with a nonpowered class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Airport and gliderport operations;

(7) Launches and landings;

(8) Fundamentals of flight;

(9) Performance speeds;

(10) Soaring techniques;

(11) Performance maneuvers;

(12) Stalls, spins, and slow flight;

(13) Emergency operations; and

(14) Postflight procedures.

(h) *Areas of operation for a glider category rating with a powered class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Airport and gliderport operations;

(7) Launches, landings, and go-arounds;

(8) Fundamentals of flight;

(9) Performance speeds;

(10) Soaring techniques;

(11) Performance maneuvers;

(12) Stalls, spins, and slow flight;

(13) Emergency operations; and

(14) Postflight procedures.

(i) *Areas of operation for a lighter-than-air category rating with an airship class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Airport operations;

(7) Takeoffs, landings, and go-arounds;

(8) Fundamentals of flight;

(9) Performance maneuvers;

(10) Ground reference maneuvers;

(11) Basic instrument maneuvers;

(12) Emergency operations; and

(13) Postflight procedures.

(j) *Areas of operation for a lighter-than-air category rating with a balloon class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Preflight procedures;

(6) Balloonport operations;

(7) Lift-offs and landings;

(8) Fundamentals of flight;

(9) Performance maneuvers;

(10) Emergency operations; and

(11) Postflight procedures.

(k) *Areas of operation for an instrument rating with the appropriate aircraft category and class rating:*

(1) Fundamentals of instructing;

(2) Technical subject areas;

(3) Preflight preparation;

(4) Preflight lesson on a maneuver to be performed in flight;

(5) Air traffic control clearances and procedures;

(6) Flight by reference to instruments;

(7) Navigation aids;

(8) Instrument approach procedures;

(9) Emergency operations; and

(10) Postflight procedures.

§ 61.189 Flight instructor records.

(a) A flight instructor must sign the logbook of each person to whom that flight instructor has given flight and ground training.

(b) A flight instructor must maintain a record (in a logbook or a separate document) that contains the following:

(1) The name of each person whose logbook or student pilot certificate that instructor has endorsed for supervised PIC flight privileges and the date of the endorsement;

(2) The name of each person that instructor has endorsed for a knowledge or practical test, and the record shall also indicate the kind of test, the date, and the results; and

(3) A copy of each training syllabus that instructor uses to conduct training.

(c) Each flight instructor must retain the records required by this section in a separate record or in a logbook for at least 3 years.

§ 61.191 Additional flight instructor ratings.

(a) A person who applies for an additional flight instructor rating on a flight instructor certificate must meet the eligibility requirements listed in § 61.183 of this part that apply to the flight instructor rating sought.

(b) A person who applies for an additional rating on a flight instructor certificate is not required to pass the knowledge test in § 61.185(a) of this part.

§ 61.193 Flight instructor endorsements and authorizations.

A person who holds a flight instructor certificate is authorized within the limitations of the person's flight instructor certificate and ratings and pilot certificate and ratings to give training and endorsements that are required for, and relate to:

(a) A student pilot certificate;

(b) A recreational pilot certificate;

(c) A private pilot certificate;

(d) A commercial pilot certificate;

(e) An airline transport pilot certificate;

(f) A flight instructor certificate;

(g) A ground instructor certificate;

(h) An additional aircraft rating;

(i) An instrument rating;

(j) A flight review, operating privilege, or recency of experience requirement of this part;

(k) An authorization for a practical test; and

(l) An authorization for a knowledge test.

§ 61.195 Flight instructor limitations and qualifications.

A person who holds a flight instructor certificate is subject to the following limitations:

(a) *Hours of training.* In any 24-consecutive-hour period, a flight instructor may not conduct more than 8 hours of flight training or any combination of commercial flying and flight training.

(b) *Aircraft ratings.* Flight instructors may not conduct flight training in any aircraft for which they do not hold—

(1) The category and class rating on their flight instructor certificate and pilot certificate; and

(2) If appropriate, a type rating on their pilot certificate.

(c) *Instrument rating.* Flight instructors who give instrument flight training for the issuance of an instrument rating or a type rating not limited to VFR must hold an instrument rating on their flight instructor certificate and their pilot certificate that is appropriate to the category and class of aircraft in which instrument training is being given.

(d) *Limitations on endorsements.* A flight instructor may not endorse a:

(1) Student pilot's certificate or logbook for supervised PIC flight privileges, unless that flight instructor has—

(i) Given that student the flight training required for supervised PIC flight privileges by this part; and

(ii) Determined that the student is prepared to conduct the flight safely under known circumstances, and subject to any limitations listed in the student's logbook, that the instructor considers necessary for safety of flight.

(2) Student pilot's certificate and logbook for a supervised PIC cross-country flight, unless that flight instructor has determined the student's flight preparation, planning, equipment, and proposed procedures are adequate for the proposed flight under the existing conditions and within any limitations listed in the logbook that the instructor considers necessary for safety of flight;

(3) Student pilot's certificate and logbook for supervised PIC flight in Class B airspace area or at an airport within Class B airspace unless that flight instructor has—

(i) Given that student ground and flight training in that Class B airspace and airport; and

(ii) Determined that the student is proficient to operate the aircraft safely.

(4) Logbook of a recreational pilot, unless that flight instructor has—

(i) Given that pilot the required ground and flight training of this part; and

(ii) Determined that the pilot is proficient to operate the aircraft safely.

(5) Logbook of a pilot for a flight review, unless that instructor has conducted a review of that pilot in accordance with the requirements of § 61.56(a) of this part; or

(6) Logbook of a pilot for an instrument proficiency test, unless that instructor has tested that pilot in accordance with the requirements of § 61.57(e) of this part.

(e) *Training in an aircraft that requires a type rating.* Flight instructors may not give flight training in an aircraft that requires the pilot in command to hold a type rating unless they hold a type rating for that aircraft on their pilot certificate.

(f) *Training received in a multiengine airplane, helicopter, or a powered-lift.* A flight instructor may not give training required for the issuance of a certificate

or rating in a multiengine airplane, helicopter, or a powered-lift, unless that flight instructor has at least 5 flight hours of operating experience as a pilot in command in the specific make and model of multiengine airplane, helicopter, or powered-lift, as appropriate.

(g) *Position in aircraft and required pilot seats for providing flight training.*

(1) A flight instructor must perform all training from a control seat in an aircraft that meets the requirements of and is in accordance with § 91.109 of this chapter.

(2) A flight instructor who provides flight training for an airman certificate or rating issued under this part must provide that flight training in an aircraft that meets the following requirements—

(i) The aircraft must have at least two pilot seats and be of the same category, class, and type, if appropriate, that apply to the flight instructor rating sought.

(ii) For single-place aircraft, the pre-supervised PIC flight training must have been received in an aircraft that has two pilot seats and is of the same category, class, and type, if appropriate, and has similar flight characteristics to that of the single-place aircraft.

(h) *Qualifications of the instructor for training first-time flight instructor applicants.*

(1) The ground training required by a person who is applying for a flight instructor certificate for the first time, must be given by a ground or flight instructor who)—

(i) Holds a current ground or flight instructor certificate with the appropriate rating, has held that certificate for at least 24 months, and has given at least 40 hours of ground training; or

(ii) Holds a current ground or flight instructor certificate with the appropriate rating, and have given at least 100 hours of ground training, if the training is given in an FAA-approved course.

(2) Except as provided for in paragraph (h)(3) of this section, the flight training required by a person who is seeking a flight instructor certificate for the first time, must be given by flight instructors who meet the eligibility requirements prescribed in § 61.183 of this part, hold the appropriate rating on their flight instructor certificate, and has held a flight instructor certificate for at least 24 months and—

(i) For training in an airplane, rotorcraft, or powered-lift rating, must have given at least 200 hours of flight training as a flight instructor;

(ii) For training in a glider rating, must have given at least 80 hours of flight training as a flight instructor; and

(iii) For training in a lighter-than-air rating, must have given at least 20 hours of flight training as a flight instructor.

(3) A flight instructor who serves as a flight instructor in an FAA-approved course must hold a current flight instructor certificate with the appropriate rating, and have satisfactorily accomplished the required initial and recurrent flight instructor proficiency tests, in accordance with the part the FAA-approved course is conducted under, and must—

(i) Meet the requirements of paragraph (h)(2) of this section; or

(ii) Meet the following requirements—

(A) Trained and endorsed at least 5 applicants for a practical test for a pilot certificate, flight instructor certificate, ground instructor certificate, or an additional rating, and at least 80 percent of those applicants passed that test on their first attempt;

(B) Given at least 400 hours of flight training as a certificated flight instructor for training in an airplane, a rotorcraft, or for a powered-lift rating;

(C) Given at least 100 hours of flight training as a flight instructor, for training in a glider rating; and

(D) Given at least 40 hours of flight training as a flight instructor, for training in a lighter-than-air rating.

(i) *Prohibition against self endorsements.* A flight instructor shall not make any self-endorsement for the furtherance of a certificate, rating, flight proficiency, flight review, authorization, operating privilege, practical test, or knowledge test that is required by this part.

§ 61.197 Renewal of flight instructor certificates.

(a) Persons who hold a flight instructor certificate that have not expired may renew their certificates for an additional 24-calendar months if they, except as provided for in paragraph (b) of this section, satisfactorily accomplish a practical test for:

(1) Renewal of their flight instructor certificate; or

(2) An additional flight instructor rating.

(b) Persons may renew their flight instructor certificate without accomplishing a practical test, by presenting to an FAA Flight Standards District Office:

(1) A record of training students that shows during the preceding 24 calendar months, they have endorsed at least 5 students for a practical test for a certificate or rating, and at least 80 percent of those students passed that test on the first attempt;

(2) A record that shows during the preceding 24-calendar months, persons have served as a company check pilot, chief flight instructor, company check airman or flight instructor in a part 121 or 135 operation, or a comparable position involving the regular evaluation of pilots, and provided the FAA Flight Standards District Office is acquainted with their duties and responsibilities and has determined they have satisfactory knowledge of current pilot training, certification, and standards; or

(3) A graduation certificate showing they have accomplished an approved flight instructor refresher course, consisting of ground or flight instruction, or both, and provided the course was satisfactorily accomplished before the expiration date on the person's flight instructor certificate.

(c) If persons accomplish the requirements of this section within the 90 days preceding the expiration date of their flight instructor certificate, they are considered to have accomplished the requirements of this section in the month due, and the certificate will be renewed for an additional 24-calendar months from the expiration date.

§ 61.199 Expired flight instructor certificates and ratings.

(a) *Flight instructor certificates.* The holder of an expired flight instructor certificate may exchange that certificate for a new certificate by satisfactorily accomplishing a practical test prescribed in § 61.187 of this part.

(b) *Flight instructor ratings.*

(1) A flight instructor rating or a limited flight instructor rating on a pilot certificate is no longer valid and may not be exchanged for a similar rating or a flight instructor certificate.

(2) The holder of a flight instructor rating or a limited flight instructor rating on a pilot certificate may be issued a flight instructor certificate with the current ratings, but only if the person satisfactorily accomplishes the required knowledge and practical test prescribed in this subpart for the issuance of that flight instructor certificate and rating.

§ 61.201 Conversion to the current flight instructor ratings.

(a) *General.*

(1) A person who holds a commercial pilot certificate for lighter-than-air category and an airship or a balloon class rating, or a flight instructor certificate that does not bear the current glider or instrument-airplane flight instructor ratings listed in § 61.5(c) of

this part, may not give training in an airship, a balloon, or a glider, or for an instrument rating in an airplane, respectively, after [insert date 2 years after the effective date of the final rule].

(2) Before [insert date 2 years after the effective date of the final rule], a person who meets the appropriate qualification requirements of this section may receive a flight instructor certificate with the current ratings.

(b) *Glider category with a powered class rating.* A flight instructor certificate with a glider category and powered class rating may be issued to a person who holds a flight instructor certificate with glider category rating, provided that person has:

(1) Received the required training in a powered glider and the flight instructor endorsements of this subpart for the issuance of the powered class rating, and has satisfactorily accomplished the required practical test; or

(2) Before [insert effective date of the final rule]—

(i) Given at least 20 hours of flight training in a powered glider as an authorized flight instructor; and

(ii) Recommended at least one student for a practical test for the issuance of glider category rating and the recommended student passed the practical test.

(c) *Glider category with a nonpowered class rating.* A flight instructor certificate with a glider category and nonpowered class rating may be issued to a person who holds a flight instructor certificate with glider category rating, provided the person has:

(1) Received the required training in a nonpowered glider and the flight instructor endorsements of this subpart for the issuance of the nonpowered class rating and has satisfactorily accomplished the required practical test; or

(2) Before [insert effective date of the final rule]—

(i) Given at least 20 hours of flight training in a nonpowered glider as an authorized flight instructor; and

(ii) Recommended at least one student for a practical test for the issuance of glider category rating and the recommended student passed the practical test.

(d) *Lighter-than air category with an airship class rating.* A flight instructor certificate with a lighter-than-air category and airship class rating may be issued to a person who holds a commercial pilot certificate with a lighter-than-air category and airship class rating, provided the person has:

(1) Received the required training in an airship and the flight instructor endorsements of this subpart for the issuance of the airship class rating and has satisfactorily accomplished the required practical test; or

(2) Before [insert effective date of the final rule]—

(i) Given at least 20 hours of flight training in an airship as a holder of a commercial pilot certificate with a lighter-than-air category and a airship class rating; and

(ii) Recommended at least one student for a practical test for the issuance of airship rating and the recommended student passed practical test.

(e) *Lighter-than-air category with an airship-instrument rating.* A flight instructor certificate with a lighter-than-air category and airship-instrument rating may be issued to a person who holds a commercial pilot certificate with a lighter-than-air category and airship class rating, provided the person has:

(1) Received the required ground training and flight training for the airship-instrument rating and the flight instructor endorsements of this subpart for the issuance of the airship-instrument rating and has satisfactorily accomplished the required practical test; or

(2) Before [insert effective date of the final rule]—

(i) Given at least 20 hours of flight training in an airship as a holder of a commercial pilot certificate with a lighter-than-air category and an airship class rating; and

(ii) Recommended at least one student for a practical test for the issuance of an airship rating and the recommended student passed the practical test.

(f) *Lighter-than air category with a balloon class rating.* A flight instructor certificate with a lighter-than-air category and balloon class rating may be issued to a person who holds a commercial pilot certificate with a lighter-than-air category and balloon class rating, provided the person has:

(1) Received the required training in a balloon and instructor endorsements of this subpart for the issuance of the balloon class rating and has satisfactorily accomplished the required practical test; or

(2) Before [insert effective date of the final rule]—

(i) Given at least 20 hours of flight training in a balloon as a holder of a commercial pilot certificate with a lighter-than-air category and a balloon class rating; and

(ii) Recommended at least one student for a practical test for the issuance of a balloon class rating and the recommended student passed the practical test.

(g) *Instrument-single-engine airplane rating.* A flight instructor certificate with an instrument-single-engine airplane rating may be issued to a person who holds a flight instructor certificate with a instrument-airplane rating, provided the person has:

(1) Received the required training and instructor endorsement of this subpart for the issuance of the instrument-single-engine airplane rating and has satisfactorily accomplished the required practical test; or

(2) Before [insert effective date of the final rule]—

(i) Given at least 20 hours of flight training in a single-engine airplane for the issuance of an airplane-instrument rating as an authorized flight instructor; and

(ii) Recommended at least one student for a practical test for the issuance of an airplane-instrument rating and the recommended student passed the practical test.

(h) *Instrument-multiengine airplane rating.* A flight instructor certificate with an instrument-multiengine airplane rating may be issued to a person who holds a flight instructor certificate with a instrument-airplane rating, provided the person has:

(1) Received the required training and instructor endorsement of this subpart for the issuance of the instrument-multiengine airplane rating and has satisfactorily accomplished the required practical test; or

(2) Before [insert effective date of the final rule]—

(i) Given at least 20 hours of flight training in a multiengine airplane for the issuance of an instrument-airplane rating as an authorized flight instructor; and

(ii) Recommended at least one student for a practical test for the issuance of an instrument-airplane rating and the recommended student passed the practical test.

(i) *Instrument-helicopter rating.* A flight instructor certificate with an instrument-helicopter rating may be issued to a person who holds a flight instructor certificate with a instrument-helicopter rating, provided the person has:

(1) Received the required training and instructor endorsement of this subpart for the issuance of the instrument-helicopter rating and has satisfactorily accomplished the required practical test; or

(2) Before [insert effective date of the final rule]—

(i) Given at least 20 hours of flight training in a helicopter for the issuance of an instrument-helicopter rating as an authorized flight instructor; and

(ii) Recommended at least one student for a practical test for the issuance of an instrument-helicopter rating and the recommended student passed the practical test.

Subpart I—Ground Instructors

§ 61.211 Applicability.

This subpart prescribes the requirements for the issuance of ground instructor certificates and ratings, the conditions under which those certificates and ratings are necessary, and the limitations upon those certificates and ratings.

§ 61.213 Eligibility requirements.

(a) To be eligible for a ground instructor certificate or rating a person must:

(1) Be at least 18 years of age;

(2) Be able to read, write, speak, and understand the English language;

(3) Satisfactorily accomplish a knowledge test on the fundamentals of instructing described in § 61.215(a)(1) of this part, except as provided in paragraph (b) of this section;

(4) Satisfactorily accomplish a knowledge test on the aeronautical knowledge areas of § 61.215(a)(2) of this part that apply to the aircraft rating sought;

(5) Satisfactorily accomplish a knowledge test on the aeronautical knowledge areas of § 61.215(a)(3) of this part for an instrument rating; and

(6) Satisfactorily accomplish a practical test on the requirements listed in § 61.217(a) of this part that apply to the ground instructor rating sought.

(b) The knowledge test required by paragraph (a)(3) of this section is not required if the person:

(1) Holds a ground or flight instructor certificate issued under this part;

(2) Holds a current teacher's certificate issued by a state, county, or city municipality, and that person is authorized to teach at an educational level of at least the 7th grade or higher; or

(3) Is regularly employed as an instructor in an accredited college or university.

(c) After [insert effective date of the final rule], the holder of a current flight instructor certificate is not eligible to apply for a ground instructor certificate that bears the same aircraft category ratings.

(d) After [insert effective date of the final rule], the holder of a flight instructor certificate bearing an instrument rating is not eligible to apply for a ground instructor certificate that bears an instrument rating.

§ 61.215 Aeronautical knowledge.

(a) A person who applies for a ground instructor certificate must present documentation of having completed a course of ground training or home study, and received an endorsement from an authorized flight instructor or ground instructor who meets the requirements of paragraph (b) of this section that the person satisfactorily accomplished the course of ground training or home study on the following knowledge areas:

(1) Fundamentals of instructing areas:

(i) The learning process;

(ii) Elements of effective teaching;

(iii) Student evaluation, quizzing, and testing;

(iv) Course development;

(v) Lesson planning; and

(vi) Classroom training technique.

(2) The aeronautical knowledge areas listed in §§ 61.97, 61.105, and 61.125 of this part that apply to the aircraft category rating sought; and

(3) The aeronautical knowledge areas listed in § 61.65 of this part, if applying for an instrument rating.

(b) The ground training required by paragraph (a) of this section must be given by a person who meets the requirements prescribed in § 61.183 or § 61.213 of this part and the requirements of this paragraph.

(1) The person must:

(i) Hold a current ground or flight instructor certificate and have held this certificate for at least 24 months; and

(ii) Have given, as an authorized ground or flight instructor, at least 40 hours of ground or flight training.

(2) If the training is given in an FAA-approved course, the person must—

(i) Meet the requirements of paragraph (b)(1) of this section; or

(ii) Have given, as an authorized ground or flight instructor, at least 100 hours of ground or flight training.

§ 61.217 Ground instructor proficiency.

(a) A person who applies for a ground instructor certificate must receive ground training and satisfactorily accomplish a practical test on the following approved areas of operation:

(1) Preparation and conduct of lesson plans for students with varying backgrounds and levels of experience and ability;

(2) Evaluation of student knowledge;

(3) Ground instructor responsibilities; and

(4) Effective analysis and correction of common student errors.

(b) Except for a person who holds a flight instructor certificate, a person must present a ground school lesson on a pilot aeronautical knowledge area topic that is appropriate to the rating sought as part of the practical test;

(c) The ground training required by paragraph (a) of this section must be given by a flight instructor or ground instructor who meets the requirements of § 61.183 or § 61.213 of this part; and

(d) The practical test for a ground instructor certificate and rating must be administered by an examiner.

§ 61.219 Ground instructor records.

(a) A ground instructor must record the following information in a person's logbook or training record to whom that instructor gives ground training, and must sign that logbook or training record entry:

(1) The amount of time of the lesson;

(2) The date the training was given; and

(3) The topics of training given.

(b) A ground instructor must maintain a record containing the following information:

(1) The name of each person whose logbook or training record that ground instructor has endorsed for satisfactory completion of a course;

(2) The name of each person whom that ground instructor has endorsed for a knowledge test and the results of that knowledge test;

(3) The name of each person that ground instructor has endorsed or recommended for a practical test, and the date of the endorsement or recommendation; and

(4) A copy of the training syllabus for each person that instructor trained.

(c) A ground instructor must retain the records required by this section for at least 3 years after the date of the endorsement.

§ 61.221 Additional ground instructor ratings.

(a) Persons who apply for an additional aircraft category rating on their ground instructor certificate, must satisfactorily accomplish a knowledge test on the aeronautical knowledge areas listed in § 61.215(a)(2) of this part, that apply to the aircraft category rating sought.

(b) Persons who apply for an instrument rating on the their ground instructor certificate must satisfactorily accomplish a knowledge test on the aeronautical knowledge areas listed in § 61.215(a)(3) of this part.

§ 61.223 Ground instructor endorsements and authorizations.

Persons who hold a ground instructor certificate, are authorized, within the ratings on their ground instructor certificate, to give ground training on the aeronautical knowledge areas and the endorsements for the training, required for the following pilot, flight

instructor, and ground instructor certificates and ratings that are issued under this part:

(a) Student pilot certificate;
(b) Recreational pilot certificate;
(c) Private pilot certificate;
(d) Commercial pilot certificate;
(e) Airline transport pilot certificate;
(f) Flight instructor certificate;
(g) Ground instructor certificate;
(h) Additional aircraft rating;
(i) Instrument rating;
(j) Flight review requirement of this part; and
(k) Recommendation for knowledge tests.

§ 61.225 Recency of experience for a holder of a ground instructor certificate.

A person's ground instructor certificate remains current for providing ground training for airman certification purposes, provided that person has:

(a) Given another person ground training and has endorsed that person for a knowledge or practical test within the preceding 12 calendar months; or

(b) Received an endorsement from an authorized flight or ground instructor, which states that the person has demonstrated satisfactory competence in the knowledge and proficiency requirements listed in §§ 61.215 and 61.217, that apply to the ground instructor ratings held.

§ 61.227 Conversion to current ground instructor ratings.

(a) *General.* A person who holds a ground instructor certificate that does not bear the new ground instructor ratings listed in § 61.5(d) of this part:

(1) May not exercise the privileges of that certificate after [insert date 2 years after the effective date of the final rule]; and

(2) Prior to [insert date 2 years after the effective date of the final rule], that person may convert an old ground instructor certificate and ratings in accordance with the provisions authorized in paragraphs (b) through (e) of this section, as appropriate.

(b) The holder of a ground instructor certificate with a basic rating may exchange that ground instructor certificate for a ground instructor certificate with an airplane category rating.

(c) The holder of a ground instructor certificate with an advanced rating may exchange that ground instructor certificate for a ground instructor certificate with an airplane category rating.

(d) The holder of a ground instructor certificate with an advanced and instrument rating may exchange that ground instructor certificate for a ground instructor certificate with an airplane category rating and instrument rating.

(e) The holder of a ground instructor certificate who also holds a flight instructor certificate may exchange that ground instructor certificate for a ground instructor certificate with the aircraft categories or instrument rating held on the flight instructor certificate.

PART 141—PILOT SCHOOLS

4. Part 141 is revised to read as follows:

Subpart A—General

Sec.
141.1 Applicability.
141.3 Certificate required.
141.5 Requirements for a pilot school certificate.
141.7 Provisional pilot school certificate.
141.9 Examining authority.
141.11 Pilot school ratings.
141.13 Application for issuance, amendment, or renewal.
141.15 Location of facilities.
141.17 Duration of certificates and examining authority.
141.18 Carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances.
141.19 Display of certificate.
141.21 Inspections.
141.23 Advertising limitations.
141.25 Business office and operations base.
141.27 Renewal of certificates and ratings.
141.29 [Reserved.]

Subpart B—Personnel, Aircraft, and Facilities Requirements

141.31 Applicability.
141.33 Personnel.
141.35 Chief instructor qualifications.
141.36 Assistant chief instructor qualifications.
141.37 Check instructor qualifications.
141.38 Airports.
141.39 Aircraft.
141.41 Flight training devices and training aids.
141.43 Pilot briefing areas.
141.45 Ground training facilities.

Subpart C—Training Course Outline and Curriculum

141.51 Applicability.
141.53 Approval procedures for a training course: General.
141.55 Training course: Contents.
141.57 Special curricula.

Subpart D—Examining Authority

141.61 Applicability.
141.63 Examining authority qualification requirements.
141.65 Privileges.
141.67 Limitations and reports.

Subpart E—Operating Rules

141.71 Applicability.
141.73 Privileges.
141.75 Aircraft requirements.
141.77 Limitations.
141.79 Flight training.
141.81 Ground training.
141.83 Quality of training.
141.85 Chief instructor responsibilities.
141.87 Change of chief instructor.
141.89 Maintenance of personnel, facilities, and equipment.
141.91 Satellite bases.
141.93 Enrollment.
141.95 Graduation certificate.

Subpart F—Records

141.101 Training records.

Appendix A—Recreational Pilot Certification Course
Appendix B—Private Pilot Certification Course
Appendix C—Instrument Rating Course
Appendix D—Commercial Pilot Certification Course
Appendix E—Airline Transport Pilot Certification Course
Appendix F—Flight Instructor Certification Course
Appendix G—Flight Instructor Instrument (Aircraft Category and Class) Certification Course
Appendix H—Ground Instructor Certification Course
Appendix I—Additional Aircraft Category or Class Rating Course
Appendix J—Aircraft Type Rating Course, for other than an airline transport pilot certificate
Appendix K—Special Preparation Courses
Appendix L—Pilot Ground School Courses

Authority: 49 U.S.C. 106(g), 40101–40104, 40109, 40113, 44701–44703, 44707, 44709, 44711, 45102–45103, 45106, and 45301–45302.

Subpart A—General

§ 141.1 Applicability.

This part prescribes:

(a) The requirements for issuing pilot school certificates, provisional pilot school certificates, and associated ratings; and

(b) The general operating rules applicable to a holder of a certificate or rating specified in paragraph (a) of this section.

§ 141.3 Certificate required.

No person may operate as a certificated pilot school without, or in violation of, a pilot school certificate or provisional pilot school certificate issued under this part.

§ 141.5 Requirements for a pilot school certificate.

An applicant that meets the requirements of this section may be issued a pilot school certificate with associated ratings if:

(a) The applicant completes the application for a pilot school certificate on a form and in a manner as prescribed by the Administrator.

(b) The applicant holds a provisional pilot school certificate, issued under this part, for at least 24 calendar months

preceding the month in which the application for a pilot school certificate is made.

(c) The applicant meets the applicable requirements of subparts A through C of this part for the school ratings sought.

(d) The applicant trained and recommended for pilot certification and rating tests, within 24 calendar months preceding the month the application is made for the pilot school certificate, at least 10 students for:

(1) A knowledge or practical test for a pilot certificate, flight instructor certificate, ground instructor certificate, or an additional rating, with such quality of training that at least 80 percent of those applicants were successful on the first attempt on a test that was conducted by an FAA inspector, or an examiner who is not an employee of the school; or

(2) An end-of-course test for a training course specified in appendix K of this part.

§ 141.7 Provisional pilot school certificate.

An applicant that meets the applicable requirements of subparts A, B, and C of this part, but does not meet the recent training activity requirements of § 141.5(d) of this part, may be issued a provisional pilot school certificate with ratings.

§ 141.9 Examining authority.

An applicant is issued an examining authority for its pilot school certificate if the applicant meets the requirements of subpart D of this part.

§ 141.11 Pilot school ratings.

(a) The ratings listed in paragraph (b) of this section may be issued to an applicant for a:

(1) Pilot school certificate, provided the applicant meets the requirements of § 141.5 of this part; or

(2) Provisional pilot school certificate, provided the applicant meets the requirements of § 141.7 of this part.

(b) The following are courses the school is authorized to conduct:

(1) *Certification and rating courses.*

(i) Recreational pilot course.

(ii) Private pilot course.

(iii) Commercial pilot course.

(iv) Instrument rating course.

(v) Airline transport pilot course.

(vi) Flight instructor course.

(vii) Flight instructor instrument course.

(viii) Ground instructor course.

(ix) Additional aircraft category or class rating course.

(x) Aircraft type rating course.

(2) *Special preparation courses.*

(i) Pilot refresher course.

(ii) Flight instructor refresher course.

(iii) Ground instructor refresher course.

(iv) Agricultural aircraft operations course.

(v) Rotorcraft external-load operations course.

(vi) Special operations course.

(vii) Test pilot course.

(3) *Pilot ground school courses.*

§ 141.13 Application for issuance, amendment, or renewal.

(a) Application for an original certificate and rating, for an additional rating, or for the renewal of a certificate under this part is made on a form and in a manner prescribed by the Administrator.

(b) Application for the issuance or amendment of a certificate or rating must be accompanied by two copies of each proposed training course curriculum for which approval is sought.

§ 141.15 Location of facilities.

The holder of a pilot school certificate or a provisional pilot school certificate may have a base or other facilities located outside the United States, provided the Administrator determines the location of the base and facilities at that place are needed for the training of students who are citizens of the United States.

§ 141.17 Duration of certificate and examining authority.

(a) Unless surrendered, suspended, revoked, or otherwise terminated, a pilot school's or a provisional pilot school's certificate expires:

(1) On the last day of the 24th calendar month from the month the certificate was issued;

(2) Except as provided in paragraph (b) of this section, on the date that any change in ownership of the school;

(3) On the date of any change in the facilities upon which the school's certificate is based;

(4) Upon notice by the Administrator that the school has failed for more than 60 days to maintain the facilities, aircraft, or personnel required for any one of the school's approved training courses; or

(5) Whenever the Administrator determines a school has not acted in good faith with a student with whom the school has a contractual agreement to provide training.

(b) A change in the ownership of a pilot school or provisional pilot school does not terminate that school's certificate, if within 30 days after the date that any change in ownership of the school occurs:

(1) Application is made for an appropriate amendment to the certificate; and

(2) No change in the facilities, personnel, or approved training courses is involved.

(c) An examining authority issued to the holder of a pilot school certificate expires on the date that the pilot school certificate expires, or is surrendered, suspended, revoked, or otherwise terminated.

§ 141.18 Carriage of narcotic drugs, marijuana, and depressant or stimulant drugs or substances.

If the holder of a certificate issued under this part permits any aircraft owned or leased by that holder to be engaged in any operation that the certificate holder has knowledge of being in violation of § 91.19(a) of this chapter, that operation is a basis for suspending or revoking the certificate.

§ 141.19 Display of certificate.

(a) Each holder of a pilot school certificate or a provisional pilot school certificate must display that certificate in a place in the school that is normally accessible to the public and is not obscured.

(b) A certificate must be made available for inspection upon request by:

(1) The Administrator;

(2) An authorized representative of the National Transportation Safety Board; or

(3) A Federal, state, or local law enforcement officer.

§ 141.21 Inspections.

Each holder of a certificate issued under this part must allow the Administrator to inspect its personnel, facilities, equipment, and records to determine the certificate holder's:

(a) Eligibility to hold its certificate;

(b) Compliance with the Federal Aviation Act of 1958, as amended; and

(c) Compliance with the Federal Aviation Regulations.

§ 141.23 Advertising limitations.

(a) The holder of a pilot school certificate or a provisional pilot school certificate may not make any statement relating to its certification and ratings which is false or designed to mislead any person contemplating enrollment in that school.

(b) The holder of a pilot school certificate or a provisional pilot school certificate may not advertise that the school is certificated unless it clearly differentiates between courses that have been approved under part 141 of this chapter and those that have not been approved under part 141 of this chapter.

(c) The holder of a pilot school certificate or a provisional pilot school certificate must promptly remove:

(1) From vacated premises all signs indicating that the school was certificated by the Administrator when relocated; or

(2) All indications (including signs), wherever located, that the school is certificated by the Administrator when its certificate has expired or has been surrendered, suspended, or revoked, or otherwise terminated.

§ 141.25 Business office and operations base.

(a) Each holder of a pilot school or a provisional pilot school certificate must maintain a principal business office with a mailing address in the name shown on its certificate.

(1) The facilities and equipment at the principal business office must be adequate to maintain the files and records required to operate the business of the school.

(2) The principal business office may not be shared with, or used by, another pilot school.

(b) Before changing the location of the principal business office or the operations base, each certificate holder must notify the FAA Flight Standards District Office having jurisdiction over the area of the new location, and the notice must be:

(1) Submitted in writing at least 30 days before the change of location; and

(2) Accompanied by any amendments needed for the certificate holder's approved training course outline.

(c) A certificate holder may conduct training at an operations base other than the one specified in its certificate, if the:

(1) Administrator has inspected and approved the base for use by the certificate holder; and

(2) Course of training and any needed amendments thereto have been approved for use at that base.

§ 141.27 Renewal of certificates and ratings.

(a) *Pilot school.*

(1) A pilot school may apply for renewal of its school certificate and ratings within 30 days preceding the month the pilot school certificate expires, provided the school meets the requirements prescribed in paragraph (a)(2) of this section for renewal of its certificate and ratings.

(2) A pilot school may have its school certificate and ratings renewed for an additional 24-calendar months, if the Administrator determines that school meets the following requirements:

(i) The personnel meet the requirements of this part;

(ii) The aircraft meet the requirements of this part;

(iii) The facility and airport meet the requirements of this part;

(iv) The approved training courses meet the requirements of this part;

(v) The training records meet the requirements of this part; and

(vi) The recent training activity and training quality requirements of § 141.5(d) of this part.

(3) A pilot school that does not meet the renewal requirements in paragraph (a)(2) of this section, may apply for a provisional pilot school certificate if the school meets the requirements of § 141.7 of this part.

(b) *Provisional pilot school.*

(1) Except as provided in paragraph (b)(3) of this section, a provisional pilot school may not have its provisional pilot school certificate or the ratings on that certificate renewed.

(2) A provisional pilot school may apply for a pilot school certificate and associated ratings provided that school meets the requirements of § 141.5 of this part.

(3) A former provisional pilot school may apply for another provisional pilot school certificate provided 180 days have elapsed since its last provisional pilot school certificate expired.

§ 141.29 [Reserved]

Subpart B—Personnel, Aircraft, and Facilities Requirements

§ 141.31 Applicability.

(a) This subpart prescribes:

(1) The personnel and aircraft requirements for a pilot school certificate or a provisional pilot school certificate; and

(2) The facilities and airport required by a pilot school or provisional pilot school on a continuous use basis.

(b) As used in the subpart, to have continuous use of a facility including an airport, the school must have:

(1) Ownership of the facility and airport for at least 6-calendar months at the time of application for initial certification and also on the date of renewal of the school's certificate; or

(2) A written lease agreement of the facility and airport for at least 6-calendar months at the time of application for initial certification and also on the date of renewal of the school's certificate.

§ 141.33 Personnel.

(a) An applicant for a pilot school or for a provisional pilot school certificate must meet the following personnel requirements:

(1) Each applicant must have adequate personnel, authorized instructors, and a chief instructor for each approved training course, who are qualified and competent to perform the duties to which they are assigned.

(2) Each applicant must have dispatchers, aircraft handlers, line and service personnel, and instructors, who are instructed in the procedures and responsibilities of that person's employment.

(3) Each applicant must have instructors who hold the ground or flight instructor certificates, as applicable, in the category and class of aircraft for the approved training course and aircraft.

(b) An applicant for a pilot school certificate or for a provisional pilot school certificate must designate a chief instructor for each of the school's approved training courses, who must meet the requirements of § 141.35 of this part.

(c) When necessary, an applicant for a pilot school certificate or for a provisional pilot school certificate may designate a person to be an assistant chief instructor for an approved training course, provided that person meets the requirements of § 141.36 of this part.

(d) A pilot school and a provisional pilot school may designate a person to be a check instructor for conducting student stage checks, end-of-course tests, and instructor proficiency checks, provided:

(1) That person meets the requirements of § 141.37 of this part; and

(2) That school has a student enrollment of at least 50 students at the time designation is sought.

(e) A person, as listed in this section, may serve in more than one position for a school, provided that person is qualified for each position.

§ 141.35 Chief instructor qualifications.

(a) To be eligible for a designation as a chief instructor for a course of training, a person must meet the following requirements:

(1) Hold a commercial pilot or an airline transport pilot certificate and a flight instructor certificate, and those certificates must contain the appropriate aircraft category, class, and instrument rating for the category and class of aircraft used in the course;

(2) Meet the pilot-in-command recent flight experience requirements of § 61.57 of this chapter;

(3) Satisfactorily accomplish a knowledge test on teaching methods, applicable provisions of the Airman's Information Manual, parts 61, 91, and 141 of this chapter, and the objectives and approved course completion

standards of the course for which the person seeks to obtain designation;

(4) Satisfactorily accomplish a proficiency test on instructional skills and ability to train students on the flight procedures and maneuvers appropriate to the course;

(5) Except for a course of training for gliders, balloons, or airships, the chief instructor must meet the applicable requirements in paragraphs (b), (c), and (d) of this section;

(6) A chief instructor for a course of training for gliders or balloons is only required to have 40 percent of the hours required in paragraphs (b) and (d) of this section; and

(7) A chief instructor for a course of training for airships is only required to have 40 percent of the hours required in paragraphs (b), (c), and (d) of this section.

(b) In addition, for a course of training leading to the issuance of a private pilot certificate or rating, a chief instructor must have:

(1) At least 1,000 hours as pilot in command; and

(2) Primary flight training experience, acquired as either an authorized flight instructor or an instructor in a military pilot primary flight training program, or a combination thereof, consisting of at least:

(i) Two years and a total of 500 flight hours; or

(ii) 1,000 flight hours.

(c) For a course of training leading to the issuance of an instrument rating or a rating with instrument privileges, a chief instructor must have:

(1) At least 100 hours of flight time under actual or simulated instrument conditions;

(2) At least 1,000 hours as pilot in command; and

(3) Instrument flight instructor experience, acquired as either an authorized flight instructor-instrument or an instructor in a military pilot basic or instrument flight training program, or a combination thereof, consisting of at least—

(i) Two years and a total of 250 flight hours; or

(ii) 400 flight hours.

(d) For a course of training other than those that lead to the issuance of a private pilot certificate or rating, or an instrument rating or a rating with instrument privileges, a chief instructor must have:

(1) At least 2,000 hours as pilot in command; and

(2) Flight training experience, acquired as either an authorized flight instructor or an instructor in a military pilot primary or basic flight training program or a combination thereof, consisting of at least—

(i) Three years and a total of 1,000 flight hours; or

(ii) 1,500 flight hours.

§ 141.36 Assistant chief instructor qualifications.

(a) To be eligible for a designation as an assistant chief instructor for a course of training, a person must meet the following requirements:

(1) Hold a commercial pilot or an airline transport pilot certificate and a flight instructor certificate, and those certificates must contain the appropriate aircraft category, class, and instrument rating for the category and class of aircraft used in the course;

(2) Meet the pilot-in-command recent flight experience requirements of § 61.57 of this chapter;

(3) Satisfactorily accomplish a knowledge test on teaching methods, applicable provisions of the Airman's Information Manual, parts 61, 91, and 141 of this chapter, and the objectives and approved course completion standards of the course for which the person seeks to obtain designation;

(4) Satisfactorily accomplish a proficiency test on the flight procedures and maneuvers appropriate to that course; and

(5) Meet the applicable requirements in paragraphs (b), (c), and (d) of this section. However, an assistant chief instructor for a course of training for gliders, free balloons or airships is only required to have 40 percent of the hours required in paragraphs (b) and (c) of this section.

(b) For a course of training leading to the issuance of a private pilot certificate or rating, an assistant chief instructor must have:

(1) At least 500 hours as pilot in command; and

(2) Primary flight training experience, acquired as either an authorized flight instructor or an instructor in a military pilot primary flight training program, or a combination thereof, consisting of at least—

(i) One year and a total of 250 flight hours; or

(ii) 500 flight hours.

(c) For a course of training leading to the issuance of an instrument rating or a rating with instrument privileges, an assistant chief flight instructor must have:

(1) At least 50 hours of flight time under actual or simulated instrument conditions;

(2) At least 500 hours as pilot in command; and

(3) Instrument flight instructor experience, acquired as either an authorized flight instructor-instrument or an instructor in a military pilot basic or instrument flight training program, or a combination thereof, consisting of at least—

(i) One year and a total of 125 flight hours; or

(ii) 200 flight hours.

(d) For a course of training other than those that lead to the issuance of a private pilot certificate or rating, or an instrument rating or a rating with instrument privileges, an assistant chief instructor must have:

(1) At least 1,000 hours as pilot in command; and

(2) Flight training experience, acquired as either an authorized flight instructor or an instructor in a military pilot primary or basic flight training program or a combination thereof, consisting of at least—

(i) One and one half years and a total of 500 flight hours; or

(ii) 750 flight hours.

§ 141.37 Check instructor qualifications.

(a) To be designated as a check instructor for conducting student stage checks and end-of-course tests and instructor proficiency checks under this part, a person must meet the eligibility requirements of this section:

(1) For checks and tests that relate to either flight or ground training, the person must satisfactorily accomplish a test, given by the chief instructor, on—

(i) Teaching methods;

(ii) Applicable provisions of the ''Airman's Information Manual,'' parts 61, 91, and 141 of this chapter; and

(iii) The objectives and course completion standards of the approved training course for the designation sought.

(2) For checks and tests that relate to a flight training course, the person must—

(i) Meet the requirements in paragraph (a)(1) of this section;

(ii) Hold a commercial pilot or an airline transport pilot certificate and a flight instructor certificate, and those certificates must contain the appropriate aircraft category, class, and instrument rating for the category and class of aircraft used in the course;

(iii) If the flight training course is for a rating in other than a glider or free balloon, hold at least a current second-class medical certificate issued in accordance with part 67 of this chapter;

(iv) If the flight training course is for a rating in a glider or free balloon, present a signed and dated statement by the person certifying that the person has no known medical defects that makes the person unable to pilot a glider or free balloon;

(v) Meet the pilot-in-command recent flight experience requirements of § 61.57 of this chapter; and

(vi) Satisfactorily accomplish a proficiency test, given by the chief instructor, on the flight procedures and maneuvers of the approved training course for the designation sought.

(3) For checks and tests that relate to ground training, the person must—

(i) Meet the requirements in paragraph (a)(1) of this section; and

(ii) Hold a current flight instructor certificate or ground instructor certificate with ratings appropriate to the category and class of aircraft used in the course.

(b) A person who meets the eligibility requirements in paragraph (a) of this section must:

(1) Be designated, in writing, by the chief instructor to conduct student stage checks and end-of-course tests and instructor proficiency checks; and

(2) Be approved by the FAA Flight Standards District Office having jurisdiction over the school.

(c) A check instructor may not conduct a stage check or an end-of-course test of any student:

(1) For whom the check instructor has served as the principal instructor; or

(2) Whom the check instructor has recommended for a stage check or end-of-course test.

§ 141.38 Airports.

(a) An applicant for a pilot school certificate or a provisional pilot school certificate must show that it has continuous use of each airport at which training flights originate.

(b) Each airport used for airplanes and gliders must have at least one runway or takeoff area that allows training aircraft to make a normal takeoff or landing under the following conditions at the aircraft's maximum certificated takeoff gross weight:

(1) Under calm wind conditions of not more than five miles per hour;

(2) At temperatures equal to the mean high temperature for the hottest month of the year in the operating area;

(3) If applicable, with the powerplant operation and landing gear and flap operation recommended by the manufacturer; and

(4) In the case of a takeoff—

(i) With smooth transition from liftoff to the best rate of climb speed without exceptional piloting skills or techniques; and

(ii) Clearing all obstacles in the takeoff flight path by at least 50 feet.

(c) Each airport must have a wind direction indicator that is visible from the ends of each runway at ground level;

(d) Each airport must have a traffic direction indicator when:

(1) The airport does not have an operating control tower; and

(2) UNICOM advisories are not available.

(e) Except as provided in paragraph (f) of this section, each airport used for night training flights must have permanent runway lights; and

(f) An airport used for night training flights in seaplanes is permitted to use adequate non-permanent lighting or shoreline lighting, if approved by the Administrator.

§ 141.39 Aircraft.

(a) An applicant for a pilot school or provisional pilot school certificate, and each pilot school or provisional pilot school, must show that each aircraft used by that school for flight training and supervised PIC flights meet the following requirements:

(1) Each aircraft must be registered as a civil aircraft of the United States;

(2) Each aircraft must be certificated with a standard airworthiness certificate or a primary airworthiness certificate, unless the Administrator determines that due to the nature of the approved course, an aircraft not having a standard airworthiness certificate or primary airworthiness certificate may be used;

(3) Each aircraft must be maintained and inspected in accordance with—

(i) The requirements of subpart E, part 91 of this chapter that apply to aircraft operated for hire; and

(ii) An inspection program for each airframe, aircraft engine, propeller, appliance, and component part.

(4) Each aircraft used in flight training must be at least a two-place aircraft with engine power controls and flight controls that can be easily reached and operated in a normal manner from both pilot stations; and

(5) Each aircraft used in a course for instrument flight training, or a training course requiring the demonstration of instrument skills, must be equipped and maintained for IFR operations.

(b) The inspection program required in paragraph (a)(3) of this section must be:

(1) A current inspection program recommended by the manufacturer;

(2) An inspection program that is currently in use by the holder of a certificate issued under part 121 or part 135 of this chapter; or

(3) An inspection program established by the applicant and approved by the Administrator.

(c) An inspection program under paragraph (b)(3) of this section must meet the following requirements:

(1) The program is approved by the FAA Flight Standards District Office having jurisdiction over the area in which the applicant is based; and

(2) That program is submitted in writing and consists of at least—

(i) The instructions and procedures for the conduct of inspections for the particular make and model aircraft, including necessary checks and tests;

(ii) The instructions and procedures for inspecting the parts and areas of each airframe, aircraft engine, propeller, appliance, and component part, including survival and emergency equipment required to be inspected; and

(iii) A schedule for performing the inspections that must be performed under the program expressed in terms of the time in service, calendar time, number of system operations, or any combination of these.

§ 141.41 Flight training devices and training aids.

An applicant for a pilot school or a provisional pilot school certificate must show that its flight training devices and training aids and equipment meet the following requirements:

(a) *Flight training devices.*

(1) Each flight training device used to obtain the maximum flight training credit allowed for flight training devices in an approved pilot training course curriculum must have:

(i) An enclosed pilot's station or cockpit that accommodates one or more flight crewmembers;

(ii) Controls to stimulate the rotation of the flight training device about three axes;

(iii) The minimum instrumentation and equipment required for powered aircraft in § 91.205 of this chapter for the type of flight operations simulated;

(iv) For VFR instruction, a means of simulating visual flight conditions, including motion of the flight training device, or projections, or models operated by the flight controls; and

(v) For IFR instruction, a means to record the flight path simulated by the flight training device.

(2) Flight training devices other than those covered under paragraph (a)(1) of this section must have:

(i) An enclosed pilot's station or cockpit that accommodates one or more flight crewmembers;

(ii) Controls to simulate the rotation of the flight training device about three axes; and

(iii) The minimum instrumentation and equipment required for powered aircraft in § 91.205 of this chapter for the type of flight operations simulated.

(b) *Training aids and equipment.* Each training aid, including any audiovisual, mockup, chart, or aircraft component listed in the approved training course outline, must be accurate and appropriate to the course for which it is used.

§ 141.43 Pilot briefing areas.

(a) An applicant for a pilot school or provisional pilot school certificate must show that the applicant has the continuous use of a briefing area located at each airport at which training flights originate, that is:

(1) Adequate to shelter students waiting to engage in their training flights;

(2) Arranged and equipped for the conduct of pilot briefings; and

(3) Except as provided in paragraph (c) of this section, a school with an instrument rating or commercial pilot course must be equipped with private landline or telephone communication to the nearest FAA Flight Service Station.

(b) A briefing area required by paragraph (a) of this section may not be used by the applicant if it is available for use by any other pilot school during the period it is required for use by the applicant.

(c) The communication equipment required by paragraph (a)(3) of this section is not required if the briefing area and the flight service station are located on the same airport and are readily accessible to each other.

§ 141.45 Ground training facilities.

An applicant for a pilot school or provisional pilot school certificate must show that:

(a) Each room, training booth, or other space used for instructional purposes is heated, lighted, and ventilated to conform to local building, sanitation, and health codes; and

(b) The training facility is so located that the students in that facility are not distracted by the training conducted in other rooms, or by flight and maintenance operations on the airport.

Subpart C—Training Course Outline and Curriculum

§ 141.51 Applicability.

This subpart prescribes the curriculum and course outline requirements for the issuance of a pilot school or provisional pilot school certificate and ratings.

§ 141.53 Approval procedures for a training course: General.

(a) *General.* An applicant for a pilot school or provisional pilot school certificate must obtain the Administrator's approval of the outline of each training course for which certification and rating is sought.

(b) *Application.*

(1) An application for the approval of an initial or amended training course must be submitted in duplicate to the FAA Flight Standards District Office having jurisdiction over the area where the school is based.

(2) An application for the approval of an initial or amended training course must be submitted at least 30 days before any training under that course, or any amendment thereto, is scheduled to begin.

(3) An application for amending a training course must be accompanied by two copies of the amendment.

(c) *Effective date.*

(1) Until [insert date one year after effective date of the final rule] an applicant for a pilot school or provisional pilot school certificate may request approval of the training courses listed in either paragraph (c)(1) (i) or (ii) of this section.

(i) Pilot school rating courses:

(A) Private pilot.

(B) Private test course.

(C) Instrument rating.

(D) Commercial pilot.

(E) Commercial test course.

(F) Additional aircraft rating.

(G) Pilot ground school.

(H) Flight instructor certification.

(I) Additional flight instructor rating.

(J) Additional instrument rating.

(K) Airline transport pilot certification.

(L) Pilot refresher course.

(M) Agricultural aircraft operations course.

(N) Rotorcraft external-load operations course.

(ii) Pilot school rating courses, [insert effective date]:

(A) Recreational pilot courses.

(B) Private pilot courses.

(C) Commercial pilot courses.

(D) Instrument rating courses.

(E) Airline transport pilot courses.

(F) Flight instructor courses.

(G) Flight instructor instrument courses.

(H) Ground instructor courses.

(I) Additional aircraft category or class rating courses.

(J) Aircraft type rating courses.

(K) Pilot refresher courses.

(L) Flight instructor refresher courses.

(M) Ground instructor refresher courses.

(N) Agricultural aircraft operations course.

(O) Rotorcraft external-load operations course.

(P) Special operations course.

(Q) Test pilot course.

(R) Pilot ground school courses.

(2) After [insert date one year after effective date of the final rule] an applicant for a pilot school or provisional pilot school certificate may only request approval of the training courses listed in paragraph (c)(1)(ii) of this section.

§ 141.55 Training course: Contents.

(a) Each training course for which approval is requested must meet the minimum curriculum requirements in accordance with the appropriate appendix of this part.

(b) Except as provided in paragraphs (d) and (e) of this section, each training course for which approval is requested must meet the minimum ground and flight training time requirements in accordance with the appropriate appendix of this part.

(c) Each training course for which approval is requested must contain:

(1) A description of each room used for ground training, including the room's size and the maximum number of students that may be trained in the room at one time;

(2) A description of each type of audio-visual aid, projector, tape recorder, mockup, aircraft component, and other special training aids used for ground training;

(3) A description of each flight training device used for training;

(4) A listing of the airports at which training flights originate and a description of the facilities, including pilot briefing areas that are available for use by the school's students and personnel at each of those airports;

(5) A description of the type of aircraft including any special equipment used for each phase of training;

(6) The minimum qualifications and ratings for each instructor assigned to ground or flight training; and

(7) A training syllabus that includes the following information:

(i) The prerequisites for enrolling in the ground and flight portion of the course that include the pilot certificate and rating (if required by this part), medical certificate (if required by this part), training, pilot experience, and pilot knowledge;

(ii) A detailed description of each lesson, including the lesson's objectives, standards, and planned time for completion;

(iii) A description of what the course is expected to accomplish with regard to student learning;

(iv) The expected accomplishments and the standards for each stage of training; and

(v) A description of the checks and tests to be used to measure a student's accomplishments for each stage of training.

(d) A pilot school may request and receive initial approval for any of the training courses of this part without specifying the minimum ground and flight training time requirements of this part, provided the following provisions are met:

(1) The school holds a pilot school certificate under this part and has held that certificate for a period of at least 24-consecutive calendar months preceding the month of the request;

(2) The school requests initial approval for no longer than 24-calendar months;

(3) In addition to the information required by paragraph (c) of this section, the training course specifies planned ground and flight training time requirements for the course;

(4) The school does not request the training course to be approved for examining authority; and

(5) The practical or knowledge test for the course is to be given by—

(i) An FAA inspector; or

(ii) An examiner who is not an employee of the school.

(e) A certificated pilot school may request and receive final approval for any of the training courses of this part without specifying the minimum ground and flight training time requirements of this part, provided the following conditions are met:

(1) The school has held initial approval for that training course for at least 24-calendar months.

(2) The school has—

(i) Trained at least 10 students in that training course within the preceding 24-calendar months and recommended those students for a pilot, flight instructor, or ground instructor certificate or rating; and

(ii) At least 80 percent of those students passed the practical or knowledge test on the first attempt, and that test was given by—

(A) An FAA inspector; or

(B) An examiner who is not an employee of the school.

(3) In addition to the information required by paragraph (c) of this section, the training course specifies planned ground and flight training time requirements for the course.

(4) The school does not request that the training course be approved for examining authority.

(f) The airman certificate of a person who does not meet the pilot flight time qualifications in ICAO Annex I will be issued with one or both of the limitations listed in paragraph (f)(1) of this section, which may be removed as prescribed in paragraph (f)(2) of this section.

(1) The airman certificate will be issued with the limitation ''Holder does not meet the pilot flight experience requirements of ICAO,'' or ''Holder does not meet the pilot-in-command flight experience requirements of ICAO,'' or both, if appropriate.

(2) The limitations, ''Holder does not meet the pilot flight experience requirements of ICAO,'' or ''Holder does not meet the pilot-in-command flight experience requirements of ICAO,'' of paragraph (f)(1) of this section, may be removed when the holder presents to the FAA satisfactory evidence of having accumulated the appropriate pilot flight time that meets the requirements of part 61 of this chapter.

§ 141.57 Special curricula.

An applicant for a pilot school or provisional pilot school certificate may apply for approval to conduct a special course of airman training for which a curriculum is not prescribed in the appendixes of this part, if the applicant shows that the training course contains features that could achieve a level of pilot proficiency equivalent to that achieved by a training course prescribed in the appendixes of this part or the requirements of part 61 of this chapter.

Subpart D——Examining Authority

§ 141.61 Applicability.

This subpart prescribes:

(a) The requirements for the issuance of an examining authority to the holder of a pilot school certificate; and

(b) The privileges and limitations of that examining authority.

§ 141.63 Examining authority qualification requirements.

(a) A pilot school must meet the following prerequisites to receive initial approval for examining authority:

(1) The school completes the application for examining authority on a form and in a manner prescribed by the Administrator;

(2) The school holds a pilot school certificate and the rating in which examining authority is sought for at least 24 consecutive calendar months preceding the month of application for examining authority;

(3) The training course for which examining authority is requested may not be a course that is approved without meeting the minimum ground and flight training time requirements of this part; and

(4) Within 24 calendar months after the date of application for examining authority, that school must meet the following requirements—

(i) The school must have trained at least 10 students in the training course for which examining authority is sought and recommended those students for a pilot, flight instructor, or ground instructor certificate or rating; and

(ii) At least 90 percent of the applicant's students passed the required practical or knowledge test for the pilot, flight instructor, or ground instructor certificate or rating on the first attempt, and that test was given by—

(A) An FAA inspector; or

(B) An examiner who is not an employee of the school.

(b) A pilot school must meet the following requirements to retain approval of its examining authority:

(1) The school completes the application for renewal of its examining authority on a form and in a manner prescribed by the Administrator;

(2) The school holds a pilot school certificate and the rating for which examining authority is sought for at least 24 calendar months preceding the month of application for renewal of its examining authority; and

(3) The training course for which examining authority is requested may not be a course that is approved without meeting the minimum ground and flight training time requirements of this part.

§ 141.65 Privileges.

A pilot school that holds examining authority may recommend a person who graduated from its course for the appropriate pilot, flight instructor, or ground instructor certificate or rating without taking the FAA knowledge or practical tests, or both, provided:

(a) The school holds examining authority for the training course from which the person graduated; and

(b) The person satisfactorily completed the training course in accordance with the school's approved training course and the provisions of this part.

§ 141.67 Limitations and reports.

A pilot school that holds examining authority may only recommend the issuance of a pilot, flight instructor, or ground instructor certificate and rating to a person who does not take an FAA knowledge or practical test, if the issuance of that certificate or rating is in accordance with the following requirements:

(a) The person graduated from a training course for which the pilot school holds examining authority.

(b) Except as provided in this paragraph of this section, the person satisfactorily completed all the curriculum requirements of that pilot school's approved training course. A person who transfers from one part 141 approved pilot school to another part 141 approved pilot school may receive credit for that previous training, provided the folowing requirements are met:

(1) The maximum credited training time does not exceed one-half of the receiving school's curriculum requirements;

(2) The person completes a knowledge and proficiency test conducted by the receiving school for the purpose of determining the amount of pilot experience and knowledge to be credited;

(3) The receiving school determines (based on the person's performance on the knowledge and proficiency test required by paragraph (b)(2) of this section) on the amount of credit to be awarded and records that credit in the person's training record;

(4) The person who requests credit for previous pilot experience and knowledge obtained the experience and knowledge from another part 141 approved pilot school and training course; and

(5) The receiving school retains a copy of the person's training record from the other school.

(c) The test given by a pilot school that holds examining authority must be approved by the Administrator and be at least equal in scope, depth, and difficulty to the comparable knowledge and practical test prescribed by the Administrator under part 61 of this chapter;

(d) A pilot school that holds examining authority may not use its practical or knowledge tests if the school:

(1) Knows, or has reason to believe, the knowledge test has been compromised; or

(2) Is notified by a FAA Flight Standards District Office, that there is reason to believe or it is known, the knowledge test has been compromised.

(e) A pilot school that holds examining authority must maintain a record of all temporary airman certificates it issues, which consists of the following information:

(1) A chronological listing that includes—

(i) The date the temporary airman certificate was issued;

(ii) The student to whom the temporary airman certificate was issued, and that student's permanent mailing address and telephone number;

(iii) The training course from which the student graduated;

(iv) The name of the person who conducted the practical or knowledge test;

(v) The type of temporary airman certificate or rating issued to the student; and

(vi) The date the student's airman application file was sent to the FAA for processing for a permanent airman certificate.

(2) A copy of the record containing each student's graduation certificate, airman application, temporary airman certificate, superseded airman certificate (if applicable), and knowledge or practical test results; and

(3) The records required by paragraph (e) of this section must be made available to the Administrator upon request and must be surrendered to the Administrator when the pilot school ceases to have examining authority; and

(f) Within 7 days after a student satisfactorily accomplishes the practical or knowledge test, the pilot school that holds examining authority must submit that student's airman application file to the FAA for processing for the issuance of a permanent airman certificate.

Subpart E—Operating Rules

§ 141.71 Applicability.

This subpart prescribes the operating rules applicable to a pilot school or provisional pilot school certificated under the provisions of this part.

§ 141.73 Privileges.

(a) The holder of a pilot school or a provisional pilot school certificate may advertise and conduct approved pilot training courses in accordance with the certificate and ratings that it holds.

(b) A pilot school that holds examining authority for an approved training course may recommend a graduate of that course for the issuance of an appropriate pilot, flight instructor, or ground instructor certificate and rating, without taking an FAA knowledge or practical test, provided the training course has been approved and meets the minimum ground and flight training time requirements of this part.

§ 141.75 Aircraft requirements.

(a) The following items must be carried on each aircraft used for flight training and supervised PIC flights:

(1) A pre-takeoff and pre-landing checklist; and

(2) The operator's handbook for the aircraft, if one is furnished by the manufacturer, or copies of the handbook if furnished to each student using the aircraft

(b) Each aircraft used in the certification and rating courses listed in § 141.11 of this part must have a standard airworthiness certificate or a primary airworthiness certificate; and

(c) Each aircraft used in the agricultural aircraft operations, external-load operation, test pilot, and special operations courses listed in § 141.11 of this part may have a restricted airworthiness certificate, if its use for training is not prohibited by the aircraft's operating limitations.

§ 141.77 Limitations.

(a) The holder of a pilot school or a provisional pilot school certificate may neither issue a graduation certificate to a student, nor recommend a student for a pilot certificate or rating, unless the student has:

(1) Completed the training specified in the pilot school's course of training; and

(2) Satisfactorily accomplished the required final tests.

(b) Except as provided in paragraph (c) of this section, the holder of a pilot school or a provisional pilot school certificate may not graduate a student from a course of training unless the student has completed all of the curriculum requirements of that course;

(c) A student may be given credit towards the curriculum requirements of a course for previous pilot experience and knowledge, provided:

(1) The credit given a student for previous pilot experience and knowledge does not exceed more than one-half of the curriculum requirements and must be based upon a proficiency test or knowledge test given by the receiving pilot school;

(2) The course credits are a result of training received from one part 141 approved school to another; and

(3) The receiving school determines the amount of course credit to be transferred, based on a proficiency test or knowledge test, or both, of the student; and

(4) Credit for training received from the other school may be given if—

(i) That other school holds a certificate issued under this part and certifies to the kind and amount of training and to the result of each stage check and end-of-course test given to that student;

(ii) The training was conducted by that other school in accordance with that school's approved training course; and

(iii) The student was enrolled in that other school's approved training course for the training being used for creditation.

§ 141.79 Flight training.

(a) No person other than an authorized flight instructor who has the ratings and the minimum qualifications specified in the approved training course outline may give a student flight training under an approved course of training;

(b) No student pilot may be authorized to start a supervised PIC practice flight from an airport until the flight has been approved by an authorized flight instructor who is present at that airport;

(c) Each chief instructor and assistant chief instructor, assigned to a training course, must complete at least once every 12 calendar months, an approved syllabus of training consisting of ground or flight training, or both, or an approved flight instructor refresher course;

(d) Each flight instructor, who is assigned to a flight training course, must satisfactorily complete the following requirements:

(1) Prior to receiving authorization to train students in a flight training course, the instructor must accomplish—

(i) A review of and receive a briefing on the objectives and standards of that training course; and

(ii) An initial proficiency check in each make and model of aircraft used in that training course in which that flight instructor gives training; and

(2) Every 12-calendar months after the month in which the flight instructor last complied with paragraph (d)(1)(ii) of this section, that instructor must accomplish a recurrent proficiency check in one of the aircraft the flight instructor trains students.

(e) Each flight instructor, who is assigned to a flight training course, must satisfactorily comply with the requirements of paragraph (d) of this section with the school's chief instructor, assistant chief instructor, or check instructor.

§ 141.81 Ground training.

(a) Except as provided in paragraph (b) of this section, each instructor, who is assigned to a ground training course, must hold a flight or ground instructor certificate with the appropriate rating for that course of training;

(b) A person who does not meet the requirements of paragraph (a) of this section may be assigned ground training duties in a ground training course, if:

(1) The chief instructor who is assigned to that ground training course finds the person qualified to give that training; and

(2) The training is given while under the supervision of the chief instructor or the assistant chief instructor who is present at the facility when the training is given; and

(c) An instructor may not be used in a ground training course until the instructor has been briefed in regard to the objectives and standards of that course by the chief instructor, assistant chief instructor, or check instructor.

§ 141.83 Quality of training.

(a) Each pilot school or provisional pilot school must meet the following requirements:

(1) Comply with its approved training course; and

(2) Provide training of such quality that meets the training quality requirements of § 141.5(d) of this part.

(b) The failure of a pilot school or provisional pilot school to maintain the quality of instruction specified in paragraph (a) of this section may be the basis for suspending or revoking that school's certificate.

(c) When requested by the Administrator, a pilot school or provisional pilot school must allow the FAA to perform any knowledge, practical, stage, or end-of-course test of its students;

(d) When a stage or end-of-course test is conducted by the FAA under the provisions of paragraph (c) of this section and the student has not completed the training course, then that test will be based on the standards prescribed in the school's approved training course; and

(e) If the practical or knowledge test, administered by the FAA under the provisions of paragraph (c) of this section that is given to a student who has completed the school's training course will be based upon the areas of operation approved by the Administrator.

§ 141.85 Chief instructor responsibilities.

(a) Each person designated as a chief instructor for a pilot school or provisional pilot school shall be responsible for:

(1) Certifying each student's training record, graduation certificate, stage check and end-of-course test reports, recommendation for course completion, and application for certification;

(2) Ensuring that each instructor satisfactorily accomplishes an initial proficiency check prior to that instructor being assigned instructing duties in the school's approved training courses and thereafter passes a recurrent proficiency check every 12-calendar months after the month in which the initial test was accomplished;

(3) Ensuring each student accomplishes the required stage check and end-of-course tests in accordance with the school's approved training course; and

(4) Maintaining training techniques, procedures, and standards for the school that are acceptable to the Administrator.

(b) The chief instructor or an assistant chief instructor must be available at the pilot school or, if away from the pilot school, be available by telephone, radio, or other electronic means, during the time that training is given for an approved training course.

(c) The chief instructor may delegate authority for conducting stage checks, end-of-course tests, and flight instructor proficiency checks to the assistant chief instructor or a check instructor.

§ 141.87 Change of chief instructor.

Whenever a pilot school or provisional pilot school makes a change of designation of its chief instructor, that school:

(a) Must immediately provide the FAA FSDO, that has jurisdiction over the area in which the school is located, with written notification of the change;

(b) May conduct training without a chief instructor for that training course for a period not to exceed 60 days while awaiting the designation and approval of another chief instructor;

(c) May, for a period not to exceed 60 days, have the stage and end-of-course tests given by—

(1) The training course's assistant chief instructor, if one has been designated;

(2) The training course's check instructor, if one has been designated;

(3) An FAA inspector; or

(4) An examiner.

(d) Must, after 60 days without a chief instructor, cease operations and surrender its school certificate to the Administrator; and

(e) The school may have its certificate reinstated, upon:

(1) Designating and approving another chief instructor;

(2) Showing it meets the requirements of § 141.27(a)(2) of this part; and

(3) Applying for reinstatement on a form and in a manner prescribed by the Administrator.

§ 141.89 Maintenance of personnel, facilities, and equipment.

The holder of a pilot school or provisional pilot school certificate may not give training to a student who is enrolled in an approved course of training unless:

(a) Each airport, aircraft, and facility necessary for that training meets the standards specified in the holder's approved training course outline and the appropriate requirements of this part; and

(b) Except as provided in § 141.87 of this part, each chief instructor, assistant chief instructor, check instructor, or instructor meets the qualifications specified in the holder's approved course of training and the appropriate requirements of this part.

§ 141.91 Satellite bases.

The holder of a pilot school or provisional pilot school certificate may conduct ground or flight training in an approved course of training at a base other than its main operations base if:

(a) An assistant chief instructor is designated for each satellite base, and

that assistant chief instructor must be available at the satellite pilot school or, if away from the premises, by telephone, radio, or other electronic means during the time that training is given for an approved training course;

(b) The airport, facilities, and personnel used at the satellite base meet the appropriate requirements of subpart B of this part and its approved training course outline;

(c) The instructors are under the direct supervision of the chief instructor or assistant chief instructor for the appropriate training course who is readily available for consultation in accordance with § 141.85(b) of this part; and

(d) The FAA Flight Standards District Office having jurisdiction over the area in which the school is located is notified in writing if training or instruction is conducted there for more than 7 consecutive days.

§ 141.93 Enrollment.

(a) The holder of a pilot school or a provisional pilot school certificate must, at the time a student is enrolled in an approved training course, furnish that student with the following:

(1) A certificate of enrollment containing—

(i) The name of the course in which the student is enrolled; and

(ii) The date of that enrollment.

(2) A copy of the training syllabus.

(b) The holder of a pilot school or provisional pilot school certificate must maintain a monthly listing of persons enrolled in each training course offered by the school.

§ 141.95 Graduation certificate.

(a) The holder of a pilot school or provisional pilot school certificate shall issue a graduation certificate to each student who completes its approved course of training.

(b) The graduation certificate must be issued to the student upon completion of the course of training and contain at least the following information:

(1) The name of the school and the number of the school certificate;

(2) The name of the graduate to whom it was issued;

(3) The course of training for which it was issued;

(4) The date of graduation;

(5) A statement that the student has satisfactorily completed each required stage of the approved course of training including the tests for those stages;

(6) The information contained on the graduation certificate must be certified by the chief instructor for that course of training; and

(7) A statement showing the cross-country training the student received in the course of training.

Subpart F—Records

§ 141.101 Training records.

(a) Each holder of a pilot school or provisional pilot school certificate must establish and maintain a current and accurate record of the participation and accomplishment of each student enrolled in an approved course of training conducted by the school, that includes the following:

(1) The record kept in a student's logbook will not suffice for the record required by this paragraph of this section; and

(2) The record must include the following information:

(i) The date the student was enrolled in the approved course;

(ii) A chronological log of the student's course attendance, subjects and flight operations covered in the student's training, and the names and grades of any tests taken by the student; and

(iii) The date the student graduated, terminated training, or transferred to another school.

(b) Whenever a student graduates, terminates training, or transfers to another school, the student's record must be certified to that effect by the chief instructor;

(c) The holder of a certificate for a pilot school or a provisional pilot school must retain each student record required by this section for at least 1 year from the date that the student:

(1) Graduates from the course to which the record pertains;

(2) Terminates enrollment in the course to which the record pertains; or

(3) Transfers to another school; and

(d) The holder of a certificate for a pilot school or a provisional pilot school must, upon request of a student, make a copy of the student's record available to the student.

Appendix A—Recreational Pilot Certification Course

1. *Applicability.* This appendix prescribes the minimum curriculum required for a recreational pilot certification course under this part, for:

(a) An airplane category with a single-engine class rating.

(b) A rotorcraft category with a helicopter class rating.

(c) A rotorcraft category with a gyroplane class rating.

2. *Eligibility for enrollment.* A person must have the following to enroll in the flight portion of the recreational pilot certification course:

(a) A student pilot certificate; and

(b) A signed and dated statement affixed to the application certifying that no known medical defect exists that would make the person unable to pilot an aircraft for the aircraft category and class rating sought.

3. *Aeronautical knowledge training.* Each approved course must include at least 20 hours of training on the following aeronautical knowledge areas, appropriate to the aircraft category and class for which the course applies:

(a) The applicable Federal Aviation Regulations for recreational pilot privileges, limitations, and flight operations, appropriate to the aircraft category and class rating for which the course applies;

(b) Accident reporting requirements of the National Transportation Safety Board;

(c) The applicable subjects in the ''Airman's Information Manual'' and the appropriate FAA advisory circulars;

(d) The use of aeronautical charts for VFR navigation using pilotage with the aid of a magnetic compass;

(e) The recognition of critical weather situations from the ground and in flight, windshear avoidance, and the procurement and use of aeronautical weather reports and forecasts;

(f) The safe and efficient operation of aircraft, including collision avoidance, and recognition and avoidance of wake turbulence and windshear conditions;

(g) The effects of density altitude on takeoff and climb performance;

(h) Weight and balance computations;

(i) Principles of aerodynamics, powerplants, and aircraft systems;

(j) Stall awareness, spin entry, spins, and spin recovery techniques, if applying for an airplane single engine rating; and

(k) Aeronautical decision making and judgment;

(l) Preflight action that includes—

(1) How to obtain information on runway lengths at airports of intended use, data on takeoff and landing distances, weather reports and forecasts, and fuel requirements;

(2) How to plan for alternatives if the planned flight cannot be completed; and

(3) Proper planning procedures for possible traffic delays.

4. *Flight training.* (a) Each approved course must include at least 30 hours of flight training (of which 15 hours must be with an authorized flight instructor and 3 hours must be supervised PIC training), on the areas of operation listed in section 4.(c) of this appendix, that are appropriate to the aircraft category and class rating for which the course applies, and must include:

(1) Except as provided in § 61.100 of this chapter, 2 hours of flight training to

and at an airport that is located more than 25 nautical miles from the airport where the applicant normally trains, which includes at least 3 takeoffs and 3 landings; and

(2) Three hours of flight training in the aircraft, that is appropriate to the aircraft category and class for which the course applies, in preparation for the practical test within 60 days preceding the date of the practical test.

(b) Each training flight must include a preflight briefing and a postflight critique of the student by the flight instructor assigned to that flight.

(c) *Areas of operation.* Flight training must include the following approved areas of operation appropriate to the aircraft category and class rating for which the course applies:

(1) *For an airplane-single engine course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance maneuvers;

(vi) Ground reference maneuvers;

(vii) Navigation;

(viii) Stalls and slow flight;

(ix) Emergency operations; and

(x) Postflight procedures.

(2) *For a rotorcraft-helicopter course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and heliport operations;

(iv) Hovering maneuvers;

(v) Takeoffs, landings, and go-arounds;

(vi) Performance maneuvers;

(vii) Navigation;

(viii) Emergency operations; and

(ix) Postflight procedures.

(3) *For a rotorcraft-gyroplane course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance maneuvers;

(vi) Ground reference maneuvers;

(vii) Navigation;

(viii) Flight at slow airspeeds;

(ix) Emergency operations; and

(x) Postflight procedures.

5. *Supervised pilot-in-command practice.* Each approved course must include at least 3 hours of supervised pilot-in-command practice on the areas of operation listed in section 4.(c) of this appendix, that is appropriate to the aircraft category and class rating for which the course applies.

6. *Stage checks and end-of-course tests.*

(a) Each student enrolled in a recreational pilot course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, and must consist of the approved areas of operation of section 4 of this appendix for the aircraft category and class rating for which the course applies.

(b) Each student must demonstrate satisfactory proficiency prior to being endorsed to operate an aircraft in supervised PIC flight.

Appendix B—Private Pilot Certification Course

1. *Applicability.* This appendix prescribes the minimum curriculum for a private pilot certification course required under this part, for:

(a) An airplane category—single-engine class.

(b) An airplane category—multiengine class.

(c) A rotorcraft category—helicopter class.

(d) A rotorcraft category—gyroplane class.

(e) A powered-lift category.

(f) A glider category—nonpowered class.

(g) A glider category—powered class.

(h) A lighter-than-air category—airship class.

(i) A lighter-than-air category—balloon class.

2. *Eligibility for enrollment.* A person must have the following to enroll in the flight portion of the private pilot certification course:

(a) A student pilot certificate;

(b) Except for course of training for a rating in a glider or balloon, hold at least a valid third-class medical certificate issued under part 67 of this chapter.

(c) For a rating in a glider or a balloon, a signed and dated statement by the person certifying that the person has no known medical defect that makes the person unable to pilot a glider or balloon.

3. *Aeronautical knowledge training.* (a) Each approved course must include at least the aeronautical knowledge areas listed in section 3.(b) of this appendix, appropriate to the aircraft category and class rating, and must include at least:

(1) 35 hours of training, if the course is for an airplane, rotorcraft, or powered lift category rating.

(2) 15 hours of training, if the course is for a glider category rating.

(3) 10 hours of training, if the course is for a lighter-than-air category with a balloon class rating.

(4) 35 hours of training, if the course is for a lighter-than-air category with an airship class rating.

(b) *Aeronautical knowledge areas.*

(1) The applicable Federal Aviation Regulations for private pilot privileges, limitations, and flight operations;

(2) Accident reporting requirements of the National Transportation Safety Board;

(3) The applicable subjects of the ''Airman's Information Manual'' and the appropriate FAA advisory circulars;

(4) Aeronautical charts for VFR navigation using pilotage, dead reckoning, and radio aids;

(5) Radio communication procedures;

(6) The recognition of critical weather situations from the ground and in flight, windshear avoidance, and the procurement and use of aeronautical weather reports and forecasts;

(7) The safe and efficient operation of aircraft, including collision avoidance, and recognition and avoidance of wake turbulence and windshear conditions;

(8) The effects of density altitude on takeoff and climb performance;

(9) Weight and balance computations;

(10) Principles of aerodynamics, powerplants, and aircraft systems;

(11) If the course of training is for an airplane category or glider category rating, stall awareness, spin entry, spins, and spin recovery techniques;

(12) Aeronautical decision making and judgment; and

(13) Preflight action that includes—

(i) How to obtain information on runway lengths at airports of intended use, data on takeoff and landing distances, weather reports and forecasts, and fuel requirements;

(ii) How to plan for alternatives if the planned flight cannot be completed; and

(iii) Proper planning procedures for possible traffic delays.

4. *Flight training.* (a) Each approved course must include the following flight training on the areas of operation listed in section 4.(c) of this appendix, appropriate to the aircraft category and class rating for which the course applies, and must include:

(1) *For an airplane-single engine course.* At least 35 hours of flight training (of which 20 hours must be with an authorized flight instructor and 5 hours must be supervised PIC training), on the approved areas of operation in section 4.(c)(1) of this appendix, and the training must include at least—

(i) Except as provided in § 61.111 of this chapter, 3 hours of cross-country flight training in a single engine airplane;

(ii) Except as provided in § 61.110 of this chapter, 3 hours of night flight training in a single engine airplane that includes—

(A) One cross country flight over 100 nautical miles duration; and

(B) Ten takeoffs and 10 landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of instrument flight training in a single engine airplane; and

(iv) Three hours of flight training in preparation for the practical test in a single engine airplane, and must have been performed within 60 days preceding the date of the test.

(2) *For an airplane-multiengine course.* At least 35 hours of flight training (of which 20 hours must be with an authorized flight instructor and 5 hours must be supervised PIC training), on the approved areas of operation in section 4.(c)(2) of this appendix, and the training must include at least—

(i) Except as provided in § 61.111 of this chapter, 3 hours of cross-country flight training in a multiengine airplane;

(ii) Except as provided in § 61.110 of this chapter, 3 hours of night flight training in a multiengine airplane that includes—

(A) One cross country flight over 100 nautical miles duration; and

(B) Ten takeoffs and 10 landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of instrument flight training in a multiengine airplane; and

(iv) Three hours of flight training in preparation for the practical test in a multiengine airplane, and must have been performed within 60 days preceding the date of the test.

(3) *For a rotorcraft-helicopter course.* At least 35 hours of flight training (of which 20 hours must be with an authorized flight instructor and 5 hours must be supervised PIC training), on the approved areas of operation in section 4.(c)(3) of this appendix, and the training must include at least—

(i) Except as provided in § 61.111 of this chapter, 3 hours of cross-country flight training in a helicopter;

(ii) Except as provided in § 61.110 of this chapter, 3 hours of night flight training in a helicopter that includes—

(A) One cross country flight over 50 nautical miles duration; and

(B) Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of flight training in preparation for the practical test in a helicopter, and must have been performed within 60 days preceding the date of the test.

(4) *For a rotorcraft-gyroplane course.* At least 35 hours of flight training (of which 20 hours must be with an authorized flight instructor and 5 hours must be supervised PIC training), on the approved areas of operation in section 4.(c)(4) of this appendix, and the training must include at least—

(i) Except as provided in § 61.111 of this chapter, 3 hours of cross-country flight training in a gyroplane;

(ii) Except as provided in § 61.110 of this chapter, 3 hours of night flight training in a gyroplane that includes—

(A) One cross country flight over 50 nautical miles duration; and

(B) Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of flight training in preparation for the practical test in a gyroplane, and must have been performed within 60 days preceding the date of the test.

(5) *For a powered-lift course.* At least 35 hours of flight training (of which 20 hours must be with an authorized flight instructor and 5 hours must be supervised PIC training), on the approved areas of operation in section 4.(c)(5) of this appendix, and the training must include at least—

(i) Except as provided in § 61.111 of this chapter, 3 hours of cross-country flight training in a powered-lift;

(ii) Except as provided in § 61.110 of this chapter, 3 hours of night flight training in a powered-lift that includes—

(A) One cross country flight over 100 nautical miles duration; and

(B) Ten takeoffs and ten landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of instrument flight training in a powered-lift; and

(iv) Three hours of flight training in preparation for the practical test in a powered-lift, and must have been performed within 60 days preceding the date of the test.

(6) *For a glider-nonpowered course.* At least 5 hours and 10 flights of flight training time from an authorized flight instructor, on the approved areas of operation in section 4.(c)(6) of this appendix, and the training must include—

(i) At least 3 flights of flight training in a nonpowered glider, in preparation for the practical test within 60 days preceding the test; and

(ii) In addition, if the course covers winch or auto tow procedures, the flight training must include at least 5 flights of flight training and 2 supervised PIC flight in a nonpowered glider on the appropriate approved areas of operation listed in section 4.(c)(6) of this appendix.

(7) *For a glider-powered course.* At least 5 hours of flight training time from an authorized flight instructor, on the approved areas of operation in section 4.(c)(7) of this appendix, and the training must include at least 3 flights of flight training in a powered glider, in preparation for the practical test within 60 days preceding the date of the test.

(8) *For a lighter than air-airship course.* At least 20 hours of flight training from an authorized flight instructor, on the approved areas of operation in section 4.(c)(8) of this appendix, and the training must include at least—

(i) Except as provided in § 61.111 of this chapter, 3 hours of cross-country flight training in an airship;

(ii) Except as provided in § 61.110 of this chapter, 3 hours of night flight training in an airship that includes—

(A) One cross country flight over 25 nautical miles duration; and

(B) Five takeoffs and five landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport.

(iii) Three hours of instrument flight training in an airship; and

(iv) Three hours of flight training in preparation for the practical test in an airship, and must have been performed within 60 days preceding the date of the test.

(9) *For a lighter than air-balloon course.* At least 8 hours of flight training that includes at least 5 flights of flight training from an authorized flight instructor, on the approved areas of operation in section 4.(c)(9) of this appendix, and includes—

(i) If the training is being performed in a gas balloon, the training must include at least—

(A) Two flights of 1 hour each;

(B) One flight involving a controlled ascent to 5,000 feet above the surface; and

(C) Two flights in preparation for the practical test within 60 days preceding the test.

(ii) If the training is being performed in a balloon with an airborne heater, the training must include at least—

(A) Two flights of 30 minutes each;

(B) One flight involving a controlled ascent to 3,000 feet above the surface; and

(C) Two flights in preparation for the practical test within 60 days preceding the test.

(b) *Use of flight training devices.*

(1) The course may include training in a flight training device, provided they are representative of the aircraft for which the course is approved for, meet requirements of this paragraph, and the training is given by an authorized ground or flight instructor.

(2) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

(c) *Areas of operation.* Each approved course must include the flight training on the areas of operation listed in this paragraph, that are appropriate to the aircraft category and class rating for which the course applies:

(1) *Areas of operation for a single engine airplane course:* Areas of operation for an airplane-single engine course are the following—

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and seaplane base operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance maneuvers;

(vi) Ground reference maneuvers;

(vii) Navigation;

(viii) Stalls and slow flight;

(ix) Basic instrument maneuvers;

(x) Emergency operations;

(xi) Night operations, except as provided in § 61.110 of this chapter; and

(xii) Postflight procedures.

(2) *Areas of operations for a multiengine airplane course:* Areas of operation for an airplane-multiengine course are the following—

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and seaplane base operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance maneuvers;

(vi) Ground reference maneuvers;

(vii) Navigation;

(viii) Stalls and slow flight;

(ix) Basic instrument maneuvers;

(x) Emergency operations;

(xi) Multiengine operations;

(xii) Night operations, except as provided in § 61.110 of this chapter; and

(xiii) Postflight procedures.

(3) *Areas of operation for a rotorcraft-helicopter course:* Areas of operation for a rotorcraft-helicopter course are the following—

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and heliport operations;

(iv) Hovering maneuvers;

(v) Takeoffs, landings, and go-arounds;
(vi) Performance maneuvers;
(vii) Navigation;
(viii) Emergency operations;
(ix) Night operations, except as provided in § 61.110 of this chapter; and
(x) Postflight procedures.

(4) *Areas of operation for a rotorcraft-gyroplane course:* Areas of operation for a rotorcraft-gyroplane course are the following—
(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Airport operations;
(iv) Takeoffs, landings, and go-arounds;
(v) Performance maneuvers;
(vi) Ground reference maneuvers;
(vii) Navigation;
(viii) Flight at slow airspeeds;
(ix) Emergency operations;
(x) Night operations, except as provided in § 61.110 of this chapter; and
(xi) Postflight procedures.

(5) *Areas of operation for a powered-lift course:*
Areas of operation for a powered-lift course are the following—
(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Airport and heliport operations;
(iv) Hovering maneuvers;
(v) Takeoffs, landings, and go-arounds;
(vi) Performance maneuvers;
(vii) Ground reference maneuvers;
(viii) Navigation;
(ix) Stalls and slow flight;
(x) Basic instrument maneuvers;
(xi) Emergency operations;
(xii) Night operations, except as provided in § 61.110 of this chapter; and
(xiii) Postflight procedures.

(6) *Areas of operations for a glider-nonpowered course:* Areas of operation for a glider-nonpowered course are the following—
(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Airport and gliderport operations;
(iv) Launches and landings;
(v) Performance speeds;
(vi) Soaring techniques;
(vii) Performance maneuvers;
(viii) Navigation;
(ix) Stalls and slow flight;
(x) Emergency operations; and
(xi) Postflight procedures.

(7) *Areas of operation for a glider-powered course:* Areas of operation for a glider-powered course are the following—
(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Airport and gliderport operations;
(iv) Takeoffs, landings, and go-arounds;
(v) Performance speeds;
(vi) Soaring techniques;
(vii) Performance maneuvers;
(viii) Navigation;
(ix) Stalls and slow flight;
(x) Emergency operations; and
(xi) Postflight procedures.

(8) *Areas of operation for a lighter than air-airship course:* Areas of operation for a lighter than air-airship course are the following—
(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Airport operations;
(iv) Takeoffs, landings, and go-arounds;
(v) Performance maneuvers;
(vi) Ground reference maneuvers;
(vii) Navigation;
(viii) Emergency operations; and
(ix) Postflight procedures.

(9) *Areas of operation for a lighter than air-balloon course:* Areas of operation for a lighter than air category-balloon course are the following—
(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Balloonport operations;
(iv) Lift-offs and landings;
(v) Performance maneuvers;
(vi) Navigation;
(vii) Emergency operations; and
(viii) Postflight procedures.

5. *Supervised pilot-in-command practice.* Each approved course must include the following supervised pilot-in-command practice on the areas of operation listed in section 4.(c) of this appendix, appropriate to the aircraft category and class rating for which the course applies, and must include:

(a) *For an airplane-single engine course.* At least 5 hours of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(1) of this appendix, and the training must include at least—

(1) One supervised PIC cross-country flight of at least more than 100 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and

(2) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(b) *For an airplane-multiengine course.* At least 5 hours of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(2) of this appendix, and the training must include at least—

(1) One supervised PIC cross-country flight over 100 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and

(2) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(c) *For a rotorcraft-helicopter course.* At least 5 hours of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(3) of this appendix, and the training must include at least—

(1) One supervised PIC cross-country flight over 50 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 25 nautical miles between the takeoff and landing locations; and

(2) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(d) *For a rotorcraft-gyroplane course.* At least 5 hours of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(4) of this appendix, and the training must include at least—

(1) One supervised PIC cross-country flight over 50 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 25 nautical miles between the takeoff and landing locations; and

(2) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(e) *For a powered-lift course.* At least 5 hours of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(5) of this appendix, and the training must include at least—

(1) One supervised PIC cross-country flight over 100 nautical miles duration, landings at a minimum of three points, and one route of the flight being a straight line distance of at least 50 nautical miles between the takeoff and landing locations; and

(2) Three takeoffs and three landings to a full stop (with each landing involving a flight in the traffic pattern) at an airport with an operating control tower.

(f) *For a glider-nonpowered course.*

(1) At least 2 flights of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(6) of this appendix; and

(2) If the course covers ground launch procedures, the supervised pilot in command time must include at least 2 flights using a winch or auto tow on the approved areas of operation in section 4.(c)(6) of this appendix.

(g) *For a glider-powered course.* At least 2 flights of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(7) of this appendix.

(h) *For a lighter than air-airship course.* At least 5 hours of supervised pilot-in-command time with an authorized flight instructor, on the approved areas of operation in section 4.(c)(8) of this appendix.

(i) *For a lighter than air-balloon course.* At least 2 flights of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(9) of this appendix, in the balloon for which the course applies.

6. *Stage checks and end-of-course tests.*

(a) Each student enrolled in a private pilot course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, and must consist of the approved areas of operation of section 4 of this appendix for the aircraft category and class rating for which the course applies.

(b) Each student must demonstrate satisfactory proficiency prior to being endorsed to operate an aircraft in supervised PIC flight.

Appendix C—Instrument Rating Course

1. *Applicability.* This appendix prescribes the minimum curriculum for an instrument rating course and an additional instrument rating course, required under this part, for:
(a) Instrument-airplane single-engine.
(b) Instrument-airplane multiengine.
(c) Instrument-helicopter.
(d) Instrument-airship.
(e) Instrument-powered-lift.

2. *Eligibility for enrollment.* A person must have the following to enroll in the flight portion of the instrument rating course:

(a) A private pilot certificate with an aircraft category and class rating appropriate to the instrument rating for which the course applies.

(b) At least a valid third-class medical certificate issued under part 67 of this chapter.

3. *Aeronautical knowledge training.*

(a) Each approved course must include the aeronautical knowledge areas listed in section 3.(b) of this appendix, appropriate to the instrument rating for which the course applies, and must include at least:

(1) 30 hours of training, if the course is for an initial instrument rating.

(2) 20 hours of training, if the course is for an additional instrument rating.

(b) Each approved course must include the following aeronautical knowledge areas:

(1) The applicable Federal Aviation Regulations for IFR flight operations;

(2) The appropriate information in the ''Airman's Information Manual;''

(3) The air traffic control system and procedures for instrument flight operations;

(4) IFR navigation and approaches by use of radio aids;

(5) Use of IFR en route and instrument charts procedure approach;

(6) The procurement and use of aviation weather reports and forecasts, and the elements of forecasting weather trends on the basis of that information and personal observation of weather conditions;

(7) The safe and efficient operation of aircraft under IFR and conditions appropriate to the instrument rating for which the course applies;

(8) The recognition of critical weather situations and windshear avoidance;

(9) Aeronautical decision making and judgment; and

(10) Flight deck resource management, to include crew communication and coordination.

4. *Flight training.*

(a) Each approved course must include the following flight training on the areas of operation listed in section 4.(d) of this appendix, appropriate to the instrument-aircraft category and class rating for which the course applies, and must include at least:

(1) 35 hours of instrument training, if the course is for an initial instrument rating.

(2) 15 hours of instrument training, if the course is for an additional instrument rating.

(b) *Use of flight training devices.*

(1) The course may include training in a flight training device, provided they are representative of the aircraft for which the course is approved for, meet requirements of this paragraph, and the training is given by an authorized ground or flight instructor.

(2) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

(c) In addition, each approved course must include the following flight training on the areas of operation listed in section 4.(d) of this appendix, appropriate to the instrument-aircraft category and class rating for which the course applies, and must include:

(1) *For an instrument-airplane single engine course.* Instrument training time from an authorized instructor, on the approved areas of operation in section 4.(d) of this appendix, and the training must include at least one cross country flight that—

(i) Is in a single engine airplane and is performed under IFR;

(ii) Is a distance of at least 250 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 100 nautical miles between airports;

(iii) Involves an instrument approach at each airport; and

(iv) Involves three different kinds of approaches with the use of navigation aids.

(2) *For an instrument-airplane multiengine course.* Instrument training time from an authorized instructor, on the approved areas of operation in section 4.(d) of this appendix, and the training must include at least one cross country flight that—

(i) Is in a multiengine airplane and is performed under IFR;

(ii) Is a distance of at least 250 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 100 nautical miles between airports;

(iii) Involves an instrument approach at each airport; and

(iv) Involves three different kinds of approaches with the use of navigation aids.

(3) *For an instrument-helicopter course.* Instrument training time from an authorized instructor, on the approved areas of operation in section 4.(d) of this appendix, and the training must include at least one cross country flight that—

(i) Is in a helicopter and is performed under IFR;

(ii) Is a distance of at least 100 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 50 nautical miles between airports;

(iii) Involves an instrument approach at each airport; and

(iv) Involves three different kinds of approaches with the use of navigation aids.

(4) *For an instrument-powered-lift course.* Instrument training time from an authorized instructor, on the approved areas of operation in section 4.(d) of this appendix, and the training must include at least one cross country flight that—

(i) Is in a powered-lift and is performed under IFR;

(ii) Is a distance of at least 250 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 100 nautical miles between airports;

(iii) Involves an instrument approach at each airport; and

(iv) Involves three different kinds of approaches with the use of navigation aids.

(5) *For an instrument-airship course.* Instrument training time from an authorized instructor, on the approved areas of operation in section 4.(d) of this appendix, and the training must include at least one cross country flight that—

(i) Is in an airship and is performed under IFR;

(ii) Is a distance of at least 50 nautical miles along airways or ATC-directed routing with one of the routes being at least a straight-line distance of 25 nautical miles between airports;

(iii) Involves an instrument approach at each airport; and

(iv) Involves three different kinds of approaches with the use of navigation aids.

(d) *Areas of operation:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Air traffic control clearances and procedures;

(iv) Flight by reference to instruments;

(v) Navigation aids;

(vi) Instrument approach procedures;

(vii) Emergency operations; and

(viii) Postflight procedures.

5. *Stage checks and end-of-course tests.*

Each student enrolled in an instrument rating course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, and must consist of the appropriate approved areas of operation of section 4 of this appendix for the aircraft category and class rating for which the course applies.

Appendix D—Commercial Pilot Certification Course.

1. *Applicability.* This appendix prescribes the minimum curriculum for a commercial pilot certification course required under this part, for:

(a) Airplane category—single-engine class.

(b) Airplane category—multiengine class.

(c) Rotorcraft category—helicopter class.

(d) Rotorcraft category—gyroplane class.

(e) Powered-lift category.

(f) Glider category—nonpowered class.

(g) Glider category—powered class.

(h) Lighter-than-air category—airship class.

(i) Lighter-than-air category—balloon class.

2. *Eligibility for enrollment.*

(a) A person must have the following to enroll in the flight portion of the commercial pilot certification course:

(1) At least a private pilot certificate;

(2) At least a valid third-class medical certificate issued under part 67 of this chapter for a rating in an aircraft other than a glider or a balloon;

(3) A signed and dated statement affixed to the application certifying that no known

medical defect exists that would make the person unable to pilot a glider or balloon, as appropriate; and

(4) If the course is for a rating in an airplane, powered-lift category, or an airship class, then the person must—

(i) Hold an instrument rating in the aircraft that is appropriate to the aircraft category and class rating for which the course applies; or

(ii) Be concurrently enrolled in an instrument rating course that is appropriate to the aircraft category and class rating for which the course applies and satisfactorily accomplish the required instrument rating practical test prior to completing the commercial pilot certification course.

(b) A person must meet the aeronautical experience requirements prescribed in part 61 of this chapter for a commercial pilot certificate that is appropriate to the aircraft category and class rating for which the course applies upon completion of this course.

3. *Aeronautical knowledge training.*

(a) Each approved course must include the aeronautical knowledge areas listed in paragraph (b) of this section, appropriate to the aircraft category and class rating for which the course applies, and must include at least:

(1) 100 hours of training, if the course is for an airplane category rating, powered lift category rating, or a lighter-than-air category with an airship class rating.

(2) 65 hours of training, if the course is for a rotorcraft category rating.

(3) 25 hours of training, if the course is for a glider category rating.

(4) 20 hours of training, if the course is for a lighter-than-air category with a balloon class rating.

(b) *Aeronautical knowledge areas.* Each approved course must include the aeronautical knowledge areas listed in this paragraph, appropriate to the aircraft category and class rating for which the course applies:

(1) The Federal Aviation Regulations that apply to commercial pilot privileges, limitations, and flight operations;

(2) Accident reporting requirements of the National Transportation Safety Board;

(3) Basic aerodynamics and the principles of flight;

(4) Meteorology to include recognition of critical weather situations, windshear recognition and avoidance, and the use of aeronautical weather reports and forecasts;

(5) Safe and efficient operation of aircraft;

(6) Weight and balance computations;

(7) Use of performance charts;

(8) Significance and effects of exceeding aircraft performance limitations;

(9) Use of aeronautical charts and magnetic compass for pilotage and dead reckoning;

(10) Use of air navigation facilities;

(11) Aeronautical decision making and judgement;

(12) Principles and functions of aircraft systems;

(13) Maneuvers, procedures, and emergency operations appropriate to the aircraft;

(14) Night and high altitude operations; and

(15) Descriptions of and procedures for operating within the National Airspace System.

4. *Flight training.*

(a) Each approved course must include the following flight training on the areas of operation listed in paragraph (c) of this section, appropriate to the aircraft category and class rating for which the course applies, and must include:

(1) *For an airplane-single engine course.* At least 20 hours of training on the approved areas of operation listed in paragraph (c)(1) of this section that includes at least—

(i) Five hours of instrument training in a single engine airplane;

(ii) Ten hours of training in a single engine airplane that has a retractable landing gear, flaps, and a controllable pitch propeller, or is turbine-powered;

(iii) One cross-country flight in a single engine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iv) Except as provided in § 61.131 of this chapter, one cross-country flight in a single engine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(v) Three hours in a single engine airplane, in preparation for the practical test within the 60 days preceding the date of the test.

(2) *For an airplane-multiengine course.* At least 20 hours of training on the approved areas of operation listed in paragraph (c)(2) of this section that includes at least—

(i) Five hours of instrument training in a multiengine airplane;

(ii) Ten hours of training in a multiengine airplane that has a retractable landing gear, flaps, and a controllable pitch propeller, or is turbine-powered;

(iii) One cross-country flight in a multiengine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iv) Except as provided in § 61.131 of this chapter, one cross-country flight in a multiengine airplane of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(v) Three hours in a multiengine airplane, in preparation for the practical test within the 60 days preceding the date of the test.

(3) *For a rotorcraft-helicopter course.* At least 20 hours of training on the approved areas of operation listed in paragraph (c)(3) of this section that includes at least—

(i) Five hours of instrument training in a helicopter;

(ii) One cross-country flight in a helicopter of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iii) Except as provided in § 61.131 of this chapter, one cross-country flight in a helicopter of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(iv) Three hours in a helicopter, in preparation for the practical test within the 60 days preceding the date of the test.

(4) *For a rotorcraft-gyroplane course.* At least 20 hours of training on the approved areas of operation listed in paragraph (c)(4) of this section that includes at least—

(i) Five hours of instrument training in a gyroplane;

(ii) One cross-country flight in a gyroplane of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iii) Except as provided in § 61.131 of this chapter, one cross-country flight in a gyroplane of at least 2 hours in duration, a total straight-line distance of more than 50 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(iv) Three hours in a gyroplane, in preparation for the practical test within the 60 days preceding the date of the test.

(5) *For a powered-lift course.* At least 20 hours of training on the approved areas of operation listed in paragraph (c)(5) of this section that includes at least—

(i) Five hours of instrument training in a powered-lift;

(ii) One cross-country flight in a powered-lift of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in day-VFR conditions;

(iii) Except as provided in § 61.131 of this chapter, one cross-country flight in a powered-lift of at least 2 hours in duration, a total straight-line distance of more than 100 nautical miles from the original point of departure, and occurring in night-VFR conditions; and

(iv) Three hours in a powered-lift, in preparation for the practical test within the 60 days preceding the date of the test.

(6) *For a nonpowered glider course.* At least 10 hours of flight training and 10 flights on the approved areas of operation of paragraph (c)(6) of this section, that includes—

(i) At least 3 flights in preparation for the practical test within the 60 days preceding the date of the test; and

(ii) If the course is for ground launch procedures privileges, the course must also include at least 5 flights of flight training in a nonpowered glider using a winch or auto tow on the approved areas of operation of paragraph (c)(6) of this section.

(7) *For a powered glider course.* At least 10 hours of flight training on the approved areas of operation of paragraph (c)(7) of this section, that includes at least 3 hours in preparation for the practical test within the 60 days preceding the date of the test;

(8) *For an airship course.* At least 20 hours of training in airships on the approved areas of operation in paragraph (c)(8) of this section, which includes at least—

(i) Three hours in an airship, in preparation for the practical test within the 60 days preceding the date of the test;

(ii) Five hours of instrument training in airships;

(iii) One cross-country flight in an airship of at least 1 hour in duration, a total straight-

line distance of more than 25 nautical miles from the original point of departure, and occurring in day-VFR conditions; and

(iv) One cross-country flight in an airship of at least 1 hour in duration, a total straight-line distance of more than 25 nautical miles from the original point of departure, and occurring in night-VFR conditions, except as provided in § 61.131 of this chapter.

(9) *For a balloon course.* At least 10 hours of flight training that includes at least 10 flights of flight training in balloons on the approved areas of operation of paragraph (c)(9) of this section, and includes—

(i) If the course is involves training in a gas balloon, the training must include at least—

(A) Two flights of 1 hour each in a gas balloon;

(B) One flight in a gas balloon involving a controlled ascent to 10,000 feet above the surface; and

(C) Two flights in a gas balloon, in preparation for the practical test within the 60-day period preceding the date of the test.

(ii) If the course involves training in a balloon with an airborne heater, the training must include at least—

(A) Two flights of 30 minutes each in a balloon with an airborne heater;

(B) One flight involving a controlled ascent to 5,000 feet above the surface in a balloon with an airborne heater; and

(C) Two flights in a balloon with an airborne heater, in preparation for the practical test within the 60-day period preceding the date of the test.

(b) *Use of flight training devices.*

(1) Training in a flight training device may be included in the course, provided it is representative of the aircraft for which the course is approved for, meets the requirements of this paragraph, and is given by an authorized ground or flight instructor.

(2) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

(c) *Areas of operation.* Each approved course must include the flight training on the areas of operation listed in this paragraph, that are appropriate to the aircraft category and class rating for which the course applies:

(1) *For an airplane-single engine course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and seaplane base operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance maneuvers;

(vi) Navigation;

(vii) Stalls and slow flight;

(viii) Emergency operations;

(ix) High altitude operations; and

(x) Postflight procedures.

(2) *For an airplane-multiengine course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and seaplane base operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance maneuvers;

(vi) Navigation;

(vii) Stalls and slow flight;

(viii) Emergency operations;

(ix) Multiengine operations;

(x) High altitude operations; and

(xi) Postflight procedures.

(3) *For a rotorcraft-helicopter course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and heliport operations;

(iv) Hovering maneuvers;

(v) Takeoffs, landings, and go-arounds;

(vi) Performance maneuvers;

(vii) Navigation;

(viii) Emergency operations;

(ix) Special operations; and

(x) Postflight procedures.

(4) *For a rotorcraft-gyroplane course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance maneuvers;

(vi) Navigation;

(vii) Flight at slow airspeeds;

(viii) Emergency operations; and

(ix) Postflight procedures.

(5) *For a powered-lift course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and heliport operations;

(iv) Hovering maneuvers;

(v) Takeoffs, landings, and go-arounds;

(vi) Performance maneuvers;

(vii) Navigation;

(viii) Stalls and slow flight;

(ix) Emergency operations;

(x) High altitude operations;

(xi) Special operations; and

(xii) Postflight procedures.

(6) *For a glider-nonpowered course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and gliderport operations;

(iv) Launches and landings;

(v) Performance speeds;

(vi) Soaring techniques;

(vii) Performance maneuvers;

(viii) Navigation;

(ix) Stalls and slow flight;

(x) Emergency operations; and

(xi) Postflight procedures.

(7) *For a glider-powered course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport and gliderport operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance speeds;

(vi) Soaring techniques;

(vii) Performance maneuvers;

(viii) Navigation;

(ix) Stalls and slow flight;

(x) Emergency operations; and

(xi) Postflight procedures.

(8) *For a lighter than air-airship course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Airport operations;

(iv) Takeoffs, landings, and go-arounds;

(v) Performance maneuvers;

(vi) Navigation;

(vii) Emergency operations; and

(viii) Postflight procedures.

(9) *For a lighter than air-balloon course:*

(i) Preflight preparation;

(ii) Preflight procedures;

(iii) Balloonport operations;

(iv) Lift-offs and landings;

(v) Performance maneuvers;

(vi) Navigation;

(vii) Emergency operations; and

(viii) Postflight procedures.

5. *Supervised pilot-in-command training.* Each approved course must include supervised pilot-in-command practice on the areas of operation listed in section 4.(c) of this appendix, appropriate to the aircraft category and class rating for which the course applies, and must include:

(a) *For an airplane-single engine course.* At least 10 hours of supervised PIC flying in a single engine airplane on the approved areas of operation in section 4.(c)(1) of this appendix, which includes at least—

(1) One cross-country flight, if the training is being performed in the state of Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(2) One cross-country flight, if the training is being performed in a State other than Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(3) 5 hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower, except as provided in § 61.131 of this chapter.

(b) *For an airplane-multiengine course.* At least 10 hours of supervised PIC flying in a multiengine airplane on the approved areas of operation in section 4.(c)(2) of this appendix, which includes at least—

(1) One cross-country flight, if the training is being performed in the state of Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(2) One cross-country flight, if the training is being performed in a State other than Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(3) 5 hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower, except as provided in § 61.131 of this chapter.

(c) *For a rotorcraft-helicopter course.* At least 10 hours of supervised PIC flying in a helicopter on the approved areas of operation in section 4.(c)(4) of this appendix, which includes at least—

(1) One cross-country flight, if the training is being performed in the state of Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(2) One cross-country flight, if the training is being performed in a State other than Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(3) 5 hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower, except as provided in § 61.131 of this chapter.

(d) *For a rotorcraft-gyroplane course.* At least 10 hours of supervised PIC flying in a gyroplane on the approved areas of operation in section 4.(c)(4) of this appendix, which includes at least—

(1) One cross-country flight, if the training is being performed in the state of Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(2) One cross-country flight, if the training is being performed in a State other than Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(3) 5 hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower, except as provided in § 61.131 of this chapter.

(e) *For a powered-lift course.* At least 10 hours of supervised PIC flying in a powered-lift on the approved areas of operation in section 4.(c)(5) of this appendix, which includes at least—

(1) One cross-country flight, if the training is being performed in the state of Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 150 nautical miles;

(2) One cross-country flight, if the training is being performed in a State other than Hawaii, that must involve landings at a minimum of three points and one of the routes having a straight-line distance of at least 250 nautical miles; and

(3) 5 hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) at an airport with an operating control tower, except as provided in § 61.131 of this chapter.

(f) *For a glider-nonpowered course.* At least 5 supervised PIC flights in a nonpowered glider on the approved areas of operation of section 4.(c)(6) of this appendix.

(g) *For a glider-powered course.* At least 5 supervised PIC flights in a powered glider on the approved areas of operation of section 4.(c)(7) of this appendix.

(h) *For a lighter than air-airship course.* At least 10 hours of pilot in command flight training with an authorized flight instructor in airships, on the approved areas of operation in section 4.(c)(8) of this appendix, which includes at least—

(i) One cross-country flight with landings at a minimum of three points, and one of the routes having a straight-line distance of at least 25 nautical miles from the original point of departure; and

(ii) 5 hours in night-VFR conditions with 10 takeoffs and 10 landings (with each landing involving a flight with a traffic pattern) except as provided in § 61.131 of this chapter.

(i) *For a lighter than air-balloon course.* At least 2 flights of supervised pilot-in-command time, on the approved areas of operation in section 4.(c)(9) of this appendix, in the balloon for which the course applies.

6. *Stage checks and end-of-course tests.*

(a) Each student enrolled in a commercial pilot course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the approved areas of operation of section 4 of this appendix for the aircraft category and class rating for which the course applies.

(b) Each student must demonstrate satisfactory proficiency prior to being endorsed to operate an aircraft in supervised PIC flight.

Appendix E—Airline Transport Pilot Certification Course

1. *Applicability.* This appendix prescribes the minimum curriculum for an airline transport pilot certification course under this part, for:

(a) An airplane category-single engine class rating.

(b) An airplane category-multiengine class rating.

(c) A rotorcraft category-helicopter class rating.

(d) A powered-lift category rating.

2. *Eligibility for enrollment.* A person must have the following to enroll in the flight portion of the airline transport pilot certification course:

(a) Meet at least one of the following requirements—

(1) Hold at least a commercial pilot certificate and an instrument rating;

(2) Meet the requirements of § 61.73 of this chapter to qualify for a commercial pilot certificate and an instrument rating, in the case of a person who is a rated pilot in the U.S. military; or

(3) Hold either a foreign airline transport pilot or foreign commercial pilot license and an instrument rating, in the case of a person who holds a pilot license issued by a member State to the International Civil Aviation Organization.

(b) Hold at least a third-class medical certificate issued under part 67 of this chapter; and

(c) Meet the aeronautical experience requirements prescribed in subpart G, part 61 of this chapter for an airline transport pilot certificate that is appropriate to the aircraft category and class rating for which the course applies upon completion of this course.

3. *Aeronautical knowledge training.*

(a) Each approved course must include the aeronautical knowledge areas listed in paragraph (b) of this section, appropriate to the aircraft category and class rating, and must include at least 40 hours of training.

(b) *Aeronautical knowledge areas.*

(1) The applicable Federal Aviation Regulations of this chapter that relate to airline transport pilot privileges, limitations, and flight operations appropriate to the aircraft rating for which the course applies;

(2) Meteorology including knowledge of and effects of fronts, frontal characteristics, cloud formations, icing, and upper air-data;

(3) General system of weather and NOTAM collection, dissemination, interpretation, and use;

(4) Interpretation of weather charts, maps, forecasts, sequences, abbreviations, symbols, and use;

(5) National Weather Service function as it pertains to operation in the National Airspace System;

(6) Windshear and microburst awareness, identification, and avoidance;

(7) Principles of air navigation under instrument meteorological conditions in the National Airspace System;

(8) Air traffic control procedures and pilot responsibilities as they relate to en route operations, terminal area and radar operations, and instrument departure and approach procedures;

(9) Aircraft loading, weight and balance, use of charts, graphs, tables, formulas, and computations, and the effects on aircraft performance that are appropriate to the aircraft category and class rating for which the course applies;

(10) Aircraft aerodynamics relating to the aircraft's flight characteristics, performance, and normal and abnormal flight regimes and characteristics that are appropriate to the aircraft category and class rating for which the course applies;

(11) Flight crewmember physiological factors;

(12) Aeronautical decisionmaking and judgment; and

(13) Flight deck resource management to include crew communication and coordination.

4. *Flight training.*

(a) *Approved course requirements.*

(1) Flight training in the approved areas of operation of paragraph (c) of this section must be included in the aircraft category and class rating for which the course applies; and

(2) At least 25 hours of flight training, of which at least 15 hours must be instrument flight training, must be included in the aircraft for which the course applies.

(b) *Use of flight training devices.*

(1) Training in a flight training device may be included, provided it is representative of the aircraft for which the course is approved, meets the requirements of this paragraph, and is given by an authorized ground or flight instructor.

(2) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of

5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

(c) *Areas of operation.* Each approved course must include the flight training on the areas of operation listed in this paragraph, that are appropriate to the aircraft category and class rating for which the course applies:

(1) For an airplane category-single engine class rating with a type rating course, if a type rating is required, are as follows—

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

(2) For an airplane category-multiengine class rating with a type rating course, if a type rating is required, are as follows—

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

(3) For a powered-lift category rating with a type rating course, if a type rating is required, are as follows—

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

(4) For a rotorcraft category-helicopter class rating with a type rating course, if a type rating is required, are as follows—

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

5. *Stage checks and end-of-course tests.*

(a) Each student enrolled in an airline transport pilot course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the approved areas of operation of section 4.(c) of this appendix in the aircraft category and class rating for which the course applies.

(b) Each student must demonstrate satisfactory proficiency prior to being endorsed to operate an aircraft in supervised PIC flight.

Appendix F—Flight Instructor Certification Course

1. *Applicability.* This appendix prescribes the minimum curriculum for a flight instructor certification course and an additional flight instructor rating course required under this part, for:

(a) Airplane category—single-engine class.
(b) Airplane category—multiengine class.
(c) Rotorcraft category—helicopter class.
(d) Rotorcraft category—gyroplane class.
(e) Powered-lift category.
(f) Glider category—nonpowered class.
(g) Glider category—powered class.
(h) Lighter-than-air category—airship class.
(i) Lighter-than-air category—balloon class.

2. *Eligibility for enrollment.* A person must have the following to enroll in the flight portion of the flight instructor or additional flight instructor rating course:

(a) A commercial or an airline transport pilot certificate, with an aircraft category and class rating appropriate to the flight instructor rating for which the course applies; and

(b) An instrument rating in an aircraft that is appropriate to the aircraft category and class rating for which the course applies, if the course is for a flight instructor-airplane, -helicopter, -powered-lift, -airship, or -instrument-(category and class) rating.

3. *Aeronautical knowledge training.*

(a) *Approved course requirements.*

Each approved course must include the knowledge areas listed in paragraph (b) of this section, and must include at least:

(1) 40 hours of training, if the course is for an initial issuance of a flight instructor certificate; or

(2) 20 hours of training, if the course is for an additional flight instructor rating.

(b) *Aeronautical knowledge areas.*

(1) The learning process;
(2) Elements of effective teaching;
(3) Student evaluation, quizzing, and testing;
(4) Course development;
(5) Lesson planning;
(6) Classroom training techniques; and
(7) The aeronautical knowledge areas in which training is required for—

(i) A recreational, private, and commercial pilot certificate that is appropriate to the aircraft category and class rating for which the course applies; and

(ii) An instrument rating that is appropriate to the aircraft category and class rating for which the course applies, if the course is for an airplane or powered-lift category, or a lighter-than-air category with an airship class.

(c) *School hours credited.*

A student who satisfactorily completed 2 years of study on the principles of education in a college or university may be credited with no more than 20 hours of the required training in paragraph (a)(1) of this section.

4. *Flight training.*

(a) *Approved course requirements.*

Each approved course must include flight training in the approved areas of operation of paragraph (c) of this section for the flight instructor rating for which the course applies; and must include at least:

(1) Twenty-five hours, if the course is for an airplane, rotorcraft, or powered-lift category rating, or a lighter-than-air category with an airship class rating;

(2) Ten hours and 10 flights, if the course is for a glider category with a nonpowered class rating;

(3) Ten hours, if the course is for a glider category with a powered class rating; or

(4) Eight flights, if the course is for a lighter-than-air category with a balloon class rating.

(b) *Use of flight training devices.*

(1) The course may include training in a flight training device, provided they are representative of the aircraft for which the course is approved for, meet requirements of this paragraph, and the training is given by an authorized ground or flight instructor.

(2) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

(c) *Areas of operation.*

Each approved course must include the flight training on the areas of operation listed in this paragraph, that are appropriate to the aircraft category and class rating for which the course applies:

(1) *For an airplane-single engine course:*

(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Airport and seaplane base operations;
(vii) Takeoffs, landings, and go-arounds;
(viii) Fundamentals of flight;
(ix) Performance maneuvers;
(x) Ground reference maneuvers;
(xi) Stalls, spins, and slow flight;
(xii) Basic instrument maneuvers;
(xiii) Emergency operations; and
(xiv) Postflight procedures.

(2) *For an airplane-multiengine course:*

(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Airport and seaplane base operations;

(vii) Takeoffs, landings, and go-arounds;
(viii) Fundamentals of flight;
(ix) Performance maneuvers;
(x) Ground reference maneuvers;
(xi) Stalls and slow flight;
(xii) Basic instrument maneuvers;
(xiii) Emergency operations;
(xiv) Multiengine operations; and
(xv) Postflight procedures.
(3) *For a rotorcraft-helicopter course:*
(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Airport and heliport operations;
(vii) Hovering maneuvers;
(viii) Takeoffs, landings, and go-arounds;
(ix) Fundamentals of flight;
(x) Performance maneuvers;
(xi) Emergency operations;
(xii) Special operations; and
(xiii) Postflight procedures.
(4) *For a rotorcraft-gyroplane course:*
(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Airport operations;
(vii) Takeoffs, landings, and go-arounds;
(viii) Fundamentals of flight;
(ix) Performance maneuvers;
(x) Flight at slow airspeeds;
(xi) Ground reference maneuvers;
(xii) Emergency operations; and
(xiii) Postflight procedures.
(5) *For a powered-lift course:*
(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Airport and heliport operations;
(vii) Hovering maneuvers;
(viii) Takeoffs, landings, and go-arounds;
(ix) Fundamentals of flight;
(x) Performance maneuvers;
(xi) Ground reference maneuvers;
(xii) Stalls and slow flight;
(xiii) Basic instrument maneuvers;
(xiv) Emergency operations;
(xv) Special operations; and
(xvi) Postflight procedures.
(6) *For a glider-nonpowered course:*
(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Airport and gliderport operations;
(vii) Launches and landings;
(viii) Fundamentals of flight;
(ix) Performance speeds;
(x) Soaring techniques;
(xi) Performance maneuvers;
(xii) Stalls, spins, and slow flight;
(xiii) Emergency operations; and
(xiv) Postflight procedures.
(7) For a glider-powered course:
(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Airport and gliderport operations;
(vii) Takeoffs, landings, and go-arounds;
(viii) Fundamentals of flight;
(ix) Performance speeds;
(x) Soaring techniques;
(xi) Performance maneuvers;
(xii) Stalls, spins, and slow flight;
(xiii) Emergency operations; and
(xiv) Postflight procedures.
(8) *For a lighter than air-airship course:*
(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Airport operations;
(vii) Takeoffs, landings, and go-arounds;
(viii) Fundamentals of flight;
(ix) Performance maneuvers;
(x) Ground reference maneuvers;
(xi) Emergency operations; and
(xii) Postflight procedures.
(9) *For a lighter than air-balloon course:*
(i) Fundamentals of instructing;
(ii) Technical subject areas;
(iii) Preflight preparation;
(iv) Preflight lesson on a maneuver to be performed in flight;
(v) Preflight procedures;
(vi) Balloonport operations;
(vii) Lift-offs and landings;
(viii) Fundamentals of flight;
(ix) Performance maneuvers;
(x) Emergency operations; and
(xi) Postflight procedures.
5. *Stage check and end-of-course tests.*
(a) Each student enrolled in a flight instructor course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the appropriate approved areas of operation of section 4 of this appendix for the flight instructor rating for which the course applies.
(b) In the case of a student who is enrolled in a flight instructor-airplane rating or -glider rating course, that student must have:
(1) Received a logbook endorsement from an authorized flight instructor on ground and flight training on stall awareness, spin entry, spins, and spin recovery procedures in an aircraft that is certificated for spins and that applies to the rating sought; and
(2) Demonstrated instructional proficiency in stall awareness, spin entry, spins, and spin recovery procedures.

Appendix G——Flight Instructor Instrument (Aircraft Category and Class) Certification Course

1. *Applicability.* This appendix prescribes the minimum curriculum for a flight instructor instrument certification course required under this part, for:
(a) Flight Instructor Instrument—airplane single-engine.
(b) Flight Instructor Instrument—airplane multiengine.
(c) Flight Instructor Instrument—helicopter.
(d) Flight Instructor Instrument—airship.
(e) Flight Instructor Instrument—powered-lift.
2. *Eligibility for enrollment.* A person must have the following to enroll in the flight portion of the flight instructor instrument course:
(a) A commercial or airline transport pilot certificate with an aircraft category and class rating appropriate to the flight instructor category and class rating for which the course applies; and
(b) A flight instructor certificate with an aircraft category and class rating that is appropriate to the flight instructor instrument (category and class of aircraft) rating for which the course applies.
3. *Aeronautical knowledge training.*
(a) *Approved course requirements.*
Each approved course must include the aeronautical knowledge areas listed in paragraph (b) of this section, appropriate to the flight instructor instrument (category and class of aircraft) rating for which the course applies, and must include at least 15 hours of training.
(b) *Aeronautical knowledge areas.*
(1) Instrument rating aeronautical knowledge areas of this paragraph that are appropriate to the flight instructor instrument (category and class of aircraft) rating for which the course applies;
(2) Learning process;
(3) Elements of effective teaching;
(4) Student evaluation, quizzing, and testing;
(5) Course development;
(6) Lesson planning; and
(7) Classroom training techniques.
4. *Flight training.*
(a) *Approved course requirements.*
Each approved course must include at least 15 hours of flight training in the approved areas of operation of paragraph (b) of this section for the flight instructor rating for which the course applies.
(b) *Use of flight training devices.*
(1) The course may include training in a flight training device, provided they are representative of the aircraft for which the course is approved for, meet requirements of this paragraph, and the training is given by an authorized ground or flight instructor.
(2) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.
(3) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.
(4) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

(c) *Areas of operation.* Each approved course must include the flight training on the areas of operation listed in this paragraph (c)(2) of this section, that are appropriate to the instrument-aircraft category and class rating for which the course applies.

(2) For a flight instructor-instrument rating course.

(i) Fundamentals of instructing;

(ii) Technical subject areas;

(iii) Preflight preparation;

(iv) Preflight lesson on a maneuver to be performed in flight;

(v) Air traffic control clearances and procedures;

(vi) Flight by reference to instruments;

(vii) Navigation aids;

(viii) Instrument approach procedures;

(ix) Emergency operations; and

(x) Postflight procedures.

5. Stage check and end-of-course tests.

Each student enrolled in a flight instructor instrument course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the approved areas of operation of section 4 of this appendix for the flight instructor instrument (category and class of aircraft) rating for which the course applies.

Appendix H—Ground Instructor Certification Course

1. *Applicability.* This appendix prescribes the minimum curriculum for a ground instructor certification course and an additional ground instructor rating course, required under this part, for:

(a) Ground Instructor—Airplane category.

(b) Ground Instructor—Rotorcraft category.

(c) Ground Instructor—Glider category.

(d) Ground Instructor—Lighter-than-air category.

(e) Ground Instructor—Powered-lift category.

(f) Ground Instructor—Instrument.

2. *Aeronautical knowledge training.*

(a) *Approved course requirements.*

Each approved course must include the knowledge areas listed in paragraph (b) of this section, appropriate to the ground instructor category and class rating for which the course applies, and must include a total of at least:

(1) 20 hours of training, if the course is for an initial issuance of a ground instructor certificate; or

(2) 10 hours of training, if the course is for an additional ground instructor rating.

(b) Aeronautical knowledge areas.

(1) Learning process;

(2) Elements of effective teaching;

(3) Student evaluation, quizzing, and testing;

(4) Course development;

(5) Lesson planning;

(6) Classroom training techniques; and

(7) Aeronautical knowledge areas in which training is required for—

(i) A private and commercial pilot certificate that is appropriate to the category and class rating for which the course applies; and

(ii) An instrument rating, if applying for a ground instructor instrument rating.

(c) *School hours credited.*

A student who satisfactorily completed 2 years of study on the principles of education in a college or university may be credited with 10 hours of the required training in paragraph (a)(1) of this section.

3. *Stage check and end-of-course tests.*

Each student enrolled in a ground instructor course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the approved knowledge areas of section 2 of this appendix for the ground instructor rating for which the course applies.

Appendix I—Additional Aircraft Category or Class Rating Course

1. *Applicability.* This appendix prescribes the minimum curriculum for an additional aircraft category rating course or an additional aircraft class rating course required under this part, for:

(a) Airplane category—single-engine class.

(b) Airplane category—multiengine class.

(c) Rotorcraft category—helicopter class.

(d) Rotorcraft category—gyroplane class.

(e) Powered-lift category.

(f) Glider category—nonpowered class.

(g) Glider category—powered class.

(h) Lighter-than-air category—airship class.

(i) Lighter-than-air category—balloon class.

2. *Eligibility for enrollment.*

A person must have the following to enroll in the flight portion of an additional aircraft category or additional aircraft class rating course:

(a) The level of pilot certificate for the additional aircraft category or class rating for which the course applies.

(b) At least a valid third-class medical certificate issued under part 67 of this chapter, if the course is for a aircraft rating in other than a glider or balloon.

(c) A signed and dated statement affixed to the application certifying that no known medical defect exists that would make the person unable to pilot a glider or balloon, as appropriate.

3. *Aeronautical knowledge training.*

Each approved course for an additional aircraft category rating and additional aircraft class rating must include:

(a) The aeronautical knowledge training that apply to that aircraft rating by this part, and that are appropriate to the aircraft rating and pilot certificate level for which the course applies; and

(b) The total aeronautical knowledge training hours of each approved course must include the ground training time required by this part that are appropriate to the aircraft rating and pilot certificate level for which the course applies.

4. *Flight training.*

Each approved course for an additional aircraft category rating or additional aircraft class must include:

(a) The flight training on the approved areas of operation of this paragraph, that are appropriate to the aircraft rating and pilot certificate level for which the course applies.

(b) The total flight training time must include the training required by this part, that are appropriate to the aircraft rating and pilot certificate level for which the course applies.

(c) Flight training devices may be used when the course includes training in a flight training device, provided it is representative of the aircraft for which the course is approved, meets the requirements of this paragraph, and the training is given by an authorized ground or flight instructor.

(d) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(e) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(f) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

5. *Stage check and end-of-course tests.*

(a) Each student enrolled in an additional aircraft category rating course or an additional aircraft class rating course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the approved areas of operation of section 4 of this appendix that are appropriate the aircraft category and class rating for which the course applies at the appropriate pilot certificate level.

(b) Each student must demonstrate satisfactory proficiency prior to being endorsed to operate an aircraft in supervised PIC flight.

Appendix J—Aircraft Type Rating Course, for Other Than Airline Transport Pilot Certificate

1. *Applicability.* This appendix prescribes the minimum curriculum for an aircraft type rating course, for other than airline transport pilot certificate, for:

(a) A type rating in an airplane category—single engine class.

(b) A type rating in an airplane category—multiengine class.

(c) A type rating in a rotorcraft category—helicopter class.

(d) A type rating in a powered-lift category.

(e) Other aircraft type ratings specified by the Administrator through aircraft type certificate procedures.

2. *Eligibility for enrollment.*

A person must have the following to enroll in the flight portion of an aircraft type rating course:

(a) At least a private pilot certificate;

(b) At least a valid third-class medical certificate issued under part 67 of this chapter;

(c) An instrument rating in the category and class of aircraft that is appropriate to the aircraft type rating for which the course applies, provided the aircraft's type certificate does not have a VFR limitation, except as provided in paragraph (d) of this section; and

(d) Be concurrently enrolled in an instrument rating course in the category and class of aircraft that is appropriate to the aircraft type rating for which the course applies and satisfactorily accomplish the required instrument rating practical test concurrently with the aircraft type rating practical test.

3. *Aeronautical knowledge training.*

(a) *Approved course requirements.*

Each approved course must include the aeronautical knowledge areas listed in paragraph (b) of this section, appropriate to the aircraft type rating for which the course applies, and must include at least 15 hours of training.

(b) *Aeronautical knowledge areas.*

(1) Proper control of airspeed, configuration, direction, altitude, and attitude in accordance with procedures and limitations contained in the Aircraft's Flight Manual, checklists, or other approved material appropriate that apply to the aircraft type;

(2) Compliance with approved enroute, instrument approach, missed approach, ATC, or other applicable procedures that apply to the aircraft type;

(3) Subjects requiring a practical knowledge of the aircraft type, its powerplant, systems, components, operational, and performance factors;

(4) The aircraft's normal, abnormal, and emergency procedures, and the operations and limitations relating thereto;

(5) The appropriate provisions of the approved Aircraft's Flight Manual;

(6) Location and purpose of inspecting of each item on the aircraft's checklist that relate to the exterior and interior preflight; and

(7) Use of the aircraft's prestart checklist, appropriate control system checks, starting procedures, radio and electronic equipment checks, and the selection of proper navigation and communication radio facilities and frequencies.

4. *Flight training.*

(a) *Approved course requirements.*

Each approved course must include:

(1) Flight training on the approved areas of operation of paragraph (c) of this section in the aircraft type for which the course applies; and

(2) At least 25 hours of flight training of which at least 15 hours must be instrument flight training in the aircraft for which the course applies.

(b) *Use of flight training devices.*

(1) The course may include training in a flight training device, provided they are representative of the aircraft for which the course is approved for, meet requirements of this paragraph, and the training is given by an authorized ground or flight instructor.

(2) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

(c) *Areas of operation.*

Each approved course must include the flight training on the areas of operation listed in this paragraph, that are appropriate to the aircraft category and class rating for which the course applies:

(1) *A type rating for an airplane-single engine course:*

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

(2) *A type rating for an airplane-multiengine course:*

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

(3) *A type rating for a powered-lift course:*

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

(4) *A type rating for a rotorcraft-helicopter course:*

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

(5) *Other aircraft type ratings specified by the Administrator through aircraft type certificate procedures:*

(i) Preflight preparation;
(ii) Preflight procedures;
(iii) Takeoff and departure phase;
(iv) Inflight maneuvers;
(v) Instrument procedures;
(vi) Landings and approaches to landings;
(vii) Normal and abnormal procedures;
(viii) Emergency procedures; and
(ix) Postflight procedures.

5. *Stage check and end-of-course tests.*

(a) Each student enrolled in an aircraft type rating course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the approved areas of operation that apply to the aircraft type rating for which the course applies at the airline transport pilot certificate level; and

(b) Each student must demonstrate satisfactory proficiency prior to being endorsed to operate an aircraft in supervised PIC flight.

Appendix K—Special Preparation Courses

1. *Applicability.* This appendix prescribes the minimum curriculum for the special preparation courses that are listed in § 141.11 of this part.

2. *Eligibility for enrollment.* A person must have the following to enroll in the flight portion of a special preparation course:

(a) A pilot, flight instructor, or ground instructor certificate that is appropriate for the operating privilege or authorization that the course applies;

(b) At least a valid third-class medical certificate issued under part 67 of this chapter, if the course involves an aircraft other than a glider or balloon; and

(c) A statement signed and dated by the person certifying the person has no known medical defect that makes the person unable to pilot a glider or balloon, as appropriate.

3. *General requirements.*

(a) To be approved a special preparation course must:

(1) Meet the appropriate requirements of this appendix; and

(2) Prepare the graduate with the necessary skills, competency, and proficiency to exercise safely the privileges of the certificate, rating, or authorization for which the course is established.

(b) An approved special preparation course must include training on the operating privileges or authorization sought, for developing competency, proficiency, resourcefulness, self-confidence, and self-reliance in the student; and

(c) An approved special preparation course must include flight training in the operating privileges or authorization sought, for developing competency, proficiency, resourcefulness, self-confidence, and self-reliance in the student.

4. *Use of flight training devices.*

(a) The approved special preparation course may include training in a flight training device, provided they are representative of the aircraft for which the course is approved for, meet requirements of this paragraph, and the training is given by an authorized ground or flight instructor.

(b) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part, may be credited for a maximum of 10 percent of the total flight training hour

requirements of the approved course, or of this section, whichever is less.

(c) Training in a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(d) Training in a flight training device that meets the requirements of § 141.41(a)(1) of this part and a flight training device that meets the requirements of § 141.41(a)(2) of this part, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or by this section, whichever is less. However, training in a flight training device that meets the requirements of § 141.41(a)(2) of this part may be credited for a maximum of 5 percent of the total flight training hour requirements.

5. *Stage check and end-of-course tests.*

Each person enrolled in a special preparation course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the approved areas of operation that are appropriate to the operating privileges or authorization sought and for which the course applies.

6. *Agricultural aircraft operations course.*

An approved special preparation course for pilots in agricultural aircraft operations must include at least the following:

(a) At least 25 hours of training on-(1) Agricultural aircraft operations;

(2) Safe piloting operating practices and procedures for handling, dispensing, and disposing agricultural and industrial chemicals, including operating in and around congested areas; and

(3) Applicable provisions of part 137 of this chapter.

(b) At least 15 hours of flight training on agricultural aircraft operations.

7. *Rotorcraft external-load operations course.*

An approved special preparation course for pilots of external-load operations must include at least the following:

(a) At least 10 hours of training on-(1) Rotorcraft external-load operations;

(2) Safe piloting operating practices and procedures for external-load operations, including operating in and around congested areas; and

(3) Applicable provisions of part 133 of this chapter.

(b) At least 15 hours of flight training on external-load operations.

8. *Test pilot course.*

An approved special preparation course for pilots in test pilot duties must include at least the following:

(a) Aeronautical knowledge training on—

(1) Performing aircraft maintenance, quality assurance, and certification test flight operations;

(2) Safe piloting operating practices and procedures for performing aircraft maintenance, quality assurance, and certification test flight operations;

(3) Applicable parts of this chapter that pertain to aircraft maintenance, quality assurance, and certification tests; and

(4) Test pilot duties and responsibilities.

(b) At least 15 hours of flight training on test pilot duties and responsibilities.

9. *Special operations course.*

An approved special preparation course for pilots in special operations that are mission specific for certain aircraft, must include at least the following:

(a) Aeronautical knowledge training on—

(1) Performing that special flight operation;

(2) Safe piloting operating practices and procedures for performing that special flight operation;

(3) Applicable parts of this chapter that pertain to that special flight operation; and

(4) Pilot-in-command duties and responsibilities for performing that special flight operation.

(b) Flight training—

(1) On that special flight operation; and

(2) To develop skills, competency, proficiency, resourcefulness, self-confidence, and self-reliance in the student for performing that special flight operation in a safe manner.

10. *Pilot refresher course.*

An approved special preparation pilot refresher course for a pilot certificate, aircraft category and class rating, or an instrument rating must include at least the following:

(a) At least 4 hours of aeronautical knowledge training on—

(1) The aeronautical knowledge areas that are applicable to the level of pilot certificate, aircraft category and class rating, or instrument rating, as appropriate, that pertain to that course;

(2) Safe piloting operating practices and procedures; and

(3) Applicable provisions of parts 61 and 91 of this chapter for pilots.

(b) At least 6 hours of flight training on the approved areas of operation that are applicable to level of pilot certificate, aircraft category and class rating, or instrument rating, as appropriate, for performing pilot-in-command duties and responsibilities.

11. *Flight instructor refresher course.*

An approved special preparation flight instructor refresher course must include at least a combined total of 16 hours of aeronautical knowledge training, flight training, or any combination of ground and flight training on the following:

(a) Aeronautical knowledge training on—

(1) The aeronautical knowledge areas of part 61 of this chapter that apply to student, recreational, private, and commercial pilot certificates and instrument ratings;

(2) The aeronautical knowledge areas of part 61 of this chapter that apply to flight instructor certificates;

(3) Safe piloting operating practices and procedures, including airport operations and operating in the National Airspace System; and

(4) Applicable provisions of parts 61 and 91 of this chapter that apply to pilots and flight instructors.

(b) Flight training to review—

(1) The approved areas of operations applicable to student, recreational, private, and commercial pilot certificates and instrument ratings; and

(2) The skills, competency, and proficiency for performing flight instructor duties and responsibilities.

12. *Ground instructor refresher course.*

An approved special preparation ground instructor refresher course must include at least 16 hours of aeronautical knowledge training on:

(a) The aeronautical knowledge areas of part 61 of this chapter that apply to student, recreational, private, and commercial pilots and instrument rated pilots;

(b) The aeronautical knowledge areas of part 61 of this chapter that apply to ground instructors;

(c) Safe piloting operating practices and procedures, including airport operations and operating in the National Airspace System; and

(d) Applicable provisions of parts 61 and 91 of this chapter that apply to pilots and ground instructors.

Appendix L—Pilot Ground School Course

1. *Applicability.* This appendix prescribes the minimum curriculum for a pilot ground school course required under this part.

2. *General requirements.* An approved course of training for a pilot ground school must include training on the aeronautical knowledge areas that are:

(a) Needed to safely exercise the privileges of the certificate, rating, or authority for which the course is established; and

(b) Conducted to develop competency, proficiency, resourcefulness, self-confidence, and self-reliance in each student.

3. *Aeronautical knowledge training requirements.*

Each approved pilot ground school course must include:

(a) The aeronautical knowledge training that apply to that aircraft rating by this part, and that are appropriate to the aircraft rating and pilot certificate level for which the course applies; and

(b) The total aeronautical knowledge training hours must include an adequate number of hours that are appropriate to the aircraft rating and pilot certificate level for which the course applies.

4. *Stage check and end-of-course tests.*

Each person enrolled in a pilot ground school course must satisfactorily accomplish the stage checks and end-of-course tests, in accordance with the school's approved training course, consisting of the approved areas of operation that are appropriate to the operating privileges or authorization that graduation from the course will permit and for which the course applies.

5. Part 143 is removed and reserved.

PART 143—[RESERVED]

Issued in Washington, D.C., on July 27, 1995.

William J. White,

Acting Director, Flight Standards Service.

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Friday
August 11, 1995

Part III

Department of Education

34 CFR Parts 76 and 667

State-administered Programs; State Postsecondary Review Program; Final Rule

DEPARTMENT OF EDUCATION

34 CFR Parts 76 and 667

RIN 1880–AA59

State-administered Programs; State Postsecondary Review Program

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends Part 76 of the Education Department General Administrative Regulations (EDGAR) to require a State to file its State plan and other related documents under a given program by a date certain or face deferral of the date on which the State may begin to obligate funds under the program. The Secretary also modifies the policy announced in the notice of proposed rulemaking (NPRM) regarding pre-award costs incurred after the date funds are available for obligation by the Secretary and before the date a State has an approved State plan. Under the modified policy, the Secretary will allow pre-award costs for matching and Maintenance of Effort expenditures because these expenditures are not subject to the Cash Management Improvement Act of 1990 (CMIA). The Secretary takes these actions to protect the Federal Government from interest liabilities under the CMIA when the Department is late in making an initial payment under a State-administered program because the State failed to submit a substantially approvable plan or other required document in a timely fashion. The Secretary also makes conforming amendments to Part 667.

DATES: These regulations take effect on September 11, 1995.

FOR FURTHER INFORMATION CONTACT: Peter Wathen-Dunn, U.S. Department of Education, 600 Independence Avenue, S.W., Room 4434, Washington, D.C. 20202–2243. Telephone: (202) 401–6700. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Cash Management Improvement Act of 1990 (CMIA) was passed by Congress to ensure greater efficiency, effectiveness, and equity in the exchange of funds between the Federal Government and the States. Under this statute and the Treasury Department's implementing regulations at 31 CFR Part 205, the Federal Government is liable for interest payments to a State that disburses its own funds for Federal program purposes before the date that Federal funds are deposited to the State's bank account for those obligations, 31 U.S.C. 6503(d). Conversely, a State must pay interest to the Federal Government from the time Federal funds are deposited to the State's account until the time that those funds are paid out by the State, 31 U.S.C. 6503(c).

The CMIA applies to ''major Federal assistance programs,'' which are determined under a chart in the implementing Treasury regulations at 31 CFR 205.4 and Appendix A to Part 205, Subpart A. The chart establishes thresholds for CMIA coverage based on a comparison between the amount of Federal funds expended in a State under a particular program and the total Federal funds expended in the State. The Treasury Department negotiates agreements with each of the States that cover a number of issues under the CMIA, including which programs of the Federal Government are covered by the CMIA in that State. Under the Treasury-State agreement, a State may choose to cover more programs under the CMIA than would be required under the regulatory chart. Thus, to determine whether a program administered by the Department is covered by the CMIA in a particular State, contact the CMIA contact person for the State. These people are usually located in fiscal offices such as a State controller's office. Many of the formula grant State-administered programs of the Department meet the threshold for coverage in most, if not all, States.

The Department of Education (Department) published a notice of proposed rulemaking (NPRM) in the **Federal Register** on December 16, 1993, (58 FR 65856) that proposed regulations to limit the Federal Government's interest liability under the CMIA. The Secretary received 60 comments in response to the NPRM from State educational agencies, State fiscal offices, a trust territory, the Treasury Department, and three national organizations. In addition to the comments, the Department has discussed this rule with the States at various conferences and presentations over the past one and one-half years. Most States asked the Department to defer the proposed rule so that it would not apply to funds made available for obligation by the Secretary starting in calendar year 1994. The reason advanced most often to support the deferral request was to give States time to adjust their schedules to a new clearance process designed to submit State plans to the Department on an earlier date. Commenters who were responsible for State administration of programs that are current-funded, such as the Library Services and Construction Act, suggested that the change in submission date would be particularly burdensome for them without greater advance notice of the change in the regulations. The commenters also asked that the Secretary not apply, in 1994, the decision not to grant pre-award costs if a State is late in submitting its State plan.

In addition to asking for the deferrals, the commenters raised many questions that had to be answered before the regulations could become effective. The Secretary decided to defer both application of the proposed rule and the decision not to grant pre-award costs so that States would have additional time to adjust their State plan development processes to the timelines in the proposed regulations. Thus, the Secretary published a notice in the **Federal Register** on May 26, 1994 (59 FR 27404) indicating his decision to defer application of the actions proposed in the NPRM until the submission of State plans in the spring and summer of 1995. After considering the comments, the Secretary has decided to apply this final rule to applications submitted in the spring and summer of 1996.

The NPRM for these regulations discussed the basis for these regulations, the history of how the Department treated late State plans in past years, the effect of the Treasury regulations implementing the Act on the Department's practices, and the Department's proposed regulations.

Analysis of Comments and Changes

An analysis of the comments and of the changes in the regulations since publication of the NPRM follows. These regulations are designed to cover the full spectrum of the Department's State-administered programs. Thus, this preamble uses examples from many programs to illustrate the applicability of the final regulations. If you have questions about the application of these regulations to a specific program of the Department, contact the program office responsible for the program.

Technical changes to the regulations have been made to improve their quality. These changes, which do not affect substance, are not discussed in this preamble.

General Comments on Interest Liability

Comment: Several commenters expressed concern over the proposed regulatory changes that would limit interest liability to States. Some States concurred with the regulations that would require States to submit a timely State plan and the Department of

Education to respond in a timely manner so interest would not be an issue. However, they believed that if the Federal Government was not responsive within a specific time frame, interest should be paid to the States.

Discussion: The purpose of the CMIA is to achieve efficient, equitable cash management practices so that no interest is exchanged. It is prudent for the Department of Education to take action to correct past practices regarding the acceptance of State plans that are submitted late. The CMIA requires the Secretary of Treasury to regulate and enforce timely disbursements of funds by Federal agencies. The final regulations require States to submit substantially approvable plans by specific dates, and the Department to respond in a timely manner, or pay interest to the States in cases where States use their own funds to pay for Federal program obligations during a period of delay caused by the Department. The Secretary is committed to conducting timely reviews of State plans.

Change: None.

What does substantially approvable mean?

Comment: Many commenters asked the Secretary to define ''substantially approvable,'' stressing the heightened importance of its meaning now that the Secretary has decided not to grant pre-award costs. Some of the commenters expressed the fear that the term could and would be interpreted differently by every program official who approves State plans. Others asked that explicit criteria be included in a definition of the term or that a term different than substantially approvable be used as a test to determine whether funds should flow to a State. One commenter suggested that the Department should authorize the flow of funds if a State made a ''good faith'' submission.

One commenter stated that there have been numerous requests to reword sections of its State plans that have been approved by other staff in past years and that the State had been asked to move sentences from one page to another or to repeat sentences that appear on one page at a later place in the State plan. To this commenter, it was unclear whether the failure to respond to these requests would have rendered the plan not substantially approvable.

Another commenter was concerned that if substantially approvable is interpreted to mean not just submission of required components, but resolution of disagreements about approvable content, the term must mean the same thing as ''fully approvable.'' This commenter believed that disagreements over interpretations of content should not delay the allocation of funds because these disagreements often take months to resolve.

Some of the commenters asked exactly what documents had to be submitted to determine whether a plan was substantially approvable. One recommended that the Department establish a regulatory list of required documents so that there could be no ambiguity about what was required to be submitted.

One commenter was concerned that minor modifications or submission of additional information should not delay the availability of Federal funds for obligation by the State.

Discussion: The Secretary has decided to continue using the term ''substantially approvable'' as the test for whether a State may begin to obligate funds under a program. Most of the programs of the Department and its predecessor, the Education Division of the former Department of Health, Education, and Welfare, have used this term since the early 1970s as the test to determine whether a State may begin to obligate funds. Under this standard, the Department decides whether a plan is substantially approvable based on whether the plan has met substantive requirements under a funding statute and regulations.

While some commenters expressed concern that the substantially approvable standard might be used to defer funding for a State based solely on the need for trivial changes to the State plan, the Department has always made its determination of whether a State plan is substantially approvable based on whether the plan has met substantive requirements under a funding statute and regulations. Thus, the need for minor modifications of a non-substantive nature will not delay the availability of Federal funds for obligation by the State.

The Secretary is aware that in some cases employees of the Department have asked for changes to elements of a State plan that might not be deficient under the ''substantially approvable'' test. These requests have been motivated by a desire to assist a State in improving its State plan and have been made in the context of other changes that have been requested as necessary to make a plan substantially approvable. In the future, employees of the Department will distinguish their requests so that State officials will know which requests must be satisfied in order to make a State plan substantially approvable.

The Secretary understands the concern that each employee of the Department may interpret the standard differently, subjecting a State to arbitrary determinations by the Department. However, the Secretary notes that front line employees of the Department who review State plans do not make the final decisions about whether a plan is substantially approvable. Those decisions are made by senior officials in consultation with program managers. Thus, a decision about whether a particular plan is substantially approvable is made by officials who are exposed to a broad array of plans and who exercise their judgment to ensure that States are treated equitably.

The following examples are taken from past experiences of the Department and demonstrate how the term ''substantially approvable'' has been applied in the context of various programs.

Example 1: Part B of the Individuals With Disabilities Education Act (IDEA)

Under the IDEA, Part B, each participating agency must permit parents to inspect and review any education record relating to their children which is collected, maintained, or used by the agency under Part B. The agency must comply with a parental request to inspect and review records without unnecessary delay and before any meeting regarding an individualized education program or hearing relating to the identification, evaluation, or placement of the child, and in no case more than 45 days after the request has been made. In one case, the State plan referenced a State statute that required that ''After an individual has been shown the private data and informed of its meaning, the data need not be disclosed to that individual for six months thereafter unless a dispute or action pursuant to this section is pending or additional data on the individual has been collected or created.'' The State was required to ensure that a parent's right to access under the Federal requirement was not limited by State statute in order for its plan to be substantially approvable.

Example 2: Rehabilitation Act of 1973

Section 101(a)(5)(A) of the Rehabilitation Act, as amended in 1992, contains the requirements for the order of selection for services. Under this section, a State plan must show and provide the justification for an order of selection that will be used by the State in determining which individuals with disabilities will be served if the State cannot serve all individuals eligible for services under the Act. The order of selection for the provision of vocational rehabilitation services must be

determined on the basis of serving first those individuals with the most severe disabilities in accordance with criteria established by the State. The State plan must also describe the outcomes and service goals for the individuals served by the State and the time within which the outcomes and service goals may be achieved.

Several State plans that indicated an inability to serve all eligible individuals have been found not to be substantially approvable because they failed to contain the State's criteria for determining which individuals with disabilities are the individuals with the most severe disabilities. In other cases, State plans were found not substantially approvable because the plans failed to indicate that the State would target its resources to serve individuals with the most severe disabilities first.

Example 3: Adult Education Act

The Adult Education Act and its implementing regulations require assurances that public and nonprofit agencies, including correctional education agencies, be provided direct and equitable access to all Federal funds provided under the State plan program. However, one State plan stated ''Correctional agencies will be eligible for any newly appropriated federal funding directly from the U.S. Department of Education for corrections educational programs.'' This language was unacceptable under the requirements of the Act and regulations. The State was asked to submit a revision to the plan to correct the deficiency. The State plan was found substantially approvable when the State revised it to say ''Eligible recipients for adult basic education funding include correctional educational agencies.''

Example 4: Library Services and Construction Act (LSCA)

One State submitted a plan in which a project for strengthening the capacity of the State Library Agency and an Administration project both included administrative expenses. The plan was not considered substantially approvable because activities that would be considered as administration of the Act are not allowed in a Strengthening project. The State was required to include all administrative expenditures under its Administration project before the plan was found substantially approvable.

Under the LSCA, a State must have an approved Long-range Program (LRP) on record with the Department, and all annual programs must be based on needs, priorities, and plans identified in the LRP. In the second year after the passage of amendments to LSCA in 1990, several State plans were not found substantially approvable because the States had not changed their LRPs to reflect new statutory priorities under the LSCA amendments. These plans were found substantially approvable when the new priorities were addressed either in a revised or amended LRP.

The examples described above indicate that the kinds of issues that must be resolved before a State plan can be found substantially approvable are not trivial and the Department's decisions in these cases are based on clear mandates in statutes and implementing program regulations. The Secretary assures the States that the Department will not find a State plan not substantially approvable simply because an assurance or other text is misplaced in the plan or there is some other non-substantive problem with the plan.

This preamble discusses the issue of what documents must be submitted under the heading ''Should the Department be required to send documents, including a list of any other documents required to prove eligibility under each program, to States by a date certain and what should be the effect of the Department's failure to do so?''

Change: None.

How do the regulations affect Maintenance of Effort and Matching Requirements?

Several commenters addressed the discussion in the NPRM regarding the effect of the proposed regulations on fiscal maintenance of effort requirements (MOE). Some confusion was created by the fact that the preamble described the MOE requirement under the Rehabilitation Act as if it were an eligibility requirement. However, under that Act, failure to meet MOE requirements does not deny eligibility. Instead, the allotment for a State is reduced by the amount that the State fails to meet the MOE requirement unless a waiver or modification of the MOE requirement is granted.

Comment: One commenter was concerned that the regulations appeared to require submission of documents demonstrating that a State had met the MOE requirements before a State plan could be considered substantially approvable. The commenter noted that this would not be workable because the financial report needed to demonstrate that MOE had been met was not available until 90 days after the end of the grant period and the State plan for a current funded program had to be submitted before the end of the prior grant period.

Discussion: The CMIA and these implementing regulations do not independently require submission of any document. The documents that must be submitted under a particular program are based on the program statute and implementing regulations.

Most program offices of the Department do not review actual MOE data before making a decision that a plan is substantially approvable. Instead, these programs require a State to submit an assurance that the State has met the MOE requirement based on currently available data. Under these programs, the Department relies on financial audits, reports, and other information to determine whether a State has met its MOE requirement for a particular year. Thus, for these programs, submission of MOE documentation, other than an assurance, would not be required before the Department made a decision about whether a State plan was substantially approvable.

One program office that does review MOE data as part of the State-plan review process is the office administering the LSCA program. Under the LSCA, the determination of whether a State has met a MOE requirement is based on a comparison of the planned expenditures of the State and the expenditures of the State from the second preceding year. Program officials for this program compare the budget of the State-plan submission against the expenditures of the State for the second preceding year before the budgeted year to determine if the State has budgeted sufficient funds to meet the MOE requirement.

Change: None.

Comment: Many commenters wanted the Department to accept, for the purpose of meeting MOE and matching requirements, non-federal expenditures made after the date that funds are available for obligation by the Secretary but before the date a State plan was found substantially approvable. Under some programs, the difference of just a few thousand dollars made a difference for a State in determining whether it met its MOE requirements.

Discussion: The Secretary has decided to modify the policy announced in the NPRM regarding pre-award costs, based on the concerns expressed in these comments. Expenditures incurred to meet matching and MOE requirements are not expenditures for which the Federal Government must deposit funds to the account of a State. Thus, these expenditures are not subject to the interest liabilities of the CMIA.

Given that the CMIA does not apply to non-Federal funds used to meet

matching and MOE requirements, the Secretary decided that he had more flexibility to permit a State to use these expenditures to meet matching and MOE requirements even though the period for obligation by the Secretary has started and the State does not yet have a substantially approvable State plan. Thus, the Secretary has decided to permit States to use these expenditures to meet matching and MOE requirements before the date a State plan is found substantially approvable. However, a State that chooses to use its funds for these types of expenditures would risk the possibility that they would be found unallowable because they do not comply with the State plan that is finally approved. The Secretary decided to change the pre-award cost policy so that States managing programs that require matching or MOE expenditures would have greater flexibility to keep those programs running with matching and MOE expenditures during a period when costs would otherwise be unallowable due to the late submission of a State plan.

The Secretary notes that the MOE determination under some programs of the Department is not based on State expenditures under the Federal program. For example, under the newly reauthorized Title I program of the Elementary and Secondary Education Act of 1965, the MOE determination is based on whether a State has expended sufficient funds on free public education. Another example is one of the MOE requirements under the LSCA Title I program under which the MOE determination is based on State expenditures under a State program that has a similar purpose to the Federal program. Under requirements such as these, State expenditures used to meet the MOE requirement do not need to be for allowable costs under the Federal program. Thus, for these types of MOE requirements, even without the change in policy regarding pre-award costs, expenditures made by a State after the start of the obligation period but before the State plan is found substantially approvable may be used by the State to meet MOE requirements.

Change: No change has been made to the regulations. However, the Secretary has modified the policy regarding pre-award costs to permit grantees to use expenditures made after the date funds become available for obligation by the Secretary and before the date a State plan is found substantially approvable to meet matching and MOE requirements.

When must State plans be submitted?

Comment: Fourteen comments were received concerning the due date specified in proposed § 76.703(a)(1) for submission of State plans. One commenter stated that the proposed submission date change for State plans would not impact that State. Four commenters were concerned that the proposed April 1 submission would be too early: (a) to allow planning time; and, (b) because State program requirements for public input prohibited early submission. One commenter was concerned that an April 1 submission date would not allow sufficient time for Departmental review and feedback to States needing to correct their plans, and still allow adequate time for States to make these corrections before the availability date. Two commenters suggested that an already lengthy process would be made still longer. One commenter believed that the time frame for receiving a plan in substantially approvable form should be 60 days before the start of the obligation period rather than 90 days before that date. Two commenters were concerned that States received their final allocations prior to plan submission in order to provide final financial reports. Three comments concerned precedence of statutory deadlines over regulatory deadlines. One commenter suggested that the Department issue a formal notification to the State when a plan is approved.

Discussion: The Secretary set the deadline date in § 76.703(a)(2) for the submission of State plans as a back-up that would be used only if a program office did not establish its own deadline for submission of State plans. The administrators for each State-administered program are free to set deadlines that are appropriate for their programs. Most State-administered programs already have deadlines that are set in statute, regulations, or direct communications with States. The Secretary is aware that the establishment of a deadline three months before the start of the obligation period could have caused hardship on some States if it had been imposed last spring, before States had time to adjust their State-plan preparation processes to mesh with the new regulations. As stated in the May 26, 1994 (59 FR 27404) document, this consideration was one of the factors that the Secretary considered in deciding to defer application of the regulations to submissions made during the spring and summer of 1995. Therefore, the Secretary has decided to leave the deadline in § 76.703(a)(2) as stated in the proposed regulations. If a State believes that the submission date for a particular program should be adjusted due to conditions particular to that program, the issue should be addressed with Department officials responsible for that program.

Change: None.

When should a plan be considered submitted?

Comment: Five commenters opposed the proposed change in the test under proposed § 76.703(b) that the Department uses to determine when a State plan is considered submitted. The proposed regulations would change the date of submission from the postmark date to the date the State plan is actually received by the Department. The commenters' reasons for opposition included: (1) the acceptance by other Federal agencies of a postmark date; (2) increased burden on States resulting from reduced time frames to complete plans because of having to mail them earlier in order to assure receipt by the Department by the required date; and (3) lack of control over the mail process, which could have negative financial consequences on States. One commenter did not present a reason for opposing the change from postmark to receipt date.

Discussion: In the past, the Department frequently received grant applications from grantees that had mailed applications on the submission date, with receipt by the Department as much as two weeks later. The lag time created by ''mail-in-transit'' has resulted in the Department having shortened review time frames for grant applicants, thereby hampering the Department's ability to complete grant reviews within its prescribed time frame. Earlier mailing of a State plan or use of an expedited delivery service by grant applicants would assure the Department a uniform application review period for all State plans under each grant program.

Change: None.

Should the Department be required to send documents, including a list of any other documents required to prove eligibility under each program, to States by a date certain, and what should be the effect of the Department's failure to do so?

Comment: Some commenters expressed the opinion that the Department should be required to send to States all State plan submission instructions and other relevant materials in a timely manner. Commenters stressed the critical importance this issue plays in allowing States sufficient time to develop and submit plans by the established date, particularly when public input is required.

Specifically, some commenters suggested the Department provide all necessary guidance three months before the States' prescribed State plan submission date, and other commenters recommended six-, four-, and two-month lead times for the receipt of these materials. Other commenters did not suggest specific time frames, but called for ''timely receipt'' of all plan instructions issued by the Department.

One commenter proposed that the regulations at § 76.703(a)(2) include a list of any other documents required to prove eligibility under each program subject to this part.

A related issue addressed by some commenters concerned proposed penalties against the Department should it fail to provide all relevant State plan materials and instructions by a date certain. Some of these commenters suggested that when guidance is late, the deadline for State plan submission should be extended by one day for each day the Department is late in providing guidance. Other commenters proposed a general waiver of the penalty to the State for late submissions if the Department transmits the guidance to the States late, and one commenter suggested an unspecified extension for the State if this occurs.

Discussion: The Secretary is committed to providing States necessary State plan information and instructions—including a list of required documents—in a timely manner. In light of this commitment, the regulation has been changed to require each program subject to these regulations to provide guidance to the States regarding the contents of State plans. The Secretary establishes the date for the delivery of guidance so that there are at least as many days between that date and the date that State plans must be submitted to the Department as there are days between the date that State plans must be submitted to the Department and the date that funds are available for obligation on July 1, or October 1, as appropriate.

In the event that the Department fails to deliver guidance as required, the deadline for the receipt of State plans will be extended one day for each day that the documents are late in being received by the State. The Secretary intends that guidance be sent to the States far enough in advance of the due date for the guidance that the information will be received by the States on or before the due date for the guidance. If a State asserts that it has received the guidance after the due date, it will have the burden of proving the date that it received the guidance. The Secretary is aware of the Department's responsibility to deliver State plan guidance on a timely basis, and will devote appropriate resources to ensure that guidance documents are delivered on a timely basis.

Change: A new paragraph (b) has been added to § 76.703 to cover deferrals of the date that a State plan must be submitted to the Department. Paragraph (b)(3) covers deferral of State plan submission dates caused by failure of the Department to deliver timely guidance to the States regarding State plan requirements.

Should there be a deadline for the Department's decision and what should be the effect of failure to meet such a deadline?

Comment: Many commenters expressed concern that the proposed regulations did not require the Department to complete a timely review such that, if State plans and other documents are submitted on time, the State has an opportunity to submit any necessary modifications or corrections before any delay in the obligation date is imposed. None of the examples in the proposed regulations indicate what will happen if the State plan is submitted in substantially approvable form, on time, but the Department fails to conduct a timely review.

Some of the commenters cited the following example: the State plan is submitted on April 1; the Department completes the review at the end of June and finds that the plan is not substantially approvable; corrections are requested but insufficient time is allowed for the State to make the corrections for an obligation date of July 1.

Several commenters recommended imposing time limits for the Departmental review of the plan. Some of these commenters suggested thirty days, while another commenter suggested forty-five days.

One commenter suggested that, if a time limit on Departmental review could not be imposed, resulting in a State agency not receiving Federal funds until after the first day the funds are available for obligation, then at the very least an appeal process with provisions for due process should be established.

One commenter suggested that if the Department were unable to complete a review in a timely manner, the State should be granted pre-award costs.

Discussion: The Secretary is committed to conducting timely reviews of State plans. If a State submits a State plan in conformance with the guidance provided, it should take less than the three months allotted for the Department to review the plan. Under these circumstances it is anticipated that any changes or corrections needed to make the plan substantially approvable will be minor and can be completed in a very limited amount of time. On the other hand, if a State submits a plan that is not in accord with the guidance provided, then it is possible that the resubmission and approval process could extend beyond the date funds are first available to the Department for obligation. If the Department fails to conduct a timely review of a State plan that is submitted in substantially approvable form on the date it is due, the State could begin to obligate funds on the date funds are available for obligation by the Secretary. Also, States have a responsibility to submit plans that are substantially approvable upon submission.

The Secretary believes that these regulations will result in States submitting timely and high quality plans and in efficient and punctual review by the various Department program offices. In view of the wide variety of content requirements for State plans under Department programs and of the number of plans reviewed by various program offices, the Secretary declines to impose intermediate time frames for Department review of State plans within this three-month period. However, the Secretary believes that the Department should be held accountable in meeting the timeliness established for review of State plans under a program. Thus, the Secretary has decided to modify the regulation so that if the Department takes longer to review a plan than established in advance, the Secretary will grant pre-award costs to the State, regardless of what the regulation would otherwise require.

Change: A new paragraph (g) has been added to § 76.703 so that if the Department takes longer to review a State plan than established under the regulation, the Secretary would grant pre-award costs.

Should the Department establish procedures for notifying the States of the results of the Department's review?

Comment: Several commenters expressed concerns about the Department's ability to maintain and review documents and notify States of the results of that review in a timely manner.

One commenter asked whether the grant award would be the indication of approval or whether there would also be an accompanying letter.

Two commenters suggested that the Department should notify the State when the initial State plan submission is received.

Discussion: The Secretary believes that the Department must be timely in

its response to States concerning the State plan submission. The Secretary will ensure that the Department establishes internal procedures in order to facilitate the notification process. The Department will establish a method of formal notification to States when the documents specified in guidance provided by the Department have been received for review. If a State submits an incomplete State plan, the Department will informally notify the State regarding the missing pieces. Also, the Department will develop internal procedures to include both formal and informal means (phone and fax messages) of notifying the States concerning the status of the review during the process. The Department officially notifies a State regarding the issuance of its grant through a notification of grant award (NGA). Some program offices may provide cover letters prior to or accompanying the NGA. It is mutually beneficial to all parties for the Department to conduct a timely review which includes periodic contact with the State.

Change: A new paragraph (c)(3) has been added to § 76.703 that will require the Department to inform States when all documents specified in Departmental guidance have been received by the Department.

Should the Department change the proposed rule about who may sign for changes to a State plan?

Comment: Two commenters expressed concern about the requirement in proposed § 76.703(e)(2) that would require a State that submits additional information to bring the State plan into substantially approvable form to secure signatures for required changes from the original submitter of the plan or an authorized delegate of that officer.

One commenter suggested that since changes to the plan often are faxed to the Department for review, the State should be allowed to supply the Department with the names of individuals who are authorized to sign the State plan.

One commenter suggested that the Department should consider not requiring signatures from other agencies (i.e. Drug Free Communities) and allow the State agency receiving the grant to submit its plan separately.

Discussion: The Secretary appreciates the difficulties that arise in securing appropriate signatures in a very short turn-around time. The Secretary agrees that submitting a list of staff authorized to sign-off on changes to the plan would be appropriate. The Department does not have the authority to waive the signature required of the Governor for the drug-free program.

The Department will work with States to develop procedures for submitting documents by electronic transmittal and appropriate means of verifying signatures.

Change: None

Should the Department establish a rule permitting waiver of the § 76.703 regulation in certain circumstances?

Comment: Several commenters requested that the regulations provide for a waiver authority or other discretion by the Department to allow pre-award costs when submission of a State plan is late. The reasons commenters felt might justify exceptions to the general rule included circumstances beyond a State's control, such as a natural disaster, absence of State program personnel due to serious medical problems or death and instances when the Federal interest in the timely beginning or continuation of a State's program would be adversely affected, or when significant impairment to the achievement of a program's objectives would result.

Discussion: The Secretary agrees with commenters that there is a need to allow the Department the discretion to allow pre-award costs for expenditures under the Federal program in some limited circumstances. However, the Secretary believes that instances in which pre-award costs are allowed under these regulations should be clear, susceptible to consistent application across programs, and narrowly tailored to situations that are truly outside the control of the State. Some programs may need to permit discretion in granting pre-award costs in program-specific situations. This authority should be addressed, as appropriate, in individual program regulations.

Change: A new paragraph (b) has been added to § 76.703 to cover deferrals for the date that a State plan must be submitted to the Department. Paragraph (b)(1) provides that the Secretary, at a State's request, may extend the submission date for a State plan and, if necessary, approve pre-award costs for a particular grant based on a Presidentially-declared disaster in the State that significantly impairs the ability of the State to submit a timely application.

Should the Department have a special rule when there is a delay in program appropriations or implementing regulations?

Comment: Several commenters noted that there are instances when, due to changing Federal statutes and regulations, States do not have notice of what the State plan requirements are in enough time to enable them to complete the development of the plan and submit it on time. One commenter noted that for one program an April 1 submission date would mean that they would have to begin preparation of the plan 12 to 15 months prior to the start of the fiscal year to which the grant applies. Commenters indicated that States should not be penalized for late submissions in circumstances where there has been a late appropriation or the Department has not notified the States in a timely manner regarding the State plan requirements for a program.

Discussion: Regarding late appropriations, the Treasury Department regulations at 31 CFR 205.11(b) already provide that if a State pays out its own funds for program purposes due to a delay in the passage of a Federal appropriations act, the Federal Government will incur an interest liability if the appropriations act covers the period of the State's expenditure and permits payment for expenditures already incurred by the State. The Secretary does not have authority to change the result under the Treasury regulations.

Regarding program regulations, as a general rule, the requirements that apply to a grant are the statutes and regulations that are in effect on the day that the grant is made. Often, legislation that imposes significant new responsibilities on States has a delayed effective date so that States have time to make the changes necessary for implementation. Similarly, the Federal rulemaking process generally incorporates a delayed effective date, although that delay may not be sufficient in some cases to allow States to make necessary changes in their State plans. Therefore, the Secretary agrees with commenters that these regulations should be modified to allow States a reasonable period of time to make needed changes in State plans.

In many instances, under current practice, if new program requirements take effect at a time that the Department determines is too close to the date on which grants are to be made to allow the State to make needed changes, the Department obtains an assurance from the State that the State is operating the program consistent with all applicable requirements, including those that are newly effective. Other assurances and documentation that the new requirements are being followed may be required by particular programs. Revisions to the State plan to incorporate changes needed as a result of the new requirements must be completed as soon as possible but generally not later than the expected

beginning of the next grant award period. The Secretary believes that this practice may continue to be appropriate for situations that can be addressed by State assurances and documentation that program requirements are being implemented. In other situations, an assurance would not be sufficient to address the new State plan requirements, even in the short run, and the Secretary may need the discretion to give States additional time to submit their applications under a program.

Change: A new § 76.704 has been added that provides that, unless the particular program has established an earlier date, the State plan must meet the requirements that were in effect for the program three months before the State plan due date and any additional requirements known on that date that are scheduled to become effective by the expected grant award date (July 1 for forward-funded programs or October 1 for current-funded programs). If any of these requirements is changed after that date (three months before the State plan due date or the other date established by the program), the Secretary may require a State to submit appropriate assurances and documentation or extend the due date for the State plan and, if necessary under an extended due date, approve pre-award costs for that program.

Should States be permitted to waive their right to interest in return for the Department's acceptance of late State plans without penalty?

Comment: One commenter suggested that the regulations provide that the Secretary could waive these regulations if the State agreed to ''waive'' its claim to interest on the State funds used for pre-award costs under the CMIA. Another commenter recommended that expenditures made during a period that a State plan is not substantially approved be exempted from the operation of the CMIA.

Discussion: The Department is without authority to require or even permit States to forego claims to interest under the CMIA. Congress delegated to the Treasury Department the authority to enforce the CMIA. The operation of the CMIA and the programs to which it applies are controlled by Treasury's CMIA implementing regulations, 31 CFR part 205, and the State-Treasury agreements under those regulations.

Change: None.

Should certain programs be exempt from the regulations in 76.703?

Comment: Commenters noted the particular problems of the programs that are not forward-funded, such as the LSCA programs and the Rehabilitation Act programs. One commenter suggested that these programs be exempted from the operation of the proposed regulations.

Discussion: As explained above, the Secretary cannot control the application of the CMIA to these programs. Thus, the Secretary does not believe that it would be prudent to exclude these programs from the operation of these Department regulations.

Change: None.

Should subgrantees be permitted to obligate funds during a period before the State may begin to obligate funds?

Comment: One comment was received regarding the relationship between proposed § 76.703 and the current § 76.704 (redesignated by this final rulemaking document as § 76.708), which provides that a subgrantee may not begin to obligate funds until the State may begin to obligate funds. The commenter noted that, under many State-administered programs, most of the funds flow through to subgrantees that are required to provide most of the services required under a program. The commenter thought that the proposed regulations should be amended so that subgrantees could begin to obligate funds even if the State had failed to submit a substantially approvable State plan. According to the commenter, this result was appropriate because subgrantees have no control over the timely preparation of the State plan but would be penalized under the proposed regulations for a State's failure to submit a substantially approvable State plan on a timely basis.

Discussion: The Secretary is aware that subgrantees must depend upon responsible management of Federal programs by the States in order to be able to obligate funds at the start of the obligation period. However, the Secretary cannot sever this dependency due to the relationship between the Department, the States, and their subgrantees. Under the framework established by Congress for State-administered programs, the Department makes grants to States and has no direct relationship with subgrantees. The Department looks to the States for proper administration of the programs. For example, when a subgrantee misspends funds under a State-administered program, the Department seeks recovery of the funds or takes other action against the State to achieve compliance by the subgrantee. In this context, a subgrantee derives its entire authority to obligate funds under a program from the State. Thus, if a State lacks authority to obligate funds, its subgrantees are equally without authority to obligate funds.

Even if the Secretary had the power to permit obligation by subgrantees before the State could obligate funds, there are good policy reasons for the Department not to permit such a practice. One of the purposes of approving a State plan is to ensure that the State is imposing correct requirements upon its subgrantees. If a State submitted a plan that was not substantially approvable and subgrantees were permitted to submit local applications for flow through funds and obligate funds under that plan, serious questions would be raised about whether the subgrantees were complying with the Federal requirements under the program.

Change: None.

What issues are raised under the Library Services and Construction Act?

Comment: One commenter suggested that instead of the proposed regulations, the Secretary pro-rate decreases to the grant awards in accordance with the days the plan is late.

Discussion: Under the LSCA statute and GEPA, the Secretary does not have the authority to decrease the grant awards due to a State's late plan submission.

Change: None.

Comment: Two commenters noted that disallowing pre-award costs under LSCA, Title II (Construction), would adversely impact on communities that need to count the cost of the land and architectural fees (both pre-award expenditures) in order to meet the 50 percent matching requirement. They recommend that the Title II construction program be exempt from these regulatory changes.

Discussion: It is highly unlikely that the LSCA Title II program will ever meet the funding threshold for coverage under the CMIA Treasury regulations in subpart A of 31 CFR part 205. The LSCA Title II program regulations require that the request for grant award be submitted to the Department after the State has approved the final working drawings. This, by implication, requires that the land be purchased and the architectural drawings be completed before the plan is submitted. The LSCA Title II regulations clearly provide that these expenditures are allowable. 34 CFR 770.11(a)(5). The Assistant Secretary will specifically authorize these pre-award costs in grant award notices under the LSCA Title II program so that the costs may be allowed to meet the requirements of the program.

Change: None.

Comment: Several commenters were concerned that State and/or local funds expended between July 1 and the effective date of the program (or the date of the acceptance of a substantially approvable plan) would not be counted

toward the matching required under the LSCA program.

Discussion: State or local funds expended between July 1 and the effective date of the program cannot be counted as matching. The LSCA Titles I and III programs begin on October 1 and end on September 30. These two programs do not exist before the October 1 effective date each year. Therefore, the Secretary notes that funds counted as matching under the program must be expended in the same time period as the Federal grant program.

The Secretary also notes that Federal carryover funds may not be obligated and expended after September 30th until there is a substantially approvable plan received by the Department.

Change: None.

Comment: Some commenters asked, given the fact that LSCA is a current-funded program and that, in many years, the Congress has not appropriated funds for LSCA by the start of the Federal fiscal year, is the October 1 date still to be the date on which the Secretary will obligate funds under § 76.703(c). They asked how this would affect the obligation and expenditure of funds between October 1 and the date that Congress actually appropriates funds for LSCA.

Discussion: Regulations covering Federal interest liabilities are found in the Treasury Department regulations implementing the Cash Management Improvement Act at 31 CFR Part 205. Specifically, § 205.11(b) addresses late appropriations and provides that the Federal Government will incur an interest liability if an appropriations act, as enacted, covers the period of the State's expenditure and permits payment for expenses already incurred by the State.

Change: None.

Comment: A commenter asked if a substantially approvable plan was submitted by April 1, could LSCA funds be obligated on July 1.

Discussion: The beginning of the obligation period for current funded programs is October 1, and, therefore, obligations generally may not occur prior to that date.

Change: None.

Comment: Many commenters noted that the examples under § 76.703(e)(3) of the proposed regulations only referred to forward-funded programs. They noted that because LSCA is not forward-funded it should be exempt from these regulatory changes.

Discussion: The Secretary will not exempt the LSCA program from these regulations because current-funded programs cannot be excluded from coverage under the CMIA.

Change: None.

Comment: It was feared by one commenter that, in trying to fit a current funded program under regulations that the commenter felt were clearly intended for forward-funded programs, there might be unforeseen problems in the future.

Discussion: The Secretary does not foresee any issues that are unique to current-funded programs. However, these regulations have been reviewed by Departmental staff knowledgeable about current-funded programs such as the LSCA in order to ensure that issues that may arise with regard to these programs are addressed.

Change: None.

Comment: Several commenters noted that, unlike forward-funded programs, planning for LSCA is done on an unknown Federal allocation. Under these regulations, the State budget might also be unknown. In addition, the staff of the State agency would be compelled to work on the plans for LSCA at the same time they must be effecting closeout of the State fiscal year.

Discussion: The commenters are correct in that State plans prepared for submission under this revised regulation would, in many cases, be based on unknown funding at either the Federal or State levels or at both levels. However, annual plans are considered estimates and are expected to be revised to reflect final Federal funding amounts. (See next discussion for details.) Submissions prior to the due date are acceptable if necessary to decrease impact on State staff.

Change: None.

Comment: Some commenters noted that State plans based on estimated figures would have to be amended at a later date so that the plan proposes activities consistent with the actual funding amounts. This would make even more complex planning and might ''* * * create confusion at the sub-grantee level, and possible fiscal chaos at the state level.'' Such added work was considered by a commenter as a violation of the Paperwork Reduction Act.

Discussion: State plans are expected to be based on an estimation of funds. Under 34 CFR 80.30(c)(ii), changes to plans or budgets that are within ten percent of the budgeted amount, require no additional Federal funding, and make no significant change to the intent of the project or plan, need not be submitted to the Department for prior approval. Because planning is done on an estimated Federal amount currently, grantees are already in the position of amending some projects after the start of the grant period. The need to amend grants, based upon a submission of actual State funding data, and the submission of the supporting data, are considered in the burden when the paperwork burden is calculated under the Paperwork Reduction Act of 1980. Therefore, these revised regulations contain no added information collection requirements.

Change: None.

Comment: Several commenters expressed concern that the required assurances under LSCA would be due prior to the passing of the State's budget confirming the availability of such funds.

Discussion: The assurances may be based on the best available information as of the date of the submission.

Change: None.

Comment: One commenter noted that the revised § 76.703 would require estimated annual expenditure reports (rather than actual report of expenditures) be accepted by the Department in order to generate a plan by July 1.

Discussion: Under current law, the Federal fiscal year ends on September 30. The report covering expenditures for that period is due to the Department at the end of December. The LSCA program plans that will use the information from the report, as a prerequisite for funding, will not be due until the following July 1, which is nine months after the expenditure period. The Secretary does not agree that only estimated expenditures and not actual expenditures could be verified during this time period. Therefore, there is no allowance for estimated annual reports.

Change: None.

Comment: Several commenters voiced a concern that some State expenditures under MOE requirements occur during the July 1 to October 1 period, and a failure to receive permission to count these expenditures towards MOE would cause a failure to qualify for Federal LSCA funding.

Discussion: MOEs under the LSCA are based on the requirement of a State to maintain the support of services of a protected program or to a protected population. Some of these expenditures may not be part of the expenditures under LSCA (such as State Aid) and only have a tenuous relationship to the Federal program. Since many of these programs are ongoing State supported efforts, the Secretary agrees that these amounts are eligible for counting as MOE from the beginning of the State fiscal year, whether or not the State plan is substantially approvable.

Change: None.

Comment: Many commenters noted that § 76.703(a)(2) establishes a due date

for State Plans, of three months prior to the date that the Secretary may obligate funds for the program. The effective date of current programs is October 1, and, therefore, plans are due on the prior July 1. Some commenters noted that such a proposed change will require new timetables at the State and local level. Most commented that the change can be implemented if given enough time. Other commenters requested that the date of October 1 be retained and cited a number of problems associated with this change.

Discussion: The program staff will have reviewed and accepted all timely and substantially approvable plans prior to the effective date of the program in order that the Secretary may make obligations in a timely manner. The retention of the October due date for the submission of State plans is impossible if all reviews are to be accomplished prior to October 1. The Department must reserve the three-month period for review (including negotiations) of the State Plans.

Change: None.

Section 76.711: Should States have to request funds by CFDA number?

The NPRM proposed to add a new § 76.708. This document adds that section as a new § 76.711.

Comment: One commenter asked why the Department would require States to use the CFDA number when the Treasury Department would not require Federal agencies to provide the CFDA number to the States for funds transmitted to the States. Conversely, the Treasury Department suggested in its comments that the Department should require all grantees to request the draw down of funds by CFDA number, because all programs that are covered in the CFDA are subject to coverage under the CMIA. A third commenter stated that a requirement to request funds by CFDA number would place an unnecessary administrative burden on States which might actually hinder timely payments under the CMIA. This commenter asked that the Department stay with the current, single-request system, which permits grantees to request funds needed under all grants to a State in a single request, without having to identify the programs for which the funds are being requested.

Discussion: As the Treasury Department stated in the preamble to the final regulations implementing the CMIA, ''CFDA numbers are key to the provisions of this rule.'' This statement was made in the context of Treasury's discussion of concerns that agencies don't always provide CFDA numbers to States when the agencies make their awards. Treasury said ''Respondents emphasized the problems created in such situations given the fact that [the Treasury regulation implementing the CMIA] relies on program CFDA numbers for tracking withdrawals and payments, and for calculating interest accruals.''

This discussion indicates Treasury's understanding that States will need to request payments by CFDA number and agencies will have to make payments by CFDA number in order to calculate interest liabilities under the Act. The Department of Education already identifies the CFDA number of a grant program whenever it issues a notification of grant award. Thus, the Secretary does not expect any increased burden for a State to check the CFDA number on a grant award document in order to request funds under a program.

Change: In response to the Treasury Department's comment, § 76.708 will require use of the CFDA number when requesting funds for any grant subject to Part 76.

Change: This final rulemaking document makes technical changes by redesignating certain sections that were not affected by the NPRM in order to make room for the new § 76.704. Current §§ 76.704, 76.705, and 76.706 have been redesignated as § 76.708, 76.709, and 76.710, respectively. Cross references to these sections in other parts of 34 CFR have been amended as appropriate.

Paperwork Reduction Act of 1980

These regulations have been examined under the Paperwork Reduction Act of 1980 and have been found to contain no information collection requirements.

List of Subjects

34 CFR Part 76

Education Department, Grant programs-education, Grant administration, Intergovernmental relations, State-administered programs.

34 CFR Part 667

Colleges and universities, Cultural exchange programs, Education, Educational study programs, Grant programs—education.

Dated: April 6, 1995.

Richard Riley,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number does not apply)

The Secretary amends Parts 76 and 667 of Title 34 of the Code of Federal Regulations as follows:

PART 76—STATE-ADMINISTERED PROGRAMS

1. The authority citation for part 76 is revised to read as follows:

Authority: 20 U.S.C. 1221e-3, 6511(a), 3474, unless otherwise noted.

2. Section 76.703 is amended by removing paragraphs (a) and (b), redesignating paragraph (c) as paragraph (h), adding new paragraphs (a) through (g), and adding notes following new paragraphs (b) and (g), to read as follows:

§ 76.703 When a State may begin to obligate funds.

(a) (1) The Secretary may establish, for a program subject to this part, a date by which a State must submit for review by the Department a State plan and any other documents required to be submitted under guidance provided by the Department under paragraph (b)(3) of this section.

(2) If the Secretary does not establish a date for the submission of State plans and any other documents required under guidance provided by the Department, the date for submission is three months before the date the Secretary may begin to obligate funds under the program.

(b) (1) This paragraph (b) describes the circumstances under which the submission date for a State plan may be deferred.

(2) If a State asks the Secretary in writing to defer the submission date for a State plan because of a Presidentially declared disaster that has occurred in that State, the Secretary may defer the submission date for the State plan and any other document required under guidance provided by the Department if the Secretary determines that the disaster significantly impairs the ability of the State to submit a timely State plan or other document required under guidance provided by the Department.

(3) (i) The Secretary establishes, for a program subject to this part, a date by which the program office must deliver guidance to the States regarding the contents of the State plan under that program.

(ii) The Secretary may only establish a date for the delivery of guidance to the States so that there are at least as many days between that date and the date that State plans must be submitted to the Department as there are days between the date that State plans must be submitted to the Department and the date that funds are available for obligation by the Secretary on July 1, or October 1, as appropriate.

(iii) If a State does not receive the guidance by the date established under

paragraph (b)(3)(i) of this section, the submission date for the State plan under the program is deferred one day for each day that the guidance is late in being received by the State.

Note: The following examples describe how the regulations in § 76.703(b)(3) would act to defer the date that a State would have to submit its State plan.

Example 1. The Secretary decides that State plans under a forward-funded program must be submitted to the Department by May first. The Secretary must provide guidance to the States under this program by March first, so that the States have at least as many days between the guidance date and the submission date (60) as the Department has between the submission date and the date that funds are available for obligation (60). If the program transmits guidance to the States on February 15, specifying that State plans must be submitted by May first, States generally would have to submit State plans by that date. However, if, for example, a State did not receive the guidance until March third, that State would have until May third to submit its State plan because the submission date of its State plan would be deferred one day for each day that the guidance to the State was late.

Example 2. If a program publishes the guidance in the **Federal Register** on March third, the States would be considered to have received the guidance on that day. Thus, the guidance could not specify a date for the submission of State plans before May second, giving the States 59 days between the date the guidance is published and the submission date and giving the Department 58 days between the submission date and the date that funds are available for obligation.

(c) (1) For the purposes of this section, the submission date of a State plan or other document is the date that the Secretary receives the plan or document.

(2) The Secretary does not determine whether a State plan is substantially approvable until the plan and any documents required under guidance provided by the Department have been submitted.

(3) The Secretary notifies a State when the Department has received the State plan and all documents required under guidance provided by the Department.

(d) If a State submits a State plan in substantially approvable form (or an amendment to the State plan that makes it substantially approvable), and submits any other document required under guidance provided by the Department, on or before the date the State plan must be submitted to the Department, the State may begin to obligate funds on the date that the funds are first available for obligation by the Secretary.

(e) If a State submits a State plan in substantially approvable form (or an amendment to the State plan that makes it substantially approvable) or any other documents required under guidance provided by the Department after the date the State plan must be submitted to the Department, and—

(1) The Department determines that the State plan is substantially approvable on or before the date that the funds are first available for obligation by the Secretary, the State may begin to obligate funds on the date that the funds are first available for obligation by the Secretary; or

(2) The Department determines that the State plan is substantially approvable after the date that the funds are first available for obligation by the Secretary, the State may begin to obligate funds on the earlier of the two following dates:

(i) The date that the Secretary determines that the State plan is substantially approvable.

(ii) The date that is determined by adding to the date that funds are first available for obligation by the Secretary—

(A) The number of days after the date the State plan must be submitted to the Department that the State plan or other document required under guidance provided by the Department is submitted; and

(B) If applicable, the number of days after the State receives notice that the State plan is not substantially approvable that the State submits additional information that makes the plan substantially approvable.

(f) Additional information submitted under paragraph (e)(2)(ii)(B) of this section must be signed by the person who submitted the original State plan (or an authorized delegate of that officer).

(g) (1) If the Department does not complete its review of a State plan during the period established for that review, the Secretary will grant pre-award costs for the period after funds become available for obligation by the Secretary and before the State plan is found substantially approvable.

(2) The period established for the Department's review of a plan does not include any day after the State has received notice that its plan is not substantially approvable.

Note: The following examples describe how the regulations in § 76.703 would be applied in certain circumstances. For the purpose of these examples, assume that the grant program established an April 1 due date for the submission of the State plan and that funds are first available for obligation by the Secretary on July 1.

Example 1. Paragraph (d): A State submits a plan in substantially approvable form by April 1. The State may begin to obligate funds on July 1.

Example 2. Paragraph (e)(1): A State submits a plan in substantially approvable form on May 15, and the Department notifies the State that the plan is substantially approvable on June 20. The State may begin to obligate funds on July 1.

Example 3. Paragraph (e)(2)(i): A State submits a plan in substantially approvable form on May 15, and the Department notifies the State that the plan is substantially approvable on July 15. The State may begin to obligate funds on July 15.

Example 4. Paragraph (e)(2)(ii)(A): A State submits a plan in substantially approvable form on May 15, and the Department notifies the State that the plan is substantially approvable on August 21. The State may begin to obligate funds on August 14. (In this example, the plan is 45 days late. By adding 45 days to July 1, we reach August 14, which is earlier than the date, August 21, that the Department notifies the State that the plan is substantially approvable. Therefore, if the State chose to begin drawing funds from the Department on August 14, obligations made on or after that date would generally be allowable.)

Example 5. Paragraph (e)(2)(i): A State submits a plan on May 15, and the Department notifies the State that the plan is not substantially approvable on July 10. The State submits changes that make the plan substantially approvable on July 20 and the Department notifies the State that the plan is substantially approvable on July 25. The State may begin to obligate funds on July 25. (In this example, the original submission is 45 days late. In addition, the Department notifies the State that the plan is not substantially approvable and the time from that notification until the State submits changes that make the plan substantially approvable is an additional 10 days. By adding 55 days to July 1, we reach August 24. However, since the Department notified the State that the plan was substantially approvable on July 25, that is the date that the State may begin to obligate funds.)

Example 6. Paragraph (e)(2)(ii)(B): A State submits a plan on May 15, and the Department notifies the State that the plan is not substantially approvable on August 1. The State submits changes that make the plan substantially approvable on August 20, and the Department notifies the State that the plan is substantially approvable on September 5. The State may choose to begin drawing funds from the Department on September 2, and obligations made on or after that date would generally be allowable. (In this example, the original submission is 45 days late. In addition, the Department notifies the State that the plan is not substantially approvable and the time from that notification until the State submits changes that make the plan substantially approvable is an additional 19 days. By adding 64 days to July 1, we reach September 2, which is earlier than September 5, the date that the Department notifies the State that the plan is substantially approvable.)

Example 7. Paragraph (g): A State submits a plan on April 15 and the Department notifies the State that the plan is not substantially approvable on July 16. The State makes changes to the plan and submits a substantially approvable plan on July 30. The Department had until July 15 to decide whether the plan was substantially approvable because the State was 15 days late in submitting the plan. The date the State may begin to obligate funds under the regulatory deferral is July 29 (based on the 15 day deferral for late submission plus a 14 day deferral for the time it took to submit a substantially approvable plan after having received notice). However, because the Department was one day late in completing its review of the plan, the State would get pre-award costs to cover the period of July 1 through July 29.

* * * * *

(Authority: 20 U.S.C. 1221e–3, 6511(a), 3474, 31 U.S.C. 6503)

3. Sections 76.704, 76.705, and 76.706 are redesignated as §§ 76.708, 76.709, and 76.710, respectively.

4. A new § 76.704 is added to read as follows:

§ 76.704 New State plan requirements that must be addressed in a State plan.

(a) This section specifies the State plan requirements that must be addressed in a State plan if the State plan requirements established in statutes or regulations change on a date close to the date that State plans are due for submission to the Department.

(b)(1) A State plan must meet the following requirements:

(i) Every State plan requirement in effect three months before the date the State plan is due to be submitted to the Department under 34 CFR 76.703; and

(ii) Every State plan requirement included in statutes or regulations that will be effective on or before the date that funds become available for obligation by the Secretary and that have been signed into law or published in the **Federal Register** as final regulations three months before the date the State plan is due to be submitted to the Department under 34 CFR 76.703.

(2) If a State plan does not have to meet a new State plan requirement under paragraph (b)(1) of this section, the Secretary takes one of the following actions:

(i) Require the State to submit assurances and appropriate documentation to show that the new requirements are being followed under the program.

(ii) Extend the date for submission of State plans and approve pre-award costs as necessary to hold the State harmless.

(3) If the Secretary requires a State to submit assurances under paragraph (b)(2) of this section, the State shall incorporate changes to the State plan as soon as possible to comply with the new requirements. The State shall submit the necessary changes before the start of the next obligation period.

(Authority: 20 U.S.C. 1221e–3, 6511(a), 3474, 31 U.S.C. 6503)

5. A new § 76.711 is added after redesignated § 76.710 and before the center heading ''REPORTS'' to read as follows:

§ 76.711 Requesting funds by CFDA number.

If a program is listed in the Catalog of Federal Domestic Assistance (CFDA), a State, when requesting funds under the program, shall identify that program by the CFDA number.

(Authority: 20 U.S.C. 1221e–3, 6511(a), 3474, 31 U.S.C. 6503)

PART 667—STATE POSTSECONDARY REVIEW PROGRAM

6. The authority citation for Part 667 continues to read as follows:

Authority: 20 U.S.C. 1099a through 1099a–3, unless otherwise noted.

7. Section 667.1 is amended by revising paragraph (d)(1)(iii) to read as follows:

§ 667.1 Scope and purpose.

* * * * *

(d)(1) * * *

(iii) 34 CFR 76.701, 76.702, 76.703, 76.704, 76.707, 76.720, 76.730, 76.731, 76.734, 76.760, and 76.761 of subpart G;

* * * * *

[FR Doc. 95–18064 Filed 8–10–95; 8:45 am]

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federal register

Friday
August 11, 1995

Part IV

Environmental Protection Agency

Certain Chemicals; Premanufacture Notices

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–51842; FRL–4942–7]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical to notify EPA and comply with the statutory provisions pertaining to the manufacture or import of substances not on the TSCA Inventory. Section 5 of TSCA also requires EPA to publish receipt and status information in the **Federal Register** each month reporting premanufacture notices (PMN), polymer exemption notices and test marketing exemption (TME) application requests received, both pending and expired. The information contained in this document clears a backlog of notices received from March 20, 1995 to May 1, 1995.

ADDRESSES: Written comments, identified by the document control number ''[OPPTS–51842]'' and the specific PMN number, if appropriate, should be sent to: Document Control Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. ETG–099 Washington, DC 20460.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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 in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPPTS–51842]. No CBI should be submitted through e-mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found under ''SUPPLEMENTARY INFORMATION'' of this document.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–545, 401 M St., SW., Washington, DC, 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: Under the provisions of TSCA, EPA is required to publish notice of receipt and status reports of chemicals subject to section 5 reporting requirements. The notice requirements are provided in TSCA sections 5(d)(2) and 5(d)(3). Specifically, EPA is required to provide notice of receipt of PMNs, polymer exemption notices and TME application requests received. EPA also is required to identify those chemical submissions for which data has been received, the uses or intended uses of such chemicals, and the nature of any test data which may have been developed. Lastly, EPA is required to provide periodic status reports of all chemical substances undergoing review and receipt of notices of commencement.

A record has been established for this notice under docket number ''[OPPTS–51842]'' (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 confidential business information (CBI), is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center (NCIC), Rm. NEM–B607, 401 M St., SW., Washington, DC 20460.

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 notice, as well as the public version, as 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

In the past, EPA has published individual notices reflecting the status of section 5 filings received, pending or expired, as well as notices reflecting receipt of notices of commencement. In an effort to become more responsive to the regulated community, the users of this information and the general public, to comply with the requirements of TSCA, to conserve EPA resources, and to streamline the process and make it more timely, EPA is consolidating these separate notices into one comprehensive notice that will be issued at regular intervals.

EPA shall provide a consolidated report in the **Federal Register** reflecting the dates PMNs, polymer exemptions and TME application requests were received, the projected notice end date, the manufacturer or importer identity, to the extent that such information is not claimed as confidential and chemical identity, either specific or generic depending on whether chemical identity has been claimed confidential. Additionally, in this same report, EPA shall provide a listing of receipt of new notices of commencement. Generic use information on these substances will be provided.

EPA believes the new format of the notice will be easier to understand by the interested public, and provides the information that is of greatest interest to the public users. Certain information provided in the earlier notices will not be provided under the new format. The status reports of substances under review, potential production volume, and summaries of health and safety data will not be provided in the new notices.

EPA is not providing production volume information in the consolidated notice since such information is generally claimed as confidential. For this reason, there is no substantive loss to the public in not publishing the data. Health and safety data are not summarized in the notice since it is recognized as impossible, given the format of this notice, as well as the previous style of notices, to provide meaningful information on the subject. In those submissions where health and safety data were received by the Agency, a footnote is included by the Manufacturer/Importer identity to indicate its existence. As stated below, interested persons may contact EPA directly to secure information on such studies. As stated in the previous paragraph, while generic use information is not included in this notice all future notices shall carry this information.

For persons who are interested in data not included in this notice, access can be secured at EPA Headquarters in the NCIC at the address provided above. Additionally, interested parties may telephone the Document Control Office at (202) 260–1532, TDD (202) 554–0551, for generic use information, health and safety data not claimed as confidential or status reports on section 5 filings.

Send all comments to the address listed above. All comments received will be reviewed and appropriate amendments will be made as deemed necessary.

This notice will identify: (I) PMNs received; (II) Polymer exemptions received.

I. 350 Premanufacture Notices Received From: 03/01/94 to 04/30/95.

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–0893	03/20/95	06/18/95	3M	(G) Adhesive intermediate	(G) Copolymer with 2-propenoic acid, isooctyl ester
P–95–0894	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with a dibasic acid and diamines
P–95–0895	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with ethylenediamine, a dibasic acid and diamines
P–95–0896	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with a dibasic acid and diamines
P–95–0897	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with a dibasic acid and a diamine
P–95–0898	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with a dibasic acid and diamines
P–95–0899	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive.	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with sebacic acid and diamines
P–95–0900	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylenediamine, sebacic acid and diamines
P–95–0901	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylenediamine, a dibasic acid and diamines
P–95–0902	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylenediamine, a dibasic acid and a diamine
P–95–0903	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylenediamine, a dibasic acid and a diamine
P–95–0904	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with a dibasic acid and diamines
P–95–0905	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with ethylenediamine, sebacic acid and diamines
P–95–0906	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with ethylenediamine, a dibasic acid and diamines
P–95–0907	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with a dibasic acid and diamines
P–95–0908	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with sebacic acid and diamines
P–95–0909	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylenediamine sebacic acid and diamines
P–95–0910	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylenediamine, a dibasic acid and diamines
P–95–0911	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylenediamine, a dibasic acid and diamines
P–95–0912	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylenediamine, sebacic acid and diamines

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–0913	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated., dimers, polymers with tall-oil fatty acids and a diamine
P–95–0914	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with ethylenediamine, tall-oil fatty acids and a dibasic acid and diamine
P–95–0915	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with ethylendiamine, tall-oil fatty acids and a diamine
P–95–0916	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with sebacic acid, a dibasic acid and diamines
P–95–0917	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with ethylenediamine, sebacic acid, a dibasic acid and a diamine
P–95–0918	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with a dibasic acid, stearic acid, ethylenediamine and diamines
P–95–0919	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with a dibasic acid, ethylenediamine, tall-oil fatty acids and diamines
P–95–0920	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, polymers with a dibasic acid ethylenediamine, tall-oil fatty acids and diamines
P–95–0921	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with a dibasic acid, ethylenediamine, stearic acid and diamines
P–95–0922	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with a dibasic acid isostearic acid, ethylenediamine and diamines
P–95–0923	03/21/95	06/19/95	CBI	(S) Used in aqueous dispersions which function as adhesive	(G) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, polymers with a dibasic acid; ethylenediamine and a diamine
P–95–0924	03/21/95	06/19/95	Dow Chemical U.S.A.	(S) Surfactant for polyurethane foam production	(G) Esterified polyglycol
P–95–0925	03/21/95	06/19/95	Dow Chemical U.S.A.	(S) Surfactant for polyurethane foam production	(G) Esterified polyglycol
P–95–0926	03/21/95	06/19/95	Olin Corporation	(S) Surfactant--/rinse aid household, industrial, insit	(G) Alcohol alkoxylate
P–95–0927	03/20/95	06/18/95	CBI	(G) Open, non-dispersive	(G) Acrylic polymer
P–95–0928	03/21/95	06/19/95	CBI	(S) Textile finish	(G) Perfluoroalkylethylacrylate copolymer
P–95–0929	03/21/95	06/19/95	CBI	(G) Component of coating with open use	(G) Amine salt
P–95–0930	03/21/95	06/19/95	CBI	(G) Component of coating with open use	(G) Cationic epoxy resin
P–95–0931	03/21/95	06/19/95	Arizona Chemical Company	(S) Resin vehicle for the production of heat-seat, web	(G) Phenolic modified rosin ester, polymer with soybean oil
P–95–0932	03/21/95	06/19/95	Huls America Inc	(S) Lubricant for use with cfc-free refrigerants	(G) Dialkyl malonate, alkyl alkenoate polymer
P–95–0933	03/21/95	06/19/95	Lilly Industrial Coatings, Inc.	(G) Intermediate for polymer	(S) Benzene, 1-(1-isocyanato-1-methylethyl)-3-(1-methylethenol) blocked with caprolactam
P–95–0934	03/21/95	06/19/95	Lilly Industrial Coatings, Inc.	(S) Electrocoating metal parts	(G) Cathodic acrylic electrocoat resin feed
P–95–0935	03/22/95	06/20/95	Dow Corning	(S) Abrasion resistant coating	(G) Acrylate-functional silica
P–95–0936	03/22/95	06/20/95	Dow Corning	(S) Abrasion resistant coating	(G) Acrylate-functional silica
P–95–0937	03/23/95	06/21/95	CBI	(S) Organic synthesis intermediate	(G) Pyrimidine salt

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–0938	03/23/95	06/21/95	CBI	(S) Organic synthesis intermediate	(G) Pyrimidine
P–95–0939	03/23/95	06/21/95	CBI	(S) Organic synthesis intermediate	(G) Organophosphate
P–95–0940	03/23/95	06/21/95	CBI	(S) Organic synthesis intermediate	(G) Amidine
P–95–0941	03/21/95	06/19/95	Percy Internationa Ltd	(S) Catalyst for use in moisture-curing urethane coating	(S) Carbonato bis (-*N*-ethyl, 2-isopropyl-1,3-oxazolane)
P–95–0942	03/23/95	06/21/95	Ciba-Geigy Corporation	(G) Textile dye	(G) Substituted phenyl azo substituted naphthalene amino triazinyl amino substituted propane
P–95–0943	03/23/95	06/21/95	CBI	(G) Polymer processing aid	(G) Styrene-acrylic polymer
P–95–0944	03/23/95	06/21/95	CBI	(G) Chlorosilane	(G) Organochlorosilane
P–95–0946	03/23/95	06/21/95	Mitsui & Co., (U.S.A.) Inc.	(G) Lubricant	(G) Reaction product of 3-alkoxy-2,2-dialkylpropanol, 2-(alkylphenoxy)ethanol and dialkylcarbonate
P–95–0947	03/27/95	06/25/95	Dow Chemical U.S.A.	(S) Intermediate	(G) Aromatic sulfonyl chloride
P–95–0948	03/27/95	06/25/95	Dow Chemical U.S.A.	(S) Magnetic media lubricant	(G) Aromatic sulfonamide
P–95–0949	03/27/95	06/25/95	Dow Chemical U.S.A.	(S) Magnetic media lubricant	(G) Aromatic sulfonamide
P–95–0950	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0951	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0952	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0953	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0954	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0955	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0956	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0957	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0958	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0959	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0960	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0961	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0962	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0963	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0964	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0965	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0966	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0967	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–0968	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0969	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0970	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohol
P–95–0971	03/27/95	06/25/95	CBI	(S) Coatings	(G) Polymer of polyisocyanate, blocked with hydroxy ester of carbamic acid and alcohoL
P–95–0972	03/27/95	06/25/95	General Polymers West	(S) Architectural coatings	(G) Polyurethane
P–95–0973	03/28/95	06/26/95	VPN, Inc.	(S) Sprayed on foilage of plants to promote growth	(G) vanadium compound
P–95–0974	03/27/95	06/25/95	Hoechst Celanese	(G) Binder in paints	(S) A polymer of: adipic acid; 1,6-hexandiol; succinic acid anhydride; neopentyl glycol; isophorone diisocyanate; diethanolaminine; bishydroxymethyl propionic acid; *N,N*-diethylethanolamine; dibutyl tin oxide
P–95–0975	03/27/95	06/25/95	Exxon Chemical Company	(S) Polymerization catalyst	(G) Aluminum organometallic compound
P–95–0976	03/27/95	06/25/95	Para-Chem Southern, Inc.	(S) Latex thickener	(S) Sodium salt of methyl acrylate and methacrylic acid co-polymer
P–95–0977	03/28/95	05/29/95	Henkel Corporation	(G) Dispersant	(G) Acrylate polymer salt
P–95–0978	03/28/95	06/26/95	High Point Chemical Corporation	(G) Industrial cleaning	(S) Poly(oxy-1,2-ethanediyl), .alpha.-(carboxymethyl)-.omega.-[(2-ethylhexyl)oxy]- (9CI)
P–95–0979	03/28/95	06/26/95	E.I. Dupont de Nemours & Co., Inc.	(G) Enclosed destructive use	(G) Fluorinated carboxylic acid, alkali metal salt
P–95–0980	03/28/95	06/26/95	E.I. Dupont de Nemours & Co., Inc.	(G) Enclosed destructive use	(G) Fluorinated carboxylic acid, alkali metal salt
P–95–0981	03/28/95	06/26/95	E.I. Dupont de Nemours & Co., Inc.	(G) Enclosed destructive use	(G) Fluorinated carboxylic acid, alkali metal salt
P–95–0982	03/28/95	06/26/95	Hercules-Sanyo Incorporated	(S) Binder resin for printing inks	(G) Metal resinate
P–95–0983	03/28/95	06/26/95	Hercules-Sanyo Incorporated	(S) Binder resin for printing inks	(G) Metal resinate
P–95–0984	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0985	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0986	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0987	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0988	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0989	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0990	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0991	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–0992	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0993	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0994	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0995	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0996	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0997	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0998	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–0999	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1000	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1001	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1002	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1003	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1004	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1005	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1006	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1007	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1008	03/28/95	06/26/95	CBI	(S) Printing ink component/ laminating adhesive	(G) Polyamide resin salt
P–95–1009	03/28/95	06/26/95	CBI	(G) Coating resin	(G) Acrylic polymer
P–95–1010	03/28/95	06/26/95	3M	(S) Surfactant	(G) Perfluoroalkyl carboxylate salt
P–95–1011	03/29/95	06/27/95	Xerox Corporation	(G) Reprographic pigment dispersant	(G) Vinyl copolymer
P–95–1012	03/29/95	06/27/95	BF Goodrich Company	(G) Topcoat used for the coating of gymnasium and other	(G) Polyurethane based on polyisocyanates, polyols and polyamine
P–95–1013	03/29/95	06/27/95	BF Goodrich Company	(G) Topcoat used for the coating of gymnasium and other	(G) Polyurethane based on polyisocyanates, polyols and polyamine
P–95–1014	03/29/95	06/27/95	BF Goodrich Company	(G) Topcoat used for the coating of gymnasium and other	(G) Polyurethane based on polyisocyanates, polyols and polyamine
P–95–1015	03/29/95	06/27/95	BF Goodrich Company	(G) Topcoat used for the coating of gymnasium and other	(G) Polyurethane based on polyisocyanates, polyols and polyamine
P–95–1016	03/29/95	06/27/95	BF Goodrich Company	(G) Topcoat used for the coating of gymnasium and other	(G) Polyurethane based on polyisocyanates, polyols and polyamine
P–95–1017	03/29/95	06/27/95	BF Goodrich Company	(G) Topcoat used for the coating of gymnasium and other	(G) Polyurethane based on polyisocyanates, polyols and polyamine
P–95–1018	03/29/95	06/27/95	BF Goodrich Company	(G) Topcoat used for the coating of gymnasium and other	(G) Polyurethane based on polyisocyanates, polyols and polyamine
P–95–1019	03/29/95	06/27/95	BF Goodrich Company	(G) Topcoat used for the coating of gymnasium and other	(G) Polyurethane based on polyisocyanates, polyols and polyamine
P–95–1020	03/29/95	06/27/95	CBI	(G) Colorant	(G) Polymeric colorant
P–95–1021	03/29/95	06/27/95	CBI	(G) Colorant	(G) Polymeric colorant

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–1022	03/29/95	06/27/95	CBI	(G) Open, non-dispersive use	(G) Polyester silane
P–95–1023	03/29/95	06/27/95	Xerox Corporation	(G) Reprographic pigment	(G) Phthalocyanine pigment
P–95–1024	03/30/95	06/28/95	CBI	(G) Open, non-dispersive use	(G) Acrylosilane resin
P–95–1025	03/31/95	06/29/95	CBI	(S) Coatings	(G) Urethane modified melamine resin
P–95–1026	03/31/95	06/29/95	Eastman Kodak Company	(G) Chemical intermediate	(G) Substituted alkylaminodihalobenzoic acid, ester
P–95–1027	03/31/95	06/29/95	CBI	(G) Processing additive	(G) Substituted metal sulfides
P–95–1028	03/30/95	06/28/95	Mycogen Corporation	(S) Biopesticides	(G) Bacillus thuringiensis delta entoxin genes
P–95–1029	03/30/95	06/28/95	Mycogen Corporation	(S) Biopesticides	(G) Bacillus thuringiensis delta entoxin genes
P–95–1030	04/03/95	07/02/95	CBI	(G) Dielectric fluid	(G) Orthoxylene compoound
P–95–1031	04/03/95	07/02/95	Osakagodo America, Inc.	(S) Coloring agent for resin	(S) 7*H*(1)Benzopyrano(3′,2′:3,4) pyrido(1,2*A*) benzimidazole-6-carbonitrile, 3-(diethylamino)-7-oxo-
P–95–1032	04/03/95	07/02/95	CBI	(G) Raw material for colorant	(S) Benzenesulfonic acid, 2-amino-4,5-dichloro-
P–95–1033	04/03/95	07/02/95	Dow Corning	(S) Silicone adhesive component	(G) Organofunctional silica
P–95–1034	04/03/95	07/02/95	CBI	(G) Open, non-dispersive	(G) Aqueous polyester polyurethane dispersion
P–95–1035	04/03/95	07/02/95	CBI	(G) Open, non-dispersive	(G) Aqueous aliphatic urethane stoving resin
P–95–1036	04/03/95	07/02/95	Shipley Company, Inc.	(S) Chemical intermediate used in the manufacture of a photoactive compound	(G) Polynuclear polyhydroxy phenol
P–95–1037	04/03/95	07/02/95	Shipley Company, Inc.	(S) Chemical intermediate used in the manufacture of PH	(G) Naphthaquinone diazide sulfonyl ester mixture of a polynuclear polyhydroxy phenol
P–95–1038	04/03/95	07/02/95	E.I. Dupont de Nemours & Co., Inc.	(S) Release sheeting, protective cladding, coatings	(G) Polyvinyl fluoride copolymer
P–95–1039	04/03/95	07/02/95	E.I. Dupont de Nemours & Co., Inc.	(S) Release sheeting, protective cladding, coatings	(G) Polyvinyl fluoride copolymer
P–95–1040	04/03/95	07/02/95	CBI	(G) Open, non-dispersive	(G) Acrylosilane resin
P–95–1041	04/03/95	07/02/95	CBI	(G) Destructive use	(G) Silane intermediate
P–95–1042	04/03/95	07/02/95	CBI	(G) Destructive use	(G) Silane intermediate
P–95–1043	04/04/95	07/03/95	CBI	(S) Paper dye	(G) Bis(substituted)carbomonocyclic azo)-carbomonocyclicol
P–95–1044	04/04/95	07/03/95	CBI	(S) Paper dye	(G) Bis(substituted)carbomonocyclic azo)-carbomonocyclicol
P–95–1045	04/04/95	07/03/95	CBI	(S) Paper dye	(G) Bis(substituted)carbomonocyclic azo)-carbomonocyclicol
P–95–1046	04/04/95	07/03/95	CBI	(S) Antioxidant/stabilizer in polymers	(G) Aryl alkyl phosphite
P–95–1047	04/04/95	07/03/95	Reichhold Chemicals, Inc.	(S) Wood coating	(G) Anionic aliphatic polyurethane dispersion
P–95–1048	04/04/95	07/03/95	CBI	(S) Electrical insulation coating	(G) Polyamideimide resin
P–95–1049	04/04/95	07/03/95	CBI	(S) Electrical insulation coating	(G) Polyamideimide resin
P–95–1050	04/04/95	07/03/95	CBI	(G) Paper strength additive	(G) Modified cationic acrylamide polymer
P–95–1051	04/04/95	07/03/95	CBI	(G) Paper strength additive	(G) Modified anionic acrylamide polymer
P–95–1052	04/05/95	07/04/95	CBI	(G) Raw material of surfactant for metal cleaning	(S) Dehydrogenated product from $C_{12–14}$ linear chained random secondary alcohols

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–1053	04/04/95	07/03/95	Hoechst Celanese	(G) Paint resin	(G) Water-soluble urethane alkyd
P–95–1054	04/05/95	07/04/95	CBI	(G) Surfactant	(G) Comdensates of methacrylic ester and aminosulfonic ester
P–95–1055	04/05/95	07/04/95	CBI	(G) Ink additve	(G) Cross linked acrylic random copolymer
P–95–1056	04/05/95	07/04/95	Lilly Industrial Coatings, Inc.	(G) Salt of electrocoat resin vehicle	(G) Epoxy resin salt
P–95–1057	04/05/95	07/04/95	Lilly Industrial Coatings, Inc.	(G) Salt of electrocoat resin vehicle	(G) Acrylic resin salt
P–95–1058	04/05/95	07/04/95	Lilly Industrial Coatings, Inc.	(G) Salt of electrocoat resin vehicle	(G) Epoxy resin salt
P–95–1059	04/06/95	07/05/95	Ciba-Geigy Corporation	(S) Intermediate for dye manufacture	(G) Substituted phenyl azo substituted phenyl amino triazinyl substituted naphthalene sulfonic acid derivative
P–95–1060	04/06/95	07/05/95	CBI	(G) Paint	(G) Polyurethane/polyurea polymer
P–95–1061	04/06/95	07/05/95	CBI	(G) Paint	(G) Polyurethane/polyurea polymer
P–95–1062	04/06/95	07/05/95	CBI	(S) Oil field corrosion inhibitor / asphalt emulsifier	(G) Alkoxylated diamine
P–95–1063	04/06/95	07/05/95	CBI	(S) Oil field corrosion inhibitor / asphalt emulsifier	(G) Alkoxylated diamine
P–95–1064	04/06/95	07/05/95	CBI	(S) Oil field corrosion inhibitor / asphalt emulsifier	(G) Alkoxylated diamine
P–95–1065	04/06/95	07/05/95	CBI	(S) Paint, ink	(G) Styrene modified polyester
P–95–1066	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1067	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1068	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1069	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1070	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1071	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1072	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1073	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1074	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1075	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1076	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1077	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1078	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1079	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1080	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–1081	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1082	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1083	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1084	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1085	04/07/95	07/06/95	Catalyst Resources, Inc	(S) Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1086	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1087	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1088	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1089	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1090	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1091	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1092	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1093	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1094	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1095	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1096	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1097	04/07/95	07/06/95	Catalyst Resources, Inc	(S)Polypropylene manufacturing catalyst	(G) A magnesium, titanium organo-complex compound
P–95–1098	04/07/95	07/06/95	Cytec Industries	(G) Crosslinking resin	(G) Tris carbamoyl triazine
P–95–1099	04/07/95	07/06/95	CBI	(G) Open, non-dispersive	(G) Styrene, divinylbenzene copolymner with trialkyl ammonium groups in OH form
P–95–1100	04/07/95	07/06/95	3M Company	(G) Resin	(G) Polymer of 1,2-ethanediol and aromatic esters
P–95–1101	04/07/95	07/06/95	3M Company	(G) Resin	(G) Polymer of 1,2-ethanediol and aromatic esters
P–95–1102	04/07/95	07/06/95	CBI	(G) A component of the material for integrate circuit F	(G) Novolac-resin from substituted phenols and formaldehyde
P–95–1103	04/07/95	07/06/95	CBI	(G) A component of the material for integrate circuit F	(G) Substituted resolcinol
P–95–1104	04/07/95	07/06/95	CBI	(G) A component of the material for integrate circuit F	(G) Substituted resorcinol
P–95–1105	04/07/95	07/06/95	CBI	(G) Reactant for specialty industrial chemicals	(G) Mixed carboxylic acids, branched
P–95–1106	04/10/95	07/09/95	Ausimont USA, Inc.	(G) Synthesis intermediate	(S) 2,2,4-trifluoro-5-trifluoromethoxy-1,3-dioxole
P–95–1107	04/10/95	07/09/95	CBI	(S) Coatings	(G) Amino urethane/urea crosslinking resin
P–95–1108	04/10/95	07/09/95	CBI	(S) Coatings	(G) Amino urethane/urea crosslinking resin salted with organic acid
P–95–1109	04/10/95	07/09/95	CBI	(S) Coatings	(G) Amino urethane/urea crosslinking resin salted with organic acid

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–1110	04/10/95	07/09/95	CBI	(G) Acrylate/methacrylate copolymer	
P–95–1111	04/10/95	07/09/95	ICI Fiberite	(S) An epoxy resin reinforced with carbon fibers for AE	(G) Functionalized elastomeric-epoxy copolymer
P–95–1112	04/10/95	07/09/95	Gelest, Inc.	(S) Surface treatment of silica employed in liquid chro	(S) 3-cyanopropyl(diisoproyl)chlorosilane
P–95–1113	04/10/95	07/09/95	E.I. Dupont de Nemours & Co., Inc.	(S) Component of glassed reinforced molding resin for A	(G) Butylene terephthalate copolymer
P–95–1114	04/10/95	07/09/95	E.I. Dupont de Nemours & Co., Inc.	(S) Component of glassed reinforced molding resin for a	(G) Butylene terephthalate copolymer
P–95–1115	04/10/95	07/09/95	Sequa Chemicals, Inc	(S) Textile finishing resin	(S) 1,3-bis(1-hydroxy-2,2-dimethoxyethyl)-2-imidazolidinone
P–95–1116	04/13/95	07/12/95	Jowat Corp.	(S) Adhesive	(G) Modified vinylacetate copolymer
P–95–1117	04/10/95	07/09/95	CBI	(G) Surfactant intermediate	(G) Alkyletherhydroxy-propylamine
P–95–1118	04/10/95	07/09/95	NOF America Corporation	(S) Compatibilizing agent for polymer blends	(G) Compatibility agent
P–95–1119	04/10/95	07/09/95	CBI	(G) Surfactant intermediate	(G) Alkyletherhydroxy-propylamine
P–95–1120	04/11/95	07/10/95	CBI	(S) Electrical insulating coating	(G) Polyamide resin
P–95–1121	04/11/95	07/10/95	CBI	(G) Crosslinking agent for coatings	(S) Polymer of cythane 2601 solids; 2-butanone oxime
P–95–1122	04/12/95	07/11/95	CBI	(G) Water-borne coating	(S) Aqueous polyurethane dispersion
P–95–1123	04/13/95	07/12/95	CBI	(G) Open, non-dispersive use	(G) Silane functional diluent
P–95–1124	04/13/95	07/12/95	CBI	(G) Infra-red absorber	(G) Aryl substituted copper phthalocyanine
P–95–1125	04/14/95	07/13/95	Hoechst Celanese	(S) Stoving industrial paints	(G) Modified alkyd resin
P–95–1126	04/14/95	07/13/95	NOF America Corporation	(S) Compatibilizing agent for polymer blends	(G) Compatibility agent
P–95–1127	04/14/95	07/13/95	The C.P. Hall Company	(G) Adhesives/coatings	(G) Polyalkyl pentanedioate polyester
P–95–1128	04/14/95	07/13/95	Great Lakes Chemical Corporation	(S) Flame retardant for foams and polymers	(G) Brominated aromatic ester
P–95–1129	04/17/95	07/16/95	3M Company	(G) Adhesive	(G) Acrylate copolymer
P–95–1130	04/17/95	07/16/95	CBI	(G) Photoresist	(G) Acryl resin
P–95–1131	04/17/95	07/16/95	CBI	(G) Photoresist	(G) Acryl resin
P–95–1132	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1133	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1134	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1135	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1136	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1137	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1138	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1139	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1140	04/18/95	07/17/95	CBI	(G) Open non-dispersive use	(G) Diketone aluminum chelate
P–95–1141	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1142	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1143	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1144	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1145	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1146	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1147	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–1148	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1149	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1150	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1151	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1152	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1153	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1154	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized aluminum hydroxide
P–95–1155	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1156	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1157	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1158	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1159	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1160	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1161	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1162	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1163	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1164	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1165	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1166	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1167	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1168	04/17/95	07/16/95	CBI	(G) Filler/flame retardant	(G) Functionalized magnesium hydroxide
P–95–1169	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1170	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1171	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1172	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1173	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1174	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1175	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1176	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1177	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1178	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1179	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1180	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1181	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1182	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1183	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1184	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1185	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1186	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1187	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1188	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1189	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1190	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1191	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1192	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1193	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1194	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1195	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay
P–95–1196	04/17/95	07/16/95	CBI	(G) Filler	(G) Functionalized clay

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–1197	04/19/95	07/18/95	Lilly Industrial Coatings, Inc.	(G) Electrocoat resin vehicle	(G) Modified epoxy resin
P–95–1198	04/19/95	07/18/95	Lilly Industrial Coatings, Inc.	(G) Salt for electrocoat resin vehicle	(G) Acrylic resin salt
P–95–1199	04/19/95	07/18/95	CBI	(G) Open, non-dispersive	(G) Aqueous emulsion of octyltriethoxysilane
P–95–1200	04/18/95	07/17/95	CBI	(G) A component of the material for IC fabrication	(G) Novolac-resin from substituted phenols and formaldehyde
P–95–1201	04/18/95	07/17/95	3M	(S) Adhesive	(G) Acrylate polymer
P–95–1202	04/20/95	07/19/95	Angus Chemical Company	(G) Chemical intermediate	(G) Alkanolamine
P–95–1203	04/20/95	07/19/95	Austin Powder Company	(S) Emulsifier in manufacturer of emulsion explosives	(S) A polymer of: *N,N*-diethylethanolamine (deea) 2-diethylaminoethanol: poly(isobutylene)-succinic anhydride
P–95–1204	04/20/95	07/19/95	CBI	(G) Quality control agent	(G) Alkoxy-alkyl-carbopolycycle
P–95–1205	04/20/95	07/19/95	CBI	(G) Quality control agent	(G) Disubstituted benzene
P–95–1206	04/19/95	07/18/95	Hoechst Celanese	(S) Binder for industrial paints	(G) Modified alkyd resin
P–95–1207	04/19/95	07/18/95	CBI	(G) Hydrocarbon process stream additive; lube oil addit	(G) Poly(alkylmethyacrylate)
P–95–1208	04/21/95	07/20/95	DIC Trading (USA) Inc.	(G) Soil repellent	(G) Fluorinated acrylic copolymer
P–95–1209	04/21/95	07/20/95	CBI	(G) Open, non-dispersive	(G) Polyester resin
P–95–1210	04/21/95	07/20/95	CBI	(G) Polymer support resin	(G) Carboxy terminated amide functionl polymer of aliphatic diols, aromatic acrboxylic acid/anhydride, tall oil fatty acid dimer, and ethoxylated polyarylphenol
P–95–1211	04/21/95	07/20/95	CBI	(G) Polymer support resin	(G) Carboxy terminated amide functionl polymer of aliphatic diols, aromatic acrboxylic acid/anhydride, tall oil fatty acid dimer, and ethoxylated polyarylphenol, ammonium salt
P–95–1212	04/21/95	07/20/95	The C.P. Hall Company	(G) Plasticizer	(S) Dibutoxypropyl adipate
P–95–1213	04/21/95	07/20/95	CBI	(G) Hydroxy terminated polyester intermediate for polyu	(G) Hydroxy terminated polyester
P–95–1214	04/21/95	07/20/95	CBI	(G) Adhesive fo flexible substances	(G) Polyether/polyester/aromatic polyurethane
P–95–1215	04/21/95	07/20/95	CBI	(G) Adhesive fo flexible substances	(G) Polyester urethane polymer
P–95–1216	04/21/95	07/20/95	E.I. Dupont de Nemours & Co., Inc.	(G) Paper fluoridizer	(G) Polysubstituted methacrylic copolymer
P–95–1217	04/25/95	07/24/95	Shipley Company, Inc.	(S) Chemical intermediate used in the manufacture of PH	(G) Naphthaquinone diazide sulfonyl ester mixture of a polynuclear polyhydroxy phenol
P–95–1218	04/25/95	07/24/95	Hoechst Celanese	(S) Binder for industrial paints, stoving enamels	(S) A polymer of: 1,6-hexanediol; 1,4-cyclohexanedimethanol; isophthalic acid; trimellitic anhydride; phenol, 4,4′-(1-methylethylidene)bis-polymer with (chloromethyl) oxirane; phosphoric acid; isopropanol; castor oil; 1,3-isobenzofurandione; trimethylolpropane; benzoic acid; 1,3-propanediol, 2,2-bis(hydroxymethyl); 1,3-isobenzofurandione, 3*a*,4,7,ta-tetrahydro-; ethanol, 2-dimethylamino
P–95–1219	04/25/95	07/24/95	The Dexter Corporation	(G) Component of structural material	(G) Epoxy resin
P–95–1220	04/25/95	07/24/95	CBI	(S) Thixotropic agent for heavy duty paints & primers &	(G) Fatty acid diamide

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
P–95–1221	04/25/95	07/24/95	3M	(G) Coating component	(G) Polyurethane polymer derivative
P–95–1222	04/26/95	07/25/95	CBI	(G) Coating component	(G) Styrene, polymer eith substituted alkenoic acid and polycarboxyalkene derivative
P–95–1223	04/26/95	07/25/95	CBI	(G) Textile additive	(G) Aromatic diol, alkoxylated, fatty acid esters of C_{8-18} and C_{18}-unsaturated.
P–95–1224	04/26/95	07/25/95	CBI	(G) Textile additive	(G) Aromatic diol, alkoxylated, fatty acid esters of C_{8-18} and C_{18}-unsaturated.
P–95–1225	04/26/95	07/25/95	CBI	(G) Textile additive	(G) Aromatic diol, alkoxylated, fatty acid esters of C_{8-18} and C_{18}-unsaturated.
P–95–1226	04/26/95	07/25/95	CBI	(G) Textile additive	(G) Aromatic diol, alkoxylated, fatty acid esters of C_{8-18} and C_{18}-unsaturated.
P–95–1227	04/26/95	07/25/95	CBI	(G) Textile additive	(G) Aromatic diol, alkoxylated, fatty acid esters of C_{8-18} and C_{18}-unsaturated.
P–95–1228	04/26/95	07/25/95	CBI	(G) Textile additive	(G) Aromatic diol, alkoxylated, fatty acid esters of C_{8-18} and C_{18}-unsaturated.
P–95–1229	04/26/95	07/25/95	CBI	(G) Open, non-dispersive	(G) Polyether polyurea urethane
P–95–1230	04/26/95	07/25/95	CBI	(G) Open, non-dispersive	(G) Polyether polyurethane
P–95–1231	04/26/95	07/25/95	CBI	(G) Open, non-dispersive	(G) Polycarbonatepolyureapolyurethane
P–95–1232	04/27/95	07/26/95	Reichhold Chemicals, Inc.	(S) Industrial maintenance coatings	(G) Epoxy curing agent
P–95–1233	04/27/95	07/26/95	Sachem, Inc.	(S) Raw material for conversion to another chemical com	(S) Ethanaminium, *N*-ethyl-*N,N-N*-dimethyl-, chloride
P–95–1234	04/27/95	07/26/95	Sachem, Inc.	(S) PH adjustment for chemical processing catalyst for	(S) Ethanaminium, *N*-ethyl-*N,N-N*-dimethyl-, hydroxide
P–95–1235	04/28/95	07/27/95	CBI	(G) Open, non dispersive	(G) Azo dyestuff
P–95–1236	04/28/95	07/27/95	Ausimont USA, Inc.	(S) Powder coatings; extrusion; injection moding; sheet	(S) Polymer of ethylene, chlorotrifluoroethylene and perfluoromethyoxydioxole
P–95–1237	04/28/95	07/27/95	Ausimont USA, Inc.	(S) Powder coatings; extrusion; injection moding; sheet	(S) Polymer of ethylene, chlorotrifluoroethylene and perfluoropropylvinylether
P–95–1238	04/28/95	07/27/95	CBI	(G) Marking ink, open, non-dispersive	(G) Cobalt chelated salt
P–95–1239	04/28/95	07/27/95	CBI	(G) Marking ink, open, non-dispersive use	(G) Cobalt chelated salt
P–95–1240	04/28/95	07/27/95	Charkit Chemical	(G) Electro plating additive	(G) Organo sulfide compound
P–95–1241	04/28/95	07/27/95	CBI	(S) Electorstatic paint primer; anti-electrified paint	(G) Potassium titanate
P–95–1242	05/01/95	07/30/95	CBI	(S) Acid dye for the coloring of leather	(G) Chromate(3-), bis 2-[[substituted-3-[(5-sulfo-1-naphthalenyl)azo]phenyl]azo]substituted monocycle(3-)]-, trisodium
P–95–1243	05/01/95	07/30/95	CBI	(G) Specialty additive	(G) Substituted alkylbenzene

II. 20 Polymer Exemption Notices Received From: 03/20/94 to 05/01/95.

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
Y–95–0081	03/21/95	04/11/95	CBI	(G) Baked enamel finish	(G) Polyester resin

Case No.	Received Date	Projected Notice End Date	Manufacturer/ Importer	Use	Chemical
Y–95–0082	03/27/95	04/17/95	Asahi Chemical Industry America Inc.	(S) Hardener of polyurethane paint	(S) Poly[oxy(1-oxo-1,6-hexanediyl)], .alpha.-hydro-.omega.-hydroxy-,ester with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, polymer with 1,6-diisocyanatohexane and 1,3,5-tris(6-isocyanatohexyl)1,3,5-triazine-2,4,6(*1H,3H,5H*)-trione, methylethylketone oxime-blocked
Y–95–0083	03/27/95	04/17/95	Asahi Chemical Industry America Inc.	(S) VCR Parts, copymachine parts, printer parts	(S) Polyoxymethylene-block-polyoxypropylene
Y–95–0084	03/28/95	04/18/95	Eastman Kodak	(S) Powdered coatings	(S) A polymer of: trans-1,4-cyclohexanedicarboxylic acid, dimethyl ester; 1,4-butanediol; 1,4-cyclohexanedicarboxylic acid; titnium tetraispropoxide
Y–95–0085	03/29/95	04/19/95	CBI	(G) Dehydration agent	(G) Propoxylated amine
Y–95–0086	04/03/95	04/24/95	Gencorp Polymer Products	(G) Coatings for use in paper and textile applications	(G) An emulsion of styrene, butadiene, acrylic copolymer in water
Y–95–0087	04/04/95	04/25/95	Uniglobe Kisco, Inc.	(S) Binder material used on the surface of plastic prin	(S) 1,3-butadiene, homopolymer, hydrogenated hydroxy-terminated, fatty acids, montan wax diesters
Y–95–0088	04/04/95	04/25/95	Gencorp Polymer Products	(G) As a coating for use in paper and textile applicati	(G) An emulsion of styrene-butadiene-acrylic copolymer in water
Y–95–0089	04/05/95	04/26/95	CBI	(G) Paint	(G) Polurethane/polyurea polymer
Y–95–0090	04/10/95	05/01/95	Mitsubishi Gas Chemical America, Inc.	(G) Additive for plastics	(G) Modified polycarbonate
Y–95–0091	04/11/95	05/02/95	CBI	(G) Structural component for articles	(G) Thermoplastic polyester urethane elastomer
Y–95–0092	04/11/95	05/02/95	CBI	(G) Structural component for articles	(G) Thermoplastic polyester urethane elastomer
Y–95–0093	04/11/95	05/02/95	CBI	(G) Structural component for articles	(G) Thermoplastic polyester urethane elastomer
Y–95–0094	04/14/95	05/05/95	Eastman Chemical Company	(S) Water-dispersible, hot melt adhesive	(S) Polymer of 1,4-cyclohexanedicarboxylic acid, dimethyl ester; 1,3-benzenedicarboxylic acid, 5-sulfo-, bis(2-ethoxyethyl) ester, sodium salt; ethanol, 2,2′oxybis-; 1,4-cyclohexanedimethanol; 1,3-propandiol, 2-ethyl-2-(hydroxymethyl); 2-propanol, titanium (4+) salt
Y–95–0095	04/18/95	05/09/95	CBI	(S) Molding resin	(S) Saturated polyester polymer
Y–95–0096	04/25/95	05/16/95	S. C. Johnson & Son, Inc.	(G) Open, non-dispersive	(G) Acrylic emulsion polymer
Y–95–0097	04/25/95	05/16/95	S. C. Johnson & Son, Inc.	(G) Open, non-dispersive	(G) Acrlyic emulsion polymer
Y–95–0098	04/25/95	05/16/95	S. C. Johnson & Son, Inc.	(G) Open, non-dispersive	(G) Acrlyic emulsion polymer
Y–95–0099	04/25/95	05/16/95	S. C. Johnson & Son, Inc.	(G) Open, non-dispersive	(G) Acrlyic emulsion polymer
Y–95–0100	04/25/95	05/16/95	S. C. Johnson & Son, Inc.	(G) Open, non-dispersive	(G) Acrlyic emulsion polymer

List of Subjects

Environmental protection, Premanufacture notices, Polymer exemptions, and Test marketing exemption applications.

Dated: July 28, 1995.

George A. Bonina,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 95–19903 Filed 8–10–95; 8:45 am]

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federal register

Friday
August 11, 1995

Part V

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 Products To Protect Children and Adolescents; Proposed Rule

Analysis Regarding FDA's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 804, and 897

[Docket No. 95N–0253]

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products To Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations governing the sale and distribution of nicotine-containing cigarettes and smokeless tobacco products to children and adolescents in order to address the serious public health problems caused by the use of and addiction to these products. The proposed rule would reduce children's and adolescents' easy access to cigarettes and smokeless tobacco as well as significantly decrease the amount of positive imagery that makes these products so appealing to them. The proposed rule would not restrict the use of tobacco products by adults.

Specifically, the proposed rule would establish 18 years of age as the Federal minimum age of purchase and would prohibit cigarette vending machines, free samples, mail-order sales, and self-service displays. It would also require that retailers comply with certain conditions regarding sales of tobacco, especially verification that the purchaser is at least 18 years of age before a tobacco sale is made. Finally, the proposed rule would limit advertising and labeling to which children and adolescents are exposed to a text-only format; ban the sale or distribution of branded non-tobacco items such as hats and tee shirts; restrict sponsorship of events to the corporate name only; and require manufacturers to establish and maintain a national public education campaign aimed at children and adolescents to counter the pervasive imagery and reduce the appeal created by decades of pro-tobacco messages and thus to help reduce young people's use of tobacco products.

The objective of the proposed 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. If this objective is not met within seven years of the date of publication of the final rule, the agency will take additional measures to help achieve the reduction in the use of tobacco products by young people. FDA is requesting comment regarding the type of additional measures that would be most effective.

DATES: Written comments and recommendations by November 9, 1995.

ADDRESSES: Submit written comments and recommendations to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

Approximately 50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco products.[1] These tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illnesses, heart disease, and other health problems.[2] Cigarettes kill more Americans each year than acquired immune deficiency syndrome (AIDS), alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.[3] On average, smokers who die from a disease caused by smoking lose 12 to 15 years of life because of tobacco use.[4]

In a separate document,[5] FDA is addressing the issue of its jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. The results of an extensive investigation and comprehensive legal analysis support a finding at this time that the nicotine in these products is a drug and that these products are nicotine-delivery devices within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). FDA proposes to regulate cigarettes and smokeless tobacco products by employing its restricted device authority, which affords the most appropriate and flexible mechanism for regulating the sale, distribution, and use of these products.

The primary objective of the proposed rule is to reduce the death and disease caused by tobacco products. Rather than banning tobacco products for the millions of Americans who are currently addicted to them, this regulation focuses on preventing future generations from developing an addiction to nicotine-containing tobacco products. In addition, the scientific evidence strongly suggests that nicotine addiction begins when most tobacco users are teenagers or younger and, thus, is a pediatric disease. Therefore, reducing the number of young people who regularly start to use tobacco products will help to prevent future generations of individuals from becoming addicted to nicotine.

The goal of the proposed rule is to help the country achieve one of the objectives of ''Healthy People 2000,'' which is to reduce the number of children and adolescents who use tobacco products by roughly one half by the year 2000. The agency has modified the goal to include a different measurement tool and established 7 years after publication of the final rule as the goal's endpoint. ''Healthy People 2000'' discussed national health promotion and disease prevention objectives in this country. It was facilitated by the Institute of Medicine of the National Academy of Sciences, with the help of the U.S. Public Health Service, and included almost 300 national membership organizations and all State health departments.[6]

To determine the most appropriate regulatory measures, the agency reviewed the current patterns of use of tobacco products. According to the 1994 Surgeon General's Report, ''Preventing Tobacco Use Among Young People: A Report of the Surgeon General'' (the 1994 Surgeon General's Report), more than 3 million American adolescents currently smoke cigarettes and an additional 1 million adolescent males use smokeless tobacco.[7] Every day, another 3,000 young people become regular smokers.[8] U.S. data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin.[9] Eighty-two percent of adults who ever smoked had their first cigarette before age 18, and more than half of them had already become regular smokers by that age.[10] Moreover, the younger one begins to smoke, the more likely one is to become a heavy smoker.[11]

Many young tobacco users become addicted to nicotine, a chemical substance in tobacco. Although they believe that they will not become addicted to nicotine or become long-term users of tobacco products, they often find themselves unable to quit smoking.[12] In fact, among smokers aged 12–17 years, 70 percent already regret their decision to smoke and 66 percent state that they want to quit.[13] Those who are able to quit experience relapse rates and withdrawal symptoms similar to those reported in adults.[14]

Long-term addiction to nicotine can result in serious chronic diseases and premature death. An adolescent whose cigarette use continues into adulthood increases his or her risk of dying from

cancer, cardiovascular disease, or lung disease.[15] In addition, smokeless tobacco use has been linked to oral cancer and other adverse effects.[16]

Although most segments of the American adult population have decreased their use of cigarettes, the prevalence of smoking by young people has failed to decline for more than a decade. Recently, smoking among young people has begun to rise.[17] Between 1991 and 1994, the prevalence of smoking by eighth graders increased 30 percent, from 14.3 percent to 18.6 percent. Among 10th grade students, it increased from 20.8 percent to 25.4 percent and for 12th grade students, it rose from 28.3 percent to 31.2 percent.[18] Between 1985 and 1994, smoking among college freshmen increased from 9 percent to 12.5 percent.[19]

Millions of American children and adolescents can easily buy or obtain cigarettes and smokeless tobacco products. The large number of young people who use these products is especially noteworthy because all States prohibit the sale of tobacco products to persons under the age of 18, and a few States prohibit cigarette sales to persons under the ages of 19 or 21.[20] These State laws, however, are rarely enforced. 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 products.[21]

In addition to easy access to tobacco products, advertising and promotional activities can influence a young person's decision to smoke or use smokeless tobacco products. Tobacco products are among the most heavily advertised products in the United States.[22] In 1993, the tobacco industry spent a total of $6.2 billion on the advertising, promotion, and marketing of cigarettes and smokeless tobacco. Of that number, 31 percent ($1.9 billion) was spent on advertising and promotional activities; 26 percent ($1.6 billion) was given to retailers in the form of cash allowances or retailer items to facilitate and enhance the sale of tobacco products, and finally, 43 percent ($2.6 billion) was in the form of financial incentives (e.g. coupons, cents off, buy one/get one free, free samples) to consumers.[23]

Tobacco product brand names, logos, and advertising messages are pervasive, appearing on billboards, on buses and trains, in magazines and newspapers, and on clothing and other goods. These ubiquitous images and messages convey to young people that tobacco use is desirable, socially acceptable, safe, healthy, and prevalent in society. One study found that 30 percent of 3 years olds and 91 percent of six year olds associate the ''Joe Camel'' cartoon figure with cigarettes.[24] Studies also show that most young people buy the most heavily advertised cigarette brands, whereas many adults buy generic or ''value category'' cigarette brands, which have little or no image advertising.[25]

In proposing this regulation, FDA examined many domestic and foreign tobacco control statutes, regulations, and legislation, as well as numerous studies and reports. FDA also reviewed recommendations from various public health organizations, including the World Health Organization, the Office of the Surgeon General, the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), and the Institute of Medicine (IOM). Two reports, the 1994 Surgeon General Report and the 1994 IOM Report ''Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths,'' were especially helpful and informative.

The agency has examined many options for reducing tobacco use by children and adolescents, and believes that an effective program must address the following two areas: (1) Restrictions on cigarette and smokeless tobacco sales that will make these products less accessible to young people; and (2) restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people along with requirements for a manufacturer-funded national education campaign aimed at those under 18 years of age to help reduce the products' appeal to these young people. A brief description of the major provisions of the proposed rule follows.

A. Sale and Distribution

The proposed rule would restrict the sale of cigarettes and smokeless tobacco products to individuals age 18 and older. This age restriction is based on the fact that most adult smokers became regular smokers before age 18.

The proposed rule would require retailers to verify the age of persons who wish to buy cigarettes or smokeless tobacco products and would eliminate ''impersonal'' methods of sale that do not readily allow age verification, such as mail orders, self-service displays, and vending machines.

The proposed rule would make each manufacturer, distributor, and retailer of tobacco products responsible for complying with the proposed restrictions. Manufacturers would be required to remove all manufacturer-supplied or manufacturer-owned self-service displays, advertising, labeling, and other items that do not conform to the requirements in the proposed rule.

The proposed rule would prohibit the distribution of free samples and would allow the exchange of coupons and other non-cash certificates only by individuals 18 or older and only in face-to-face transactions. Currently, young people, including children in elementary school, are often able to obtain free samples despite industry-imposed age restrictions on such distributions.

The proposed rule would also prohibit the sale of single cigarettes (''loosies'') and ''kiddie packs (less than 20 to a pack) which, due to their relatively low price and easy concealment, have been shown to be particularly appealing to children and adolescents.

Further, the proposed rule would prohibit manufacturers from using a trade name or brand name of a non-tobacco product for a cigarette or smokeless tobacco product. This will prevent a manufacturer from transferring the images, good will, and appeal of a popular non-tobacco product to a tobacco product.

B. Labeling, Advertising and Educational Programs

Advertising that reaches children would be in black and white, text-only format. Studies indicate that children and adolescents are very receptive to images and cartoons and less attentive to texts. However, the proposed rule would not affect advertising in publications with primarily adult readership—imagery and color would continue to be permitted in such publications. Finally, outdoor advertising of tobacco products located within 1,000 feet of schools and playgrounds would be banned. Consequently, the proposed rule would help reduce the appeal of advertising to children and adolescents without affecting informational messages conveyed to adults.

The proposed rule would prohibit the sale or distribution of brand identifiable non- tobacco items and services, proof-of-purchase sales, games and contests, and sponsorship of events in the brand name, as well as advertising for these items, services, and events.

The proposed rule would require manufacturers to establish and maintain a national educational campaign in order to counter the pervasive imagery and reduce the appeal created by decades of pro-tobacco messages and, thus, help reduce young people's use of tobacco products. Evidence exists that mass media antismoking campaigns conducted nationally between 1967 and 1970, and more recently, in Vermont and California, have had a sustained

effect on preventing teens from starting to smoke and on significantly reducing per capita cigarette consumption.

C. Healthy People 2000 Objective

Seven years after publication of the final rule, the agency would determine whether additional restrictions on tobacco products are required by using outcome-based objectives modeled on the ''Healthy People 2000'' report. One of the goals for tobacco use established by that report is to reduce by roughly one half the percentage of young people using tobacco products by the year 2000. If this objective is not met within the time specified by the rule, FDA would take additional measures to help achieve the reduction in young people's use of tobacco products. The proposed rule requests comment on which additional measures should be adopted.

The agency intends to adopt one or more additional provisions only if the continued use of cigarettes and smokeless tobacco products by children and adolescents indicates that the goal of reducing tobacco use by young people by roughly half had not been met.

The remainder of this discussion of the proposed rule (hereinafter ''preamble'') is organized as follows: Chapter II examines the use of cigarettes and smokeless tobacco products by children and adolescents, and the health consequences of using nicotine-containing tobacco products; Chapter III describes the provisions of the proposed rule and provides the rationale for each of the requirements; Chapter IV reviews the legal authority for these specific requirements, and Chapters V through VIII provide analyses required by the Paperwork Reduction Act of 1980, various Executive Orders, as well as provides analyses of various economic and environmental impacts.

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II. Cigarette and Smokeless Tobacco Product Use Among Children and Adolescents

Each year, the cigarette industry loses about 1.7 million customers in the United States; about 400,000 die from diseases caused by their smoking and another 1.3 million quit smoking.[1] To offset the sales lost to smokers who die or quit smoking, cigarette manufacturers rely on young people as the primary source of new customers. Each day, approximately 3,000 young people become regular smokers,[2] serving as the industry's major domestic source of replacement smokers.

A. Epidemiology of Tobacco Use Among Children and Adolescents

In 1965, the year following the first Surgeon General's Report[3] describing the relationship between smoking and diseases such as lung cancer, chronic bronchitis, and emphysema, 42.4 percent of the overall adult population in the United States smoked.[4] By 1990, the prevalence of smoking in the United States had declined to 25.5 percent.[5] The greatest reduction in adult smoking occurred from 1987 to 1990, when the prevalence of smoking declined by 1.1 percentage point annually, twice the rate of decline during the preceding 20 years.[6] The prevalence of smoking among adults leveled off at 25.6 percent in 1991 and was 26.5 percent in 1992. This change was due to a change in the definition of current smokers, rather than an increase in prevalence. The new definition incorporates some day (i.e., less than daily, occasional, or infrequent) smoking.[7] The estimate for 1992 with the old definition was 25.6 percent—the same as in 1991. In 1993, under the new definition, prevalence was 25.0 percent.[8]

The long-term downward trend in adult smoking contrasts with the trends in smoking among young people. The Institute of Medicine noted that the number of high school seniors who have smoked in the last 30 days remained ''basically unchanged since 1980,'' at approximately 30 percent, and further reported that 16.7 percent of 8th grade students were current smokers (that is, had smoked within the past 30 days), and 8.3 percent smoked daily.[9] The prevalence of cigarette smoking in recent years among 8th and 10th grade students has risen significantly and provides cause for great concern. For example, among 8th grade students, 14.3 percent in 1991 and 18.6 percent in 1994 were current smokers; among 10th grade students, 20.8 percent in 1991 and 25.4 percent in 1994 were current smokers.[10]

The 1994 Surgeon General's Report reviewed several different surveys and found that the estimated percentage of adolescents who have ever smoked cigarettes ranged from approximately 42 percent (as reported by the 1991 National Household Survey on Drug Abuse) to 70 percent (as reported by the 1991 Youth Risk Behavior Survey).[11] The 1994 Surgeon General's Report also found that 28 percent of high school seniors were current smokers.[12] (The most recent data reported by the Monitoring the Future Project indicates that in 1994 the number of high school seniors who were current smokers had risen to 31.2 percent.)[13] Further, the 1994 Surgeon General's Report states that seven to 13 percent of adolescents were frequent or heavy smokers, consuming at least one-half pack daily or smoking 20 days or more of the 30 days in a survey period.[14]

Approximately 3 million children under the age of 18 are daily smokers.[15] One study found that children between the ages of 8 and 11 who are daily smokers consume an average of 4 cigarettes daily, and those who are between the ages of 12 and 17 average nearly 14 cigarettes daily. The study also estimated that adolescents consume an estimated 947 million packs of cigarettes and 26 million containers of smokeless tobacco annually and account for annual tobacco sales of $1.26 billion.[16] Another study estimates that teenagers in 1991 smoked 516 million packs of cigarettes and spent $962 million purchasing them.[17] As stated previously, these figures are especially significant given that all States prohibit the sale of tobacco to persons under the age of 18 (with some States prohibiting sales to persons under the age of 19 and one State, Pennsylvania, prohibiting cigarette sales to persons under the age of 21).[18] Unfortunately, few States successfully enforce their laws restricting tobacco sales to minors.[19]

Studies have also suggested that the age one begins smoking can greatly influence 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. Those who started smoking by early adolescence were more likely to be heavy smokers than those who began smoking as adults.[20] Another study found that high school students who smoked their first cigarette during childhood smoked more often and in greater amount than those who first tried smoking during adolescence.[21]

The escalating use of smokeless tobacco products by underage persons presents an additional and growing public health problem. Smokeless tobacco products include chewing tobacco and snuff and are also known as ''spit tobacco'' or ''spitting tobacco.'' In 1970, the prevalence of snuff use among males was lowest in those 17 to 19 years of age and the highest use was by men aged 50 or more. By 1985, a dramatic shift had occurred, and males between 16 and 19 were twice as likely to use snuff as men aged 50 and over.[22] An estimated 3 million users of smokeless tobacco products were under the age of 21 in 1986,[23] when Congress enacted the Comprehensive Smokeless Tobacco Health Education Act (the Smokeless Act) (15 U.S.C. 4401). The Smokeless Act required the Secretary of Health and Human Services (the Secretary) to inform the public of the health dangers associated with smokeless tobacco use, required warning labels on packages, banned advertising on electronic media subject to the Federal Communications Commission's jurisdiction (such as television and radio), and encouraged States to make 18 years the minimum age for purchasing smokeless tobacco products. Despite the Smokeless Act and State laws prohibiting sales to minors, a high percentage of persons under the age of 18 use smokeless tobacco products. For example:

- 1991 school-based surveys estimated that 10.7 percent of U.S. high school seniors and 19.2 percent of male 9th to 12th grade students use smokeless tobacco.[24]
- A 1992 national household-based survey of U.S. children found that 11.9 percent of males 12–17 years of age were using smokeless tobacco.[25]
- Among high school seniors who had ever tried smokeless tobacco, 73 percent did so by the ninth grade.[26]

In some parts of the United States the rates are especially high. According to the 1990–91 Youth Risk Behavior Survey, the smokeless tobacco product use rates among males in grades 9 through 12 were as high as 34 percent in Tennessee, 33 percent in Montana, 32 percent in Colorado, and 31 percent in Alabama and Wyoming.[27]

Native American youth are especially vulnerable to smokeless tobacco product use. The rates for both males and females are extremely high, ranging from 24 percent to 64 percent, and at rates that, in some areas, are 10 times higher than those for non-Native

Americans.[28] Studies also suggest that Native Americans begin using smokeless tobacco products at much earlier ages than non-Native Americans. A 1986 survey at the Rosebud Sioux Reservation in South Dakota revealed that 21 percent of kindergarten children used smokeless tobacco products,[29] and a survey of Native Americans in the state of Washington indicated that 33 percent of former users and 57 percent of current users started using smokeless tobacco products before the age of 10.[30]

The recent and very large increase in the use of smokeless tobacco products by young people and the addictive nature of these products has persuaded the agency that these products must be included in any regulatory approach that is designed to help prevent future generations of young people from becoming addicted to nicotine-containing tobacco products.

B. The Health Effects Associated With Cigarettes and Smokeless Tobacco Products

Over 400,000 Americans die each year from smoking-related illnesses. This equates to more than one of every five deaths in the United States.[31] If an adolescent's tobacco use continues for a lifetime, there is a 50 percent chance that the person will die prematurely as a direct result of smoking.'' [32] 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 smoking related diseases.[33] Smoking is responsible for about 30 percent of all cancer deaths,[34] including 87 percent of all lung cancer deaths; 82 percent of deaths from chronic obstructive pulmonary disease (COPD); [35] 21 percent of deaths from coronary heart disease; [36] and 18 percent of deaths from stroke.[37] Further, a causal relationship exists between cigarette smoking and cancers of the larynx, mouth, esophagus, and bladder; and atherosclerotic peripheral vascular disease, cerebrovascular disease (stroke), and low-birth weight babies.[38] Cigarette smoking is also a probable cause of infertility and peptic ulcer disease and contributes to, or is associated with, cancers of the pancreas, kidney, cervix, and stomach.[39]

Much of the following brief discussion is abstracted from several Surgeon General's reports. The Surgeon General's reports summarize thousands of peer-reviewed scientific studies and are themselves peer-reviewed and subjected to significant scientific scrutiny.

1. Health Effects of Cigarette Smoking

Epidemiologic studies provide overwhelming evidence that smoking causes lung cancer.[40] The risk of getting lung cancer may be more than 20 times greater for heavy smokers than nonsmokers.[41] The relationship between smoking and lung cancer is due to the numerous carcinogens in cigarette smoke.[42] Cigarette smoking caused an estimated 117,000 deaths from lung cancer in 1990.[43]

The risk of getting lung cancer increases with the number of cigarettes smoked and the duration of smoking, and decreases after cessation of smoking.[44] Starting smoking at an earlier age increases the potential years of smoking and increases the risk of lung cancer.[45] Studies have shown that lung cancer mortality is highest among adults who began smoking before the age of 15.[46]

Cigarette smoking also causes cancer of the larynx, mouth, and esophagus.[47] According to current estimates, 82 percent of laryngeal cancers are due to smoking and about 80 percent of the 10,200 deaths from esophageal cancer in 1993 can be attributed to smoking.[48] The risk of oral cancer among current smokers ranges from 2.0 to 18.1 times the risk in people who have never smoked and can be reduced more than 50 percent after quitting.[49] The risk of esophageal cancer among current smokers ranges from 1.7 to 6.4 times the risk in people who have never smoked and can also be reduced by about 50 percent after quitting.[50]

Epidemiologic studies demonstrate that cigarette smoking contributes to the development of pancreatic cancer.[51] The reason for this relationship is unclear, but may be due to carcinogens or metabolites present in the bile or blood.[52] In 1985, the proportion of pancreatic cancer deaths in the United States attributable to smoking was estimated to be 29 percent in men and 34 percent in women.[53]

Cigarette smoking accounts for an estimated 30 to 40 percent of all bladder cancers and is a contributing factor for kidney cancer.[54] The increased risk of kidney and bladder cancer may be related to the number of cigarettes smoked per day, and the risk decreases following smoking cessation.[55]

Smoking appears to be a contributing factor for cancer of the cervix. The association between cigarette smoking and cervical cancer persists after control is made for risk factors, such as age at first intercourse and the number of sexual partners, that predispose a woman to developing sexually-transmitted diseases. The inclusion of these risk factors, however, may not completely rule out confounding by sexually-transmitted diseases. However, the findings that components of tobacco smoke can be found in the cervical mucus of smokers, that the mucus of smokers is mutagenic, and that former smokers have a lower risk of getting cervical cancer than current smokers are consistent with the hypothesis that smoking is a contributing cause of cervical cancer.[56]

The 1982 Surgeon General's Report concluded that stomach cancer is associated with cigarette smoking.[57] Studies show a slight increase in mortality from stomach cancer in smokers compared with nonsmokers.[58]

Smoking is a leading cause of heart disease. The 1964 Surgeon General's Report noted that male cigarette smokers had higher death rates from coronary heart disease than nonsmokers.[59] Subsequent reports have concluded that cigarette smoking contributes to the risk of heart attacks, chest pain, and even sudden death.[60] Overall, smokers have a 70 percent greater death rate from coronary heart disease than nonsmokers.[61]

Ischemic heart disease resulting from cigarette smoking claimed nearly 99,000 lives in 1990.[62] One study estimates that 30 to 40 percent of all coronary heart disease deaths are attributable to smoking.[63] Smokers between the ages of 40 and 64, who smoked more than one pack a day, were shown to have a risk of coronary heart disease that is 3.2 times higher than people who do not smoke.[64]

Several processes that are likely to contribute to heart attacks are influenced or caused by smoking: atherosclerosis, thrombosis, coronary artery spasm, cardiac arrhythmia, and reduced capacity of the blood to deliver oxygen. The nicotine and carbon monoxide in cigarette smoke are believed to be responsible for heart disease, but other components, such as cadmium, nitric oxide, hydrogen cyanide, and carbon disulfide, have also been implicated.[65] Female smokers who also use oral contraceptives increase their risk of heart attacks tenfold.[66]

Smoking also increases a person's risk of atherosclerotic peripheral vascular disease, especially if the smoker is diabetic.[67] Complications of this disease include decreased blood delivery to the peripheral tissues, gangrene, and ultimately loss of the affected limb. Smoking cessation is the most important intervention in the management of peripheral vascular disease.[68]

Smoking is a cause of stroke.[69] Stroke is the third leading cause of death in the United States.[70] The association of

smoking with stroke is believed to be mediated by the mechanisms responsible for atherosclerosis (narrowing and hardening of the arteries), thrombosis, and decreased cerebral blood flow in smokers.[71] Female smokers who use oral contraceptives are at an increased risk of having a stroke.[72]

Cigarette smoking is the leading cause of chronic obstructive pulmonary disease (COPD) in the United States. Approximately 84 percent of the COPD deaths in men and 79 percent of the COPD deaths in women are attributable to cigarette smoking.[73] The risk of death from COPD may depend on how many cigarettes a person smokes daily, how deeply the person inhales, and the age when the person began smoking.[74] The number of cigarettes smoked per day is a strong indicator for the presence of the principal symptoms of chronic respiratory illness, including chronic cough, phlegm production, wheezing, and shortness of breath.[75]

Smoking's effects on lung structure and function appear within a few years after cigarette smoking begins.[76] Children who smoke suffer from respiratory illnesses more than children who do not smoke. Adolescents who smoke may experience inflammatory changes in the lung, reduced lung growth, and may not achieve normal lung function as an adult.[77]

Cigarette smoking is a probable cause of peptic ulcer disease.[78] Peptic ulcer disease is more likely to occur in smokers than in nonsmokers, and the disease is less likely to heal, and more likely to cause death in smokers than nonsmokers.[79] Quitting smoking reduces the chances of getting peptic ulcer disease and is an important component of effective peptic ulcer treatment.[80]

Studies also show that women who smoke have reduced fertility.[81] One study showed that smokers were 3.4 times more likely than nonsmokers to take more than 1 year to conceive.[82]

Smoking's severe detrimental effects during pregnancy are well documented.[83] Women who smoke are twice as likely to have low birth weight infants as women who do not smoke.[84] Smoking also causes intrauterine growth retardation of the fetus.[85] Mothers who smoke also have increased rates of premature delivery.[86]

Smoking may lead to premature infant death. Babies of mothers who smoke are more likely to die than babies born to nonsmoking mothers.[87] A recent meta-analysis reported that use of tobacco products by pregnant women results in 19,000 to 141,000 miscarriages per year, and 3,100 to 7,000 infant deaths per year. In addition, the meta-analysis attributed approximately two-thirds of deaths from sudden infant death syndrome to maternal smoking during pregnancy.[88] By another estimate, if all pregnant women stopped smoking, there would be 4,000 fewer infant deaths per year in the United States.[89]

2. Health Effects of Smokeless Tobacco Products

Smokeless tobacco use can cause oral cancer.[90] The risk of oral cancer increases with increased exposure to smokeless tobacco products, particularly in those areas of the mouth where smokeless tobacco products are used.[91] The risk of cheek and gum cancers is nearly 50 times greater in long-term snuff users than in nonusers.[92] Snuff and chewing tobacco contain potent carcinogens, including nitrosamines, polynuclear aromatic hydrocarbons, and radioactive polonium.[93]

Smokeless tobacco use can cause oral leukoplakia, a precancerous lesion of the soft tissue that consists of a white patch or plaque that cannot be scraped off.[94] One study of 117 high school students who were smokeless tobacco users revealed that nearly 50 percent of these students had oral tissue alterations.[95] There is a 5 percent chance that oral leukoplakias will transform into malignancies in 5 years.[96] The leukoplakia appears to decrease or resolve upon cessation of smokeless tobacco use.[97]

Smokeless tobacco use causes oral cancer and oral leukoplakia and may be associated with an increased risk of cancer of the esophagus. Smokeless tobacco use has been implicated in cancers of the gum, mouth, pharynx, and larynx. Snuff use also causes gum recession and is associated with discoloration of teeth and fillings, dental caries, and abrasion of the teeth.[98]

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III. Description of the Proposed Rule

The proposed rule would create a new part 897 of Title 21 of the Code of Federal Regulations governing the labeling, advertising, sale, and distribution of cigarettes and smokeless tobacco. The Commissioner has proposed that nicotine-containing cigarettes and smokeless tobacco products be regulated as restricted devices within the meaning of section 520(e) of the act (21 U.S.C. 360j(e)). The regulations are being proposed pursuant to the authority of section 520(e) of the act, which authorizes the agency to regulate the sale, distribution, and use of certain devices. Certain of the provisions in the regulation are also being proposed pursuant to the authority of sections 201, 502, 510, 701, and 704 of the act.

In brief, the proposed rule is intended to support current State laws regarding sales to minors by reducing the appeal of cigarettes and smokeless tobacco to, and limiting access by, persons under 18 years of age. The overall goal of the proposed rule is to decrease the rates of death and disease caused by tobacco products by substantially reducing the number of young people who begin using cigarettes or smokeless tobacco products.

The proposed rule consists of five subparts. Subpart A, General Provisions, would set forth scope and purpose provisions and provide definitions. Subpart B, Sale and Distribution to Persons Under 18 Years of Age, would describe the responsibilities of manufacturers, distributors, and retailers concerning the manufacture, sale, and distribution of cigarettes and smokeless tobacco products. Subpart C, Labels and Educational Messages, would require each manufacturer to establish and maintain a national public educational program, including major reliance on television messages, in order to combat the pervasive imagery and appeal created by decades of pro-tobacco messages, and, thus, to discourage young people from using cigarettes and smokeless tobacco products. Subpart D, Labeling and Advertising, would limit advertising and labeling to which children and adolescents are exposed to a text-only format; ban the sale or distribution of branded non-tobacco items such as hats and tee shirts; and restrict sponsorship of events to the corporate name only. Finally Subpart E, Miscellaneous Requirements, would describe the records and reports that must be submitted to FDA or made available for inspection, discuss the rule's relationship to State and local laws or requirements, and require one or more additional measures to be taken if the prevalence of tobacco use is not significantly reduced within seven years of the publication of the final rule.

A. Subpart A—General Provisions

Subpart A would contain three provisions that describe the rule's scope and purpose and provide definitions that apply throughout part 897.

1. Section 897.1—Scope

Proposed § 897.1(a) would state that part 897 is intended to establish conditions under which nicotine-containing cigarettes and smokeless tobacco products may be sold, distributed, or used. The 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. 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. Proposed § 897.1(b) would note that all references to regulatory sections in the Code of Federal Regulations are to Title 21 unless otherwise noted.

2. Section 897.2—Purpose

Proposed 897.2(a) would state that part 897 is intended to help prevent persons younger than 18 years of age from becoming addicted to nicotine, thereby avoiding the life-threatening consequences often associated with tobacco use. The proposed rule would accomplish this goal by reducing the appeal of and access to cigarettes and smokeless tobacco products by persons under 18 years of age; it would preserve access to cigarettes and smokeless tobacco products by persons 18 years of age and older. Proposed § 897.2(b) would add that the provisions are intended to provide important information about product use to users and potential users.

3. Section 897.3—Definitions

Proposed 897.3 would establish definitions of terms used in the proposed rule, such as ''cigarette'' (897.3(a)) and ''distributor'' (897.3(c)). In drafting the definitions, FDA examined existing definitions in Federal laws and regulations and paid special attention to existing definitions in other FDA regulations. These definitions are contained in the proposed codified language.

Proposed 897.3(e) contains the definition of ''nicotine,''which is based, in part, on the chemical name and formula for nicotine in the ''Merck Index''(10th Edition). The agency also notes that, while the proposed rule defines ''cigarette,'' in part, as a product that ''contains or delivers nicotine,'' it is aware that some companies are trying to develop chemical substances that are pharmacologically active or are as addictive as nicotine or that would be used to enhance nicotine's pharmacological qualities. The agency's investigation has focused primarily on cigarettes and smokeless tobacco products that contain nicotine, and FDA would therefore consider a cigarette-like product that contains a pharmacologically active or addictive substance in place of nicotine to be a ''new'' drug delivery device that would be outside the scope of this regulation. To be legally marketed, such a product would require premarket approval.

B. Subpart B—Sale and Distribution to Persons Under 18 Years of Age

Subpart B would establish certain conditions or requirements for the sale and distribution of cigarettes and smokeless tobacco pursuant to section 520(e) of the act. These provisions are intended to reduce access to cigarettes and smokeless tobacco products by children and adolescents. Studies show that it is easy for most young people to obtain tobacco products. The University of Michigan Monitoring the Future Study in 1993 reported that 75 percent of 8th graders and nearly 90 percent of 10th graders said it would be fairly easy or very easy to get cigarettes.[1] According to a 1990 survey of 9th graders, 67 percent of current smokers said they usually buy their own cigarettes.[2] Further, interviews conducted by the Department of Health and Human Services' (DHHS) Office of the Inspector General in 1986 found that 94 percent of junior and high school students said that ''it was either never or only rarely difficult'' to buy smokeless tobacco products.[3]

Most children and adolescents who smoke purchase their own cigarettes. A 1991 study showed that an estimated 516 million packs are consumed by young people every year; almost half of these packs are sold to minors.[4] The 1994 Surgeon General's Report 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 averaged 88 percent in studies of vending machines.[5]

A significant percentage of young people can also easily purchase smokeless tobacco products directly from retailers. Studies examining smokeless tobacco product purchases by young people suggest that direct successful underage purchases range from 30 percent (for junior high school students) to 62 percent (for senior high school students).[6] Interviews conducted by the DHHS' Office of the Inspector General in 1986 found that 90 percent of smokeless tobacco users in junior and senior high schools said they purchased their own smokeless tobacco products.[7]

Youth access restrictions have been found to be effective in reducing illegal sales and some studies have demonstrated that efforts to reduce access have led to a decrease in tobacco use by young people. In Woodridge, IL, for example, a comprehensive community intervention involving retailer licensing, regular compliance checks, and penalties for merchant violations significantly reduced illegal sales from 70 percent to less than 5 percent almost 2 years later. Further, rates of experimentation and regular smoking dropped by more than 50 percent among seventh and eighth graders.[8]

In contrast, attempts to reduce sales to young people by relying exclusively on educational programs for retailers were not nearly as effective. For example, one study found that minors were able to buy cigarettes in 73 percent of stores receiving informational packages on preventing illegal sales to minors.[9] After a comprehensive retailer education program was conducted, illegal sales to minors decreased to 68 percent of stores. However, after citations were issued to violative establishments, over-the-counter illegal sales dropped to 31 percent.[10]

The proposed rule would prohibit the sale and distribution of cigarettes and smokeless tobacco products to individuals younger than 18. This restriction parallels the age restrictions established by almost all States. Moreover, it is based on the fact that most people who become regular smokers do so at a young age. For instance, the IOM reported that the average age when people become ''daily'' smokers is 17.7 years.[11] According to the National Household Surveys on Drug Abuse (1991), 53 percent of people who ever smoked became regular smokers by the time they were 18 years old.[12] Further, 82 percent of those who had ever smoked daily first tried a cigarette before the age of 18.[13]

Available data documenting the course of a young person's ability to quit smoking after initiating smoking support the need for an age restriction. A study tracking students from grades 6 to 12 in six Minnesota communities noted a ''striking pattern'' that:

* * * once students become weekly smokers, they are unlikely to give up cigarettes. Of the students who were current smokers, an increasing percentage remained smokers over the years of follow-up; they were either unable or unwilling to quit smoking. Of the self-reported quitters, 13% to

46% returned to weekly smoking by the next year's measurement period.[14]

The study found that ''students who smoke are increasingly unlikely to quit as they get older.'' [15]

Effectively prohibiting sales to people younger than 18 years of age will therefore help reduce the number of adolescents and youths who become daily smokers. FDA also selected the age limit of 18 to be consistent with the 1992 Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act [16] that conditions receipt of substance abuse grants on States adopting laws prohibiting the sale and distribution of cigarette and smokeless tobacco products to minors under age 18, and because the majority of States have set 18 as the age of purchase of these products.

1. Section 897.10—General Responsibilities of Manufacturers, Distributors, and Retailers

Proposed 897.10 would describe the general responsibilities of manufacturers, distributors, and retailers, and would make manufacturers, distributors, and retailers responsible for ensuring that the cigarettes and smokeless tobacco products they manufacture, label, advertise, package, sell, distribute, or otherwise hold for sale comply with all the applicable regulations under proposed Part 897.

2. Section 897.12—Additional Responsibilities of Manufacturers

Proposed 897.12 would provide that, in addition to its other responsibilities, each manufacturer would be responsible for removing all self-service displays, violative advertising, labeling, and other manufacturer- or distributor-supplied items from each point of sale. Proposed § 897.12(b) would require each manufacturer to monitor, through visual inspection on each visit to a point of sale (carried out in the normal course of the manufacturer's business), to assure the proper labeling, advertising, and distribution of its products. This provision would not create a new responsibility or burden for companies (typically the smaller ones) who do not visit retail locations as part of their usual business practice. The obligation to inspect exists only for those companies (typically the larger ones) for whom visits are part of their usual business practice.

Further, because there are detailed contracts between the larger cigarette manufacturers and retailers, proposed 897.12 should not impose a significant burden on these manufacturers. For example, a Non-Self-Service Carton Shelf Plan for the R.J. Reynolds Tobacco Co. specified that '' [t]he height of the top shelf cannot exceed 72 inches and must have a height capacity of seven cartons * * *'' and that the cigarette display or shelves ''* * * must be in total view of the consumer * * *'' and ''* * * may not be placed more than 10 feet from point-of-purchase.'' [17] Another plan, titled ''R.J. Reynolds Tobacco USA Savings Center Display Plan,'' created six different pay scales for retailers; the retailers would receive more money if they sold a large volume of cigarettes. Under this plan, R.J. Reynolds would also provide a ''merchandiser'' to display its products, and the retailer would agree to stock the ''designated RJR shelf rows'' ''no less than five cartons high,'' and not alter the shelves or reduce the amount allocated to R.J. Reynolds products.[18] In both plans, the retailer also agreed to permit R.J. Reynolds representatives to ''plan-o-gram, adjust, and divide its allocated space as deemed necessary'' and to ''make reasonable audits of performance and to inspect and rotate R.J.R's products in stores under contract.'' [19]

Former sales representatives and managers interviewed by FDA stated that manufacturers keep extremely detailed records about each retailer. Some records noted whether the retailer should be visited weekly, biweekly, monthly, etc.; other entries included the types of displays in the retailer's establishment. At least one company also gave portable computers to its representatives; the data entered into these computers were downloaded nightly and sent to company headquarters. These detailed contracts and records demonstrate that the manufacturers are heavily involved in establishing and maintaining retailers' displays and that the proposed rule's requirements that each manufacturer be responsible for removing violative advertising, labeling, and self-service displays, and for performing a visual inspection on each subsequent business call are both feasible and reasonable.

3. Section 897.14—Additional Responsibilities of Retailers

Proposed 897.14 would establish additional responsibilities for retailers. Proposed 897.14(a) would require the retailer or the retailer's employees to verify that people who intend to purchase cigarettes or smokeless tobacco products are legally entitled to do so. Verification would be by direct visual inspection of each prospective purchaser and, if necessary, would include the use of a photographic identification card with a birth date. Examples of documents that would be acceptable are a driver's license or a college identification card. The proposal would require an identification card with a picture and a birth date because such identification cards are more reliable than other forms of identification. FDA invites comment on whether the final rule should contain more specific requirements concerning the types of identification that would comply with this provision.

The agency has found strong support for the additional retailer responsibilities that this section would impose. According to a recent report endorsed by 26 State attorneys general, industry training films and programs used by retailers regarding tobacco sales had little or no impact on preventing illegal sales to minors and, in some retail sectors, high employee turnover rates complicated training efforts. Moreover, determining a young customer's age through visual examination alone proved to be difficult. Thus, the attorneys general recommended requiring proof of age of anyone who does not appear to be at least 26 years old.[20]

Additionally, studies indicate that minors who are able to purchase cigarettes and other tobacco products from stores are rarely asked to verify their age. For example, in one study, 67 percent of minors (mean age: 15 years) were asked no questions when they attempted to purchase cigarettes.[21] Store cashiers tried discouraging the minors from buying cigarettes in only 7 percent of the spot checks conducted by the authors. In 14 percent of the cases, the cashiers actually ''encouraged the minor's purchase by offering matches, suggesting a cheaper brand, or offering to make up the difference if the minor was 'short on cash'.'' [22]

In another report, five minors between the ages of 13 and 16 were sent to various locations to buy cigarettes. Despite signs at some locations that prohibited entry by persons under the age of 21, the minors were able to buy cigarettes, even when they admitted they were under 21. For smokeless tobacco products, studies show that half of the stores examined were willing to sell smokeless tobacco products to minors.[23] In contrast, in Everett, WA, where a local ordinance required proof of age if the prospective buyer did not appear to be of legal age to purchase cigarettes, over 60 percent of students between the ages of 14 and 17 reported being asked for proof of age when they attempted to buy cigarettes, and tobacco use, among 14 to 17-year-olds, declined from 25.3 percent to 19.7 percent overall.[24]

Proposed § 897.14(b) would prevent the retailer or an employee of the retailer from using any electronic or mechanical device in providing cigarettes or smokeless tobacco products to the purchaser. Requiring the retailer's employees to hand cigarettes or smokeless tobacco products to customers, after checking identification, has the practical effect of making access to such products more difficult for young people.

Proposed § 897.14(c) would prohibit the retailer or an employee of the retailer from opening a cigarette, cigarette tobacco, or smokeless tobacco product package to sell or distribute a cigarette, or cigarettes (often referred to as ''singles'' or ''loosies'') or any quantity of cigarette tobacco or of a smokeless tobacco product from that package. The agency is proposing this restriction because the primary market for ''loosies'' is children and adolescents. One California study found that 101 of 206 stores sold single cigarettes to minors and adults, and more stores sold single cigarettes to minors than to adults.[25] A survey in Nashville, TN, found that one-quarter of the stores sold single cigarettes.[26]

Additionally, the IOM noted that the sale of single cigarettes is attractive to children due to the low costs, could make children more willing to experiment with tobacco products, and that single cigarettes may be easier for children to shoplift.[27] Consequently, the IOM advocated banning the sale of single cigarettes.[28] Several States, including Mississippi, Oklahoma, South Dakota, Tennessee, and Washington, already restrict the sale of unpackaged tobacco products, and a working group of State attorneys general recently recommended that single cigarette sales be prohibited.[29]

4. Section 897.16—Conditions of Manufacture, Sale and Distribution

a. *Restrictions on product names.* Proposed 897.16(a) would prohibit prospectively the use of a trade or brand name for a non-tobacco product as the trade or brand name for a cigarette or smokeless tobacco product. The agency is aware of three brands of cigarettes that have used this strategy: Harley-Davidson, Cartier, and Yves St. Laurent's Ritz cigarettes. In the final rule, the agency intends to exempt those brands that already use the trade or brand name of a non-tobacco product.

This provision would complement the requirements in proposed subpart D (regarding labeling and advertising) that would reduce the appeal of cigarettes and smokeless tobacco products to people younger than 18. FDA believes that this provision is necessary to prevent manufacturers from circumventing the purpose of this proposed rule. As discussed elsewhere, the imagery associated with tobacco products is an important factor in why young people smoke. This provision would prevent tobacco manufacturers from capitalizing on the imagery of other consumer products by using the brand name of those products for tobacco products.

b. *Minimum package size.* Proposed § 897.16(b) would make 20 cigarettes the minimum package size for cigarettes. FDA selected 20 because the vast majority of cigarette packs in the United States contain 20 cigarettes. The proposal is intended to preclude firms from manufacturing packages that contain fewer than 20 cigarettes; these packs, sometimes referred to as ''kiddie'' packs, usually contain a small number of cigarettes, are easier to conceal, and are less expensive than full-size packs. (Young people, who generally have little disposable income, can be particularly sensitive to the price of cigarettes and may choose not to smoke as the price increases.[30]) Further, FDA is aware that Lorrilard Tobacco Company is offering a pack containing only 10 cigarettes of its Newport brand for sale and that another firm is experimenting with single cigarettes packed in individual tubes.[31]

One study showed that 56.3 percent of all 14 to 15 year old adolescent smokers surveyed in one urban area of Australia had purchased kiddie packs in the month prior to the survey, compared with only 8.8 percent of adult smokers. The study concluded, ''If we fail to take strong action against the well targeted marketing methods of tobacco companies then the adolescent smoking rates recorded in this study are likely to remain high.'' [32]

The Nova Scotia Council on Smoking and Health reported that 49 percent of tobacco users in the sixth grade purchased kiddie packs of 15 cigarettes.[33] Another study of Australian schoolchildren reported that 30 percent of the 12-year olds preferred packages containing 15 cigarettes compared to 11 percent of the 17-year olds.[34] The Australian study, however, also reported that older children preferred cigarette packages that contained 25 cigarettes. Consequently, even though FDA has no evidence that firms intend to market cigarette packages that contain more than 20 cigarettes, the agency invites comment as to whether proposed § 897.16(b) should also state the maximum package size for cigarettes.

c. *Impersonal modes of sale.* Proposed § 897.16(c) would permit cigarettes and smokeless tobacco products to be sold only in a direct, face-to-face exchange between the retailer or the retailer's employees and the consumer. The proposal would prohibit specifically cigarette vending machines, self-service displays, mail-order sales, and mail-order redemption of coupons.

i. *Vending Machines.* Studies indicate that a significant percentage of adolescents are able to obtain their cigarettes from vending machines and that such purchases occur regardless of locks, warning signs, and other restrictions. In 1994, CDC examined 15 recent tobacco inspection surveys to investigate underage sales to minors. While 73 percent of over-the-counter outlets made illegal sales to children and adolescents, 96 percent of vending machine sales were successful.[35]

A 1989 survey of 10th grade students in Minnesota indicated that 71 percent had purchased tobacco from vending machines.[36] Another 1989 report found that, in California, minors between the ages of 14 and 16 were able to purchase cigarettes from vending machines 100 percent of the time.[37] A 1992 study in Minnesota involving minors between the ages of 12 and 15 reported a 79 percent success rate in purchasing cigarettes from vending machines.[38] Children in the Washington, D.C. area, New York, Colorado, and New Jersey who were sent to purchase cigarettes from vending machines achieved 100 percent success rates.[39] The 1994 Surgeon General's Report examined nine studies on cigarette purchases from vending machines and found that underage persons were able to purchase cigarettes 82 to 100 percent of the time, with a weighted-average rate of 88 percent.[40]

Moreover, younger children use vending machines to purchase cigarettes more often than older adolescents. A study commissioned by the vending machine industry revealed that 22 percent of 13-year olds who smoke reported purchasing cigarettes from vending machines ''often'' compared with only 2 percent of 17-year olds. Twenty-two percent of 13- to 17-year-olds who smoke report purchasing cigarettes from vending machines ''often''or ''occasionally.''[41]

FDA is aware that some jurisdictions have attempted to place locks, post warning signs, or restrict placement of vending machines to curtail access by young people. These efforts have had only limited success. A 1992 report examining vending machines in St. Paul, MN, indicates the limitations of requiring locking devices on vending machines. Despite a 1990 city ordinance requiring locking devices on vending machines, the rate of noncompliance by

merchants was 34 percent after 3 months and 30 percent after 1 year.[42] Underage buying increased from 30 percent 3 months after the ordinance had been enacted to 48 percent after 1 year.[43] Further, in those locations where locking devices were not placed on vending machines, underage buying was successful 91 percent of the time.[44] The study concluded that the use of locking devices on vending machines was less effective than a vending machine ban.

In 1994, CDC examined minors' access to cigarette vending machines in Texas. CDC noted that Texas law requires cigarette vending machine owners to post signs on their machines stating that sales to persons under the age of 18 are illegal. Despite these laws, minors between the ages of 15 and 17 successfully bought cigarettes from vending machines 98 percent of the time.[45]

Laws restricting placement of vending machines also appear to be ineffective. In one study, 14-year-old children were able to purchase cigarettes from vending machines 77 percent of the time despite State laws requiring the machines to be ''in the immediate vicinity, plain view and control of an employee'' and to bear signs concerning illegal purchases by minors.[46] Six surveys conducted in bars, taverns, private clubs, and liquor stores in five states found that minors were able to successfully purchase cigarettes in vending machines between 70 percent and 100 percent of the time, about the same rate as elsewhere.[47] In these surveys, the sales rates for ''adult only'' locations were similar to the rates for vending machine cigarette sales located elsewhere in the communities, indicating that restricting cigarette vending machines to places such as bars and liquor stores does not serve as an impediment to young people buying cigarettes. Additionally, according to the vending machine industry's research, 77.5 percent of all cigarette vending machines are already in ''adult'' areas such as bars, lounges, offices, college campuses, and industrial plants.[48] Therefore, it is likely that restricting cigarette vending machines to these areas would have a minimal effect on reducing sales to young people.

Studies also have shown that the use of vending machines by young people appears to be highest in those areas with strong access restrictions. In Santa Fe, New Mexico, where selling to minors was not against the law, vending machines were used 18 percent of the time by teen smokers.[49] By contrast, in Vallejo, California, where local merchants were actively requiring photographic identification, a survey found that teen smokers used vending machines 56 percent of the time (thereby making vending machines the most common source of cigarettes for young people.[50]) Therefore, if access restrictions are imposed such as requiring retailers to verify age, it is likely that vending machines may become an even more important source of cigarettes for young people.

Because minors, especially very young children who try smoking, rely on vending machines to purchase tobacco products, and because State and local laws restricting placement of, or requiring locking devices on, vending machines appear to be ineffective, the agency believes that the only practical approach to curtailing young people's access to such products is to eliminate vending machines and other impersonal modes of sale. Moreover, government enforcement of vending machine locking devices would entail a greater regulatory burden than enforcing a complete ban because authorities would need to ensure the devices were installed and operating properly, and that store employees were using them correctly.[51]

Consequently, proposed § 897.16(c) would require retailers to hand the product to the consumer. This proposed requirement would have the added effect of preventing persons younger than 18 from evading the proposed rule's age requirement by shifting their purchasing patterns from stores to vending machines or mail orders. Further, the agency notes that this aspect of the proposed rule is consistent with recommendations from the IOM,[52] the Public Health Service,[53] a working group of State attorneys general,[54] and findings by the Office of the Inspector General, DHHS.[55]

Finally, data from the vending machine industry show that cigarettes account for a small and declining portion of total vending machine revenues.[56] Using industry data from 1993, calculations indicate that daily sales from cigarette vending machines average approximately $10 per machine/per day.[57] In 1993, cigarettes comprised 4.7 percent of total vending machine revenues compared to 45.5 percent in 1960.[58] Between 1992 and 1993, vending machine revenues from cigarettes dropped 25 percent.[59] While total revenues from cigarette vending machines have been decreasing, revenues from most other product categories sold in vending machines, such as juice and other cold drinks, rose dramatically.[60] Further, the number of cigarette vending machines decreased significantly from 373,800 to 181,755 between 1988 and 1993.[61] Recognizing that more and more states and localities have enacted restrictions or bans on cigarette vending machines, machines are being produced that can be converted to dispense other products.[62] Furthermore, according to the National Automatic Merchandising Association, the association representing the vending machine industry, virtually no new shipments of cigarette vending machines have been made since 1990, compared with 32,065 shipments in 1976.[63]

ii. *Self-service displays.* Proposed § 897.16(c) would also prohibit self-service displays. Self-service displays enable young people to quickly, easily, and independently obtain tobacco products. This restriction is intended to prevent young people from helping themselves to tobacco products and to increase the direct interaction between the sales clerk and the underage customer. This restriction is also consistent with the 1994 IOM Report's recommendation. IOM reviewed surveys of grade school students in New York, and Wisconsin, and noted that many students—over 40 percent of daily smokers in Erie County, NY and Fond du Lac, WI—shoplifted cigarettes from self-service displays.[64] IOM found that eliminating self-service displays would make it more difficult for children to obtain cigarettes, especially if the children had to purchase the cigarettes from a store clerk (as would be required under this proposal). IOM further noted that ''placing the products out of reach reinforces the message that tobacco products are not in the same class as candy or potato chips.'' [65]

A California study compared smoking prevalence among minors in five counties before and after the institution of ordinances prohibiting self-service merchandising (display and sale) and requiring only vender-assisted sales. The rate of tobacco sales to minors in the five counties dropped 40 to 80 percent and the decrease was still in evidence 2 years after the survey. Moreover, the study found that the ban on self-service significantly increased the checking of young purchasers' identification by retail clerks and, in particular, discouraged younger adolescents from attempting to buy tobacco.[66]

iii. *Mail-order sales.* In addition to prohibiting the sale of tobacco products in vending machines and the use of self-service displays, proposed § 897.16(c) would prohibit mail-order sales and redemption of mail-order coupons. Mail-order sales provide no face-to-face interaction to verify the age of the consumer. The current industry practice merely requires that the customer provide a birth date or check a box on

the mail-order card to verify, for example, that he/she is 21. The agency concludes that proposed § 897.16(c) would significantly reduce access to cigarettes and smokeless tobacco products by persons younger than 18. The ban of mail-order sales is recommended by the IOM [67] and Philip Morris recently announced that it would discontinue mail-order sales in order to reduce access to young people.[68]

d. *Free samples.* Proposed § 897.16(d) would prohibit manufacturers, distributors, and retailers from distributing free samples of tobacco products. The agency is proposing this restriction because many young people, including elementary school children, receive free samples.[69] Free samples are often distributed at ''mass intercept locations'' such as street corners and shopping malls, and events such as music festivals, rock concerts, and baseball games. They have been distributed at zoos, at bars and restaurants where entertainers perform and promote the product, and through the mail.[70] Free samples give young people a ''risk-free and cost-free way to satisfy their curiosity'' about tobacco products and, when distributed at cultural or social events, may increase social pressure on young people to accept and use the free samples.[71]

For smokeless tobacco products, distribution of free samples to young people has been a foundation of the growth strategy of the UST (makers of Skoal, Copenhagen, Happy Days, and other smokeless tobacco products).[72] In 1992 and 1993, the smokeless tobacco industry spent nearly $16 million annually on the distribution of free samples. The industry's largest expenditure in 1993 was on coupons and retail value-added articles to encourage trial use ($32 million).[73]

Despite industry-imposed age restrictions on the distribution of samples, underage persons are able to obtain samples either by lying about their age or by enlisting older friends and relatives to obtain samples for them.[74] The lure of free samples can also be quite attractive; one advertising campaign offering a sample pack of Skoal Bandits reportedly generated 400,000 responses in a 3-month period.[75]

Even elementary school children are able to obtain free cigarette samples easily. One survey examined five schools in Chicago and a sample of students at DePaul University. Four percent of the elementary school students reported receiving free samples of cigarettes themselves. Nearly half of the elementary and high school students and one-quarter of the college students ''* * * reported having seen free cigarettes given to children and adolescents.'' [76] In another survey, one-third of approximately 500 New Jersey high school students who were current or former smokers reported receiving free cigarette samples before the age of 16.[77]

The distribution of free samples to minors occurs despite the industry's voluntary code against distributing cigarettes to persons under the age of 21. The recent IOM report noted several problems with the industry's voluntary code, stating that ''distribution to minors appears to be nearly inevitable.'' [78] While the voluntary code instructs employees distributing samples to ask for identification and ask other questions if they suspect a potential recipient to be under age, distribution of samples to minors occurs anyway because the samplers are often placed in crowded places and constrained by time:

> There is a significant time constraint in asking for proof of age from all young-looking individuals who solicit samples, not to mention the time required for the myriad of other questions which samplers are instructed to ask. Samplers are often surrounded on all sides by those soliciting samples and a dozen or more outstretched arms waiting (or grabbing) for samples * * * those passing out samples are usually quite young themselves. These youthful distributors may lack the psychological wherewithal to request proof of age and refuse solicitations from those in their own peer group.[79]

Consequently, the ineffectiveness of the industry's voluntary code and the fact that State laws that ban or restrict the distribution of free samples are rarely enforced led IOM to recommend prohibiting distribution of free samples in public places and through the mail.[80] The National Cancer Institute reached a similar conclusion in 1991, and stated, ''The offer of free cigarettes and smokeless tobacco products is reminiscent of the drug pusher who gives the first sample free to get his customer hooked.'' [81] The proposed rule is consistent with IOM's and NCI's recommendations.

C. Subpart C—Labels and Educational Programs

Proposed subpart C would provide the established name for cigarettes and smokeless tobacco products that is required by sections 502 of the act. In addition, it would require that cigarette and smokeless tobacco manufacturers fund a national program including educational messages in order to undo the effects of young people's near constant exposure to pro-tobacco messages and, thus, to discourage young people from using cigarettes and smokeless tobacco products, pursuant to sections 201, 502, and 520(e) of the act.

1. Section 897.24—Established Names for Cigarettes and Smokeless Tobacco Products

Proposed § 897.24 would provide the ''established name'' for cigarettes, cigarette tobacco, and smokeless tobacco products. This provision is intended to implement section 502(e)(2) of the act, which states that a device shall be deemed misbranded if its label fails to display the established name for the device ''in type at least half as large as that used thereon for any proprietary name or designation for such 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, proposed § 897.24 would consider ''cigarettes,'' ''cigarette tobacco,'' and the common or usual names for smokeless tobacco products (such as ''moist snuff'' or ''loose leaf chewing tobacco'') as established names.

2. Section 897.29–Educational Programs Concerning Cigarettes and Smokeless Tobacco Products

The Surgeon General's 1994 Report suggested that ''a nationwide, well-funded antismoking campaign could effectively counter the effects of cigarette advertising in its currently permitted media forms.'' [82] IOM also recommended that ''counter-tobacco advertisements should be intensified to reverse the image appeal of pro-tobacco messages, especially those that appeal to children and youths.'' [83]

FDA's proposal is consistent with the Surgeon General's and IOM's findings. Proposed 897.29 would require each manufacturer to establish and maintain a national public educational program, including major reliance on television messages, to combat the effects of the pervasive and positive imagery that has for decades helped to foster a youth market for tobacco products.

FDA based proposed 897.29, in part, on historical experience. From July 1, 1967 to December 31, 1970, the Federal Communications Commission, as part of

the ''Fairness Doctrine,'' required broadcasters to provide a significant amount of time for antismoking messages on television and radio. Thus, one antismoking message appeared for every three or four industry-sponsored, prosmoking advertisements. This amounted to approximately $75 million (in 1970 dollars) in commercial air time for antismoking messages annually, until a ban on prosmoking advertisements on television and radio became effective on January 1, 1971. Thus, for several years, the American public was exposed to both pro- and antismoking messages.

During this time, per capita cigarette consumption declined 7 percent, from 4,280 in 1967 to 3,985 in 1970. Most of the 7 percent decline (6.2 percent) was attributable to the anti-smoking messages.[84] This was the first time since the early 1930's that per capita consumption declined consecutively for 3 years and was one of the largest declines ever recorded. Additionally, a study of nearly 7,000 adolescents found that adolescent smoking rates declined during this period.[85] The greatest decline occurred in the first year that the antismoking messages appeared. A 1972 econometric analysis confirmed that the antismoking messages had up to a 5.6 times greater effect on cigarette consumption than promotional cigarette advertising.[86] When the antismoking messages ended on television and radio (due to the Federally-mandated ban on advertising on television and radio, thereby ending the application of the Fairness Doctrine), per capita cigarette consumption began to rise.

A similar experience occurred in Greece during the late 1970's.[87] In an effort to reduce cigarette consumption, the Greek government launched an antismoking campaign and, in 1978, banned cigarette advertising on television and radio. In 1979, the Greek Government intensified its antismoking effort by adding television and radio counter-advertising as well as a community-based print education campaign. This enhanced campaign lasted 2 years but was discontinued following a change in government, with the ban on television and radio advertising remaining. Evaluation of this experience revealed that, during the counter-advertising phase, the annual increase in per capita tobacco consumption dropped to zero, compared to the pre-campaign advertising ban rate of 6 percent increase in consumption. When the campaign ended, the annual rate of increase in tobacco consumption quickly increased to earlier levels. This experience suggests that intensive health education and counter-advertising campaigns can be effective.

There have been numerous research and demonstration projects evaluating the effectiveness of counter-advertising and mass-media smoking cessation programs.[88] As the research designs have evolved, more has been learned about which types of programs are effective and under what conditions. Most recently, well-evaluated studies of programs in Vermont, California, and elsewhere suggest that mass-media and counter-advertising campaigns can have a sustained effect on both preventing teens from starting to smoke and in helping smokers quit.

In Vermont, researchers tested the effect of mass-media and school health education programs.[89] Students exposed to both school and media interventions were 35 percent less likely to have smoked in the past week than students exposed only to the school program, and this preventive effect persisted for at least 2 years following the completion of the intervention program. The decrease occurred even in students who were considered to be at slightly higher risk of becoming smokers because of demographic considerations (lower family income).

There have been similar results in helping smokers interested in quitting. In California, the Department of Health Services has been conducting a $26 million multi-year media campaign to prevent teens from starting to smoke and help adult smokers quit. In a preliminary study of the campaign's effectiveness, researchers found that the state media campaign ''had a negative impact on cigarette consumption, while industry advertising had a positive impact on cigarette consumption.'' The authors concluded that ''[t]his suggests, as one would expect, that increasing state media expenditures and decreasing industry advertising are both effective ways to deter smoking.''[90] According to a recent evaluation, the media campaign's advertisements directly influenced 7 percent (33,000) of Californians who quit smoking in 1990 to 1991, and contributed to the quitting of another 173,000.[91] The California media program has also resulted in high levels of awareness among young people,[92] and may have contributed to stopping the rise in teen smoking that had been occurring in California prior to the campaign.[93]

FDA has proposed general criteria in the codified language. The following describes one set of requirements for such a program that the agency is considering requiring in a final rule. FDA is soliciting comments on whether the described program would accomplish the goal of creating an effective national program that would correct and combat the effects of the pervasive positive imagery in advertising and, thus, help reduce young people's use of tobacco products or whether additional or different requirements would be preferable. The program would be national in scope and could require that the companies purchase certain times and places on television programming (referred to in the industry as a ''buy''). For example, a television buy could: (1) Devote at least 80 percent of its resources to television messages, both on network and on cable television, during prime time hours (between the hours of 8 p.m. and 11 p.m.), early fringe time (between the hours of 4 p.m. and 6 p.m.), and access time (time that is allocated to local broadcasting stations); (2) be directed to persons between the ages of 12 and 17 years; and (3) be national in scope. Moreover, the buy could include advertising time in at least 50 percent of television programs rated by a national rating service as being in the top 20 for persons between the ages of 12 and 17 and corresponding to the demographic profile of underage tobacco users by gender, racial, and ethnic characteristics, and the remaining percentage in programs with either high concentration or high coverage to young people. The buy could ensure that the manufacturer reach an average of 70 to 90 percent of all persons between the ages of 12 and 17 years five to seven times per 4-week period. (The 4-week period is often referred to as a ''flight.'') Such requirements would help to ensure that the educational messages reach large numbers of young people and are consistent with the way in which advertising is typically purchased. In addition, to ensure that the messages change over time and remain novel and of interest to young people, each message could be limited in use so that each message would be presented no more than 15 times per quarter to the top two-fifths (referred to as top two quintiles) of television viewers between the ages of 12 and 17 and who watch the most television.

The industry members could select from a variety of messages maintained by FDA. FDA could collect and maintain a file of messages developed by states with active tobacco control programs (such as California and Massachusetts), from voluntary health organizations (as was done by broadcasters during the Fairness Doctrine period), and from other appropriate sources, including messages developed and submitted by the tobacco

companies. FDA could determine which messages would be appropriate in consultation with other entities and offices within the Department of Health and Human Services, such as CDC's Office on Smoking and Health; with other federal agencies with expertise in consumer behavior and marketing, such as the Federal Trade Commission; and with consultants and contractors who are expert in communications theory and practice. FDA, in consultation with other federal agencies and other experts, could review the messages to ensure that their language and imagery are effective with 12- to 17-year olds. Each message would be evaluated to determine if it were designed to influence those beliefs and attitudes of 12- to 17- year olds that are most likely to affect the initial decision to smoke (or to start using smokeless tobacco products), the decision to continue smoking (or continue to use smokeless tobacco products), and/or the decision to quit. Examples of appropriate messages include those addressing addiction, weight control, effective ways to refuse a cigarette and other social influences that are related to youth smoking.

Moreover, an appropriate educational program could require each manufacturer to submit, on a quarterly basis, analyses of every television buy by time period on network television (referred to as ''day part''), cable, and other media, prepared and executed by the party or parties responsible for the advertising. This requirement could fulfill the manufacturer's responsibility to report on the effectiveness of the program.

In addition, each manufacturer could conduct tracking studies of persons between the ages of 12 and 17. This would enable the manufacturers to determine how effective their educational programs and buys were. The studies could be performed twice per year and would need to meet recognized industry standards for tracking studies, such as measuring recall and recognition of the televised messages. These studies could be given to FDA, which could review the results of the industry's testing in consultation with other experts as needed, in order to help the agency refine its selection criteria for messages.

Finally, the remaining 20 percent of the messages could be placed in other media, with emphasis on radio and outdoor advertising. Consideration should be given to ensuring that these messages appear in media that are heavily used by young people.

Under proposed § 897.29, each manufacturer would devote an amount of money to the corrective educational program proportionate to its share of the total advertising and promotional expenditures of the cigarette and smokeless tobacco industry. Thus, a company whose expenditures equal 40 percent of total industry expenditures would be required to allocate an amount equal to 40 percent of the total monies required. The agency calculated the amount of money that would be allocated to the initial corrective educational program by looking at the period of time when the Fairness Doctrine was in effect. It was estimated that, at that time, approximately $75 million a year in air time was provided by broadcasters for anti-smoking messages, which translates to $290 million in 1994 dollars. In order to ensure an effective program, the agency is proposing that approximately half that amount, or $150 million a year, be allocated initially. Under this proposal, the agency could determine each manufacturer's proportionate share of the overall advertising and promotional expenditures of the cigarette or smokeless tobacco industry by referring to the most recent figures reported to the FTC under the Cigarette Act or the Smokeless Act. This provision is intended to ensure that the corrective educational programs are adequately funded in proportion to each manufacturer's overall reported advertising and promotion expenses.

D. Subpart D—Labeling and Advertising

1. Introduction

Proposed subpart D would establish certain requirements for cigarette and smokeless tobacco product labeling (excluding product labels) and advertising pursuant to sections 520(e), 502(q), and 502(r) of the act. The proposal would apply similar requirements to labeling and advertising in print media because both are used 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. Therefore, FDA has decided to place the labeling provisions with the advertising requirements rather than place the labeling provisions with those pertaining to product labels.

Regulating cigarette and smokeless tobacco product labeling and advertising is essential to decrease young people's use of tobacco products. Proposed subpart D would preserve the informational component of labeling and advertising while decreasing their appeal to children and adolescents.

Briefly, the proposed regulations would require that advertising in any publication with a youth readership of more than 15 percent (youth being defined as under 18) or more than 2 million children and adolescents under 18 be limited to a text-only format in black and white. Advertising in any publication that is read primarily by adults would be permitted to continue to use imagery and color. Pursuant to section 502(r), the proposed regulations would require that cigarette advertising contain a statement of the product's established name, intended use, and a brief statement regarding relevant warnings, precautions, side effects, and contradictions. In addition, brand identifiable non-tobacco items, such as hats and tee shirts, and brand identifiable sponsorship of events, such as the Virginia Slims Tennis Tournament or a sponsored event using a tobacco product logo or symbol, would be prohibited.

Section 201(m) of the act (21 U.S.C. 321(m)) defines ''labeling'' as ''all labels and other written, printed, or graphic matter'' that are on an article or its containers or wrappers, or ''accompanying such article.'' In interpreting the phrase ''accompanying such article,'' the Supreme Court has held that it is not necessary for the labeling to physically accompany the product (see *Kordel* v. *United States,* 338 U.S. 345, 350 (1948)). Thus, labeling includes traditional promotional items, such as booklets, calendars, movies, etc., and also less obvious types of labeling, such as clocks, coffee mugs, desktop toys, and even tee shirts.[94] FDA would, therefore, consider non-tobacco items distributed by cigarette and smokeless tobacco companies with the product's brand name or product identification printed on them (e.g., tee shirts, hats, pens, golf tees) to be ''labeling,'' and these would be prohibited.

Subpart D is based, in part, on the recommendations of major U.S. and world health organizations and on current efforts by other countries to reduce tobacco use. These organizations and countries support advertising restrictions as an essential part of any comprehensive program to reduce or eliminate smoking by young people. The American Medical Association, American Heart Association, American Cancer Society, American Lung Association, American Academy of Family Physicians, the World Health Assembly, and the World Health Organization have recommended restrictions on advertising and promotion including a total ban of all promotional and advertising activities.[95]

Additionally, the recent IOM report recommended that, to ensure that one clear message about the health risks of tobacco use is disseminated, the government should see to it that the ''contradictory message [minimizing the risk] now conveyed by the tobacco industry''is stopped.[96] The report recommended many restrictions that are similar to those in the proposed rule. For example, the report recommended that advertising either be banned entirely or restricted to a text-only format.[97] The IOM said that such an approach would ''eliminate all the images that imply that tobacco use is beneficial and make it attractive, and that encourage young people to use tobacco products.'' [98]

The proposed labeling and advertising regulations are also based upon numerous studies and reports. The first and most compelling piece of evidence supporting restrictions on cigarette and smokeless tobacco product labeling, advertising, and promotion is that these products are among the most heavily advertised products in America. Between 1970 (1 year before Federal law prohibited cigarette advertisements on television and radio) and 1993, cigarette advertising and promotional expenditures increased from $361 million to $6 billion, a 1,562 percent increase.[99] These messages were disseminated in print media, on billboards, at point of sale, by direct mail, on specialty items (hats, tee shirts, lighters), at concerts and sporting events, in direct mail solicitations, as sponsorships on television, and in other media. FDA is concerned that the amount of advertising, its attractive imagery, and the fact that it appears in so many forums, overwhelms the government's health messages.

Advertising and promotion of smokeless tobacco products, although a much smaller market than cigarettes, also increased over the years. The largest increase in advertising expenditures for smokeless tobacco products occurred for moist snuff. U.S.Tobacco (UST), the market leader in moist snuff, increased its television advertising expenditures from $800,000 in 1972 to $4.6 million in 1984,[100] an increase of 485 percent. By 1993, total advertising and promotional expenditures for smokeless tobacco products exceeded $119 million. This increase was largely attributable to the advertising of moist snuff ($71.4 million).[101] This increase in expenditures corresponds to the growth of the moist snuff portion of the smokeless tobacco market, from 36 million pounds in 1986 to 50 million pounds in 1993. All other segments of the smokeless tobacco market declined during that period.[102]

In addition to spending large amounts on advertising, the cigarette and smokeless tobacco product industries have disseminated a variety of advertising and promotional messages that have had an enormous impact upon young people's attitudes towards smoking. In summarizing its analysis of the industry's advertising practices, IOM stated:

> The images typically associated with advertising and promotion convey the message that tobacco use is a desirable, socially approved, safe and healthful, and widely practiced behavior among young adults, whom children and youths want to emulate. As a result, tobacco advertising and promotion undoubtedly contribute to the multiple and convergent psychosocial influences that lead children and youths to begin using these products and become addicted to them.[103]

The pervasiveness and magnitude of the labeling and advertising for these products create an atmosphere of ''friendly familiarity'' [104] that affects and shapes a young person's views towards tobacco products. Thus, FDA's decision to propose stringent regulations for labeling and advertising is based upon compelling evidence that advertising and labeling play an important role in shaping a young person's attitude towards, and willingness to experiment with, cigarettes and smokeless tobacco products.

2. Advertising, Labeling, and Adolescents

Products may be advertised and promoted for their symbolic or fanciful attributes. Advertising utilizing this technique tries to convey that consumption of the product will enhance the user's self image [105] or image in the community. Consumers purchasing products for these symbolic attributes hope to acquire the image as well as the product itself.[106] This psychosocial consumer phenomenon is particularly descriptive of adolescent consumer behavior. As one consumer psychologist remarked:

> [adolescence] create[s] a lot of uncertainty about the self, and the need to belong and to find one's unique identity as a person becomes extremely important. At this age, choices of activities, friends, and ''looks''often are crucial to social acceptance. Teens actively search for cues from their peers and from advertising for the ''right''way to look and behave.* * * Teens use products to express their identities, to explore the world and their new-found freedoms in it, and also to rebel against the authority of their parents and other socializing agents. Consumers in this age sub-culture have a number of needs, including experimentation, belonging, independence, responsibility, and approval from others. Product usage is a significant medium to express these needs.[107]

For example, adolescent males often use ''such 'macho' products as cars, clothing, and cologne to bolster developing and fragile masculine self-concepts.'' [108]

Adolescents view cigarettes as a symbol to be used in helping to create a desired self image and to communicate that image to others. Cigarette advertising reinforces this symbolism and links smoking to success, social acceptance, sophistication, and a desirable lifestyle. The rugged and masculine Marlboro Man conveying, in the words of the Chief Executive Officer and President of Philip Morris, ''elements of adventure, freedom, being in charge of your own destiny,'' [109] and the cool Joe Camel, giving humorous dating tips, provide imagery that adolescents can accept as identifying badges. Not surprisingly, these brands are among the most popular with young people. One Canadian tobacco company described its ''masculine''targeting in these words:

> Since 1971, [the company's] marketing strategy has been to position [a cigarette brand] as a ''masculine trademark for young males.'' It has been our belief that lifestyle imagery conveying a feeling of independence/freedom should be used to trigger the desire for individuality usually felt by maturing young males.[110]

Advertising for cigarette brands targeted to women have proven successful in attracting young female smokers. One study correlated trends in rising smoking initiation rates among girls with the introduction of several brands targeted at women. Some of these campaigns utilized themes thought to be appealing to women (e.g. liberation and feminism, images of slimness and sophistication). The advertising campaigns preceded a rapid increase in smoking initiation rates among girls under 18 that was not accompanied by any increase in smoking rates for women, boys, or men.

Thus, advertising can play an important role in a youth's decision to use tobacco. Many researchers, including those within the cigarette industry, have advanced a stage-based model of smoking uptake.[111] The first, preparatory stage is when a child or adolescent starts forming his or her attitudes and beliefs about smoking, and sees smoking as a coping mechanism, as a badge of maturity, as a way to enter a new peer group, or as a means to display independence.[112] During this stage, pervasive advertising imagery that glamorizes tobacco use may be an important factor in shaping beliefs. The

middle, trying and experimenting stages occur when the first cigarette is smoked, often at the urging of a peer, and becomes repeated but irregular. It is important to note that those who experiment often, or begin smoking at an early age, are much more likely to become regular smokers.[113] Therefore, age of initiation is important.

The final stage, nicotine dependence and addiction, is characterized by a physiological need for nicotine. At this stage, the adolescent develops a tolerance for nicotine and can experience withdrawal symptoms (such as dysphoric or depressed mood, insomnia, irritability, frustration or anger, anxiety, and difficulty concentrating) if he or she attempts to quit. However, of those who try to quit, few succeed without help, and there is a high probability of relapse.[114]

In the early stages of smoking, i.e., at initiation, psychosocial factors are decisive, and those factors are most often capitalized on in the themes used in tobacco product advertising. In the final stage, as smoking takes hold, physiological factors (and even health concerns) dominate. A document prepared by Imperial Tobacco Ltd. stated:

> At a younger age, taste requirements and satisfaction in a cigarette are thought to play a secondary role to the social requirements. Therefore taste, until a certain nicotine dependence has been developed, is somewhat less important than other things.[115]

Many behavioral and personal characteristics influence an adolescent's decision to use cigarettes or smokeless tobacco products, including: rebelliousness; risk-taking personality; use of other legal or illegal drugs; belief in the perceived utility of smoking (to cope with stress, control weight, or improve one's self-image); low self-esteem or depression; disbelief of or discounting health risks; and poor academic achievement.[116] Cognitive factors specific to children and adolescents also play a role in the early decision to smoke. Children and adolescents often focus on present needs and concerns, and ignore risks that might exist in the future. They exhibit a sense of personal invulnerability that permits them to act as if they were immortal.[117] Tobacco advertising plays on these feelings and exploits these adolescent vulnerabilities. As one report, created for a Canadian cigarette company, stated:

> Starters no longer disbelieve the dangers of smoking, but they almost universally assume these risks will not apply to themselves because they will not become addicted. Once addiction does take place, it becomes necessary for the smoker to make peace with the accepted hazards. This is done by a wide range of rationalizations.[118]

3. Industry's Marketing Practices

Industry documents indicate that cigarette manufacturers have conducted extensive research on smoking behavior and attitudes in young people and how advertisements should be made to appeal to young people. Documents from Philip Morris' files indicate that the company did, at least on one occasion, conduct research about the smoking habits of young people, questioning people in Iowa, including teen-agers as young as 14.[119] More specifically, research conducted for a Canadian affiliate of one U.S. cigarette firm focused on the need to attract young consumers, stating:

> Ads for teenagers must be denoted by a lack of artificiality, and a sense of honesty. Attempts at use of celebrities ***do not seem to really click. If freedom from pressure and authority can also be communicated, so much the better.[120]

Research conducted by an American cigarette firm, and confirmed by other tobacco companies, revealed another significant behavior: most smokers continue to purchase the brand they smoked when they became regular smokers. Brand loyalty is seen in many consumer products (such as toothpaste, coffee, and automobiles) but is particularly strong for tobacco products. A 1989 ''Wall Street Journal''article showed cigarettes as having the highest percentage of brand loyalty among consumers of any consumer product, at 71 percent.[121]

Knowledge about brand loyalty among cigarette smokers, coupled with the fact that most smokers began smoking before the age of 18, may explain why cigarette manufacturers have focused advertising and promotional efforts on younger people. R.J. Reynolds devised what it called a ''Young Adult Smokers'' (''YAS'') program that was apparently designed to appeal specifically to young smokers, 18 to 24 year olds, and more narrowly to 18 to 20 year olds. An element of that program, known as FUBYAS, an acronym for First Usual Brand Young Adult Smokers, captured the concept that a smoker's first regular brand is the brand a smoker will stay with for years. This program featured the use of promotional items, such as hats and tee shirts bearing the Camel brand name, the cartoon Joe Camel, and imagery, that appealed to young people. Although these programs were ostensibly directed at people between the ages of 18 and 24, company memoranda suggest that the target population included high school students. For example, on January 10, 1990, a manager in Sarasota, Florida, issued a memorandum asking cigarette sales representatives to identify stores:

> * * * that are heavily frequented by young adult shoppers. These stores can be in close proximity to colleges [,] high schools or areas where there are a large number of young adults [who] frequent the store.[122]

On May 3, 1990, when the ''Wall Street Journal'' published this memorandum, the cigarette firm stated that the memorandum was a ''mistake'' and violated company policy by targeting high schools.[123]

Yet, on April 5, 1990, a manager in Moore, OK, issued a similar memorandum regarding the YAS program asking sales and service representatives to identify what was termed ''Retail Young Adult Smoker Retailer Accounts.''One criterion for identifying a YAS account included facilities ''located across from, adjacent to are [*sic*] in the general vicinity of the High Schools or College Campus [*sic*].'' [124] This second memorandum suggests that promotions aimed at high school students were part of the company's marketing strategy.

Sales figures suggest that the YAS program was extremely effective. Camel quickly became one of the most popular cigarette brands among people under age 18. Prior to the introduction of the Joe Camel campaign, Camel cigarettes commanded no more than 3 or 4 percent of the youth market. One year into the campaign, the youth share rose to 8.1 percent and by 1991 it was at least 13 percent.[125]

While not all advertising campaigns are so blatantly directed at juveniles, campaigns using more universal themes can be as effective with young people. According to an advertising executive with the advertising agency that created the Marlboro cowboy, ''The Marlboro cowboy dispels the myth that in order to attract young people, you've got to show young people.'' The cowboy theme of independence can be translated into other venues that have appeal for young people and be sold as an appropriate and desirable image. According to John Landry, the Philip Morris executive credited with designing the Marlboro campaign, the Marlboro theme sells because it fits young people's desires. In 1973, Philip Morris sponsored the Marlboro Cup for the first time. Landry recalls that ''Secretariat [the winning horse] became a hero to young people. Youth were reaching out for something, and someone they could identify with * * *

'Marlboro Country' fit these desires, this search people were going through.'' ''Something young people could trust.''A candid appraisal of the purpose of the Marlboro theme was provided by the marketing director with Philip Morris in Argentina, ''Marlboro magic—people using things with [the] Marlboro logo * * * was projected to other products around it and when those kids who were playing with Marlboro merchandise 5 to 10 years ago—when they start smoking they'll smoke Marlboro.'' [126]

With regard to smokeless tobacco products, the U.S. Tobacco Company (UST) successfully revived a declining market by targeting young people, especially young men, in its promotion and advertising. In 1970, the segment of the population with the highest use of these products was men over age 50, and young males were among the lowest. Fifteen years later, there had been a 10-fold increase in the use of smokeless tobacco products among young males, whose use was double that of men over age 50.[127]

The increased use of smokeless tobacco products by young people was precisely the objective of a marketing strategy of UST set in motion almost 30 years ago. In 1968, officials at UST held a marketing meeting 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.'' [128] Another official who attended the meeting was quoted as saying, ''We were looking for new users—younger people who, by reputation, wouldn't try the old products.'' [129] When a rival company developed a smokeless tobacco product that 9-year-old children began using, a UST regional sales manager reported to UST's national sales manager that the product was mostly used by children and young adults ''from 9 years old and up'' and noted that this age was ''four or five years earlier than we have reached them in the past.'' [130]

Responding to a question years later about why so many young males were buying smokeless tobacco, Louis F. Bantle, then chairman of the board of UST said, ''I think there are a lot of reasons, with one of them being that it is very 'macho'.'' [131] Playing to this ''macho'' perception of smokeless tobacco by young males, advertisements for smokeless tobacco products have traditionally used a rugged, masculine image and have been promoted by well-known professional athletes. UST's successful penetration into the youth market is indicated in a statement by Mr. Bantle: ''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'.'' [132]

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 for recruiting new, younger users.[133]

Tobacco companies deny any youth-directed advertising and promotion activities.[134] Moreover, the industry claims that advertising plays no role in a person's decision to start smoking; that tobacco advertising is designed solely to capture brand share from competitors and maintain product loyalty. The industry further claims that the tobacco market is a ''mature'' market in which awareness of the product is universal and overall demand is either stable or declining.[135] In a mature market, the industry contends, advertising functions to merely shift customers from one brand to another, but does not act as a stimulus to new customers to enter the market.

One purpose of cigarette advertising may be to encourage or discourage brand switching among current tobacco users. Some experts believe, however, that this same advertising encourages new consumers to begin using these products.[136] Tobacco advertising, promotion, and marketing, on which the industry spends over $6 billion each year, may serve both purposes largely out of market necessity. Market expansion, in the sense of new customers entering the market, must occur to maintain total tobacco sales and avoid a significant market decline. ''[T]he cigarette industry has been artfully maintaining that cigarette advertising has nothing to do with total sales * * * [T]his is complete and utter nonsense. The industry knows it is nonsense,'' wrote a former cigarette advertising executive.[137]

Evidence indicates that acquiring a portion of the ''starter'' market, overwhelmingly people in their teens, is regarded by the industry as essential to a company's continuing economic viability. One document acquired from Imperial Tobacco Limited (ITL) of Canada, a sister company of the Brown & Williamson Company in the United States, states:

> 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.''[138]

To further this goal, ITL hired a consulting research company to investigate attitudes about smoking among people aged 15 years and older. The purpose of the research, i.e., how best to recruit new smokers, is indicated in the following statement:

> It is no exaggeration to suggest that the tobacco industry is under siege. The smoker base is declining, primarily as a function of successful quitting. And the characteristics of new smokers are changing such that the future starting level may be in question.[139]

Similar attitudinal research was done for R.J.R.-MacDonald, Inc., the Canadian subsidiary of R.J. Reynolds.[140] A report entitled YOUTH 1987 closely examined the lifestyles and value systems of ''young men and women in the 15–24 age range.'' The report said the research would:

> provide marketers and policymakers with an enriched understanding of the mores and motives of this important emerging adult segment which can be applied to better decision making in regard to products and programs directed at youth.[141]

A similar research objective was described in a 1969 research paper presented to the Philip Morris Board of Directors.[142] The paper stated that one of its objectives was to probe ''[w]hy do 70 million Americans * * * smoke despite parental admonition, doctors'' warnings, governmental taxes, and health agency propaganda?'' [143] The paper continues:

> There is general agreement on the answer to the first [question—why does one begin to smoke.] The 16 to 20-year old begins smoking for psychosocial reasons. The act of smoking is symbolic; it signifies adulthood, he smokes to enhance his image in the eyes of his peers.[144]

Cigarette manufacturers are also aware of the difficulties young people encounter when they try to quit smoking. Studies prepared for a Canadian affiliate of a U.S. cigarette company state:

> However intriguing smoking was at 11, 12, or 13, by the age of 16 or 17 many regretted their use of cigarettes for health reasons and because they feel unable to stop smoking when they want to.[145]

Another document declares:

[T]he 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.[146]

Thus, these documents and reports suggest that cigarette manufacturers know that young people are vital to their markets and that they need to develop advertising and other promotional activities that appeal to young people. They also suggest that cigarette manufacturers know that once those young people become regular smokers, that they, like adult smokers, find quitting smoking to be very difficult, and most young people fail in their attempts to quit.

4. Empirical Research on the Effects of Cigarette Advertising Activities on Young People

The 1994 Surgeon General's Report concluded that ''[a] substantial and growing body of scientific literature has reported on young people's awareness of, and attitudes about, cigarette advertising and promotional activities.'' The report also found that ''[c]onsidered together, these studies offer a compelling argument for the mediated relationship of cigarette advertising and adolescent smoking.'' [147] The Surgeon General's Report and the Institute of Medicine's report [148] find that there is sufficient evidence to conclude that advertising and labeling play a significant and important contributory role in a young person's decision to use cigarettes or smokeless tobacco products.

a. *Studies of advertising recall, approval of advertising, and young people's response to advertising.* Many studies have shown that young people are aware of, respond favorably to, and are influenced by cigarette advertising.[149] Even relatively young children are aware of cigarette advertisements and can recall salient portions. A recent Gallup survey found that 87 percent of adolescents surveyed could recall seeing one or more tobacco advertisements and that half could identify the brand name associated with one of four popular cigarette slogans.[150] One study found that over 34 percent of 12- to 13-year-old California children surveyed could name a brand of cigarettes that was advertised, despite the fact that Federal law bans cigarette and smokeless tobacco product advertising on both radio and television, the usual medium of information for children and adolescents.[151]

Other studies show that children who smoke are more likely to correctly identify cigarette advertisements and slogans in which the product names have been removed than are non-smokers.[152] One study surveyed a group of U.S. high school students and found a positive relationship between smoking level and cigarette advertisement recognition. Regular smokers recognized 61.6 percent of the tobacco advertisements while non-smokers recognized 33.2 percent.[153]

Another study measured cigarette advertising exposure among adolescents by determining which magazines they read and the number of cigarette advertisements in each magazine. The study found that two factors, advertising exposure and whether a friend or friends smoked, were predictive of smoking status or intention to smoke. The authors contended that the findings are consistent with the theory that cigarette advertising successfully represents, through attractive imagery, that smoking is a facilitator for acquiring a desired characteristic or goal.[154]

These studies raised the question of whether smoking causes a person to recognize advertisements or whether a person's exposure to or recognition of advertisements leads to smoking or increases the likelihood that a person will smoke. One study designed specifically to address this issue [155] showed that causality flowed in both directions: experimentation with cigarettes prompted subjects to attend to and retain information from cigarette advertisements (smoking status determined whether the child attended to advertising) and the amount of information retained by each subject from cigarette advertisements predicted the subjects' experimentation with cigarettes (causality).[156]

Another study attempted to address the issue of causality by questioning Glasgow school children at two different times, 1 year apart. The study asked 640 Glasgow children between the ages of 11 and 14 about their intention to smoke and their recognition of cigarette advertising. Children who were more inclined to smoke between the time when the two interviews were conducted tended to be more aware of cigarette advertising at the first interview than children who were less inclined to smoke. The study concluded that cigarette advertising has predisposing, as well as reinforcing, effects on children's attitudes towards smoking and their smoking intentions.[157]

Other studies relating children's misperceptions about the prevalence of smoking to advertising exposure and smoking status have found that overestimating smoking prevalence appears to be a very strong predictor of smoking initiation and progression to regular smoking.[158] The 1994 Surgeon General's Report found that young people overestimate the prevalence of cigarette smoking [159] and that advertising's pervasiveness plays a role in this misconception. One unpublished study cited in the Surgeon General's Report supports this finding. The study found that children in Los Angeles (where cigarette advertising and promotional campaigns are prevalent) were nearly three times more likely to overestimate the prevalence of peer smoking than were children in Helsinki, Finland (where there has been a total ban on advertising since 1978).[160] Moreover, adolescent smokers are more likely to overestimate the prevalence than adolescent non-smokers.[161] Overestimating smoking prevalence, as well as self-reported exposure to advertising, have both been positively correlated with the intention to smoke.[162]

Additional evidence indicates that children smoke many fewer brands than adults and that their choices, unlike adults, are directly related to the amount and kind of advertising.[163] CDC recently reported that 86 percent of underage smokers who purchase their own cigarettes purchase one of three brands: Marlboro (60 percent), Camel (13.3 percent) and Newport (12.7 percent).[164] These three brands were also the three most heavily advertised brands in 1993.[165] While Marlboro has long been the most popular brand among young people, Camel's share of the youth market increased from around 3 percent to 13.3 percent as a result of the invigorated Joe Camel campaign.

Adult preferences, on the other hand, are more dispersed. The three most commonly purchased brands among all smokers (as measured by market share) accounted for only 35 percent of the overall market share. (Camel had approximately 4 percent of the market and its market share did not change as a result of the Joe Camel advertising.) Furthermore, the most popular ''brand'' of cigarette among adult smokers was no brand at all: 39 percent of all cigarettes sold in the first quarter of 1993 were from the ''price value market'' which includes private label, generics, and plain-packaged products.[166] These brands typically rely on little or no advertising and little or no imagery on their packaging.

These studies present evidence that advertising plays a significant role in children's smoking behavior. There are, in addition, individual case studies that

illustrate the profound effect that certain cigarette advertising campaigns can have on the youth market.

b. *The effect of selected advertising campaigns, which were effective with children.* Two American studies and one British study analyzed alleged youth-oriented campaigns to determine what effect they had on the underage market. One U.S. study examined the effect on the youth market of R.J. Reynolds' advertising campaign for Camel brand cigarettes. In the mid 1980's, R.J. Reynolds sought to revitalize its Camel brand cigarettes. It gave its symbol, the Camel, a new, more hip personality. It transformed the symbol into ''Joe Camel,'' an anthropomorphic ''spokescamel.'' The campaign featured Joe as a humorous figure in history, as an advisor to young adults with ''smooth moves'' and eventually as one of a gang of hip camels (''the hard pack'' band and the gang at the watering hole bar). The study analyzed 1990 data from the California Tobacco Survey which consisted of a telephone survey of 24,296 adults and 5,040 children under the age of 18. The study found that teenagers were twice as likely as adults to identify Camel cigarettes as one of the two most advertised brands.[167]

One study explored the power of the Joe Camel campaign to penetrate the youth market. The study found that children as young as 3 years old could identify Joe Camel as a symbol for smoking. This recognition ranged from 30 percent of 3 year olds, to 91 percent of 6 year olds. In fact, the recognition rates for Joe Camel surpassed the rates for certain children's products, cereals, computers, and network television symbols.[168] A similar study funded by R.J. Reynolds found that 72 percent of 6 year olds and 52 percent of children between the ages of 3 and 6 could identify Joe Camel. These rates exceeded the recognition rates for Ronald McDonald, which were 62 percent of the 6 year olds and 51 percent of children between the ages of 3 and 6.[169] The higher recognition rates for Joe Camel are remarkable because, unlike Ronald McDonald who appears in television commercials during children's viewing hours, Federal law prohibits cigarette advertisements on television.

Data collected by researchers for the State of California found that in 1990, 23.1 percent of the under age 18 market in California purchased Camel as their brand. This represented a 230 percent increase over its pre-''Joe Camel'' 1986 rate. The same growth rate did not occur for adults.[170] Nationally, Camel had less than 3 percent of the youth market before the brand was repositioned in 1988 and Joe Camel was introduced.[171] By 1989, Camel's share of the youth market had risen to 8.1 percent,[172] and by 1992, 13 to 16 percent.[173] During this same period, Camel's share of the adult market barely moved from its 4 percent level.[174]

The other American study used data from the National Health Interview Survey to study trends in smoking initiation among 10- to 20-year-olds from 1944 through 1980. The study found that initiation rates for 18- to 20-year-old women peaked in the early 1960's and steadily declined thereafter. Initiation rates for girls under 18, however, increased abruptly around 1967. This was the same period when brands specifically intended for women were introduced and heavily advertised. The initiation rate was particularly steep for women who did not attend college. The initiation rate for girls under the age of 18 peaked in 1973—about the same time that sales for these brands (Virginia Slims, Silva Thins, and Eve) peaked. Between 1967 and 1973, smoking initiation rates increased around 110 percent for 12-year-old girls, 55 percent for 13-year-olds, 70 percent for 14-year-olds, 75 percent for 15-year-olds, 55 percent for 16-year- olds, and 35 percent for 17-year-olds.[175]

In contrast, initiation rates for men declined from 1944 to 1949 and did not decline again until the middle to late 1960's. Initiation rates for boys under 16 showed little change during the entire study period. The study concluded that advertising for women's brands during this period was positively associated with increased smoking uptake in girls under 18 years of age.[176]

The British study looked at a campaign featuring a flippant and humorous character named ''Reg.'' The study found that 91 percent of 11- to 15-year-olds recognized the ads, compared with 52 percent of 33- to 55-year-olds. Teenagers who liked the advertisements were more likely to smoke. In fact, it was one of the two brands that most children smoked. During the period in which Reg was advertised, smoking by 11- to 15-years-olds in northern England increased from 8 percent to 10 percent, but the rate for this same age group in southern England, where the advertisements did not appear, remained stable at 7 percent.[177] The government, pursuant to the industry's voluntary code, later requested that the company discontinue the advertising campaign because of its disproportionate appeal to children.

These studies provide compelling evidence that promotional campaigns can be extremely effective with young people.

c. *Direct quantitative studies.* There are many direct quantitative studies of the relationship between advertising and tobacco use and of the effects of advertising restrictions and bans on consumption. 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 effects on consumption and the effectiveness of advertising restrictions on reducing youth smoking.

A large, multinational study commissioned by the New Zealand Government examined consumption trends in 33 countries between 1970 and 1986.[178] Controlling for income, price, and health education, the study found that the greater a government's degree of control over tobacco promotion, the greater the annual average fall in tobacco consumption and in the rate of decrease of smoking among young people.[179] One of the report's most relevant conclusions was that, among the 18 countries with data on youth smoking, there is evidence of a relationship between stringent government restrictions on tobacco promotion and reduced uptake of smoking among young people. The report concluded that there appeared to be a greater decrease in smoking uptake in those countries with the most stringent measures compared with those countries where advertising had not been affected.[180]

Other studies that have looked at populations in general provide evidence that restrictions can have an important effect on total consumption and provide inferential evidence of similar positive effects on youth smoking. One such study conducted by the Chief Economic Advisor of the Department of Health of the Government of Great Britain found that advertising tends to increase consumption of tobacco products and that restrictions on advertising tend to decrease tobacco use beyond what would have occurred in the absence of regulation.[181] After performing an in-depth analysis of data from the four countries (Norway, Finland, Canada, and New Zealand) which had varying degrees of tobacco advertising restrictions and for which data exist, the study concluded that restrictions, including bans on some forms of advertising or on all advertising, resulted in an overall decrease in consumption. The study suggests that Norway's restrictions on all advertising, sponsorship, and indirect advertising produces a 9 to 16 percent reduction in consumption over the long run.[182] Finland's ban on advertising and

restrictions on other nonadvertising measures reduced cigarette smoking by 6.7 percent.[183]

Canada's Tobacco Products Control Act, which became effective on January 1, 1989, banned most print advertising, restricted sponsorship, and forbade indirect advertising (e.g., use of trade names on non-tobacco items). Although advertising restrictions often take time to be fully effective, the study found that in only 2 years following the institution of government regulation, consumption was reduced 2.8 percent more than would have been expected had there been no advertising restrictions.[184]

Another study looked at tobacco consumption per adult in the 22 countries of the Organization for Economic Cooperation and Development between 1960 and 1986.[185] The report reaffirmed the New Zealand Board's conclusion 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 which permitted promotion.[186]

Other studies try to measure the effect that advertising has on the general level of consumption in a country. Advertising can have an increased effect on consumption, even in those countries where the smoking rate has been falling. The analyses are able to determine whether consumption would have fallen at a greater rate but for the advertising, and ascribe that difference (the slowed rate of decline) to advertising.

One New Zealand study provides evidence that changes in advertising expenditures can have an effect on youth smoking behavior. The study analyzed the total sales of cigarettes sold by New Zealand supermarkets over a 42 week period. The study design included advertising that had recently been modified to contain newly-mandated, strong, varied disease warnings that occupied 15 percent of the advertisement. Moreover, no human form could be displayed in the advertising except a hand and forearm, and one color apart from black was usually used. The results indicated that advertising for upscale brands of cigarettes did not raise cigarette consumption, but that consumption of an inexpensive brand with a heavy youth appeal did increase with increased advertising. Moreover, the study found that the advertising for the new, inexpensive brand had the additional effect of recruiting young smokers and increasing the market base.[187]

Studies that assessed the response of large population groups to changes in advertising generally confirm a finding that advertising has a positive effect on consumption. The most recent comprehensive analysis of existing studies on the effect of advertising expenditures on consumption rates was done in the English study, discussed above. Among other things, the study looked at the effect of yearly fluctuations in advertising expenditures within several countries, but principally within the United States and United Kingdom. The result was that the ''preponderance of positive results points to the conclusion that advertising does have a positive effect on consumption.'' [188] Individual, smaller studies [189] have examined the same question and confirmed a finding of effect of advertising on consumption.[190]

5. Summary of Evidence

The agency concludes that the preponderance of quantitative and qualitative studies of cigarette advertising suggests: (1) A causal relationship between advertising and youth smoking behavior, and (2) a positive effect of stringent advertising measures on smoking rates and on youth smoking. Moreover, industry statements indicate the importance of the youth market segment to the industry's continued success. Actions taken by industry members to attract young smokers have also resulted in attracting children and adolescents. Finally, examples of specific campaigns directed at young people support the hypothesis that cigarette advertising and promotion play an important role in encouraging young people to start smoking, to sustain their smoking habit, and to increase consumption. Therefore, the agency finds that stringent restrictions on advertising are essential if smoking by adolescents is to be reduced.

6. Proposed Subpart D—Labeling and Advertising

a. *General overview*. Proposed subpart D would establish regulations on the labeling and advertising of cigarettes and smokeless tobacco products. Proposed subpart D consists of four sections. Proposed § 897.30 would establish the scope of permissible forms of labeling and advertising. Proposed § 897.32 would set forth the format and content requirements. Proposed § 897.34(a) would prohibit the sale and distribution of non-tobacco items and services that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristics; proposed § 897.34(b) would prohibit proof of purchase gifts and games of chance and contests; and § 897.34(c) would prohibit sponsorship of events that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristics. Proposed § 897.36 would address false and misleading labeling and advertising. These sections are discussed more fully below.

The proposed rule would establish different labeling and advertising requirements for cigarettes and smokeless tobacco products. These differences result from different Federal preemption provisions contained in the two Federal laws requiring warning labels on those products. Briefly, FDA believes that the Cigarette Act only preempts FDA's authority to require additional statements about smoking and health on cigarette packages, while the Smokeless Act prohibits FDA from requiring additional information about health and tobacco use in advertising as well as on the package of smokeless tobacco products. For a more complete discussion, see section IV.C. below.

b. *Proposed § 897.30—permissible forms of labeling and advertising.* Proposed § 897.30 would set forth the permissible forms of labeling and advertising for cigarettes and smokeless tobacco products. 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. In brief, § 897.30(a) of the proposed rule would define permissible outlets for labeling and advertising as newspapers, magazines, periodicals, billboards, posters, placards, entries and teams in sponsored events, promotional materials, audio and/or video formats, and delivered at the point of sale. Proposed § 897.30(b) would prohibit outdoor advertising of tobacco products from appearing outside of buildings within 1,000 feet of an elementary or secondary school or playground. 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 believes that this a reasonable restriction and notes that the cigarette industry's voluntary ''Cigarette Advertising and Promotion Code,'' revised in 1990, contains a similar

provision concerning schools and playgrounds.

These labeling and advertising requirements are an effort to control the proliferation of promotional messages that attract young people. As discussed above, advertising and promotion can play a significant role in young people's smoking behavior. The agency finds that restricting the permissible forms of media would help prevent young people from starting to use cigarettes and smokeless tobacco products and becoming addicted to those products. Proposed § 897.30 (a) would describe the range of known labeling and advertising media currently used by cigarette and smokeless tobacco product companies.

It is important to note that the proposal would not affect any other limitations on labeling or advertising, such as the radio and television advertising bans placed on cigarette and smokeless tobacco product advertising (the Cigarette Act, 15 U.S.C. 1331, 1334 and the Smokeless Act, 15 U.S.C. 4401, 4402(f)) nor any other actions taken by Federal agencies (e.g., FTC's ''Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986,'' 16 CFR Part 307 (1994)).

c. *Proposed § 897.32—format and content requirements for labeling and advertising.* Proposed § 897.32 would describe the format and content requirements for cigarette and smokeless tobacco product labeling and advertising. This section would establish requirements in three principal areas: text-only format, the product's established name, and a brief statement of the risks of using cigarettes.

i. *Text-only advertising.* The agency considered various options available to control advertising's influence on young people, from a full ban on all advertising and promotion, to restrictions on advertising and promotional practices that children actually view. FDA's proposed rule would address the need to eliminate advertising's influence on young people and, at the same time, preserve advertising's informative aspects—that is, to provide useful information to consumers legally able to purchase these products. Therefore, the agency agrees with the IOM's recommendation that advertising and labeling should appear in text-only format because this format would reduce the attraction and appeal that cigarette and smokeless tobacco product advertising have for young people. Recognizing that it is difficult to draw the line between advertising that should be restricted or regulated and advertising that does not pose an unreasonable risk of influencing young people, the agency requests comment on the appropriateness of the proposed regulations and whether other alternatives would be more appropriate or effective.

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. This text-only requirement is intended to reduce the appeal of cigarette and smokeless tobacco product labeling and advertising to persons younger than 18 without affecting the informational message conveyed to adults.

However, FDA believes that advertising in publications that are read primarily by adults should be allowed to use imagery and color because the effect of such advertising on young people would be nominal. Therefore, advertisements in publications with primarily adult readership would not be restricted to a text-only format. The agency proposes to define such publications as those: (a) Whose readers age 18 or older constitute 85 percent or more of the publication's total readership, or (b) that is read by two million or fewer people under age 18, whichever method results in the lower number of young people. The readership of a publication is the total number of people that read any given copy of that publication. 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. A reader is one who said that he/she read the last issue of a publication. Prior to 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.

The concept of text-only advertising requirements is not new. The cigarette industry has employed text-only advertisements in the past, particularly when it sought to inform or educate consumers about company policies or important issues. See, e.g., ''In the Matter of R.J. Reynolds Tobacco Co.,'' 111 F.T.C. 539 (D. 9206) (1988) (a text-only advertisement that disputed that cigarette smoking was related to coronary heart disease); ''Washington Post,'' October 18, 1994, at p. A11; ''Washington Post,'' October 20, 1994, at p. A17; ''Time,'' 144(19): 42(1994) (Philip Morris text-only advertisement which discussed environmental tobacco smoke); ''Tobacco Control and Marketing: Hearings Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce,'' R.J. Reynolds, to the Honorable Edolphus Towns (Reynolds' text-only advertisement about youth smoking).

Several studies show how strongly images appeal to young people. Photographs, pictures, cartoons, and other graphics allow the advertiser to encode its sales message in a way that makes the advertisement more compelling and memorable.[191] Imagery ties the products to a positive visual image that can be used consistently in all advertising media as well as on the product package itself.[192]

Adding visual images to a text advertisement can produce greater recall and a more positive product rating.[193] Not surprisingly, studies have shown 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.[194]

One study examined 243 seventh and eighth grade students in Chicago to determine the appeal (likability) of different types of cigarette advertising. The study compared a Joe Camel advertisement, an advertisement with a model, and a text-only advertisement. The results indicated that adolescents found advertisements containing pictures and cartoons to be significantly more appealing than advertisements with human models; advertisements with any imagery were more appealing than text-only advertisements. These results are particularly compelling because a study by the Advertising Research Foundation found that an advertisement's ''likability'' is the best predictor of product sales.[195]

In arriving at its proposal, FDA considered other options, including banning all advertising or restricting the type of imagery used.[196] FDA believes that the evidence detailed above would justify a ban on all or most advertising and promotion of tobacco products. The studies cited and industry statements and actions already discussed in this proposal indicate the positive effect that advertising can have on young people's smoking behavior, while other studies establish that bans on cigarette advertising can help reduce overall consumption and youth initiation. Given the extremely grave health consequences of a lifetime of smoking, actions taken that would help achieve a lower initiation rate among young people would be authorized as a matter of law and justified as a matter of public health policy.

Moreover, young people are currently exposed to billions of dollars worth of tobacco advertising and promotion that

use attractive imagery and do not rely on objective product claims. The industry's claims that this advertising exists solely to maintain brand loyalty or induce smokers to switch. However, as noted previously, tobacco advertising and promotion appear to have a more profound effect on brand choices by young people (86 percent of young people smoke the three most advertised brands) than on adults, whose choice is more often based on price (39 percent of the market is comprised of generic and discount products.) Furthermore, brand loyalty runs higher for cigarettes than for any other product. Thus, significant expenditures would not appear to be necessary to retain loyal consumers and would appear to be excessive and wasteful if they are expended merely to get people to switch brands.

While a total ban on advertising, therefore, would likely be justified, FDA believes that limiting advertisements and labeling to which children are exposed to a text-only format is less burdensome and would effectively reduce the appeal of tobacco products to children and adolescents. Further, while some have suggested prohibiting only youth-oriented images, the agency has been unable to define the subset of advertising and labeling directed to young people based upon the media selected or the location of the advertising. For example, billboards are always visible to young people, and there are few, if any, publications that children and adolescents cannot see. Thus, the proposed text-only requirement would offer the most protection for children and adolescents while still enabling informative advertising to reach persons aged 18 and older. Given the complexities of this subject, however, FDA invites comment on other potential methods that may exist for curtailing advertising's appeal to young people.

ii. *Non-tobacco items and sponsorship.* Proposed § 897.34(a) would prohibit the sale or distribution of all non-tobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. As noted above, advertising expenditures have risen dramatically in the past two decades, and the distribution of the marketing expenditures represents a major shift in marketing trends. In 1970, the amounts spent on traditional advertising represented 82 percent of total spending, but, by 1991, this figure had fallen to approximately 17 percent.[197] The remaining funds devoted to marketing cigarettes are spent on a variety of promotional activities designed to assure advantageous placement of products in retail outlets, get products into a prospective consumer's hand through the use of coupons and samples, and provide gifts, contests, and other non-tobacco items and gifts to create special appeal and reduce real price.[198]

Proposed § 897.34(a) would pertain to non-tobacco items and services (other than cigarettes or smokeless tobacco products) that the tobacco companies market, license, distribute, or sell. Manufacturers often provide branded, non-tobacco items as an inducement to purchase cigarettes or generate purchases through the use of proof-of-purchase coupons. Both R.J. Reynolds and Philip Morris utilize this popular technique by providing either a coupon with each package (Camel cash) or indicating that each package was worth a number of credits towards a purchase (Marlboro miles). Each company also printed glossy catalogues with items and gifts that could be purchased using ''cash'' or credits. Either method creates an incentive to purchase the tobacco product by reducing the product's real price; the consumer gets the product and the non-tobacco ''gift.''

The IOM found that this form of advertising is particularly effective with young people.[199] 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. A 1992 Gallup survey found that about half of adolescent smokers and one quarter of non-smokers owned at least one of these items.[200] Similar data were reported for a group of ninth graders from New York State. Among these ninth-graders, 48 percent of occasional smokers and 28 percent of non-smokers reported owning branded clothing.[201]

A recent report found that tobacco companies spent $600 million on programs that provide promotional items in exchange for proofs-of-purchase (usually by catalogue). Although the tobacco industry states that these items are meant for individuals over the age of 20, many teens report participating in promotional activities, with participation ranging from 25.6 percent of 12- to 13-year-olds and 42.7 percent of 16- to 17-year-olds owning a promotional item. The report found that 68.2 percent of current smokers participated, and 28.4 percent of non-smokers participated. The report concluded that there is an association between participating in promotions and a person's susceptibility to tobacco use. It also noted that participation in promotions has the same ability to predict susceptibility to tobacco use as does use by a household member.[202] These proposed provisions would eliminate these items and therefore would prevent young people from wearing such items and becoming ''walking advertisements.''[203]

Proposed § 897.34(b) would prohibit all proof of purchase sales or gifts of non-tobacco items as well as all contests, lotteries, or games of chance that are linked to the purchase of, or in consideration for the purchase of a tobacco product. Because contests and lotteries are usually conducted through the mail, the agency has not been able to devise regulations that would reduce a young person's access to contests or lotteries.

Proposed 897.34(c) would also prohibit a sponsored event from being identified with a cigarette or smokeless tobacco product brand name or any other brand identifying characteristic. Entries and teams in sponsored events are to be treated as labeling under § 897.30 and § 897.32 and would be required to be in text-only, black and white format. Any other athletic, musical, artistic, or other social or cultural event would be permitted to be sponsored in the name of the tobacco company. However, the event would not be permitted to include any brand name (alone or in conjunction with any other words), logo, symbols, motto, selling message, or any other indicia of product identification similar or identical to those used for any brand of cigarettes or smokeless tobacco products. The corporation in whose name the sponsorship would be permitted, would be required to have been in existence on January 1, 1995. This latter provision is intended to prevent manufacturers from circumventing this restriction by incorporating separately each brand that they manufacture for use in sponsorship.

Sponsorship by cigarette and smokeless tobacco companies associates tobacco use with exciting, glamorous, or fun events, such as car racing and rodeos. It provides an opportunity for what sponsorship experts call ''embedded advertising''[204] that actively creates a ''friendly familiarity'' between tobacco and sports enthusiasts, many of whom are children and adolescents. Those watching a sponsored event, including children and adolescents, repeatedly see the sponsor's brand or

corporate name linked with an event they enjoy. For example, sponsoring a race car, motorcycle, or boat enables manufacturers to place cigarette brand names and logos on the vehicles and drivers' uniforms; by sponsoring the event itself, the manufacturers may also place cigarette brand names and logos on the event and on official's clothing.

IEG, the leading source in the United States for sponsorship information and consulting services, is also the only company that tracks and analyzes sponsorship of sporting and other events and causes. It publishes the IEG Sponsorship Report, an international biweekly newsletter on sponsorship, as well as an industry report titled, ''IEG's Complete Guide to Sponsorship: Everything you need to know about sports, arts, event, entertainment and cause marketing.''[205] In this primer for companies considering sponsorship, it defines sponsorship as ''a cash and/or in-kind fee paid to a property (typically in sports, arts, entertainment, or causes) in return for access to the exploitable commercial potential associated with that property.''[206] According to the IEG, ''[s]ponsorship, the fastest growing form of marketing, is unregulated in the U.S.''[207] In North America, total sponsorship grew from $850 million in 1985 to more than $4.2 billion in 1994 and is done by thousands of companies.[208] The IEG further notes that for the cost of a 30-second spot on the Super Bowl telecast, a company can sponsor a NASCAR Winston Cup car and receive more than 30 hours of television coverage.[209]

The report states that companies can link sponsorship directly to product usage or sales.[210] The Chairman and CEO of R.J. Reynolds summed up the underlying purpose of sponsorship for his company by saying, ''We made it clear from the day we announced our sponsorship of the Grand National Division that we were in the business of selling cigarettes, not the racing business.''[211]

The cigarette[212] and smokeless tobacco industry[213] has been involved in sponsorships for many years and was at one time one of the dominant sponsors of events. More recently other industries have become increasingly involved in sponsoring events and causes and today the packaged goods, retail, and financial service industries are the leading sponsors of events. Although the tobacco industry accounts for only 4 percent of all sponsored events,[214] FDA has concluded that sponsored events are a significant part of the successful marketing of tobacco products and that sponsorship should be regulated under this proposal.

Companies often choose to sponsor events in order to heighten their visibility, shape consumer attitudes, communicate commitment to a particular lifestyle, and to drive sales.[215] The IEG reports that sponsorship offers several advantages over traditional advertising. According to the IEG, sponsorship is generally more effective in ''establishing qualitative attributes, such as shaping consumers' image of a brand, increasing favorability ratings and generating awareness.''[216] IEG also states that companies with huge advertising budgets and high consumer awareness (such as tobacco companies), ''are looking to the event to have a rub-off effect on their image and ultimately their sales.''[217] One marketing executive of a company that sponsors professional beach volleyball said, ''Consumer attitudes are the hardest thing to change * * * the more our brand is part of events that are part of a consumer's lifestyle, the more we can affect his or her attitude toward the product.''[218]

Image compatibility is listed by IEG as the number one factor in determining which events to sponsor. IEG encourages companies to consider whether the event offers the imagery it is trying to establish and whether it depicts a lifestyle with which the company wants to be associated.[219] A senior Philip Morris executive explained how the sponsorship of racing car events by Marlboro is consistent with the cowboy imagery associated with Marlboro: ''We perceive Formula One and Indy car racing as adding, if you will, a modern-day dimension to the Marlboro Man. The image of Marlboro is very rugged, individualistic, heroic. And so is this style of auto racing. From an image standpoint, the fit is good.''[220]

The tobacco industry's sponsorship of events also can lead to associations (often referred to as ''tie-ins'') with youth-oriented items that extend the imagery. A sponsored event ''can bring excitement, color, and uniqueness to a [point-of-purchase] display and can be merchandised weeks or months in advance.''[221] For example, auto racing's popularity with children led one toy manufacturer to sponsor a Sprint car team in the 1991 ''World of Outlaw'' series, sponsored principally by UST. The toy company made toy racing cars with Marlboro and Camel decals. Another toy company made toy cars with Copenhagen and Skoal decals; Copenhagen and Skoal are the two major smokeless tobacco product brands for UST.[222] Additionally, ''Inside Winston Cup Racing Sports Club Magazine'' reportedly included a page called Kids Korner with puzzles and games for children.[223]

Sponsorship's impact can be measured by the amount of ''free'' advertising that appears on television. The amount and financial value of television exposure gained by a firm can be substantial. According to one study, Marlboro cigarette's sponsorship of a Championship Auto Racing Team in the 1989 season gave Marlboro nearly 3 ½ hours of television exposure and 146 mentions of the brand name. This exposure had a value of $8.4 million. In the Indianapolis 500, Marlboro received more than $2.6 million in advertising exposure. In the Marlboro Grand Prix, race officials wore Marlboro Grand Prix shirts and caps, and the Marlboro logo or name appeared 5,933 times during the broadcast.[224]

Another study used the ''Sponsor's Report'' to estimate the value of all product exposure for most U.S. auto races. In 1992, 354 motorsport broadcasts were measured. These programs had a total viewing audience of 915 million people, of whom 64 million were children and adolescents. Exposure value for all sponsors was $830 million. Tobacco products accounted for 8.2 percent ($68 million) of the total. 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.[225]

Sponsorship's effectiveness also can be measured by a change in consumer awareness of or attitudes toward a product or company. Evidence regarding sponsorship's impact on young people is somewhat limited, but reports indicate that cigarette manufacturers' sponsorship of sporting events can lead young people to associate brand names with certain life styles or activities or can affect their purchasing decisions.

One study of children in Glasgow found that one-third of the 10- and 11-year-old children surveyed correctly matched cigarette brands to the sports that their manufacturers sponsored. Many children between the ages of 6 and 17 surveyed could specify a brand and the sponsored sport or game, and nearly half of the children associated a life style or image (such as ''excitement'' and ''fast racing cars'') to cigarette brands, even when the cigarette advertisement made no reference to the sport.[226] Another study also found an increase in awareness of the sponsored brands and concluded that even fairly brief exposure to tobacco-sponsored sports on TV may increase considerably

the levels of brand awareness as long as it is linked to well-publicized images.[227]

In Australia, the percentages of children in four different States between the ages of 12 and 14 who smoked were similar. However, their cigarette brand purchases mirrored the brands that had sponsored sporting events in their respective States. For example, more than 44 percent of children in New South Wales and Queensland smoke Winfield, the sponsor of the Queensland Rugby League, whereas, in South Australia, about 44 percent of children smoke Escort, which sponsors the South Australia's Australian Rules Escort Cup. This study demonstrates the effectiveness of sports sponsorship in influencing children's choice of cigarettes.[228]

Finally, a study was conducted in which approximately 100 boys in a secondary school were shown a 15-minute videotape containing an advertisement promoting a cigarette company's sponsorship of a sporting event while another 100 boys were shown the same video with an advertisement of a non-tobacco company's sponsorship of a sporting event. Exposure to the advertisement for the tobacco-sponsored event did not significantly change the boys' general attitudes to smoking. However, non-smoking students who saw the tobacco sponsorship advertisement had a significantly higher level of agreement with the statement that ''smoking doesn't harm people if they play sports'' than did nonsmokers who were not exposed to this advertisement. According to the study's authors: ''Our study suggests that advertising of sponsorships reinforces existing behaviors, and has the potential to increase the rate at which young males smoke by negating the ill-effects associated with smoking. We also conclude that these promotions do affect those under the age of 18 by creating associations with events, teams or personalities with whom they identify.''[229]

The proposed rule is intended to break the link between tobacco company-sponsored events and use of tobacco. These provisions are intended to reduce the so-called ''friendly familiarity'' that sponsorships and items generate among young people.

iii. *Established name and intended use.* Proposed § 897.32(b) would require each piece of advertising for cigarettes, cigarette tobacco, or smokeless tobacco products, permitted under § 897.30(a), to state the product's established name and give a statement of its intended use. 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 * * * printed prominently and in type at least half as large as that used for any trade or brand name thereof.'' The agency has determined that the established names for these products are the common and usual names: ''cigarettes,'' ''cigarette tobacco,'' ''loose leaf chewing tobacco,'' ''plug chewing tobacco,'' ''twist chewing tobacco, ''moist snuff,'' and ''dry snuff.'' (These names would be codified at proposed § 897.24.)

The product's established name would be followed by the words, ''a Nicotine-Delivery Device.'' 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 finds 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 which affirmatively identifies the products to persons reading the advertising.

iv. *The brief statement.* Under proposed § 897.32(c), cigarette advertising (permitted under § 897.30(a)) would contain information regarding relevant warnings, precautions, side effects, and contraindications. This brief statement is required under section 502(r)(2) of the act. Section 502(r)(2) does not require that labeling contain a brief statement and the agency does not intend to place such a requirement on labeling (e.g., vehicles, entries or teams in sponsored events). Because of the products' serious ''potentiality for harmful effect,'' the proposal would specify the text of the brief statement. This would ensure that all advertisements contain the same, required information in a manner that is consistent, readable, clear and conspicuous, and not misleading to the reader.

FDA is generally responsible for approving information in the brief statement to ensure that the appropriate risks and benefits are communicated. In this case, the risks associated with cigarettes are much greater than those for any other consumer product on the market, and hundreds of different cigarette brands exist. The proposed rule, therefore, would provide, as an example, the following text for one of the brief statements to ensure that important information is communicated in an informative manner to young people and that the information is consistent for all cigarette brands:

''ABOUT 1 OUT OF 3 KIDS WHO BECOME SMOKERS WILL DIE FROM THEIR SMOKING.''

FDA will include in the final rule the exact language for any and all brief statements to ensure that this important information is conveyed accurately and effectively. In addition, the agency requests comment on what other information should be included in the brief statements concerning relevant warnings, precautions, side effects, and contraindications.

Support for the proposed brief statement comes from the European Union''s report on the labeling of tobacco products. The report states that ''[t]he warnings which are perceived as being the most credible are, in general, those which draw attention to the risk of death, the risk of illness and to the addiction caused by smoking. Credibility is reinforced when the message is felt to apply personally to the reader or which describes a risk which may be felt by the reader to concern them personally.''[230]

During the comment period for this proposed rule, FDA intends to perform extensive focus group testing on the proposed brief statement[s]. The testing will evaluate the content and various formats for the brief statement[s] to determine if the warnings are communicated effectively. The agency will base the design, the format and content of the brief statement[s] on the results of this testing and the comments received to the proposed rule.

FDA is not proposing that advertising list cigarette ingredients, but FDA is aware that several surveys and studies show that cigarette users would like to know more about the ingredients in, or the chemical constituents of, smoke delivered by cigarettes. In a survey of 2,345 adults, 93 percent agreed that tobacco companies should be required to list additives on package labels the way food and drug companies are required to list ingredients.[231] Those surveyed believed that in order to inform consumers about the risks involved in smoking, more comprehensive information about cigarette ingredients and combustion by-products should be provided to the consumer.

Section 502(r)(2) of the act (21 U.S.C. 352(r)(2)) states that ''in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health,'' a restricted device shall be misbranded unless its advertising and other descriptive printed matter include ''a full description of the components of

such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued * * * after an opportunity for a hearing.'' However, the Cigarette Act and the Smokeless Act both require submissions of reports or lists of ingredients to the Secretary (see 15 U.S.C. 1335a and 4403) that must be kept confidential. The agency tentatively concludes that these provisions may preclude FDA from requiring components or ingredients to be listed in all advertising and other printed matter. Therefore, FDA has decided, at this time, not to require a description of components or ingredients, but invites comment on whether it should initiate proceedings to determine whether the agency should require a listing of the component parts or ingredients of these restricted devices and the impact of the Cigarette Act's and the Smokeless Act's provisions on the agency's authority.

IOM recently recommended that a ''regulatory agency should take steps to inform consumers about the meaning of statements regarding tar and nicotine yields.'' [232] Some manufacturers voluntarily disclose the quantities of tar and nicotine, as determined by the FTC method, in their labeling or advertising, and one Surgeon General's warning states, ''Cigarette Smoke Contains Carbon Monoxide.''

Consumers are aware that cigarettes produce tar and carbon monoxide and that they contain nicotine. Most consumers, however, do not understand the FTC rating numbers or the health implications of each constituent.[233] The proposed rule would not explain the FTC ratings because of the controversy surrounding the FTC method for determining tar, nicotine, and carbon monoxide.

In December 1994, a conference was held under the auspices of an Ad Hoc Committee of the President's Cancer Panel (the Ad Hoc Committee) to consider the continuing usefulness of the FTC method. Although the full report is not yet available, the Ad Hoc Committee's relevant conclusions were:

> The smoking of cigarettes with lower machine-measured yields has a small effect in reducing the risk of cancer caused by smoking, no effect on the risk of cardiovascular diseases, and an uncertain effect on the risk of pulmonary disease. * * *
>
> The FTC test protocol does not accurately reflect actual human smoking, which is not standardized, but is characterized by wide variations.

The Ad Hoc Committee recommended, among other things, that: (1) The FTC protocol be changed to produce a range of tar, nicotine, and carbon monoxide ratings for each brand to better reflect the intensity with which each cigarette can be smoked; and (2) the range of ratings for each brand should be communicated to consumers. The Ad Hoc Committee recognized that designing the new test and determining how to convey the information to consumers would require the involvement of many agencies, including the National Institutes of Health, FDA, and CDC, and would also take time. The Ad Hoc Committee recommended against measuring other smoke constituents, but suggested that smokers be informed of ''other hazardous smoke constituents'' in packages and in advertising.

The FTC is considering whether and how to implement these recommendations. Until that occurs, FDA will not propose any requirements concerning tar, nicotine, and carbon monoxide ratings, but the agency requests comment on whether it should implement one of the recommendations of the Ad Hoc Committee by proposing to require manufacturers to provide information about these substances through a package insert and/or to provide information about nicotine in labeling and advertising.

In considering the design of the warning, FDA notes that research indicates that novel formats for warnings are most likely to capture the viewer's attention.[234] The FTC reported in 1981 on the noticeability of messages inside a rectangle, octagon, circle and arrow, and enlarged rectangle.[235] The report concluded that the circle and arrow and octagon were noticed and recalled more often. Recall of the message in the circle and arrow was 64 percent, whereas recall of the same message in a rectangle (the shape used in current cigarette advertising) was only 28 percent.[236] Other studies describe the importance that format has in conveying the information and ensuring that it is sufficiently processed.[237] Factors such as print size, color, contrast, graphic design, positioning (e.g. at the top of each page of advertising), shape, spacing, font style, and highlighting are all important considerations for effectively communicating information, particularly to young people.

In addition, FDA notes that several studies have demonstrated that rotating messages assists in maintaining their noticeability. FTC concluded, in its 1981 investigation of cigarette advertising practices, that a ''rotational warning system would provide sufficient repetition of each message to contribute to long term recall of that message, while decreasing the likelihood that any one message would become so familiar and so overexposed that its effectiveness would 'wear out.''' [238] The report concluded that quarterly rotated messages would assist in maintaining the novelty of the message, thus enhancing noticeability.[239] Additionally, the report concluded that shorter messages which are rotated are specific and concrete and are more easily converted into mental images. These messages are recalled more readily.[240]

The Centre for Behavioural Research on Cancer in Australia described a process of ''habituation'' that occurs with warnings and health messages. Under this process, a person's response to a warning or health message declines as that person increases his or her exposure to the warning or health message.[241] It found that habituation is greater as the frequency of exposure increases and is reduced if exposure to the stimulus is stopped for a period of time,[242] as can be the case if the messages are dissimilar and rotated.

The proposed regulation requires that the brief statement be readable, clear, conspicuous, prominent, and contiguous to the current Surgeon General's warning. FDA requests comments on the text and design of the brief statements, particularly in its ability to reach young people, and/or whether and what design specifications should be established. Specifically, it requests comment on how best to insure that the statement will be clear, conspicuous, and prominently displayed.

d. *False or misleading labeling and advertising.* Proposed § 897.36 would declare the labeling or advertising of cigarettes and smokeless tobacco products to be false or misleading if the labeling or advertisement 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 for the product.'' This provision would implement section 201(n) of the act, which states that labeling or advertising may be misleading based on ''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,'' and section 502(q)(1) of the act, which declares a restricted device to be misbranded if ''its advertising is false or misleading in any particular.'' FDA emphasizes that

proposed § 897.36 is meant to be illustrative rather than exhaustive. There may be other ways in which labeling or advertising would be ''false or misleading.'' For example, advertising or labeling that stated that a study showed that smoking can cure emphysema would be false and misleading.

The agency's regulations concerning prescription drug advertising provide great specificity as to what constitutes violative advertising, 21 CFR part 202. The agency has decided that this same degree of specificity is not practical in the case of a widely used consumer product. Tobacco advertising contains an unlimited variety of claims that make categorization difficult. Therefore, the agency has tentatively concluded that it will 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.

E. Subpart E—Miscellaneous Requirements

Proposed subpart E would consist of three provisions. These provisions would provide record and report requirements, describe the rule's relationship to state and local laws, and require additional measures if the prevalence of tobacco use is not dramatically reduced within seven years of the date the final rule is published.

1. Section 897.40—Records and Reports

Proposed § 897.40 would address reports and records. In brief, proposed § 897.40(a) would require each manufacturer to submit to FDA copies of all labels and labeling, and a representative sample of its advertising for enforcement purposes. The proposal would also permit a manufacturer to submit a representative sample of its labels if they would be similar for multiple packages or products. Proposed § 897.40(a) would direct manufacturers to send information and reports to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20857, with each section plainly marked, i.e., ''Labels,'' or ''Labeling and Advertising,'' whichever is appropriate.

This provision is the minimum required by section 510(j) of the act (21 U.S.C. 360(j)), which requires submission to FDA of labels, labeling, and a representative sample of advertising for restricted devices. As explained elsewhere in this document, the agency intends to regulate cigarettes and smokeless tobacco products as restricted devices rather than as drug products, but will assign all of such products to the Center for Drug Evaluation and Research (CDER). Thus, proposed § 897.40(a) reflects the statutory requirement in section 510(j) and would direct copies of labels to the Documents and Records Section in CDER. Proposed § 897.40(b) would authorize FDA employees to inspect records, particularly for purposes of review, copying, or any other use related to the enforcement of the act. This requirement is similar to the inspection authority under the medical device tracking regulations at 21 CFR 821.50 and implements the agency's inspection authority contained in section 704 of the act.

2. Section 897.42—State and Local Requirements

Proposed § 897.42 would address preemption of State and local requirements. Section 521(a) of the act (21 U.S.C. 360k(a)) states 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(a) would require manufacturers, distributors, and retailers to comply with any more stringent State or local requirements relating to the sale, distribution, labeling, or advertising of cigarettes and smokeless tobacco products provided that the State or local requirement does not conflict with FDA regulations. These more stringent state requirements would, therefore, be part of the regulatory scheme and would not be preempted. For example, the proposal would not preempt a State law raising the minimum age for purchasing cigarettes to 21 or prohibiting cigarette or smokeless tobacco product advertisements on billboards located near schools.

FDA is aware that many States and local governments have enacted innovative and effective laws and regulations pertaining to cigarettes and smokeless tobacco products, and the agency encourages future activity in these areas. Moreover, because the proposed rule addresses only the sale, distribution, labeling, and advertising of cigarettes and smokeless tobacco products, State and local requirements in other areas are not affected. For example, the proposal clearly would not preempt State laws regarding licensing, taxes, or smoking in public areas.

If a State or local government is uncertain whether section 521(a) of the act preempts a particular law or regulation, proposed § 897.42(b) would permit the State or local government to easily and expeditiously request and receive an advisory opinion from FDA. Regulations governing applications for exemptions from Federal preemption of State and local requirements applicable to devices can be found at 21 CFR part 808.

FDA is aware of several recent court decisions construing section 521 of the act to preempt certain common law tort actions with respect to medical device products. FDA does not believe that section 521 should be read to give any preemptive effect to these proposed regulatory requirements over tort actions with respect to tobacco products. FDA specifically invites comment on this issue.

3. Additional Regulatory Measures

FDA is also proposing that additional provisions aimed at further reducing the appeal of tobacco advertising and thus discouraging young people from using cigarettes or smokeless tobacco products be required if, seven years from the date the final rule is published, FDA finds that the percentage of young people under the age of 18 who smoke, or the percentage of young men who use smokeless tobacco, has not decreased roughly by 50 percent. This goal could be measured using data of national tobacco use rates of children and adolescents. One method would be:

1. For cigarette manufacturers, the percentage of daily cigarette smokers among 12th graders is at least 50 percent less than it was in 1994 as measured by an objective, scientifically valid, and generally accepted program such as the Monitoring the Future Project (MTFP) for both the reference (1994) and target years (seven years from the date of the publication of the final rule); or

2. For smokeless tobacco product manufacturers, the percentage of male regular smokeless tobacco product users (any use in the past 30 days) among 12th graders is at least 50 percent less than it was in 1994 as measured by an objective, scientifically valid, and generally accepted program for both the reference (1994) and target years (seven years from the date of the publication of the final rule) and the percentage of female regular smokeless tobacco product users among 12th graders is no greater than it was in 1994 as measured in both the reference (1994) and target years.

The Institute for Social Research at the University of Michigan collects and maintains the data from the MTFP. The

project is funded through the National Institute on Drug Abuse. The survey utilizes both a cross-sectional and a longitudinal design, with self-administered surveys in a sample of selected schools. Data for daily smoking by 12th graders have been collected annually since 1976. Smokeless data for any use within past 30 days are available for the years 1986 to 1989 and 1992 to 1994 for 12th graders. (Twelfth graders are a suitable surrogate for the upper age of the prohibited smoking age because twelth graders are 17–18 years old.) The MTFP is one of the more consistent and complete data sets available on young people and provides a stable and reliable basis for measuring the proposed reductions. FDA is requesting comment on the appropriateness of using this data set, including whether the methodology used by MTFP is appropriate for this purpose or on whether other measures would be more reliable and enforceable.

FDA derived its outcome-based objectives from the ''Healthy People 2000'' objectives. ''Healthy People 2000'' discusses national health promotion and disease prevention objectives in this country. This report was facilitated by IOM of the National Academy of Sciences, with the help of the U.S. Public Health Service, and included almost 300 national membership organizations and all State health departments. The report was the product of eight regional hearings and testimony from more than 750 individuals and organizations. Contributors included the CDC, the National Institutes of Health, the American Academy of Pediatrics, the American Heart Association, the American Medical Association, the American Cancer Society, the American Lung Association, the Blue Cross and Blue Shield Association, the American College of Physicians, and the Federation of American Societies for Experimental Biology.

Recognizing that reducing cigarette smoking by youth is an important national priority, the ''Healthy People 2000'' report established a basic goal for the year 2000 to reduce by half the initiation of cigarette smoking by children and youth and to reduce by 39.4 and 55.1 percent the use of smokeless tobacco by young men.

The ''Healthy People 2000'' objectives for cigarettes required the smoking prevalence among young people (ages 20 to 24) to be cut in half in 13 years—from 30 percent in 1987 to 15 percent by the year 2000. The proposed regulation takes as its premise the type of outcome established in ''Healthy People 2000.'' However, because the time frame is different, the proposed regulation would use data as it measures actual usage by high school seniors, a group closer in age to the relevant age group. The prevalence of daily cigarette smoking among high school seniors was 19.4 percent in 1994. Calculating from 1994, daily smoking prevalence among high school seniors must be reduced by half to 9.7 percent seven years after date of the final publication of the rule. Any major changes in the methodology of this survey would require a reassessment of the objective in light of the influences of the changes on the survey's prevalence estimates.

The ''Healthy People 2000'' smokeless tobacco goals are to reduce use in 12- to 17-year-old males by 39.4 percent in 12 years—from 6.6 percent in 1988 to 4.0 percent in the year 2000 and for 18- to 24-year-old males by 55.1 percent—from 8.9 percent in 1987 to 4.0 percent by the year 2000. The proposed rule also modifies the ''Health People 2000'' goal reflecting the different time frame. The objectives also will use data for the nation's high school seniors to monitor progress in reducing the prevalence of smokeless tobacco use. Since high school seniors are 17- to 18-years-old, the percent reduction for high school seniors should be about midway between that required for males 12- to 17-years-old (i.e., 39.4 percent) and 18- to 24-years-old (i.e., 55.1 percent). Thus, a 50 percent reduction would be required to be in compliance with this proposed regulation. Smokeless tobacco use rates (once in 30 days) for senior high school boys was 20.3 percent in 1994. Therefore, the goal would be 10.2 percent. (Failure to reach these objectives would justify the imposition of additional regulatory requirements on the sale, distribution, and use of cigarettes and smokeless tobacco products. Recognizing that smokeless tobacco use by young girls is not extensive (2.6 percent in 1994), the agency believes that an additional goal might be considered—that smokeless tobacco use by young females not increase. This goal would help prevent the development of a new market for smokeless tobacco products.

While the agency finds that the proposed rule is a comprehensive approach that should prove effective in regulating these products, it recognizes that additional measures might be necessary because many different factors may affect a young person's decision to start smoking or use smokeless tobacco products. Additionally, the tobacco industry has shown its ability to find new outlets for promoting its products when restrictions are imposed; for example, within a relatively short period of time after the federally imposed electronic media ban became effective, the cigarette industry redirected the funds spent on television and radio advertising to traditional print and outdoor media. Over time, more nontraditional forms of advertising emerged, including using non-tobacco items (e.g., tee shirts and hats) that served as ''walking billboards,'' placing products in movies, creating massive lists of smokers to target by direct mail, publishing magazines with articles as well as advertising, creating ''friendly familiarity'' and good will for tobacco products by sponsoring sporting and artistic events and by having its sponsored events appear on television (in spite of the television advertising ban).[243] In addition, in Canada, the cigarette companies evaded a ban on sponsorship in the name of a brand variety (but not in the company's corporate name), by creating corporate identities for relevant brands. These new corporations could then legally sponsor events.[244]

Therefore, to guard against this possibility, and to provide for an additional incentive for the companies to take appropriate actions, the agency is proposing that one or more additional measures would be imposed in the event that the outcome-base objectives provided in proposed § 897.44 are not achieved.

At the time a final rule is published, FDA intends to propose specific additional measures. The agency invites public comment on what regulatory measures(s) should be considered. The agency reiterates that additional measures would become operational only if the outcome-based objectives are not achieved.

Finally, the agency requests comment on what would be the appropriate schedule for implementing the provisions of the final rule. It is likely that the final rule would contain some provisions that could not be complied with immediately following the date that the final rule becomes effective. FDA is seeking comment on, and information about, such matters as size of inventories, manufacturing practices, retooling, useful life of equipment, and other similar business considerations. The agency will take the information provided on these issues into account when it established the implementation schedule for the final rule.

F. Other Amendments

The proposed rule would also make two minor amendments to existing regulations. The proposal would exempt cigarettes and smokeless tobacco

products from the Statement of Identity requirements for over-the-counter devices at 21 CFR 801.61 and from the reporting requirements at 21 CFR parts 803 and 804. Section 801.61 stems, in part, from the Fair Packaging and Labeling Act, and Tobacco products are exempt from the statute's requirements. Therefore, the proposed rule would exempt cigarettes and smokeless tobacco products for 21 CFR 801.61.

Parts 803 and 804 pertain to the reporting of deaths, serious injuries, and malfunctions associated with devices. FDA is proposing to exempt cigarettes and smokeless tobacco products from these reporting requirements because the adverse health effects attributable to cigarettes and smokeless tobacco products are extensive and well-documented, and the agency sees little benefit in requiring manufacturers and distributors of these products to report such information to FDA.

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- In countries where tobacco has been promoted virtually unrestricted in all media, consumption has markedly increased (+1.7 percent per year).
- In countries where advertising has been totally banned or severely restricted, the percentage of young people who smoke has decreased more rapidly than in countries where tobacco promotion has been less restricted.
- When the results of this study of promotion/consumption trends in 33 countries between 1970 and 1986 are put alongside the evidence from econometrics studies * * * it seems more likely than not that, other factors remaining unchanged, the elimination of tobacco promotion *causes* a reduction in tobacco consumption and smoking prevalence to a level below what it would have been otherwise.
- Tobacco consumption increases when tobacco promotion is permitted and real price is allowed to fall; consumption declines markedly when promotion is totally banned and prices [are] raised *Id.,* pp. xxiii, xxiv, 76. See also IOM Report, p. 125.

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240. *Id.*

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242. *Id.*

243. ''Wall Street Journal,'' December 27, 1994, at p. B5.

244. Sweanor, D.T., ''Measures Adopted by the Tobacco Industry to Circumvent Canada's Tobacco Products Control Act,'' p. 3, August 1994.

IV. Legal Authority

A. Regulation of Nicotine-Containing Tobacco Products

As more fully described in ''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,'' the Food and Drug Administration has conducted an extensive investigation and comprehensive legal analysis. The results of that inquiry support a finding at this time that the nicotine in cigarettes and smokeless tobacco products is a drug within the meaning of the act because it is intended to affect the structure or function of the body and it achieves its intended effects through chemical action within the human body. Based on the evidence now before the agency, cigarettes and smokeless tobacco products are drug delivery systems whose purpose is to deliver nicotine to the body in a manner in which it can be most readily absorbed by the consumer and, hence, are devices.

Thus, these products are combination products within the meaning of 21 U.S.C. 353 (g) and 21 CFR 3.2(e) that the agency has the discretion to regulate using drug authorities, device authorities, or a combination of both

authorities. The agency proposes to make these products subject to regulation pursuant to the act's device authorities. The remainder of this discussion explains the regulatory framework for combination products; why nicotine-containing cigarettes, loose tobacco, and smokeless tobacco products are drug/device combination products; and why the agency can exercise its discretion to regulate them only under the act's device provisions. Finally, this section discusses a number of other legal issues raised by the provisions of the proposed rule.

1. The Federal Food, Drug, and Cosmetic Act and Combination Products

As part of the Medical Device Amendments of 1976, Congress established, for the first time, a premarket approval mechanism for certain devices. Congress also expanded the act's device definition to expressly include items such as implements, machines, implants, and in vitro reagents. ''Device'' was defined as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure of any function of the body of man or other animals, and which 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.

Pub. L. No. 94–295 (1976).

The act was amended by the Safe Medical Devices Act of 1990, among other reasons, to recognize and provide for the regulation of products that constitute a combination of a drug, device, or biological product (21 U.S.C. 353(g)). The Safe Medical Devices Act also modified the act's drug and device definitions to conform them to the new section regarding primary jurisdiction over combination products. (See S. Rep. 101–513). Among these modifications is that the definition of ''drug'' no longer excludes devices or their components, thereby eliminating the notion that ''drug'' and ''device'' are mutually exclusive terms.

In light of the act's public health protection purposes, the agency has consistently construed the device definition broadly, and courts have upheld this interpretation. *United States* v. *An Undetermined Number of Unlabeled Cases,* 21 F.3rd 1026, 1028 (10th Cir. 1994); *United States* v. *22 Rectangular Devices,* 714 F. Supp. 1159, 1162 n.7 (listing additional examples), 1164–65 (D. Utah 1989); see, e.g., *United States* v. *23, More or Less, Articles, etc.* 192 F.2d 308, 309 (2d Cir. 1951) (phonograph records used in treating insomnia).

Because the act's definition of device is a statutory term of art, it encompasses a very wide assortment of items. Obvious examples of devices are simple medical implements such as thermometers or tongue depressors and more complicated electronic products such as X-ray machines or cardiac pacemakers. Less obvious examples of devices include in vitro reagents and other products used for diagnostic purposes, such as culture media made from snake venom (21 CFR 864.8100, 864.8950) and animal and human sera (21 CFR 864.2800). FDA also regulates many organic substances as devices. For example, a simple plant product that consists of nothing more than coagulated tree sap, gutta percha, which is used to fill the root canal in a tooth, is a device (21 CFR 872.3850). All of these articles are devices because they are instruments, apparatuses, implements, machines, contrivances, implants, in vitro reagents, or another similar or related article with uses or effects encompassed by the act. Therefore, understanding what can properly be regarded as a device for purposes of the act requires a statutory, not a lay, understanding of the term. The following discussion identifies the parts of cigarettes, loose cigarette tobacco, and smokeless tobacco that are devices, and explains why these products are drug delivery systems.

2. Cigarettes, Smokeless Tobacco Products, and Loose Tobacco Are Drug Delivery Systems

Because drugs cannot be administered in pure chemical form, drug delivery systems are designed and used to deliver drugs into the body's circulatory system or to specific target sites in the body at predetermined, controlled rates.[1] FDA considers articles such as instruments, machines, contrivances, implants, or other similar or related articles, whose primary purpose is the delivery of a drug, and that are distributed with a drug product to be drug delivery systems. Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, Section VII.A.1.(b) (October 31, 1991). These articles are often called ''pre-filled delivery systems.'' Examples of these combination products include contrivances containing drugs, such as pre-filled syringes, transdermal patches, and metered-dose inhalers. *Id*. CDER has primary jurisdiction over the regulation of such products, and has the authority to use drug provisions, device provisions, or a combination of drug and device provisions to regulate particular drug delivery systems. *Id*.

Cigarettes and smokeless tobacco products function like drug delivery systems in that they contain a drug, nicotine; are used to deliver the 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 discarded. Only the nicotine delivered by these products achieves its primary intended purpose by chemical action in or on the body. The subsections below explain in greater detail why these products are drug delivery systems.

a. *Cigarettes.* Cigarettes are drug delivery systems consisting of a drug, nicotine, and device components that include the tobacco itself, the paper the tobacco is rolled in and, in the case of filter cigarettes, the filter. A cigarette is analogous to a metered-dose inhaler, an instrument that converts a drug into an aerosolized form for inhalation and delivery to the lungs for absorption into the bloodstream.

Although lighting a cigarette appears to be a simple action, there is, in fact, a complex process taking place within the cigarette. A cigarette consists of carefully blended and treated nicotine-containing rolled tobacco. The blended and treated tobacco is wrapped in paper that is precisely treated so that the entire tobacco rod burns in a controlled manner. Attached to the tobacco rod (in 95 percent of U.S. cigarettes) is a filter with many possible design features, including vents and chambers. The primary purpose of parts of the cigarette, and the cigarette itself, a consciously engineered and, in the industry's own words, ''highly-engineered''[2] product, is to effectuate the delivery of a carefully controlled amount of the 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.

In this manner, an average American cigarette yields approximately 1.0 mg of nicotine, although the smoker can adjust

this yield by the manner in which the cigarette is smoked, e.g., by puffing more or less frequently, by inhaling more or less deeply, or by covering, with the fingers holding the cigarette or the lips, the vent holes that may be part of the filter.

As discussed in ''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,'' there is significant evidence now before the agency that the manufacturers of cigarettes intend, as a primary purpose of these products, to deliver the drug nicotine to consumers. That evidence supports a finding at this time that part of a cigarette, the nicotine, is a drug under the act. However, as described above, cigarettes are not simply packaged nicotine. Rather, they are carefully engineered, complex products that are designed to deliver a controlled amount of nicotine to the consumer using such device components as the tobacco, the paper, and the filter.

Nicotine-containing loose cigarette tobacco is used by smokers who roll their own cigarettes usually with paper made for that purpose. The evidence before the agency supports a finding at this time that the processed loose cigarette tobacco product is a device for the same reasons that the tobacco in factory-made cigarettes to be a device: it contains within it the drug intended to be consumed and is not dependent upon being metabolized for the achievement of its principal intended purpose, i.e., the delivery of nicotine, and must be lit and burned in order for the nicotine to be released in a form in which it can be absorbed by the body.

b. *Smokeless Tobacco Products.* Four principal kinds of smokeless tobacco are manufactured in the United States: loose leaf, plug, twist or roll, and oral snuff. Loose leaf chewing tobacco consists of tobacco leaves that have been heavily treated with licorice and sugars. Plug tobacco is made from tobacco that is immersed in a mixture of licorice and sugar and then pressed into a plug. Twist tobacco is produced from leaves that are flavored and twisted to resemble a rope. Oral snuff is available in both dry and moist varieties. Dry snuff consists of powdered tobacco that contains flavor and aroma additives. Moist snuff is fine particles of tobacco that hold considerable moisture; many types are made with a variety of flavorings such as wintergreen or mint.[3] Chewing tobacco and snuff are treated by the manufacturer to achieve an alkaline pH that facilitates absorption of nicotine.[4]

Smokeless tobacco products function like temporary implants or infusion devices that deliver a controlled amount of nicotine to the cheek and gum tissue for absorption into the bloodstream. The device element of smokeless tobacco products is the tobacco, which contains the drug nicotine and delivers the nicotine to the cheek and gum tissue for absorption into the body, but is not intended to be consumed. Instead, in normal use, most of the tobacco is extruded from the mouth after absorption of the nicotine. This extrudable portion of the product does not achieve its primary intended purpose through chemical action in the mouth, but allows nicotine to be extracted from the tobacco by the user's saliva and: (a) mechanically holds the nicotine in a form that is palatable, thereby allowing sufficient time for absorption of nicotine through the cheek and gum tissue; and (b) delivers chemical agents, primarily alkalines, to increase the pH within the oral cavity, to affect the rate of absorption of nicotine through the cheek and gum tissue.

3. FDA May Exercise Its Discretion to Regulate Cigarettes and Smokeless Tobacco Products Under the Device Provisions of the Act

As explained above, the agency's factual and legal inquiry supports a finding at this time that nicotine-containing cigarettes and smokeless tobacco products are drug/device combination products, namely, drug delivery devices. Under the combination product authority of section 503 of the act, FDA must designate a component of FDA to regulate combination products based on a determination of the product's ''primary mode of action.'' In the case of cigarettes and smokeless tobacco, the primary mode of action is that of a drug, due to the nicotine, and, therefore, primary jurisdiction over these products belongs in CDER. CDER's primary jurisdiction over cigarettes and smokeless tobacco is not determinative, however, of which provisions of the act apply. Rather, the agency has the discretion to regulate these drug delivery systems using drug authorities, device authorities, or a combination of both authorities. (See 21 CFR 3.2(e)(1994); 56 FR 58754 at 58754 and 58755 (November 21, 1991); Intercenter Agreement, Section VII.A.1.(b).) It is within FDA's discretionary power to determine which, if any, of the available regulatory authorities it will employ in the regulation of a product. See *Heckler* v. *Chaney*, 470 U.S. 821 (1985).

In determining which statutory authority to apply to these products, FDA has carefully considered the regulatory schemes for human drug products and devices, as well as the differing effects of these regulatory schemes on the millions of Americans who use these products. If FDA were to regulate cigarettes, cigarette tobacco, and smokeless tobacco under the drug authorities of the act, the new drug provisions would be applied, and each nicotine-containing cigarette, cigarette tobacco, and smokeless tobacco product would either have to: (a) be shown to be not a ''new drug'' because it is generally recognized as safe and effective (21 U.S.C. 321(p)); or (b) be the subject of an approved new drug application containing, among other things, adequate tests of the safety and substantial evidence of the effectiveness of the product. (See 21 U.S.C. 355.) In light of the accumulated data on the adverse health effects of tobacco, neither of these outcomes can be viewed as a realistic possibility in currently marketed products. The products would be unapproved new drugs, and as such, FDA could require their removal from the market. (See 21 U.S.C. 331(d), 355(a).)

The agency does not believe that their sudden and total withdrawal from the market would provide the best means of protecting the public health. The nicotine in tobacco products is highly addictive and is the principal reason adults continue to use tobacco products in the face of clear evidence of harm. Major recent studies reveal that the vast majority of the Nation's more than 50 million cigarette and smokeless tobacco users are addicted to the nicotine in these products. Surveys also show that while as many as 70 percent of current smokers would like to quit, only a tiny percentage are able to quit permanently. Studies on smokeless tobacco users show a similar pattern of persistent attempts to quit with extremely low success rates.[5]

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. Moreover, banning all tobacco products may not achieve the primary health objective addressed in this regulation, i.e. reducing the number of children and adolescents who become addicted to these products. Given the long,

widespread use of these products in this country, it is not unreasonable to assume that a black market and/or smuggling would develop to supply addicted users with the products they require. The 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. Thus, FDA believes that a ban on all tobacco products would not eliminate smoking and would not be in the best interest of the public health at this time.

Given the dangerous health consequences of the continued use of cigarettes and smokeless tobacco products, however, the agency believes that some strong action is necessary to protect the public health. As explained in the next section, FDA has chosen to regulate these combination products using the Act's device provisions, rather than the drug provisions, because application of the device authorities would allow the continued marketing of the affected products under certain prescribed conditions established under notice and comment rulemaking procedures.

As discussed above, the primary jurisdiction over these combination products within FDA lies in CDER. This designation is appropriate because of CDER's expertise in pharmacology and drug delivery; addiction, the disease associated with tobacco use; and the regulation of pre-filled drug delivery systems. CDER, however, has the authority to use drug provisions, device provisions, or a combination of drug and device provisions in regulating these products.

4. Regulation of Cigarettes and Smokeless Tobacco Under the Device Authorities

As currently marketed, cigarettes and smokeless tobacco products are not safe and effective. Chronic use of tobacco products causes disease and premature death in a significant proportion of users.

Both the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990 were designed to provide an array of regulatory tools that could provide reasonable assurance of the safety and effectiveness of devices. Since tobacco products are plainly not safe, one regulatory tool available under the statute is to ban the products, making their sale illegal. The legal basis for such a ban would be that tobacco products present an unreasonable and substantial risk of illness or injury. See section 516 of the act. Because of the addictiveness of tobacco products, however, tobacco products present special problems not ordinarily associated with devices. As discussed in the preceding section, in the case of cigarettes and smokeless tobacco products, a ban would not be in the best interest of the public health.

While premarket approval of a device has generally been regarded as the regulatory control that provides the greatest assurance of safety and effectiveness, on occasion the agency has chosen not to use premarket approval for critical devices that potentially raise significant safety and efficacy issues. For example, the agency has announced that it will no longer enforce premarket approval requirements for heart valve allografts. See the **Federal Register** of October 14, 1994 (59 FR 52078). FDA took this action after concluding that other regulatory controls would be more appropriate than premarket approval to provide reasonable assurance of the safety and effectiveness of these products. See also *Heckler* v. *Chaney*, 470 U.S. 821 (1985) (upholding agency's decision not to enforce premarket approval requirements for use of prescription drugs for lethal injection).

The Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990 provide the agency with considerable flexibility in identifying the most appropriate scheme for regulating products. These device provisions authorize the agency to use the regulatory tools that most appropriately protect the public from unsafe or ineffective devices. Moreover, these device provisions permit the agency to tailor the regulatory controls authorized under the statute to address the specific risks associated with individual devices. The following tools, among others, may be used to help provide reasonable assurance of safety and effectiveness for individual devices: special controls (section 514 of the act); premarket approval (section 515 of the act); product development protocols (section 515 of the act); notification and recall (section 518 of the act); device tracking (section 519(e) of the act); custom devices (section 520(b) of the act); restrictions on sale, distribution, and use (section 520(e) of the act); and postmarketing surveillance (section 522 of the act). Where the public cannot be appropriately protected from a hazardous device using the tools on which the agency might otherwise rely for a device posing a substantial risk, FDA has discretion to employ other, more appropriate regulatory controls provided by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

In the situation presented by widespread addiction to cigarettes and smokeless tobacco, where restrictions on supply would not be effective, the goals of the statute can best be achieved by preventing future users from becoming addicted to tobacco products. Restrictions on the sale and distribution of cigarettes and smokeless tobacco products to young people, as well as restrictions on advertising that fosters appeal and creates a demand for tobacco products among young people, are therefore the appropriate tools to attain the goal of reasonable assurance of safety and effectiveness for cigarettes and smokeless tobacco products, even if the goal can only be reached over one or more generations.[6]

The agency believes that the measures proposed in this regulation will reduce the exposure of children and adolescents to the health risks associated with tobacco use; will greatly reduce the number of individuals who are now, or may in the future become, addicted to nicotine in these products; and, from an epidemiological perspective, the combined effects of the proposed measures will, under the unique circumstances of these products, provide the most reasonable assurance of their safety.

The Medical Device Amendments provide authority to restrict the sale and distribution of products, like tobacco, for which there cannot otherwise be reasonable assurance of safety and effectiveness. Section 520(e) of the act, which authorizes FDA to restrict the sale and distribution of certain devices, provides regulatory tools that would enable FDA to achieve the goal of reducing demand for tobacco products. Therefore, FDA is proposing to declare cigarettes and smokeless tobacco products ''restricted devices'' and to impose restrictions on the underage sale and distribution of these tobacco products, pursuant to section 520(e) of the act.

5. Restricted Device Authority Under Section 520 of the Act

Section 520(e)(1)(B) of the act authorizes FDA to issue regulations restricting the sale, distribution, or use of a device:

> if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

Because of the potentiality for harmful effects from cigarettes and smokeless tobacco products, there cannot be reasonable assurance of the safety and effectiveness of these products short of

additional restrictions designed to prevent new users from becoming addicted to nicotine-containing tobacco products and to provide information to current users on how to quit.

As discussed earlier in this document, cigarettes and smokeless tobacco products have substantial ''potentiality for harmful effect'' because they are both addictive and pose a significant risk to the health of users. The most effective way to provide reasonable assurance of the safety and effectiveness of tobacco products is to prevent future generations from using and becoming addicted to these products in the first instance, and as explained elsewhere in this document, tobacco use is typically initiated during childhood and adolescence. The mean average age when people become daily smokers is 17.7 years of age.[7] Moreover, those who start smoking in childhood are more likely to become heavier smokers than those who start smoking in adolescence, and those who start as adolescents are more likely to become heavier smokers than those who start as adults. Thus, the age at which an individual starts smoking is an important factor that influences the intensity of that person's smoking as an adult, and consequently his or her ultimate health risks. These facts are echoed in one of the major conclusions of the 1994 Surgeon General's Report: ''Nearly all first 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.''[8]

The proposed restrictions on sale and distribution of tobacco products are therefore designed to substantially reduce the number of children and adolescents who become addicted to tobacco. The proposed regulations would restrict young people's access to tobacco (see proposed §§ 897.12, 897.14, and 897.16), decrease the allure of the advertising and promotion of these products (see proposed §§ 897.30, 897.32, 897.34, and 897.36), and provide educational messages aimed at young people to combat pervasive pro-tobacco messages and thus to help them resist tobacco use (see proposed § 897.29).

Access. Although State and local laws impose certain restrictions on the access of young people to tobacco, over a million children and adolescents continue to become regular tobacco users each year. Unless additional measures are imposed to substantially reduce this number, cigarettes and smokeless tobacco will continue to cause disease and death in each subsequent generation. Thus, without additional restrictions designed to eliminate or substantially reduce the initiation of cigarettes and smokeless tobacco use by children and adolescents, there cannot be reasonable assurance of the safety of these products.

Advertising. For the many reasons described in this document, advertising plays a role in influencing a young person's decision to purchase and use these products. This advertising is particularly attractive to persons under the age of 18. Sections 502 (q) and (r) of the act give the agency specific authority over the advertising of restricted devices to ensure that it is truthful, nonmisleading, and contains important information about the risks associated with the use of the product. Thus, section 502(q) of the act declares misbranded any restricted device whose advertising is ''false or misleading in any particular'' (see proposed § 897.36) and section 502(r) requires that ''all advertisements and other descriptive printed matter'' associated with a restricted device must contain certain specified information, including a brief statement of ''relevant warnings, precautions, side effects, and contraindications'' (see proposed § 897.32).

In addition, the agency has proposed restrictions on the sale of these products, specifically to prohibit all sales to those under the age of 18. Advertising with attractive imagery, brand identifiable non-tobacco items, and sponsorship of events are appealing to young people under age 18 and are effective in influencing their decision to use tobacco products. The advertising techniques that would be prohibited by the proposed rule encourage an unauthorized use of these products and thus cause them to be misbranded.

Most importantly, FDA also has been granted broad authority in section 520(e) of the act, under which the agency may place restrictions on the sale, the distribution, or the use of certain devices where the potentiality for harm makes these restrictions necessary. The broad sweep of this language implies authority to regulate many aspects of the commercialization of a restricted device. FDA is interpreting this section to authorize restrictions on the product's distribution, its offering for sale (including inducements to sale), the sale itself, and the consumer's use (including the product's misuse). This reading of section 520(e) of the act is required if the agency is to have the ability to regulate restricted devices effectively and avoid having its efforts undercut. For example, the agency is proposing to prohibit the sale of tobacco products to those under age 18. If a manufacturer advertises its tobacco products in such a way that it has the effect of encouraging underage individuals to purchase these products, the restriction on the sale of the product would be significantly undermined. In such a case, section 520(e) of the act provides the agency the additional authority to curtail the advertising practices that threaten the effectiveness of its sale restrictions.

Just as restrictions must be placed on young people's access to tobacco products in order to limit their ability to purchase these products, it is equally important to place restrictions on the marketing practices (including advertising and promotion) of the tobacco industry. Certain advertising and promotional practices of the tobacco industry play a significant and important contributory role in a young person's decision to use cigarettes and smokeless tobacco products.

As detailed more fully in Chapter III, subpart D, individual studies illustrate the profound effect that certain tobacco campaigns have had upon the youth market. Moreover, studies have indicated that comprehensive restrictions on advertising can help reduce children's demand for these products.

Restrictions on advertising are necessary in order to reduce the demand for tobacco products by young people and therefore their desire to purchase these products. Accordingly, placing restrictions on certain marketing and advertising practices of the tobacco industry is necessary to restrict the ''sale, distribution, or use'' of these products.

Information and Educational Messages. FDA has determined that an educational program about cigarettes and smokeless tobacco products is a restriction that is necessary because of the ''potentiality for harmful effect'' of these products. As discussed above, it is necessary to impose restrictions to discourage children and adolescents from using and becoming addicted to these products and to provide important health information to those who are currently addicted to these products to allow them to decrease or cease their use of these products. The brief statements that would be mandated by the proposed rule will be designed to provide some information for current users, but are not specifically addressed to, nor narrowly targeted to, the adolescent nonuser. Consequently, given the effect of the pervasive and long standing pro-tobacco messages on young people, FDA is proposing an educational campaign, national in scope

and specifically directed to adolescent nonusers. The goal of this effort is to combat the attractive imagery fostered by decades of tobacco advertising, in order to reduce the number of individuals, especially children and adolescents, who will become addicted to the nicotine in these products.

In addition, company-financed educational messages are not an uncommon remedy. FDA has imposed a similar educational requirement for hearing aids, which are also regulated as restricted devices under section 520(e) of the act. The agency requires that a User Instructional Brochure be distributed to each prospective hearing aid user. In addition to providing directions for the safe and effective use of this product, this brochure describes the adverse reactions, side effects, warnings, and limitations associated with the hearing aid. It also encourages prospective users to seek medical evaluation by a licensed physician before purchasing the product. The agency requires that specified user information be provided to educate consumers about the risks of other FDA-regulated products such as Shiley heart valves, silicone breast implants, and certain childhood immunizations.

Finally, FDA regulations provide specific language for certain disclosures in prescription and over-the-counter drug labeling, see ''Pregnancy—Nursing Warning'' for aspirin and aspirin-containing products, 21 CFR 201.63; ''Disclosure of Drug Efficacy Study Evaluations in Labeling, and Advertising,'' 21 CFR 201.200; warning concerning ''Isoproterenol Inhalation Preparations,'' 21 CFR 201.305; and warning concerning ''Drugs with Thyroid Hormone Activity,'' 21 CFR 201.316.

Unlike the users of other restricted devices, however, the youthful potential users of tobacco products are not easily identified. Because tobacco products and tobacco advertising are distributed so widely, and have been so effective at creating positive images of tobacco use, educational information cannot realistically be specifically targeted to those particular individuals susceptible to taking up smoking. Therefore, the most effective way to reach the target audience is to mandate a widespread educational campaign as described in § 897.29 of the proposed rule.

The proposed provision on educational messages is also authorized, in addition to section 520(e) of the act, under sections 502(a), 502(q), and 201(n) of the act (21 U.S.C. 352(a), 352(q), and 321(n)). Sections 502 (a) and (q) of the act state that a device shall be deemed to be misbranded if either its labeling or advertising is false or misleading in any particular. Section 201(n) of the act directs FDA, in determining whether the labeling or advertising of an article is misleading, to examine the representations made or suggested in the labeling or advertising as well as ''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 * * *.'' The proposed educational message requirement is consistent with these statutory provisions because it is intended to help ensure that cigarette and smokeless tobacco product advertising and labeling is not false or misleading and to counteract the appeal of these products previously created by advertising, thereby providing important, material information regarding the consequences of cigarette or smokeless tobacco product use by young people in a manner that is appropriate for that age group. FDA's interpretation of sections 502(a)′ and 201(n) of the act and its authority to require the dissemination of information to persons who use human drug products has been upheld in federal court. (See *Pharmaceutical Manufacturers Association* v. **Food and Drug Administration,** 484 F.Supp. 1179 (D.Del.), *aff'd*, 634 F.2d 106 (3rd Cir. 1980) (per curiam) (upholding FDA's authority to require mandatory patient package inserts)).

Finally, although the Cigarette and Smokeless Tobacco Acts[9] prohibit advertising for cigarettes and smokeless tobacco in specified communications media, including television and radio, they do not prohibit all discussions of cigarettes and smokeless tobacco on television. Specifically, they do not prevent broadcasters from airing public service announcements regarding the dangers of tobacco use and they likewise would not prohibit tobacco manufacturers from purchasing air time to broadcast government mandated and approved educational messages to young people to encourage them not to smoke or use smokeless tobacco.

Although the required messages would concern smoking and smokeless tobacco use, they do not constitute ''advertising'' within the meaning of those acts. The U.S. Court of Appeals for the District of Columbia in *Public Citizen* v. *FTC*, 869 F. 2d 1541 (D.C. Cir. 1989), gave a common sense definition of the word ''advertising'' in its recent interpretation of the Smokeless Act:

> Our understanding of the common meaning of the term ''advertising,'' consistent with that contained in Webster's Third New Int'l Dictionary (1976), is that it involves any action to ''call public attention to a [a product] * * * so as to arouse a desire to buy.'' At the most basic level this is surely what smokeless tobacco companies are doing when they splash their brand logos and selling messages across T-shirts and other promotional items.

Id. at 1554 (modifications in original). Government approved messages that seek to discourage young people from using tobacco are intended to have the opposite effect of advertising as defined in *Public Citizen* and, therefore, do not constitute advertising.

Information for current smokers. FDA has carefully tailored these restrictions to aspects of the sale and distribution of tobacco products that create a demand for these products among children and adolescents and that permit their continued access to tobacco products despite State and local laws against sale to young people. The most effective regulatory tool available to FDA to help current smokers stop using tobacco products is to require that information be provided through advertising. FDA is therefore proposing to require a brief statement in cigarette advertising giving the health risks of tobacco use. (See § 897.32(c)).

6. Conclusion

Without the restrictions contained in this proposed rule designed to prevent future generations from becoming addicted to tobacco products, there cannot be reasonable assurance of the safety and effectiveness of cigarettes and smokeless tobacco products. FDA seeks the most rational regulatory structure for cigarettes, cigarette tobacco, and smokeless tobacco products permitted under the act to achieve an important public health goal, and simultaneously, to avoid what might be widely regarded as an unwanted and ultimately unsuccessful result.

The agency's comprehensive investigation and legal analysis support a finding at this time that cigarettes, cigarette tobacco, and smokeless tobacco are subject to regulation on the basis of their nicotine content and intended use. Each of these products employs a device component to achieve its effect on the body, and therefore each is a drug/device combination product. As such, FDA may, in its discretion, regulate them using the act's device provisions.

The device provisions permit the continued marketing of the affected products under certain prescribed conditions designed to substantially reduce the number of young people who become addicted to tobacco products and thereby to break the cycle of

addiction and disease fostered by tobacco products.

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5. Severson, H.H., ''Enough Snuff: St Cessation from the Behaviorial Clinical, and Public Health Perspectives,'' in ''Smokeless Tobacco or Health, An International Perspective,'' Smoking and Tobacco Control Monograph 2, DHHS, PHS, NIH, NIH Publication No. 93–3461, pp. 281–282; Glover, E.D., ''Conducting Smokeless Tobacco Cessation Clinics,'' *American Journal of Public Health,* vol. 76, No. 2, p. 207, 1986; Hatsukami, D., R. Nelson, and J. Jensen ''Smokeless Tobacco: Current Status and Future Directions, *British Journal of Addiction,* vol. 86, pp. 559–563, 1991; Glover, E.D. and P.N. Glover, ''Smokeless Tobacco Cessation and Nicotine Reduction Therapy,'' in ''Smokeless Tobacco or Health, An International Perspective, Smoking and Tobacco Control,'' Monograph 2, DHHS, PHS, NIH, NIH Publication No. 93–3461, pp. 291–295; Ary, D.V., et al., ''An In-Depth Analysis of Male Adolescent Smokeless Tobacco Users: Interview with Users and Their Fathers,'' *Journal of Behavioral Medicine,* vol. 12, pp. 449–467, 1989.
6. The Medical Device Amendments also provide authority to remedy unsafe products by forcing corrections in their design. See sections 514 and 518 of the Act. FDA has determined, however, that there are insufficient data available at this time to permit the conclusion that modifications in cigarettes and smokeless tobacco products would make them safe or even substantially safer.
7. 1994 SGR, p. 67.
8. 1994 SGR, p. 5.
9. 15 U.S.C. 1335 and 15 U.S.C. 4402(f).

B. Other Requirements

As explained above, FDA is proposing to regulate cigarettes and smokeless tobacco products as devices and, in accordance with section 520(e) of the act, is proposing to restrict their sale, distribution, and use. As devices, the products would also be subject to various pre-existing requirements in the statute and the regulations. These regulations include the general labeling requirements for devices at 21 CFR part 801 (excluding § 801.62); establishment registration and device listing requirements at 21 CFR part 807; and good manufacturing practice requirements at 21 CFR part 820.

Under section 502(q)(2) of the act, a restricted device that is sold, distributed, or used in violation of regulations prescribed under section 520(e) of the act shall be deemed to be misbranded. Therefore, nicotine-containing cigarettes and smokeless tobacco products that are marketed in violation of the proposed rule would be regarded by FDA as misbranded. It is already the case under the laws of all 50 States that retailers are liable when a sale of cigarettes or smokeless tobacco products is made to an underage individual. Perhaps the most significant effect of the proposed rule with regard to potential legal liability is that manufacturers, as well as retailers and distributors, could be held responsible for violations of the regulations. As with other violative manufacturer activities under the act, such a finding could result in various sanctions, including: fines, injunctions, civil money penalties, product seizure, and prosecution.

C. Preemption Under the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act

Although sections 502(q), 502(r), and 520(e) of the act give FDA authority to regulate the sale, distribution, and use of a restricted device and to impose certain requirements on all advertisements and other descriptive printed matter, both the Cigarette Act and the Smokeless Act contain provisions that limit the exercise of Federal, State, and local authorities. The agency has reviewed its statutory authority in light of these two statutes and concludes that neither the Cigarette Act nor the Smokeless Act preclude FDA from regulating these products or enacting each of the provisions in the proposed regulation.

1. The Cigarette Act

The Cigarette Act requires, among other things, specific warning notices on cigarette packages and advertisements. The Cigarette Act contains express language regarding other Federal and State regulation:

> (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 Act.

15 U.S.C. 1334. The proposed rule takes into account the Federal preemption provision of the Cigarette Act and is consistent with this statutory prohibition.

The preemption provision of the Cigarette Act regarding advertising and promotion applies only to State action. Hence, because the proposed rule would impose Federal, not State, requirements, the proposed rule's labeling and advertising requirements are permissible under 15 U.S.C. 1334(b).

In addition to being permissible under the Cigarette Act, the proposed rule would actually further Congressional intent to protect cigarette packages from diverse, nonuniform, and confusing cigarette labeling and advertising regulations. The proposal would require inclusion of certain information in cigarette advertisements, and these requirements would apply to cigarettes sold and distributed throughout the United States. Under this scheme, States could not impose ''diverse, nonuniform, and confusing'' labeling or advertising requirements, Cigarette Act, Public Law 89–92, as amended by Public Law 91–222 (April 1, 1970) and Public Law 93–109 (September 21, 1973); 15 U.S.C. 1331 (1973).

Two recent cases support the interpretation that the Cigarette Act does not establish an absolute prohibition against Federal action. In *Cipollone* v. *Liggett Group, Inc.,* the Supreme Court considered whether the Cigarette Act preempted an action by an individual against a cigarette manufacturer for breach of express warranty that cigarettes ''did not present any significant health consequences,'' failure to warn consumers about health hazards, fraudulent misrepresentation of health hazards to consumers, and conspiracy to ''deprive the public of medical and scientific information about smoking.'' 112 S. Ct. 2608, 2613–14 (1992). The Court examined the preemption provision in the Cigarette Act and the amendments contained in the Public Health Cigarette Smoking Act and stated that,

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a ''reliable indicium of congressional intent with respect to state authority,'' * * * ''there is no need to infer congressional intent to pre-empt state laws from the substantive provisions'' of the legislation * * * Congress'' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.

Id. at 2618 (citations omitted) (emphasis added).

The Court found that the preemption provisions ''merely prohibited state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels'' and held that the preemption provisions did not constitute an absolute prohibition against all Federal and State action. *Id.*

The Supreme Court in *Freightliner Corp.* v. *Myrick,* 115 S. Ct. 1483 (1995) clarified its language in *Cipollone.* The Court stated ''[t]he fact that an express definition of the preemptive reach of a statute ''implies''—*i.e.,* supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied preemption.'' *Id.* at 1488 (emphasis added.) The Court noted that it would still be appropriate to conduct the proper analysis to determine if preemption should be implied. Having said that, the Court stated that such an analysis had been done in *Cipollone.* Finally, the Court found no implied preemption in *Freightliner* even in the absence of federal regulation.

The California Supreme Court, in *Mangini* v. *R.J. Reynolds Tobacco Co.,* 875 P.2d 73 (Cal. en banc), *cert. denied,* 115 S.Ct. 577 (1994), considered whether the Cigarette Act precluded an action under California law for engaging in an ''unlawful, unfair, or fraudulent business act or practice'' by using ''unfair, deceptive, untrue, or misleading advertising.'' The petitioner claimed that R.J. Reynolds had illegally targeted minors in its Joe Camel advertising campaign. R.J. Reynolds asserted that its cigarettes were properly labeled and, therefore, that California could not impose any regulation regarding cigarette advertising if the regulation were based on smoking and health. It added that a prohibition against selling cigarettes to minors was based on underlying health concerns and that only the Federal Government could prevent advertisements that urge minors to smoke. The California Supreme Court applied the analysis in *Cipollone* and held that, while the petitioner's action would prohibit cigarette advertising directed at minors, the underlying legal duty for the petitioner's action was not based on smoking and health. The California Supreme Court held that, ''The predicate duty is to not engage in unfair competition by advertising illegal conduct or encouraging others to violate the law.'' *Id.* at 80. As for the argument that allowing state law claims to proceed would violate congressional policy favoring a comprehensive Federal program for cigarette labeling and advertising, the court disagreed, stating,

> State law prohibitions against advertisements targeting minors do not require Reynolds to adopt any particular label or advertisement ''with respect to any relationship between smoking and health;'' rather, they forbid any advertisements soliciting unlawful purchases by minors. The prohibitions do not create '' 'diverse, nonuniform, and confusing'' standards. Unlike state law obligations concerning the warning necessary to render a product 'reasonably safe,' state law proscriptions'' against advertisements targeting minors 'rely on a single, uniform standard:'' ' do not target minors.

Id. at 80 (quoting 112 S.Ct. at 2624). Consequently, the court held that,

> It is now asserted that plaintiff's effort to tread upon Tobacco Road is blocked by the nicotine wall of congressional preemption. The federal statute does not support such a view. Congress left the states free to exercise their police power to protect minors from advertising that encourages them to violate the law. Plaintiff may proceed under that aegis.

Id. at 83. The Supreme Court later denied R.J. Reynolds' petition for a writ of *certiorari.* See 115 S.Ct. 577 (1994). Although *Mangini* concerned preemption of State action, the California Supreme Court's decision and the U.S. Supreme Court's denial of *certiorari* indicate a judicial intent not to extend the Cigarette Act's preemption provisions beyond its literal terms. Thus, restrictions on cigarette companies allegedly targeting children are not restrictions based on ''smoking and health.'' See also *Banzhaf* v. *Federal Communication Commission,* 405 F.2d 1082, 1089 (D.C. Cir. 1968), *cert. denied,* 396 U.S. 842 (1969) (preemption provision of the 1965 Cigarette Act did not bar the Federal Communication Commission from requiring radio and television stations to broadcast anti smoking messages: ''Nothing in the 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.'' (footnote omitted))

Applying these cases to FDA's proposed rule, the agency believes that the proposed requirement for a brief statement about smoking and health is not preempted.

2. The Smokeless Act

For smokeless tobacco products, the Smokeless Act states in part:

> (a) Federal action
>
> No statement relating to the use of smokeless tobacco products and health, other than the statements required by [this title,] 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). The proposal would not require any messages in advertising because the Smokeless Act's preemption provision is broader than the preemption provision in the Cigarette Act and preempts any Federal (as well as State) action mandating health/safety messages in advertising.

Thus, given these statutory restrictions and court precedent, FDA has determined that neither the Cigarette Act nor the Smokeless Act preempts any aspect of the proposed rule.

D. Constitutional Issues—Regulation of Speech and the First Amendment

The proposed rule's restrictions on commercial speech are consistent with the First Amendment's protection of freedom of expression. The Supreme Court distinguishes between commercial speech and other forms of speech with respect to First Amendment rights. Traditionally, commercial speech was not granted any protection under the Constitution. More recently, the Supreme Court has granted commercial speech limited constitutional protection. See *Ohralik* v. *Ohio State Bar Ass'n,* 436 U.S. 447, 456, *reh'g denied,* 439 U.S. 883 (1978); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748 (1976); *Bigelow* v. *Virginia,* 421 U.S. 809, 818 (1975). The Supreme Court, in *Edenfield* v. *Fane,* 113 S. Ct. 1792 (1993), stated:

> [c]ommercial speech [ ] is ''linked inextricably'' with the commercial arrangement that it proposes, * * * so the State's interest in regulating the underlying transaction may give it a concomitant interest in the expression itself. * * * For this reason, laws restricting commercial speech, unlike laws burdening other forms of protected expression, need only be tailored in a reasonable manner to serve a substantial state interest in order to survive First Amendment scrutiny.

Id. at 1798 (citations omitted).

It is undisputed that the ''Constitution * * * affords a lesser protection to commercial speech than to other constitutionally guaranteed expression.'' *United States and Federal Communication Commission* v. *Edge Broadcasting Co.,* 113 S.Ct. 2696, 2703 (1993) (citations omitted). Accord, *City of Cincinnati* v. *Discovery Network, Inc.,* 113 S.Ct. 1505, 1513 (1993); *Board of Trustees of the State University of New York* v. *Fox,* 492 U.S. 469, 475, *mot. denied,* 493 U.S. 887 (1989); *Central Hudson Gas and Electric Corp.* v. *Public*

Service Commission, 447 U.S. 557, 563 (1980); *Ohralik,* 436 U.S. at 455–56. Therefore, although commercial speech is protected, the government has latitude to regulate commercial speech in ways it could not regulate other forms of expression. *Friedman* v. *Rogers,* 440 U.S. 1, 10 n.9 (1979) (''When dealing with restrictions on commercial speech we frame our decisions narrowly, ''allowing modes of regulation [of commercial speech] that might otherwise be impermissible in the realm of noncommercial expression.'' (citation omitted).

In *Central Hudson Gas & Electric Corp.* v. *Public Service Commission of New York,* the Supreme Court established a four-prong test to determine whether restrictions on commercial speech are unconstitutional. The first prong states that for commercial speech to come within the protection of the First Amendment the speech must concern lawful activity. The other prongs relevant to an analysis of restrictions on commercial speech are:

(2) The government interest that is asserted to justify the proposed limitation must be substantial;

(3) The proposed limitation must directly advance the government's interest; and

(4) The proposed limitation should be no more extensive than is necessary to serve that interest.

Central Hudson, 447 U.S. 557, 566 (1980).

Since *Central Hudson,* the Supreme Court has taken a permissive view of the government's regulation of commercial speech and has upheld several restrictions on commercial speech. FDA believes that the proposed restrictions on the labeling and advertising of cigarettes and smokeless tobacco products, and the requirement that manufacturers fund and disseminate a media-based educational campaign, also would withstand any First Amendment challenge.

The *Central Hudson* analysis begins with the second prong. The proposed rule meets the requirements of the second prong because it serves the substantial government interest of protecting the public health. The Supreme Court has held that the government's ''interest in the health, safety, and welfare of its citizens constitutes a 'substantial' governmental interest.'' *Posadas de Puerto Rico Associates* v. *Tourism Company of Puerto Rico,* 478 U.S. 328, 341 (1986) (Court upheld restrictions on advertising of casino gambling to residents of Puerto Rico). Accord, *Fox,* 492 U.S. 469 (1989); *Metromedia Inc.* v. *City of San Diego,* 453 U.S. 490, 507–08 (1981). *National Council for Improved Health* v. *Shalala,* Memorandum Decision and Order, Civil No. 94–C–5090 (June 30, 1995) (U.S. District Court for the district of Utah rejected claim that FDA's regulation of dietary supplements violated First Amendment protection.) In this instance, the proposed rule's labeling and advertising restrictions and mandated educational campaign would reduce the use of cigarettes and smokeless tobacco products by those young individuals 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. The proposed rule, therefore, reflects a substantial government interest in public health.

The proposed rule also meets the third prong of the *Central Hudson* test by directly advancing the government's substantial interest. 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. *Metromedia,* 453 U.S. at 509 (''We likewise hesitate to disagree with the accumulated, common-sense judgments of local lawmakers and of the many reviewing courts that billboards are real and substantial hazards to traffic safety.'')

The agency's proposed restrictions on advertising and labeling are based on its review of the evidence that shows that advertising plays an important role in young people's decisions to use tobacco products. Such evidence, consisting of numerous published studies, reports, and recommendations by the industry, health professionals, consumer groups, and public health organizations, demonstrates how advertising and labeling may make young people more receptive to using cigarettes and smokeless tobacco products and how the regulatory approach proposed by FDA may reduce the potential harm to young people. See *Florida Bar* v. *Went for It,* 63 U.S.L.W. 4644 (1995) (anecdotal record sufficient to meet third prong of *Central Hudson*). The Supreme Court has specifically deferred to the government's conclusion that advertising increases consumption of a product. In *Edge,* the Court stated:

> Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments. Here, as in *Posadas de Puerto Rico,* the Government obviously legislated on the premise that the advertising of gambling serves to increase the demand for the advertised product. Congress clearly was entitled to determine that broadcast of promotional advertising of lotteries undermines North Carolina's policy against gambling, even if the North Carolina audience is not wholly unaware of the lottery's existence. Congress has, for example, altogether banned the broadcast advertising of cigarettes, even though it could hardly have believed that this regulation would keep the public wholly ignorant of the availability of cigarettes.

Edge, 113 S.Ct. at 2707 (citations omitted). Accord, *Posadas,* 478 U.S. at 341–42 (Puerto Rican legislature's belief that advertising of casino gambling aimed at Puerto Rican residents would increase demand for it was a reasonable one); *Dunagin* v. *City of Oxford, Miss.,* 718 F.2d 738, 748 n.8 (5th Cir. 1983) (''whether there is a correlation between advertising and consumption is a legislative and not an adjudicative fact question''), *cert. denied,* 467 U.S. 1259 (1984).

The proposed rule's requirement that the manufacturers provide funds for a media-based educational campaign is similarly supported by ample evidence that such educational campaigns have been very effective in reducing initiation and prevalence of tobacco use by young people. The proposed rule directly addresses the serious public health problem caused by tobacco use by young people in a manner that ''will in fact alleviate [the harm] to a material degree.'' *Edenfield,* 113 S.Ct. at 1800.

Unlike the advertising restrictions (text-only format, ban on promotional items, and restrictions on sponsorship), which would help reduce the appeal of future advertising to young people, the proposed education campaign is necessary to address the widespread misconceptions about tobacco use among young people that have in part been created by the ubiquitous advertising and promotional practices of the tobacco industry. For example, the industry currently spends nearly $2 billion creating appealing imagery and sponsoring and advertising events that associate their products with lifestyles that are attractive and popular with young people.

The amount of advertising, the variety of its format (e.g. advertisements, on hats, at concerts, on televised sponsored events), and the appeal of its messages compete effectively with the health messages of the government and health authorities. One consequence is that many young people believe that tobacco products are an important part of growing up and being ''cool.'' Another consequence is that young people remain ignorant of the strength of the

addiction to tobacco products and the relevance to them of the long-term health risks. In the short run, the educational messages would help counter these information deficits and, in the long run, they would provide young people with appropriate information to help them resist tobacco use.

The agency gathered enough evidence regarding the association between promotion and use of cigarettes and smokeless tobacco products and the efficacy of an appropriately designed educational campaign to tentatively conclude that the proposed rule's restrictions on commercial speech would alter young people's smoking behavior. Therefore, the restrictions can be said to ''directly advance'' the legitimate government goal of decreasing the use of these harmful products. (For a discussion of the evidence, see the discussion pertaining to proposed Subpart D, ''Labeling and Advertising.'')

Finally, the proposed rule meets the fourth prong of the *Central Hudson* test, which the Court has modified to require that the governmental regulation of commercial speech not be over broad. 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. *Fox,* 492 U.S. at 4774–4780. The Supreme Court stated:

> What our decisions require 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, as we have put it in other contexts discussed above, a means narrowly tailored to achieve the desired objective. Within those bounds we leave it to governmental decisionmakers to judge what manner of regulation may best be employed.

Id. at 480 (citations omitted) (emphasis added). Accord, *Edenfield,* 113 S.Ct. at 1798 (''[L]aws restricting commercial speech, unlike laws burdening other forms of protected expression, need only be tailored in a reasonable manner to serve a substantial state interest in order to survive First Amendment scrutiny.''); *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626, 651 (1985) (''[W]e hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.'')

This holding is consistent with the Supreme Court's earlier decisions regarding the overbreadth doctrine. The Supreme Court has held that the overbreadth doctrine—which permits an attack on a statute on the basis that it might be applied unconstitutionally in circumstances other than those before a court—applies weakly, or not at all, to commercial speech.

> Since advertising is linked to commercial well-being, it seems unlikely that such speech is particularly susceptible to being crushed by overbroad regulation. Moreover, concerns for uncertainty in determining the scope of protection are reduced; the advertiser seeks to disseminate information about a product or service that he provides, and presumably he can determine more readily than others whether his speech is truthful and protected.

Bates v. *State Bar of Arizona,* 433 U.S. 350, 381 (citations omitted), reh'g denied 434 U.S. 881 (1977).

As with the third prong, the Supreme Court has expressed a willingness to defer this determination to the regulating body. Since *Fox,* the courts have applied the ''reasonable fit'' standard to uphold the regulation of commercial speech. See *Edge,* 113 S.Ct. at 2705 (upholding restrictions on the broadcast of lottery advertisements); *South-Suburban Housing Center* v. *Greater South Suburban Bd. of Realtors,* 935 F.2d 868, 892 (7th Cir. 1991) (upholding restrictions on the mailing of solicitations to people who had registered with the municipality their desire not to receive them, as ''reasonable fit'' with the desire to protect residential privacy), *cert. denied.* 502 U.S. 1074, 112 S.Ct. 971 (1992); *Puerto Rico Tele-Com, Inc.* v. *Ocasio Rodriguez,* 747 F.Supp. 836, 845 (D.P.R. 1990) (upholding a cease and desist order by the Puerto Rico Department of Consumer Affairs (DACO) prohibiting a long-distance phone carrier from using a price study in a deceitful or misleading way as ''a reasonable 'fit' between DACO's orders against plaintiff and its mandate to protect consumers''); *Central American Refugee Center* v. *City of Glen Cove,* 753 F.Supp. 437, 440 (E.D.N.Y. 1990) (upholding ordinance prohibiting solicitation of employment from a vehicle or by a pedestrian on a public street as a ''reasonable fit'' with the governmental interest in protecting vehicle passengers and people crossing the street). Moreover, the Court has granted greater leeway and upheld reasonable regulations of commercial speech with regard to socially harmful activities. *Edge,* 113 S.Ct. 2696 (upholding Federal prohibition of lottery advertising on radio in non lottery State); *Posadas de Puerto Rico Associates,* 478 U.S. 328 (1986) (upholding ban of advertising of casino gambling directed to Puerto Rican citizens); *Capital Broadcasting Co.* v. *Mitchell,* 333 F.Supp. 582 (D.D.C. 1971), affd. mem, 405 U.S. 1000 (1972) (upholding broadcast ad ban on cigarette advertising); nothing in *Rubin* v. *Coors Brewing Company,* 63 U.S.L.W. 4319 (April 19, 1995) is to the contrary (statutory prohibition against statements of alcohol content of beer on labels or in advertising failed completely to advance the governmental interest asserted of preventing ''strength wars'' among brewers).

The agency believes that, because it could have banned the sale or distribution of the product, or banned certain of the marketing and promotional practices of the tobacco industry, the lesser steps of regulating labeling and advertising and requiring manufacturers to fund a government approved educational campaign are reasonable. As the Supreme Court has stated:

> [I]t is precisely *because* the government could have enacted a wholesale prohibition of the underlying conduct that it is permissible for the government to take the less intrusive step of allowing the conduct, but reducing the demand through restrictions on advertising.

Posadas, 478 U.S. at 346 (emphasis in original). More specifically, the Court stated:

> Legislative regulation of products or activities deemed harmful, such as cigarettes, alcoholic beverages, and prostitution, has varied from outright prohibition on the one hand. * * * to legalization of the product or activity with restrictions on stimulation of demand on the other hand. * * * To rule out the latter, intermediate kind of response would require more than we find in the First Amendment.

Id. at 346–347 (citations omitted). This analysis applies not only to the restrictions on the type of advertising permitted (text-only), but also the requirement that the manufacturers fund and disseminate a government approved educational campaign. The Supreme Court has stated that the government may dictate the form of, and information in, commercial speech. *Virginia Pharmacy,* 425 U.S. at 771 n.24 (''They may also make it appropriate to require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.''); *In re R.M.J.,* 455 U.S. 191, 201 (1982) (''warning or disclaimer might be appropriately required* * *in order to dissipate the

possibility of consumer confusion or deception''); *Bates*, 433 U.S. at 384.

As noted above, on several occasions the agency has imposed similar educational requirements—e.g., user instructional brochures—in order to reduce consumer confusion or to prevent the misuse of a device. In those circumstances, the agency has required that the company use agency approved language. Courts have approved of similar ''corrective'' or ''coerced'' speech ordered by other federal agencies. See *Warner-Lambert Co.* v. *FTC*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978) (corrective advertising is appropriate where company has engaged in a long history of deceptive advertising and the misperceptions continue even in the absence of current advertising); *United States* v. *Frame*, 885 F.2d 1119 (3rd Cir. 1989) (court upheld legislation that required beef producers, including those who objected, to pay an assessment to fund pro-beef commercials written and disseminated by a quasi-government board), *cert. denied*, 493 U.S. 1094 (1990).

In conclusion, the agency believes that the evidence would support a ban on all advertising and, therefore, that the more limited restrictions imposed by this proposed rule are reasonable as proportionate to the agency's desired goal—to reduce tobacco-related illnesses and deaths by helping to prevent young people from becoming addicted to the nicotine in cigarettes and smokeless tobacco products. The requirements proposed here serve to prevent distribution of these products to young people, to reduce the effectiveness of advertising and promotion on young people, and to ensure that an appropriate educational campaign is aimed at young people. Thus, the means chosen are a reasonable fit to the substantial interest and, consequently, pass the final prong of the *Central Hudson* test.

V. Paperwork Reduction Act of 1980

The proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection requirements are shown below with an 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 proposed rule would collect information from manufacturers and retailers of cigarettes and smokeless tobacco products. The proposed rule would require such persons to: use established names for cigarettes and smokeless tobacco products; establish and maintain educational programs; observe certain format and content requirements for labeling and advertising; and submit labels, labeling, and advertising to FDA.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

CFR Section	Annual No. of responses	Annual frequency	Average burden per response	Annual burden hours
897.24	1,000	1	40 hours	40,000
897.29	1,000	1	1,000 hours	1 million
897.32	200,000	1	20 minutes	66,667
897.40	200,000	1	20 minutes	66,667
Total				1,173,334

The agency has submitted a copy of the proposed rule to OMB for its review of these information collections. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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. Comments should be sent to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office, Washington, DC 20503, Attn: Desk Officer for FDA.

VI. Executive Orders

A. Executive Order 12606: The Family

Executive Order 12606 directs Federal agencies to determine whether policies and regulations may have a significant impact on family formation, maintenance, and general well-being. FDA has analyzed this proposed rule in accordance with Executive Order 12606, and has determined that it has no potential negative impact on family formation, maintenance, and general well-being.

FDA has determined that this rule will not affect the stability of the family, and particularly, the marital commitment. It will not have any significant impact on family earnings.

The proposed rule would not impede the parental authority and rights in the education, nurture, and supervision of children. Rather, the proposed rule would, if finalized, help the significant majority of American families that seek to discourage their children from using cigarettes and smokeless tobacco products. The pervasive promotion and easy availability of these products, despite existing laws in all 50 States prohibiting their sale to children, severely hinder the individual family from carrying out this function by itself.

Section 1(g) of Executive Order 12606 requires that FDA assess the proposed rule in light of the message, if any, it sends to young people ''concerning the relationship between their behavior, their personal responsibility, and the norms of our society.'' The proposed rule would, if finalized, help reduce the conflict between the anti-smoking messages issued by Federal and State authorities and the pro-tobacco messages seen in advertising. 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.

Although Executive Order 12606 does not require that individuals or organizations be permitted to participate in proposed rulemaking proceedings, FDA expressly requests all such interested parties to submit comments and suggestions regarding this rule's effect on the family.

B. Executive Order 12612: Federalism

Executive Order 12612 requires Federal agencies to carefully examine regulatory actions to determine if they would have a significant effect on federalism. Using the criteria and principles set forth in the order, FDA has considered the proposed rule's impact on the States, on their relationship with the Federal Government, and on the distribution of power and responsibilities among the various levels of government. FDA concludes that this proposal is consistent with the principles set forth in Executive Order 12612.

Executive Order 12612 states that agencies formulating and implementing policies are to be guided by certain federalism principles. Section 2 of Executive Order 12612 enumerates fundamental federalism principles. Section 3 states that, in addition to these fundamental principles, executive departments and agencies shall adhere, to the extent permitted by law, to certain listed criteria when formulating and implementing policies that have federalism implications. Section 4 lists special requirements for preemption.

Executive Order 12612 recognizes that 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)). The constitutional basis for FDA's authority to regulate drugs and devices is well established.

Moreover, in developing the provisions of this proposed rule, the agency carefully considered the provisions of the proposed rule implementing section 1926 of the Public Health Service Act, the Substance Abuse Prevention and Treatment block grant program. As a condition of receipt of such grants, a State must have in place a law that prohibits the sale or distribution of any tobacco product to individuals under age 18 and enforce the law in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18. The statute prescribes random, unannounced inspections, but otherwise allows the States considerable flexibility in designing their enforcement programs. By imposing the explicit obligations on manufacturers, distributors, and retailers to control access by children and adolescents to nicotine-containing cigarettes and smokeless tobacco products, the FDA proposals will help States achieve their goals under their substance abuse programs. FDA therefore believes that the two programs complement each other.

The proposed rule would establish uniform minimum standards with respect to the labeling, advertising, sale, and distribution of nicotine-containing cigarettes, cigarette tobacco, and smokeless tobacco products. The proposed rule would expressly provide, however, that these regulations do not preempt State and local laws, regulations, and ordinances that establish higher standards with respect to these products, or affect these products in areas not covered by the proposed rule, e.g., environmental smoke.

The proposed regulation of nicotine-containing cigarettes, cigarette tobacco, and smokeless tobacco is narrowly drawn. First, it focuses on reducing methods of promotion that are either expressly designed to appeal to American youths, or that are designed without regard to their appeal to American youths. Second, it focuses on reducing the easy access of these nicotine containing products by American youths.

The agency concludes that the policy proposed in this document: Has been assessed in light of the principles, criteria, and requirements in Executive Order 12612; is not inconsistent with that Order; will assist States in fulfilling their obligation under the Substance Abuse Prevention and Treatment block grant program; will not impose additional costs or burdens on the States; and will not affect the States' ability to discharge traditional State governmental functions.

Section 4 of Executive Order 12612 states that an executive department or agency proposing to act through rulemaking to preempt State law is to provide all affected States notice and opportunity for appropriate participation in the proceedings. As required by the Executive Order, States have, through this notice of proposed rulemaking, an opportunity to participate in the proceedings (section 4(e)). Consistent with Executive Order 12612, FDA requests information and comments from interested parties, including but not limited to State and local authorities, on these issues of federalism.

C. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

Executive Order 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 that 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) 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 has considered whether the proposed rule would result in a ''taking'' of private property. The proposed rule would, if finalized, restrict outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, eliminate cigarette vending machines and self-service displays, ban all brand identifiable non-tobacco items, such as hats and tee shirts, prohibit the use of a trade name of a non-tobacco item for any tobacco product, and require established names and a brief statement on labels, labeling, and/or advertising. In addition, the proposed rule would require that all sponsored events be carried out only in the corporate name. While these requirements might affect private property, they do not constitute ''takings.''

In determining whether a governmental action has resulted in a ''taking,'' recent court decisions have

generally required either a physical invasion of the property or a denial of all economically beneficial or productive use of the property (other than real property), and have 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.'' See *Lucas* v. *South Carolina Coastal Council,* _____ U.S. _____, 112 S.Ct. 2886, 2893 (1992); *Andrus* v. *Allard,* 444 U.S. 51, 65 (1979) (reduction in value is not necessarily a taking); *Golden Pacific Bancorp* v. *United States,* 15 F.3d 1066, 1071–73 (Fed. Cir. 1994) (heavily regulated bank could not have developed a historically rooted expectation of compensation so Federal take-over did not require compensation), *cert. denied,* 115 S.Ct. 420 (1994); *Midnight Sessions, Ltd.* v. *City of Philadelphia,* 945 F.2d 667 (3rd Cir. 1991) (denial of license to operate an all-night dance hall did not constitute a taking because it did not deny all economically viable use of the property), *cert. denied,* 503 U.S. 984 (1992); *Elias* v. *Town of Brookhaven,* 783 F.Supp. 758 (E.D.N.Y. 1992) (loss of profit or the right to make the most profitable use does not constitute a taking); *Nasser* v. *City of Homewood,* 671 F.2d 432 (11th Cir. 1982) (deprivation of most beneficial use of land or severe decrease in property value does not constitute a taking). Indeed, in *Andrus* v. *Allard,* the Supreme Court wrote,

> Suffice it to say that government regulation—by definition—involves the adjustment of rights for the public good. Often this adjustment curtails some potential for the use or economic exploitation of private property. To require compensation in all such circumstances would effectively compel the government to regulate by *purchase.* ''Government 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.''

Andrus, 444 U.S. at 65 (emphasis in original; citations omitted).

Here, the proposed rule would not require the government to physically invade or occupy private property, so the first inquiry is whether the proposed rule, if finalized, would deny all economically beneficial or productive use of property. The proposal would prohibit outdoor advertising from being located within 1,000 feet of any elementary or secondary school or playground. However, cases involving advertising restrictions illustrate that restrictions on the size and placement of advertising may be acceptable if they represent a valid exercise of governmental authority or do not deny all economically viable uses of the property. See *Sign Supplies of Texas, Inc.* v. *McConn,* 517 F.Supp. 778, 782 (S.D. Tex. 1980) (city ordinance on sign and billboard size, height, and location did not constitute a taking and was a valid regulation of injurious and unlawful acts). In this instance, the proposed restriction against outdoor advertising represents an exercise of the agency's statutory authority to restrict certain devices and permit labeling and advertising to continue under certain conditions.

Neither would the proposed rule effect a taking of vending machines or self-service displays. Although vending machines would no longer be permitted to be used to sell cigarettes or smokeless tobacco products, they would continue to have economic value if they were modified for other uses. FDA notes that a recent issue of *Vending Times* stated that cigarette vending sales declined in 1993 and that:

> Many traditional machines were modified to sell both full-value and generic/subgeneric styles at two prices, and glass-front machines gained favor as cigarette merchandisers because of their high selectivity, flexible pricing, attractive display, and *convertibility to other uses if cigarette vending becomes illegal.*

''Vending Cigarettes,'' *Vending Times, Census of the Industry Issue,* 1994 at p. 42 (emphasis added).

This statement indicates that compliance with this regulation would not result in a ''taking'' of vending machines. Similarly, self-service displays, in many instances, could be moved, adapted, or locked to comply with the requirement of direct transfer from retailers to consumers. Thus, like vending machines, self-service displays would retain their utility rather than losing their value.

Non-tobacco items that bear the brand name, logo, symbols, mottos, selling messages, or any other indicia of a cigarette or smokeless tobacco product are often given away free as promotional items or packaged with tobacco products as incentives to purchase the product. Banning brand identifiable non-tobacco items as a marketing tool and limiting sponsorship of events would not constitute a taking because, like vending machines and self-service displays, they can be modified or adapted to fit other needs. FDA notes that the FTC, in 1991, had to consider whether its proposal to require warning messages on ''utilitarian objects'' bearing the names, logos, or selling messages of smokeless tobacco product firms or brands constituted a taking. The FTC acknowledged that small businesses and one advertising association claimed that the FTC's rule would impose economic burdens on them, but felt that such claims were unsubstantiated. The FTC quoted an authority in consumer product regulation as stating that firms that produce these ''utilitarian items'' must be ''adaptable and flexible to meet different needs of changing marketplace demands'' and that they are able to transfer resources to other potential customers with only short term sales transaction costs. See 56 FR 11653, at 11661 (Mar. 20, 1991); see also *Georgia-Pacific Corp.* v. *United States,* 640 F.2d 328, 360 (Ct. Cl. 1980) (''It is settled that not all losses suffered by the owner are compensable under the fifth amendment. The government must pay only for what it takes, not for opportunities which the owner may have lost.'') (citation omitted). FDA also notes that, until a final rule becomes effective, firms could easily adjust their business practices to adapt to the proposed regulations or to phase out utilitarian items and, therefore, not have such items in stock when the rule becomes effective.

Finally, prohibiting the use of non-tobacco names on tobacco products and requiring labels, labeling, and advertising to carry the product's established name and a brief statement would represent too slight a ''taking'' to warrant constitutional concern. With respect to the prohibition against the use of non-tobacco names, the non-tobacco product firm would lose its ability to license its name to any tobacco company, but it would be free to exploit its trade name with any other industry. There have been very few instances (such as ''Harley- Davidson' cigarettes) of tobacco companies licensing a non-tobacco trade name. The agency recognizes that these brands might still be in the marketplace and would apply this provision prospectively only.

Nevertheless, even if the agency's proposed actions could constitute a ''taking,'' FDA finds that the actions are consistent with section 4(d) of the order. The labels, labeling, and advertising for cigarettes and smokeless tobacco products convey images of status, sophistication, maturity, and adventure or excitement that are particularly appealing to young people. Their effectiveness at attracting young people is reflected in studies showing that young people tend to smoke the most heavily advertised brands and that very young children are able to recognize brand logos and imagery. The appeal generated by labels, labeling, and advertising, coupled with easy access, creates the risk that young people will

smoke cigarettes or use smokeless tobacco products, thereby exposing themselves to the long-term health risks associated with those products. Consequently, FDA has carefully drafted the proposed rule to convey information regarding warnings, precautions, side effects, and contraindications in order to inform consumers about the use of these products. The advertising requirements in proposed subpart D are also narrowly drafted to allow advertising to continue under certain conditions rather than prohibit all advertising. This will enable adults to continue receiving advertising messages while decreasing the advertisements' appeal to young people.

Vending machines and self-service displays offer young people easy access to cigarettes and smokeless tobacco products even though State laws prohibit cigarette sales to minors and some States or localities require locking devices on or specific placement of vending machines. Thus, the requirement that retailers physically provide the product to the consumer substantially advances the purpose of protecting the public health by eliminating easy, unmonitored access to such products by underage persons. This requirement is not disproportionate to the risk presented by vending machines and self-service displays because many studies demonstrate how easily minors can purchase cigarettes from vending machines, and other documents indicate that shoplifting is another method young people use to acquire these products.

Non-tobacco items and sponsored events that bear the brand name, logo, symbols, mottos, selling messages, or any other indicia of a cigarette or smokeless tobacco product act like advertising, conveying images of status, sophistication, maturity, and adventure or excitement that appeal to young people. Reports demonstrate that many young people, even those under the legal age, possess these items or seek coupons or certificates to obtain these items. The items, in conjunction with labeling, other advertising activities, and sponsored events, create the impression that smoking or smokeless tobacco product use is more prevalent and acceptable in society than it actually is and, as a result, increase the risk that young people will smoke cigarettes or use smokeless tobacco products and expose themselves to the long-term health risks associated with those products. Thus, banning tobacco promotions on non-tobacco items and in conjunction with sponsored events is appropriate.

As for the estimated potential cost to the government in the event that a court finds a taking to exist, FDA is unable to provide an approximate figure. There is little publicly available and precise data or information on each activity that would arguably be the subject of a regulatory taking, and section 704 of the act prohibits FDA from requiring financial, sales, or pricing data during an inspection. Consequently, the agency would appreciate receiving information to enable it to determine the potential cost to the government if a court found the actions described in this proposed rule to be a taking.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8), (a)(11), and (e)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96–354) and under the Unfunded Mandates Reform Act (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; distributive impacts and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in Section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000, (adjusted annually for inflation). That Act also requires (in Section 205) 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 proposed rule is consistent with the principles set in the Executive Order and in these two statutes. In addition, this document has been reviewed by the Office of Management and Budget as an economically significant regulatory action under Executive Order 12866.

The estimated benefits of the proposed rule were based on FDA's finding that compliance with the proposed requirements would help to achieve the Department's ''Healthy People 2000'' goals. Each year, an estimated 1 million adolescents begin to smoke cigarettes. This analysis calculates that at least 24 percent of these youngsters will ultimately die from causes related to their nicotine habit. (Other epidemiological studies suggest even higher rates of excess mortality. For example, CDC projections indicate that 1 in 3 adolescents who smoke will die of smoking-related disease.) As a result, FDA projects that the achievement of the ''Healthy People 2000'' goals 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. At a 3 percent discount rate, the monetary value of these benefits are projected to total from about $28 to $43 billion per year and are comprised of about $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 total benefits to about $9.1 to $10.4 billion per year.) In addition, the proposed rule would prevent numerous serious illnesses associated with the use of smokeless tobacco products.

The full realization of this goal would require the active support and participation of State and local governments, civic and community organizations, tobacco manufacturers, and retail merchants. Even if only a fraction of the goal were achieved, the benefits would be substantial. For example, as shown in Table 1, 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 $2.9 to $4.3 billion a year.

To comply with the initial requirements of the rule, FDA projects that manufacturers and retailers of tobacco products would incur one-time costs ranging from $26 to $39 million and annual operating costs of about $227 million (see Table 2). Manufacturers would be responsible for about $15 to $28 million of the one-time costs and $175 million of the annual

costs (mostly for educational programs). In addition, they would face significant advertising restrictions. Retailers would pay $11 million in one-time costs and $52 million in annual costs. On an annualized basis, using a 3 percent discount rate over 15 years, costs for these initial requirements total about $230 million (also about $230 million at a 7 percent discount rate). Achieving the ''Healthy People 2000'' goals, however, could demand still further efforts by tobacco manufacturers to restrict youth access to tobacco products. Moreover, FDA plans to propose additional requirements that would become effective only if these goals were not met.

TABLE 1—ANNUAL ILLNESS-RELATED BENEFITS OF ALTERNATIVE EFFECTIVENESS RATES
[Undiscounted lives and life-years; 3% discount rate for monetary values]

Fraction of teenage cohort deterred	Fewer adult smokers ** (No.)	Lives saved (No.)	Life-years saved (No.)	Medical savings ($bils.)	Morbidity-related productivity savings ($bils.)	Mortality-related willingness-to-pay		Total benefits	
						Life-years saved ($bils.)	Lives saved ($bils.)	Low ($bils.)	High ($bils.)
1/2 *	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	18.8	28.8
1/5	100,000	24,100	362,100	1.1	0.4	9.9	15.9	11.4	17.4
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	2.9	4.3

* Estimate used in analysis.
** Assumes 50% of adolescents who are deterred from smoking refrain as adults.

TABLE 2—INDUSTRY COSTS FOR CORE PROVISIONS
[$mils.]

Requirements by sector *	One-time costs	Annual operating costs	Total annualized costs **
Tobacco Manufacturers	15–28	175	177
Visual Inspections		24	24
Training		1	1
Label Changes	4–17		1
Self-Service Ban	11		1
Educational Programs		150	150
Retail Establishments	11	52	53
Training		10	10
I.D. Checks		28	28
Self-Service Ban	11	14	15
TOTAL	26–39	227	230

* Advertising restrictions are considered under distributional effects.
** Sum of one-time costs annualized over 15 years at 3 percent and annual operating costs.

Consumers would incur costs to the extent that they lose positive utility received from the imagery embodied in product advertising campaigns. Consumers would also lose the convenience offered by the use of cigarette vending machines. Costs for these compliance activities were based on the agency's best estimate of the resources that would be needed to establish effective programs for decreasing the incidence of lifelong addictions to nicotine-containing cigarettes and smokeless tobacco products.

In addition to the costs described above, the proposal would create distributional and transitional effects. While the overall impact of these changes on the national economy would be small, because dollars not spent on tobacco-related expenditures would be spent on other goods or services, several individual industries would be affected. Tobacco manufacturers and suppliers would face increasingly smaller sales, because reduced tobacco consumption by youth would lead, over time, to reduced tobacco consumption by adults. The impact of this trend on industry revenues would be extremely gradual, requiring over a decade to reach an annual decrease of even 4 percent, substantially mitigating the costs associated with any resource dislocation. Also, if State excise tax rates on tobacco products remain at current levels, State tax revenues would decrease slowly over time, falling by $252 million by the tenth year.

Tobacco manufacturers spent $6.2 billion on advertising, promotional, and marketing programs in 1993, and about 30 percent would be substantially altered to reflect the various ''text only'' restrictions or other prohibitions. If tobacco advertising outlays declined, various service agencies and communications media (including suppliers of retail counter and other display space) would need to attract replacement sponsors. Similarly, vending machine operators would need to find substitute products to replace that portion of their revenue that is currently derived from the sale of cigarettes. Many of these adjustments would occur quickly (e.g., TV networks reportedly recouped advertising revenues within 1 year of the 1971 ban), but others could create short-term disruptions as businesses moved to replace lost product lines.

In sum, FDA finds that compliance with this proposed rule would impose some economic costs on the tobacco industry and short-term costs on several other industry sectors. With regard to small businesses, most impacts would

be small or transitory. For a small retail convenience store not currently complying with this proposal, the additional first year costs could reach $320. For those convenience stores that already check customer identification, these costs fall to $35. Moreover, the proposed rule would not produce significant economic problems at the national level, as the gradual displacement in tobacco-oriented sectors would be largely offset by increased output in other areas. Thus, pursuant to the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation would greatly exceed the compliance costs that it would impose on the U.S. economy. In addition, the agency has considered other alternatives and determined that the current proposal is the least burdensome alternative that would meet the ''Healthy People 2000'' goals.

B. Statement of Need for Proposed 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 products. 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.[1]

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 new 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 believes that various elements of market failure are relevant to the problem of teenage tobacco addiction, the agency also believes that the proposed regulatory action could be justified even in the absence of a traditional market failure. As noted above, 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. However, FDA 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''[2] to note that ''[t]he economic analysis of market failure deals with choice by adults.'' FDA finds this statement consistent with its view that even if many children make rational choices,[3] 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.[4]

In particular, FDA finds that the imagery used in industry advertising and promotional programs obscures adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products. The preceding sections of this preamble describe numerous studies on the shortcomings of the risk perceptions held by children. Although most youngsters acknowledge the existence of tobacco-related health risks, 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 that has not been adequately remedied by 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.''[5] Although several empirical studies have 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,[6] 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.''[7]

A further market failure would exist if the use of tobacco imposed external or spillover 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 whether smokers pay their own way is the 1991 study by Manning, et al., ''The Cost of Poor Health Habits,''[8] 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 examined estimates of the potential magnitude of the omitted costs and concurred with this finding.[9]

C. Regulatory Benefits

1. Prevalence-Based Studies

The benefits of the proposed regulation include the costs that would be avoided by eliminating 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.[10]

In a recent statement, the 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.[11] More recently, the CDC estimated the 1993 smoking-attributable costs for medical care, alone, at $50 billion.[12] 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.'' [13] 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 regulatory-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 has relied on these incidence-based studies to value the beneficial effects of the proposed 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 would 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 would translate to reduced rates of lifetime tobacco consumption
- A projection of the extent to which the reduced rates of lifetime tobacco consumption would decrease the number of premature deaths and lost life-years
- An exploration of various means of estimating the monetary value of the expected health improvements.

The annual benefits of the proposed regulation are 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.

3. Reduced Incidence of New Young Tobacco Users

Each year, an estimated 1 million youngsters become new smokers. The proposed regulation targets this group 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. 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 ⅔ for regular smokers).[14]

The proposed advertising and promotional restrictions would augment these efforts to limit the attraction of tobacco products to underage consumers. As discussed in detail in the preamble above, no one study has definitively quantified the precise impact of advertising or of advertising restrictions. Nevertheless, the majority of the relevant research indicates that advertising restrictions would 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.'' [15] Similarly, after a careful examination of available studies, Clive Smee, Chief Economic Adviser to the UK Department of Health determined that, ''the balance of evidence thus supports the conclusion that advertising does have a positive effect on consumption.'' [16]

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 40 percent to 80 percent.[17]

In the August 26, 1993, **Federal Register**, the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age. FDA strongly supports the basic objectives of this program, but believes that their full achievement would demand a broad arsenal of controls; including industry programs to complement and fortify the new State inspectional programs, together with restrictions on industry advertising and promotions to counter the influence of ongoing marketing activities. While quantitative estimates of the effectiveness of these activities cannot be made with certainty, FDA believes that, if aggressively implemented and supported by both industry and public sector entities, comprehensive 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.

The agency acknowledges the imposing size of the required effort and understands that the performance goals may not be fully attainable if the affected industry sectors choose to ignore the new incentives established by the proposed regulation. After all, the industry's long- term profits hinge on attracting new customers. Nonetheless, FDA is confident that the combined effect of the proposed restrictions on advertising and promotion, prohibition of self-service tobacco products (including vending machines), new labeling information and educational programs, and age verification obligations for retailers would significantly diminish the allure as well as the access to tobacco products by youth. Moreover, if the performance goals are not met 7 years after the effective date of the final rule, additional requirements would enhance the effectiveness of these activities. Thus, this study projects regulatory benefits on the presumption that the ''Healthy People 2000'' goals would be met, but also presents results for effectiveness levels that are considerably smaller.

4. Reduced Rate of Lifetime Tobacco Use

As part of its regulatory proposal, SAMHSA assumed that its new monitoring program would significantly reduce the amount of underage

smoking, but its methodology did not project these reduced smoking rates into adult years. SAMHSA acknowledged the conservative nature of its estimate and noted the likelihood that the majority of the cost savings would accrue over long time spans, ''as each cohort of non-smoking youth ages into non-smoking adults.'' Nevertheless, SAMHSA did not quantify these lifetime benefits, ''because there are so many uncertainties as to future outcomes.'' While agreeing that long term benefit projections are uncertain, FDA is convinced that estimates based on valid assumptions can provide reasonable approximations of future cost savings.

The major beneficiaries of the proposed rule are those individuals who would otherwise become addicted to tobacco early in life, but who are unlikely to start using tobacco products as an adult. Evidence from SAMHSA suggests that this percentage will be high as most smokers become daily cigarette smokers before the age of 18. 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.'' FDA agrees with that assessment, but notes that the above percentage may not reflect the ultimate demand for tobacco consumption that may occur if adolescent access is effectively limited. Thus, to account for this possibility, FDA conservatively assumed that this proposed regulation would prevent the use of tobacco as an adult for only one half of the estimated 500,000 youngsters who would be deterred from starting to smoke each year. Accordingly, FDA has calculated the annual benefits of the proposed rule from the lifetime health gains associated with preventing 250,000 adolescents from ever smoking as an adult.

5. Lives Saved

FDA calculated the number of smoking-related deaths that would be averted by the 250,000 lifetime nonsmokers (who in the absence of the proposed regulation would be smokers) from age-specific differences in the probability of survival for smokers and nonsmokers. The probability of survival data for the agency's estimate were 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 compared the probability of death for smokers versus nonsmokers within each 10-year period. Differences in the probabilities of death were then multiplied by the number of smokers remaining at the start of each 10-year period. Excess deaths among smokers in all age groups totaled almost 28 percent of the 250,000 cohort. Because these data do not account for potentially confounding variables, such as alcohol consumption, or other lifestyle differences, FDA adjusted the mortality estimate to 24 percent to reflect findings by Manning et al.[18] that such nontobacco lifestyle factors may account for 13 percent of excess medical care expenditures. FDA recognizes that this 24 percent mortality estimate may be too low. For example, Peto, et al. found that about half of all adolescents who continue to smoke regularly will eventually die from smoking-related disease.[19] Moreover, CDC projects that up to 1 in 3 adolescent smokers may die prematurely. Nevertheless, for this analysis, FDA relied on the probabilities shown in Table 3, corrected by the 13 percent lifestyle influence adjustment, to project that achieving the ''Healthy People 2000'' performance goal would prevent about 60,200 smoking-related fatalities among each year's cohort of potential new smokers.[20]

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 was used to calculate the present value of the projections. (Most health-related cost-effectiveness studies use rates of from 3 to 5 percent. FDA presents summary estimates below for rates of both 3 and 7 percent.) On the assumption that it would be 20 years before each year's cohort of new adults reached the midpoint of the 35 to 45 age bracket and 60 years to reach the 75 to 85 age bracket, these calculations indicate that, on a present value basis, the proposed rule would save 15,863 lives per year.

6. Life-Years Saved

The number of life-years that would 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 non-smokers. 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.[21] Deducting the 13 percent lifestyle adjustment indicates that over the full lifetime of each cohort, the proposed regulation would gain an estimated 905,000 life-years, or about 15 years per life saved. On a discounted basis, the proposed rule would save an estimated 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 has developed estimates of the value of the reduced medical costs and the increased worker productivity that would result from

fewer tobacco-related illnesses. In addition, since productivity measures do not adequately value the avoidance of premature death, FDA has 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,[22] who found that lifetime medical costs for male smokers were 32 percent higher than for male neversmokers and lifetime medical costs for female smokers were 24 percent higher than for female neversmokers. Hodgson determined that the present value of the lifetime excess costs were about $9,400 in 1990 dollars (future costs discounted at 3 percent).[23] As noted earlier, the incidence-based study by Manning et al., implies that about 13 percent of the excess medical costs are attributable to factors other than smoking. Accounting for this reduction and adjusting by the consumer price index (CPI) 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). Since FDA projects that the proposed regulation would prevent 250,000 of these individuals from smoking as adults, the medical cost savings attributable to the proposed regulation is 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 proposed 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 are due to discounting.[24] Consequently, 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.[25] 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. Further, because the long-term decline in smoking prevalence has exceeded the growth in population, the estimated incidence-based costs were reduced 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 one year's cohort of 1,000,000 new smokers, is about $3.5 billion. Based on FDA's estimate that the proposed regulation would prevent 250,000 youths per year from smoking as adults, the estimated annual benefits from reduced morbidity amount to about $879 million.

10. Benefits of Reduced Mortality Rates

From a societal welfare perspective, OMB 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.[26] 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 study[27] 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.[28] 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, which is intuitively appealing because it places a greater value on the avoidance of death at a younger than at an older age, 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 approaches, 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 translates to about $116,500 per life year. Since the proposed regulation would save 211,391 discounted life-years annually, this approach yields annual benefits of $24.6 billion. FDA notes that this approach does not attribute any value to lost consumer utility from tobacco product consumption and solicits public comment on this methodology.

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.[29] A reduction in the number of smokers, and the coinciding number of cigarettes smoked, would result in a drop in the number of fires over the years. If the number of fires fell by the same percentage as the expected reduction in cigarette sales, this would imply present value savings due to fewer fires 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. Moreover, these estimates do not include costs for nonfatal injuries or for providing temporary housing.

12. Summary of Benefits

The discussion above demonstrates the formidable magnitude of plausible estimates 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 tobacco-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 $9.1 to $10.4 billion.) These totals do not include the benefits expected from fewer fires (over $200 million annually), reduced passive smoking, or decreased use of smokeless tobacco products. Moreover, while FDA believes these effectiveness projections are plausible, much lower rates would still yield impressive results. Table 1 above summarized 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.

D. Regulatory Costs

OMB guidelines for Regulatory Impact Analysis direct that agency cost estimates reflect the opportunity costs of the proposed alternative (i.e., the value of the benefits foregone as a consequence of that alternative.)[30] According to these guidelines, estimates should include ''private-sector compliance costs, government administrative costs, and costs of reallocating workers displaced as a result of the regulation * * * Such costs may include the value (opportunity cost) of benefits foregone, losses in consumers' or producers'' surpluses, discomfort or inconvenience, and loss of time.''[31] Accordingly, FDA finds that the proposed rule would impose new burdens on the manufacturers of tobacco products and less stringent requirements on retailers of tobacco products. In addition, certain other industry sectors would experience lost sales and employment, but these effects would be largely offset by gains to other sectors, as discussed in section VIII.E. of this document.

A critical variable underlying several of the cost estimates is the number of retail outlets that sell tobacco products. According to the Retail Trade Census, a total of 2.4 million retail trade establishments operated in 1987. Unfortunately, the Retail Trade Census publishes product line data for only the 1.5 million retail establishments with payroll. Of these, about 275,000 report sales for the broad merchandise line of ''Cigars, cigarettes, and tobacco.'' FDA does not know how many of the nonpayroll outlets sell tobacco products. There were about 215,000 nonpayroll outlets among the most likely establishment types (grocery stores, service stations, drug stores, liquor stores, drinking places, general merchandise, and eating places.) If all of these nonpayroll stores sold tobacco products (an unreasonably high estimate considering that only 34 percent of those with payroll reported sales of tobacco merchandise), the total number of retail establishments selling over-the-counter tobacco products would be 275,000 + 215,000, or 490,000. Moreover, these data may overstate the number of outlets operating at any one time, because they represent the number of establishments in business at any time during the year and outlet turnover is significant. The figure may be understated, however, if a substantial number of nonpayroll stores that sell tobacco products are classified among other establishment types.

Alternatively, New Jersey issued about 18,300 retail cigarette sales licenses in 1988, but the census estimate for the number of retail establishments with payroll selling tobacco products in that state was only about 6,000. This implies that over twice as many nonpayroll outlets sell tobacco products as outlets with payrolls. If the New Jersey licensing data, which imply about 2.4 cigarette licenses per 1,000 population, were extrapolated to the United States, they project to about 600,000 such outlets nationwide. However, this estimate also may overstate the current number of establishments selling tobacco products at any one time, because of the high failure rate among small businesses obtaining licenses (i.e. more licenses issued than establishments surviving).

Neither the census nor the New Jersey data account for those outlets that may convert cigarette vending machine sales to over-the-counter sales once vending machines are banned as proposed in this regulation. Industry estimates of the number of cigarette vending machines in operation in 1993 vary from 182,000[32] to 480,000[33]. FDA does not know how many of these operations would convert to over-the-counter sales, but for this study, the agency has assumed that about 100,000 establishments would initiate new over-the-counter operations to replace lost vending machine sales. Thus, FDA estimates that a maximum of about 700,000 retail outlets would continue to sell tobacco products.

1. Costs to Manufacturers

a. *Core requirements.* Under the proposed regulation, manufacturers of tobacco products would incur compliance costs for the following requirements: visual inspections of retail outlets, training manufacturers' representatives, changing package labels, assisting self-service bans, and financing consumer education programs.

b. *Visual inspections.* The manufacturer is responsible for removing all items that do not comply with the requirements of this proposal and for visually inspecting each retail establishment during any visit to such establishment, to ensure that the products are appropriately labeled, advertised, and sold, or distributed. Thus, manufacturer inspections would be required during every business visit to a tobacco-selling outlet by a manufacturer's representative. As manufacturers' representatives routinely visit most retail outlets selling their products, the proposed requirement would provide a periodic scrutiny of retail tobacco operations without imposing additional travel costs. FDA cannot project these costs precisely, as the intensity of the audit would vary with the characteristics of the retail operation, but the agency believes that most manufacturers' representatives would need little incremental time to conduct routine audits. On average, FDA estimates that each audit would be accomplished by a relatively quick assessment that would take no more than 2 to 3 minutes. The assumption of an additional 3 minutes per visit implies a total of 30 minutes a day for a manufacturer's representative who may visit an average of 10 outlets daily. At a labor cost of $25 per hour, the annual cost of the additional one-half hour spent daily on monitoring would be $3,250 per employee.

FDA does not know how many manufacturers' representatives currently make sales calls on tobacco product retailers, but preliminary results from the 1992 U.S. Census of Manufacturers indicate that cigarette manufacturers employ about 7,300 nonproduction workers. Thus, if all nonproduction workers were engaged in retail sales, the industry monitoring costs would approach $24 million per year ($3,250 × 7,300). However, many nonproduction employees serve in management or clerical positions. Moreover, the above cost estimate fails to account for the likely relationship between the total time needed for a manufacturers'

representative to visit a retail outlet and the type of promotional activities permitted. For instance, the ban on self-service displays may cause manufacturers' representatives to spend less time conducting display inspections. Thus, FDA suspects that the above cost estimate may be high.

c. *Training.* Each manufacturer's representative would have to receive training on the requirements of the regulation and the new monitoring responsibilities of their position. FDA estimates that this training could be accomplished in about 8 hours. Thus, assuming that the 7,300 estimate for the number of manufacturers' representatives adequately accounts for normal employee turnover, the annual training costs would total about $1 million.

d. *Label changes.* The proposed regulation requires that the tobacco product package contain the established name of the tobacco product in a specified size. FDA has estimated the compliance costs for printing new labels in the event that new labels would be needed.

Approximately 933 varieties of cigarettes are currently produced in the United States.[34] FDA does not have information on the number of smokeless tobacco varieties, but has assumed that the total number of cigarette and smokeless tobacco varieties is 1,000. FDA also assumes that most varieties of cigarettes are packaged in both single packs and cartons, but that each variety of smokeless tobacco is packaged in only one type of package. Consequently, the total number of labels was calculated as: 933 cigarette varieties × 2 package types per variety (individual packs and cartons) + 67 smokeless tobacco varieties = 1,933 package types.

FDA used two approaches to estimate the cost to industry of changing these labels. The first approach used information compiled by The Research Triangle Institute (RTI) in its report to FDA on the cost of changing food labels.[35] 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 $5,412,400 for all 1,933 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.[36] The Canadian Government estimated a cost of $30 million to change labels for about 300 cigarette varieties. Most Canadian cigarettes are sold in two sizes and about 20 percent are also sold in flip top packages.[37] 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; 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.

e. *Self-service ban.* The proposed regulation would ban the use of self-service displays by requiring vendors to physically provide the regulated tobacco product to all purchasers. An estimated one-time cost of $22.5 million for effecting this change is derived below in section VIII.D.3. Although any new behind-the-counter shelving or locking cases must be located at the retail level, the prevailing business practice is for tobacco manufacturers' sales representatives to assist and even pay for this equipment.[38] Since FDA cannot know if manufacturers would continue this practice, this study assumes that manufacturers and retailers would share these costs equally by apportioning $11 million to each.

f. *Educational program.* The proposed regulation requires manufacturers of both cigarettes and smokeless tobacco products to fund consumer educational programs. FDA estimates that the requirements of this provision equate to a total cost of about $150 million annually for cigarette and smokeless tobacco product manufacturers.

g. *Restricted advertising/promotion.* The determination of the industry costs attributable to the proposed restrictions on tobacco product advertising is complex. While there is no doubt that individual companies 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. FDA does not accept industry's stated views on this issue, particularly with respect to the impact of advertising and promotional programs on youth. Nevertheless, FDA does not consider it appropriate to count as a societal cost the *voluntary* reduction in the consumption of tobacco products that would result from reduced advertising outlays. Although industry sales would fall, consumer dollars no longer used on tobacco products would be redirected to other more highly valued areas. Thus, for the most part, the resulting reduction in industry sales and profits would not be societal costs, but rather distributional effects, as discussed below under that heading. Moreover, as shown in that section, any short-term frictional or relocation impacts would be significantly moderated by the gradual phase-in of the economic effects. As there are different views regarding the appropriate methodology for assessing these advertising consequences, FDA asks for public comment on the correct approach.

h. *Producer surplus.* Although voluntary decreases in the sale of tobacco products would not impose substantial long-term societal costs, mandatory restraints on the access of consumers to desired products would imply economic costs. Economists typically measure 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 from Cummings et al. indicate that youngsters under the age of 18 consume 318 million packs of cigarettes per year, leading to industry profits of $117 million.[39] On the assumption that the proposed regulation would reduce teenage smoking by one-half, these profits would fall by about $58 million. However, since most of this profit is derived from illegal sales to youths, FDA has not counted this figure as a societal cost.

2. Outcome-Based Activities

FDA plans to propose additional requirements that would become effective only if the rule's outcome-based objectives are not met. To avoid these consequences, manufacturers may decide it is in their best interest to initiate or to increase their support of programs that discourage underage purchasing of tobacco products.

Alternative activities. Tobacco manufacturers may decide to actively support the achievement of the

''Healthy People 2000'' goals in order to avoid the need to comply with any optional provisions. For example, the industry could work to reduce the prevalence of underage tobacco use by contributing either financial or staffing resources to local civic or public programs, by developing and disseminating effective educational materials, or by establishing its own surveillance programs. FDA does not know which of these activities, if any, the industry might support; but the cost of such activities could be substantially less than the cost of complying with an optional provision of the outcome-based objective. For example, if the cost of a retail surveillance visit were $25, an industry program to monitor selling procedures in all 700,000 retail outlets twice a year would cost $35 million. SAMHSA estimated that the establishment and implementation of effective State-administered retail surveillance systems would cost about $30 million annually.

3. Costs to Retail Outlets

SAMHSA recognized that retail businesses would bear new costs for duties such as training staff, posting signs, and checking for compliance. It believed the largest component of these costs would be for the ''time spent in instructing sales clerks that they must avoid selling to minors and in dealing with occasional lapses.'' SAMHSA projected these costs at roughly $100 per year per establishment, or $100 million for an estimated 1 million establishments. SAMHSA noted, however, that ''effective training may already be in place in a third or more of all businesses.''[40] FDA has developed its own estimates of the costs likely to be incurred by the retail sector for additional employee time or other expenses and finds that they do not differ substantially from the SAMHSA estimate.

Training. SAMHSA reports that the average retail store has 12 employees, which implies a total of 8.4 million (12 × 700,000) affected retail employees. Assuming retail employee compensation of $15,410 annually,[41] providing instructions for 15 minutes per employee amounts to about $16 million per year. Adopting the SAMHSA finding that one-third of the retail outlets are already conducting some training lowers this cost to $10 million.

I.D. checks. Retail establishments would bear additional costs if they must check the identification of purchasers, because many establishments do not currently conduct such checks. The burden imposed would vary with the flow of business in any particular outlet. In some instances, the additional workload might compel the hiring of additional employees. At other times, the age verification would cause little productive time loss, or the establishment would shift some of the cost to customers through an increase in the average amount of time customers wait in line to make purchases. For this analysis, FDA has assumed that the affected establishments would bear all of the costs imposed by this requirement. Based on data from the 1994 Surgeon General's Report[42] on the tobacco consumption of cigarette smokers 5 to 6 years after high school, and national data on the annual per capita consumption of smokeless tobacco,[43] FDA estimates that consumers aged 18 to 26 purchase 2.4 billion tobacco products a year. Since FDA does not know how many of these purchases are for multiple items, the agency has conservatively assumed that the number of consumer transactions is about 2.2 billion. The time needed to conduct identification checks for these transactions would vary, but if 75 percent of the transactions were extended by 10 seconds and the average value of employee time was $15,410,[44] the added time cost would amount to 2.1 cents per purchase, or $35 million per year. Assuming current compliance at 20 percent reduces the incremental costs to $28 million. Tobacco transactions involving underage smokers were excluded from this calculation, based on the assumption that they would decline dramatically once compliance with the regulation was achieved.

Self-service ban. The proposed ban on self-service displays would affect a number of retail stores, although shoplifting concerns have already caused many establishments to place tobacco products in areas not directly accessible to customers. Retailers that have discontinued self-service displays have typically modified their stores by either: (1) Placing tobacco products on shelving located directly behind or near all checkout lines, (2) placing tobacco products behind one or two checkout lines only, 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 typically 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 determines 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.[45]

Certain retail outlets that sell large volumes of cigarettes by the carton would bear the greatest burden from this proposed provision, because the physical size of cartons may preclude their placement in close proximity to a cashier. Most cigarette cartons are sold in the 56,000 largest retail outlets, including 23,000 supermarkets,[46] 12,800 general merchandise outlets, and 20,200 chain drug stores.[47] If three-quarters of these outlets spent an average of $300 each for labor and materials to accomplish this relocation, the one-time cost would be about $12.6 million. The remaining 645,000 smaller retail establishments would typically need to do much less, since small packages can almost always be stored adjacent to or directly above a cashier. Most outlets already keep the majority of cigarette packs in such restricted areas, although most smokeless tobacco products may have to be relocated. FDA has assumed that 50 percent of these smaller outlets would take 2 hours, and 25 percent would take 4 hours to complete any necessary relocation of stock. At an estimated $7.70 labor cost per hour, this adds a one-time cost of $9.9 million, for a total of about $22.5 million. As noted above under the ''Cost to Manufacturers'' section, manufacturers often pay partially or even completely for behind-the-counter shelving or locking cases for use in retail establishments. Thus, FDA assumed that this $22.5 million one-time cost would be shared equally by manufacturers and retail outlets.

The required reconfiguration of tobacco displays may also impose added labor costs for each purchase transaction, especially for those outlets that adopt signaling-type systems or that move inventory to areas located further from employee workstations. To estimate any additional labor costs, FDA has assumed 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 of cigarettes. Based on an estimated 900 million retail transactions for cigarette cartons and an annual employee compensation of $15,410,[48] this added labor cost projects to about $14 million per year. This estimate understates actual costs if the required changes have a greater than expected adverse affect on labor productivity, but overstates actual costs if current compliance exceeds 25

percent. Also, some of the added costs would be offset by reductions in product pilferage. Since FDA does not know the relative magnitude of these potentially offsetting factors, the agency has retained the $14 million figure as its best preliminary estimate of the labor costs that would be imposed by the self-service ban.

In total, FDA projects that the retail sector would incur one-time costs of about $11 million and annual costs of about $52 million. As shown above in Table 2, the sum of the one-time costs imposed on the manufacturing and retail sectors for the initial provisions would range from about $26 to $39 million, whereas the total annual costs would be about $227 million. For these provisions, the sum of these annualized one-time costs (15 years at 3 percent discount rate) and annual operating costs yield about $230 million per year (also about $230 million at 7 percent discount rate).

4. Costs to Consumers

a. *Advertising restrictions.* Advertising restrictions may impose costs on society if they disrupt the dissemination of relevant information to consumers. According to the Bureau of Economics of the FTC, 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.[49]

FDA has considered each of these issues in turn. While agreeing that certain forms of advertising offer substantial benefits to consumers, the agency nevertheless believes that the proposed tobacco product advertising restrictions would impose few significant societal costs. As discussed in the preamble above, the proposed regulation does not prohibit factual, written advertising. Thus, the proposed rule would not impede the dissemination of important information to consumers. While 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. The implications of FTC's second point, which addresses the effect of advertising restrictions on market power and prices, is less obvious, as various empirical studies have reached conflicting conclusions. Nevertheless, from FDA's perspective, even if advertising restrictions led to higher prices, this result would discourage tobacco consumption and thereby enhance the public health. 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 would 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.'' [50]

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.[51] 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. The proposed rule would allow 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 dramatically over the years, currently constituting only about 5 percent of the industry's total advertising and promotion budget.) Conversely, the extraordinary growth in industry advertising and promotion has been 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.

b. *Consumer surplus.* 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. Since it reflects the difference between the price the consumer would be willing to pay and the actual market price, it is used by economists to measure welfare losses imposed by consumer product bans. However, FDA's proposed rule imposes no access restrictions on adults, who would be free to consume tobacco products if they so desired. Thus, FDA has not included any value for lost consumer surplus in its estimate of societal costs.

c. *Inconvenience.* Some adult consumers would be inconvenienced by the unavailability of cigarette vending machines. FDA believes that over time, most smokers would adjust their purchasing patterns to reflect this circumstance. However, the agency has not attempted to quantify the degree of this disutility and asks public comment on its potential cost.

E. Distribution and Transitional Effects

The proposed regulation would impose a variety of sector-specific distributive effects. Those sectors affiliated with tobacco and tobacco products would lose sales revenues and these losses would grow over time. On the other hand, nontobacco related industries would gain sales, because dollars not spent on tobacco would be spent on other commodities.

1. Tobacco Industry

For its calculation of regulatory benefits, FDA estimated that implementation of the proposed regulation would reduce the cigarette consumption of underage smokers by one-half. As discussed above, based on data presented in Cummings et al., FDA estimates that teenage smokers under the age of 18 consumed about 318 million packs of cigarettes in 1991. If the proposed regulation cuts these sales by one-half, the resulting annual drop in industry revenue would be $143 million (assuming manufacturer share of 50 percent of retail price, or 90 cents per pack.) 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,

increasing the number of adult nonsmokers by 250,000 per year. Since each adult smoker consumes about 500 packs per year, lost sales revenues would amount to an additional $113 million per year.

In sum, FDA estimates that annual cigarette revenues would decline slowly over time; falling by $143 million in the first year (while only teenagers are affected), by $593 million in the fifth year, and by $1.2 billion in the tenth year. The U.S. Bureau of the Census reports the value of 1992 cigarette shipments at $28.8 billion. Thus, this regulation is projected to reduce revenues from cigarette sales by only 0.5 percent in the first year, 2.1 percent in the fifth year, and 4.0 percent in the tenth year following implementation. While these reductions are significant, the gradual phasing of the impacts would significantly dissipate any associated economic disruption. For example, data from a 1992 report on the contribution of the tobacco industry to the U.S. economy prepared by Price Waterhouse for the Tobacco Institute [52] implies that, over a 10-year period, a 4 percent reduction in sales would result in the displacement of about 1,000 jobs annually among warehousers, manufacturers, tobacco growers and wholesalers.

2. Vending Machine Operators

The proposed regulation would prohibit all vending machine sales of regulated tobacco products. In recent years, cigarette vending sales have dropped precipitously, due to numerous restrictive State and local ordinances. FDA does not have a definitive estimate of the intensity of this decline, but is aware of two industry surveys that confirm its importance. The Vending Times 48th Annual Census of the Industry [53] shows a 6 percent drop in the number of cigarette vending machines from 1992 to 1993, but a 39 percent decline since 1983. The total number of packs sold reportedly dropped almost 60 percent over this decade, from 2.7 billion to 1.1 billion. A second survey, the ''1994 State of the Industry Report,'' *Automatic Merchandiser* (The Monthly Management Magazine for Professional Vending and OCS Operators) [54] found an even steeper recent decline; reporting that the projected number of cigarette vending machines fell from 250,425 in 1992 to 181,755 in 1993, a drop of over 27 percent. That survey shows operator revenues from cigarettes falling from $835 million in 1992 to $624 million in 1993, down 25 percent. While the impact of this one product area is significant for the vending operators, the report found that this sector currently generates about $18 billion in total sales volume and explains that ''Cigarettes, which have been on the downslide for several years, are fortunately only a small percentage (3.4 percent in 1993) of the total pie, thus the drop did not hurt total revenues significantly.'' The proposed prohibition of vending sales would require these firms to develop new markets to replace these sales revenues.

3. Advertising Sector

In their annual reports to the FTC, manufacturers of cigarettes and smokeless tobacco reported 1993 advertising and promotional/marketing expenditures of $6.0 billion and $119 million, respectively. Approximately $1.9 billion (31 percent) of these outlays would be significantly impacted by the proposed rule as they are primarily directed to consumer advertising and promotion. Of the remaining outlays, about $2.6 billion (43 percent) go 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 affect on these expenditures would be much more modest.

FDA cannot reasonably forecast the future marketing strategies of tobacco manufacturers, but can foresee some fall in the approximately $1.0 billion worth of current advertising that would be affected by the proposed ''text only'' requirement. (The ''text only'' restriction does not apply to publications where children comprise less than 15 percent of the readership or are fewer than 2 million.) The impact of these restrictions on the various advertising media and agencies is difficult to determine. For example, in response to Canada's recently imposed advertising ban, that country's billboard industry ''quickly replaced $20 million in lost cigarette revenues with ads for food, soap, toothpaste and beer.'' [55] ''In 1971, network TV ad revenue dropped 6 percent without cigarette advertising * * *, but by 1972 network TV * * * had recouped its ad base.'' [56] Current advertising revenues affected by the restrictions on billboard advertising near schools and playgrounds are also likely to be replaced by advertising revenues for other products. Nevertheless, if the tobacco industry were to cut its advertising outlays by one-half of the ''text only'' categories, this dollar figure amounts to less than one-half of 1 percent of the reported $131.3 billion spent on U.S. media advertising in 1992.[57] FDA is also aware that prohibiting the distribution of nontobacco specialty items bearing the name or logo of tobacco products would affect a substantial number of specialty manufacturers. In comments to the FTC,[58] the Specialty Advertising Association International noted that it ''represents 4,400 firms that manufacture or sell utilitarian objects imprinted with advertising * * * predominantly small businesses.'' To the extent that these products include only a corporate name without brand association, they could remain marketable. However, 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.

4. Retail Outlets

In addition to incurring the direct costs of compliance described above, some retail establishments may receive smaller promotional allowances (slotting fees) from manufacturers, following the prohibition of self-service displays and advertising imagery. Industry promotional allowances totaled about $1.6 billion in 1993, or $2,600 per outlet if spread evenly among the estimated 600,000 retail outlets currently selling tobacco products over-the-counter. It is likely that, notwithstanding these restrictions, manufacturers would continue to compete vigorously for the best display space available, so that few fees would be discontinued. For example, a recent Canadian study [59] suggests 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.'' 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.'' [60] Nevertheless, the agency is aware of at least one report indicating the ''[l]oss of industry-paid slotting fees to some retail merchants because of the removal of self-service promotional tobacco displays, racks and kiosks.'' [61]

5. Other Private Sectors

The Tobacco Institute's Price Waterhouse report [62] purports to measure the induced effect on the national economy of spending by the tobacco core and supplier sector employees and their families. It calculates that induced or multiplier effects result in 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, other analysts conclude that such ratios should not be used to assess longer term national economic impacts, because resources diverted from the production of tobacco would be reallocated to the production of other goods and services. ''If the focus is longer term, involving a period of, say, more than two 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.'' [63] Furthermore, over the long term, regional impacts of the regulation would be similarly diffused.

6. State Tax Revenues

The proposed rule would decrease State tobacco tax revenues as fewer youths become addicted to tobacco products. These excise tax losses would increase as more of these youths become non-smoking adults. According to the Tobacco Institute, State cigarette excise taxes totaled $6.2 billion for the year ending June 30, 1993.[64] Since State excise taxes on other tobacco products (including smokeless tobacco) were $226 million, FDA assumes that the total State excise taxes on tobacco products affected by this proposal are about $6.3 billion annually. As described above, FDA estimated that compliance with this proposal would reduce cigarette sales by a gradually increasing rate over time, falling by 0.5 percent in the first year, 2.1 percent in the fifth year, and 4 percent in the tenth year. Thus, the proposed rule would decrease State excise taxes on affected tobacco products by from $31 million in the first year to $252 million in the tenth year. Since tobacco taxes represented less than 1 percent of total State tax revenues in 1992,[65] even the estimated tenth year impact measures only 0.03 percent of all State tax revenues. Nonetheless, if necessary, State governments could raise tobacco product excise rates to offset these revenue losses. The issue is complex, however, because a full evaluation of the fiscal consequences of this proposal must consider a variety of public health impacts. For example, state Medicaid programs would benefit from reduced medical care expenditures, but they may also need to finance nursing home expenditures that climb with increased life expectancy.

F. Small Business Impacts

The Regulatory Flexibility Act requires agencies to determine whether the effects of regulatory options would impose a significant impact on a substantial number of small entities and to consider those options which would minimize these impacts. Although most manufacturers of tobacco products are large corporations, the distribution of the product involves numerous small enterprises that would be affected by the proposed rule. For example, as explained earlier, the proposal would initially reduce the revenues of vending machine operators by at least 3.4 percent and almost three quarters of all vending machine operators are small businesses, having annual sales of less than $1 million.[66] Further, the proposed rule would affect the distribution of specialty items showing a tobacco product logo or name. According to the Specialty Advertising Association International, 80 percent of the manufacturers and 95 percent of the distributors in this industry have annual sales below $2 million. While the market place in which these firms compete traditionally demands a quick response to constantly shifting market trends, this rule would have at least short-term impacts on many of these firms.

The proposed regulation would also affect numerous retail establishments, primarily convenience stores, but also small grocery stores, small general merchandise stores and small gasoline stations. Table 4 displays the relative share of the tobacco market for major types of tobacco-dispensing outlets in 1987. As shown, food stores and service stations received almost 75 percent of all tobacco sales revenue and tobacco products comprised 5 to 6 percent of the total sales of many of these establishments. The great majority of these retail outlets are small businesses.

TABLE 4.—SALES OF TOBACCO PRODUCTS AS A PERCENTAGE OF TOTAL SALES—1987

[Establishments with Payroll Only]

Establishment type	Tobacco sales		% of total sales	
	($ mils)	(%)	Establishments handling tobacco	All establishments
All	23,231	100	5.0	1.6
Food Stores	13,057	56	5.0	4.3
Service Stations	4,280	18	6.5	4.2
Drug and Proprietary	2,152	9	5.1	4.0
General Merchandise	1,470	6	2.1	0.8
Liquor Stores	706	3	7.2	3.8
Eating and Drinking	182	1	2.4	0.1

Source: 1987 Census of Retail Trade, Merchandise Line Sales.

To illustrate the effects of this proposal on a typical small retail store, FDA separately estimated the likely compliance costs for an average-sized convenience store that sells 300 packages of tobacco products daily, of which about 50 might be purchased by young adults aged 18 to 26. Based on the cost assumptions described above, the outlet's first year costs would total about $320, with the largest single cost, $285, 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 $35. This estimate does not account for the possible reduction in promotional allowances, although these allowances might fall following a ban on self-service marketing. Alternatively, as noted above, manufacturers would continue to compete for the best shelf space for their products, perhaps even

more so if they find that ''text only'' advertising erodes the stimulus effect of point-of-purchase advertising. Thus, the proposed advertising restrictions could enhance the share of the industry's advertising and promotion budget that is directed towards promotional allowances in retail outlets.

G. Alternatives

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 was 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. It is possible, however, that the industry might implement certain features of this approach in order to avoid the optional performance-based provision that would become effective if the ''Healthy People 2000'' goals were not met.

A second alternative considered by the agency was to require package inserts containing educational information in cigarette and smokeless tobacco products. FDA had incomplete date to estimate the additional cost of this requirement, but based on comments submitted by industry in response to a Canadian proposal, preliminarily projected one-time costs of about $490 million and annual operating costs of about $54 million. FDA did not select this alternative as the agency was not certain that the benefits of this provision would justify the large 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, where they can easily purchase tobacco products for classmates. This alternative would have added costs of about $34 million annually, mostly due to lost producer profits. The proposed regulation restricts access to regulated tobacco products for persons under the age of 18, because most adult smokers have already become regular smokers by the age of 18, and because that age limit is already consistent with most State and local laws.

The agency also considered restricting rather than prohibiting sales from vending machines. However, as stated in the preamble above, studies indicated that measures such as placing locks on vending machines or restricting their placement failed to prevent young people from purchasing cigarettes from vending machines.

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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 897

Cigarettes, Smokeless tobacco, Labeling, Advertising, Sale and Distribution, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 801, 803, and 804 be amended and that a new part 897 be added as follows:

Note: The part number for part 897 as proposed at 60 FR 32417 will be changed by the agency in a future issue of the **Federal Register**.

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 801.61 is amended by adding a new paragraph (d) to read as follows:

§ 801.61 Statement of identity.

* * * * *

(d) This provision does not apply to cigarettes or to smokeless tobacco products as defined in part 897 of this chapter.

PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: Secs. 502, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 371, 374).

4. Section 803.1 is amended by adding a new paragraph (d) to read as follows:

§ 803.1 Scope.

* * * * *

(d) This part does not apply to cigarettes or to smokeless tobacco products as defined in part 897 of this chapter.

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 804.1 is amended by adding a new paragraph (c) to read as follows:

§ 804.1 Scope.

* * * * *

(c) This part does not apply to distributors of cigarettes or smokeless tobacco products as defined in part 897 of this chapter.

7. New part 897 is added to read as follows:

PART 897—CIGARETTES AND SMOKELESS TOBACCO PRODUCTS

Subpart A—General Provisions

Sec.
897.1 Scope.
897.2 Purpose.
897.3 Definitions

Subpart B—Sale and Distribution to Persons Under 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 and Educational Programs

897.24 Established names for cigarettes and smokeless tobacco products.
897.29 Educational programs concerning cigarettes and smokeless tobacco products.

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 non-tobacco items and services, contests and games of chance and sponsorship of events.
897.36 False or misleading labeling and advertising.

Subpart E—Miscellaneous Requirements

897.40 Records and reports.
897.42 Preemption of State and local requirements and requests for advisory opinions.
897.44 Additional regulatory measures.

Authority: Secs. 502, 510, 520, 701, 704 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 352, 360, 360j, 371, 374).

Subpart A—General Provisions

§ 897.1 Scope.

(a) This 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 device provisions of the Federal Food, Drug, and Cosmetic Act.

(b) 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 conditions for the sale, distribution, and use of cigarettes and smokeless tobacco products in order to:

(a) Reduce 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

(b) Provide important information regarding the use of these products to users and potential users.

§ 897.3 Definitions.

(a) *Cigarette* means any product (including components, accessories, or parts) which contains or delivers 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;

(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; or

(3) Any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco described by paragraphs (a)(1) or (a)(2) of this section) and as to which 1,000 units weigh not more than 3 pounds.

(b) *Cigarett tobacco* means any 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 marketing of cigarettes or smokeless tobacco products, whether domestic or imported, at any point from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the cigarettes or smokeless tobacco products, or the package of the cigarettes or smokeless tobacco products.

(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. The term does not include any person who only distributes finished cigarettes or smokeless tobacco products.

(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 products 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 products for personal consumption.

(h) *Retailer* means any person who sells or distributes cigarettes or smokeless tobacco products to individuals for personal consumption.

(i) *Smokeless tobacco* means any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity.

Subpart B—Sale and Distribution to Persons Under 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 products 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:

(a) 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 under this part;

(b) Through its representatives, when they visit any point of sale in their normal course of business, visually inspect and ensure that the products are labeled, advertised, and distributed in accordance with 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 products to any person (other than a distributor or retailer) comply with the following requirements:

(a) The retailer or an employee of the retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing or intending to purchase the product is younger than 18 years of age;

(b) The cigarette or smokeless tobacco product shall be provided to the person purchasing the product by the retailer or by an employee of the retailer, without the assistance of any electronic or mechanical device (such as a vending machine or remove-operated machine); and

(c) The retailer or an employee of the retailer shall not break or otherwise open any cigarette package or smokeless tobacco product to sell or distribute individual cigarettes or number of cigarettes or any quantity of cigarette tobacco or of a smokeless tobacco product that is smaller than the quantity in the unopened product.

§ 897.16 Conditions of manufacture, sale, and distribution.

(a) *Restriction on product names.* A manufacturer may 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 tobacco products on which a trade or brand name of a nontobacco product was in use on January 1, 1995.

(b) *Minimum cigarette package size.* No manufacturer, distributor, or retailer shall sell or cause to be sold, 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.* Cigarettes and smokeless tobacco products may be sold only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include, but are not limited, vending machines, self-service displays, mail-order sales, and mail-order redemption of coupons.

(d) *Free samples.* Manufacturers, distributors, and retailers may not distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco products.

Subpart C—Labels and Educational Programs

§ 897.24 Established names for cigarettes and smokeless tobacco products.

Each cigarette or smokeless tobacco product package, carton, box, or container of any kind that is offered for sale, sold, or otherwise distributed shall bear 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.

§ 897.29 Educational programs concerning cigarettes and smokeless tobacco products.

(a) Each manufacturer shall establish and maintain an effective national public educational program to discourage persons under 18 years of age from using cigarettes and smokeless tobacco products. The major portion of this program must appear on television.

(b) Each manufacturer shall allocate an amount for the educational program that is proportionate to its share of the total advertising and promotional expenditures for the most recent year reported by all manufacturers to the Federal Trade Commission pursuant to the Federal Cigarette Labeling and Advertising Act or the Comprehensive Smokeless Tobacco Health Education Act. The Total amount to be spent shall be $150,000,000 per year.

Subpart D—Labeling and Advertising

§ 897.30 Scope of permissible forms of labeling and advertising.

(a) This subpart does not apply to cigarette or smokeless tobacco product package labels. A manufacturer, distributor, or retailer may distribute or cause to be distributed:

(1) Advertising which bears the cigarette or smokeless tobacco product brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification only in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, an placards in accordance with paragraph (b) of this section; and in nonpoint of sale promotional material (including direct mail); and

(2) Labeling which bears the cigarette or smokeless tobacco product brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification only in point of sale promotional material; audio and/or video formats delivered at a point of sale; and on entries and teams in sponsored events.

(b) No outdoor advertising, including but not limited to billboards, posters, or placards, may be placed within 1,000 feet of any playground, elementary school or secondary school.

§ 897.32 Format and content requirements for labeling and advertising.

(a) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, labeling and advertising permitted under § 897.30 shall use only black text on a white background. This section shall not apply to advertising appearing in adult newspapers, magazines, periodicals, or other publications (whether periodic or limited distribution). For the purposes of this section, an adult newspaper, magazine, periodical, or publication, as measured by competent and reliable survey evidence, is any newspaper, magazine, periodical, or publication:

(1) Whose readers aged 18 years or older constitute 85 percent or more of the total readership, and

(2) That is read by fewer than 2 million persons under age 18.

(b) Each manufacturer, distributor, and retailer 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 of the Federal Food, Drug, and Cosmetic Act, the product's established name and a statement of its intended use as follows: ''Cigarettes—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''.

(c) Each manufacturer, distributor, and retailer of cigarettes shall include, in all advertising, but not labeling, permitted under § 897.30(a), a brief statement, such as the one specified below, printed in black text on a white background:

About one out of three kids who become smokers will die from their smoking.

(d) The statement required under paragraph (c) of this section shall be readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning.

§ 897.34 Sale and distribution of non-tobacco items and services, contests and games of chance and sponsorship of events.

(a) No manufacturer, distributor, or retailer shall market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item or service (other than cigarettes or smokeless tobacco products), 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 similar or identifiable to those used for cigarettes or smokeless tobacco products.

(b) No manufacturer, distributor, or retailer shall offer or cause to be offered any gift or item, or the right to participate in any contest, lottery, or

game of chance to any person purchasing cigarettes or smokeless tobacco products 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 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 product identification similar or identical to those used for cigarettes or smokeless tobacco products. A manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event in the name of the corporation which manufactures the tobacco product, provided that both the registered corporate name and the corporation were in existence prior to January 1, 1995.

§ 897.36 False or misleading labeling and advertising.

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 for the product.

Subpart E—Miscellaneous Requirements

§ 897.40 Records and reports.

(a) Each manufacturer shall, on an annual basis, submit:

(1) Copies of all labels, except that a manufacturer may submit a representative sample of such labels if the labels will be similar for multiple packages or products; and

(2) Copies of all labeling and a representative sampling of advertising.

(b) The manufacturer shall send this information to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20852. The information should be plainly marked as ''Labels'', or ''Labeling and Advertising'', whichever is appropriate.

(c) Manufacturers, distributors, and retailers shall, upon the presentation by an FDA representative of official credentials, 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 the FDA representative for purposes of inspection, review, copying, or any other use related to the enforcement of the Federal Food, Drug, and Cosmetic Act and this part.

§ 897.42 Preemption of State and local requirements and requests for advisory opinions.

(a) *General.* In addition to the requirements imposed under this part, manufacturers, distributors, and retailers shall comply with any more stringent State or local requirements relating to the sale, distribution, labeling, advertising, or use of cigarettes and smokeless tobacco products, provided that those State or local requirements do not conflict with the requirements under this part. These more stringent State or local requirements are not preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)).

(b) *Requests for advisory opinions.* (1) Any State or political subdivision of a State may request an advisory opinion from the Food and Drug Administration with respect to the preemptive effect of this part on any particular State or local requirement. The request for an advisory opinion should comply with the requirements at § 10.85 of this chapter. The agency may, in its discretion and after consulting the State or political subdivision, treat a request for an advisory opinion as an application for exemption from preemption under § 808.20 of this chapter.

(2) The Commissioner, on his or her own initiative, may issue an advisory opinion relating to a State or local requirement if he or she finds that:

(i) Section 521(a) of the Federal Food, Drug, and Cosmetic Act does not preempt a State or local requirement for which an application for exemption from preemption has been submitted under § 808.20 of this chapter because the State or local requirement is equal to or substantially equivalent to a requirement under the Federal Food, Drug, and Cosmetic Act, is not a requirement within the meaning of section 521(a) of the Federal Food, Drug, and Cosmetic Act, or is more stringent than and does not conflict with the requirements under this part, or

(ii) Issuance of an advisory opinion is in the public interest.

§ 897.44 Additional regulatory measures.

Seven years after the publication date of any final rule based on the proposed rule published in the **Federal Register** on (date of publication of the final rule), if the percentage of people under the age of 18 years who smoke cigarettes has not decreased by 50 percent since 1994 (as determined by an objective, scientifically valid, and generally accepted program), and/or if the percentage of males under the age of 18 years who use smokeless tobacco products has not decreased by 50 percent since 1994 (as determined by an objective, scientifically valid, and generally accepted program), and the percentage of females under the age of 18 years who use smokeless tobacco products has increased since 1994 (as determined by an objective, scientifically valid, and generally accepted program), then the agency shall take additional measures to help achieve the reduction in the use of tobacco products by children and adolescents described above.

Dated: August 9, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 95–20051 Filed 8–10–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0253J]

Analysis Regarding The Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; analysis regarding agency jurisdiction.

SUMMARY: The Food and Drug Administration (FDA) is publishing 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,'' and announcing the availability of appendices to this document. FDA has conducted an extensive investigation and has engaged in comprehensive analysis regarding the agency's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. The results of that inquiry and analysis support a finding at this 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. Nonetheless, because the agency recognizes the unique importance of the jurisdictional issue as well as the factual justification for any proposed rule in this area, the agency invites comment on these matters. Comments submitted will receive full and serious consideration.

DATES: Written comments by November 9, 1995.

ADDRESSES: ''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'' and its appendices may be purchased from Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402, 202–783–3238. ''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'' and its appendices are available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380

SUPPLEMENTARY INFORMATION: The appendices referred to in the 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'' are available from GPO (address above).

Elsewhere in this issue of the **Federal Register**, the agency is publishing a proposed regulation of nicotine-containing cigarettes and smokeless tobacco products. The agency recognizes the unique importance of the jurisdictional issue underlying this regulation as well as the factual justification for any proposed rule in this area. The agency invites comments on these matters. Comments submitted will receive full and serious consideration.

The text of ''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'' follows:

BILLING CODE 4160–01–F

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

U. S. Food and Drug Administration
Department of Health and Human Services
August, 1995

PREFACE

The Food and Drug Administration (FDA) has conducted an extensive investigation and has engaged in comprehensive legal analysis regarding the agency's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. The results of that inquiry and analysis support a finding at this time that nicotine in cigarettes and smokeless tobacco products is a drug, and that these products are drug delivery devices within the meaning of the Food, Drug, and Cosmetic Act. Nonetheless, because the agency recognizes the unique importance of the jurisdictional issue as well as the factual justification for any proposed rule in this area, the agency invites comment on these matters. Comments submitted will receive full and serious consideration.

Elsewhere in the same issue of the Federal Register in which this document is published, the agency is issuing a proposed regulation of nicotine-containing cigarettes and smokeless tobacco products under the restricted device provisions of the Act. Comments should be sent to FDA's Dockets Management Branch and identified with the docket number 95N-0253J. Comments should be submitted by the date identified in the Federal Register.

Traditionally, the FDA has initiated enforcement actions in cases where the agency determines that a product is a drug or a delivery device. Because the agency has elected to embark on this initiative through rulemaking, no enforcement action will be brought pending completion of that process.

SUMMARY TABLE OF CONTENTS

INTRODUCTION

PART ONE: LEGAL ANALYSIS OF JURISDICTION OVER TOBACCO PRODUCTS

I. **CIGARETTES AND SMOKELESS TOBACCO PRODUCTS "AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY" BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION.**

II. **TOBACCO MANUFACTURERS "INTEND" THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS.**

III. **NICOTINE-CONTAINING CIGARETTES AND SMOKELESS TOBACCO PRODUCTS ARE DRUG DELIVERY SYSTEMS THAT ARE APPROPRIATELY REGULATED AS DEVICES**

PART TWO: FINDINGS

EVIDENCE THAT CIGARETTES AND SMOKELESS TOBACCO ARE INTENDED TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY

I. **NICOTINE HAS DRUG EFFECTS ON THE BODY**

II. **STATEMENTS, RESEARCH, AND ACTIONS BY TOBACCO COMPANIES**

PART THREE: REGULATORY OBJECTIVES

APPENDICES

DETAILED TABLE OF CONTENTS

INTRODUCTION vi

PART ONE: LEGAL ANALYSIS OF JURISDICTION OVER TOBACCO PRODUCTS 1

INTRODUCTION AND SUMMARY 2

I. CIGARETTES AND SMOKELESS TOBACCO PRODUCTS "AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY" BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION 6

II. TOBACCO MANUFACTURERS "INTEND" THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS 10
- A. OBJECTIVE INTENT IS THE APPROPRIATE STANDARD. 11
- B. THE EVIDENCE DEMONSTRATES INTENT TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY 21
  - 1. The Addictive, Psychoactive, and Other Pharmacological Effects of Nicotine Are Widely Known and Foreseeable by Any Reasonable Person in the Position of a Tobacco Manufacturer. 22
  - 2. Consumers Use Tobacco Products to Obtain the Pharmacological Effects of Nicotine and to Satisfy Their Addiction to Nicotine. 29
  - 3. Tobacco Manufacturers Know That Nicotine Has Pharmacological Effects and That Consumers Use Tobacco for Those Effects, and Have Acted to Facilitate That Use. 30

III. NICOTINE-CONTAINING CIGARETTES AND SMOKELESS TOBACCO PRODUCTS ARE DRUG DELIVERY SYSTEMS THAT ARE APPROPRIATELY REGULATED AS DEVICES. 60

CONCLUSION 65

APPENDIX TO LEGAL ANALYSIS 68

PART TWO: FINDINGS 71

I. NICOTINE HAS DRUG EFFECTS ON THE BODY 73
- A. NICOTINE HAS PHYSIOLOGICAL AND CENTRAL NERVOUS SYSTEM EFFECTS 74
- B. NICOTINE IS ADDICTIVE 78
  - 1. Major Public Health Groups and Leading Experts Concur 78
  - 2. Epidemiological Data Establishes That Tobacco Users Display the

Clinical Symptoms of Addiction 86
3. Laboratory Studies Establish That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Substances 94
4. Nicotine's Sensory Effects Are Secondary to its Psychoactive Effects 102
5. Other Factors Associated with Tobacco Use Are Secondary 106
C. MARKETED TOBACCO PRODUCTS DELIVER PHARMACOLOGICALLY ACTIVE DOSES OF NICOTINE 108
1. Amount of Nicotine Necessary to Produce a Physiological Response in the Central Nervous System 108
2. Nicotine Delivery From Currently Marketed Tobacco Products ... 110
D. CONSUMERS USE TOBACCO PRODUCTS FOR DRUG EFFECTS ... 115
1. To Satisfy Addiction 115
2. To Affect Mood and Control Weight 118

II. STATEMENTS, RESEARCH, AND ACTIONS BY TOBACCO COMPANIES 121
A. INDUSTRY STATEMENTS ON NICOTINE'S DRUG EFFECTS 122
1. Statements That Nicotine's Drug Effects Are Essential to Tobacco Use 123
2. Statements Recognizing That Nicotine Is Addictive 143
3. Statements That Tobacco Products Are Nicotine Delivery Systems 156
B. INDUSTRY RESEARCH ON THE DRUG EFFECTS OF NICOTINE .. 160
1. Industry Research on Nicotine's Effects on the Brain 164
2. Industry Research on Nicotine Delivery to the Blood and Brain ... 174
3. Industry Research Establishes That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Drugs 179
C. INDUSTRY RESEARCH ON THE CONSUMER'S NEED FOR AN ADEQUATE DOSE OF NICOTINE 183
1. Industry Research on Importance of Supplying Sufficient Nicotine to Provide Consumer Acceptance and "Satisfaction" 183
2. Industry Research to Determine the Minimum and Maximum "Dose" of Nicotine Required by Consumers of Tobacco 188
3. Industry Research on How Consumers "Compensate" to Achieve an Adequate Dose of Nicotine 198
4. Industry Research and Knowledge of Tobacco Users' Inability to Quit 206
D. INDUSTRY PRODUCT DEVELOPMENT RESEARCH TO ENSURE AN ADEQUATE DOSE OF NICOTINE 213
1. Industry Emphasis on Nicotine in Product Development Research 213
2. Industry Research on Maintaining Adequate Nicotine Delivery When Lowering Tar 222

E. INDUSTRY MANIPULATION AND CONTROL OF NICOTINE DELIVERY IN MARKETED TOBACCO PRODUCTS 232
1. Industry Manipulation and Control of Nicotine in Cigarettes 232
2. Industry Manipulation and Control of Nicotine in Smokeless Tobacco 273
F. INDUSTRY ALTERNATIVE TOBACCO PRODUCTS 289
1. Industry Development of Nicotine Substitutes That Mimic Nicotine's Drug Effects 289
2. Industry Research on Acetaldehyde As a Reinforcer 298
3. Industry Development of Alternative Cigarettes That Deliver Nicotine 302
G. INDUSTRY KNOWLEDGE THAT NICOTINE'S SENSORY EFFECTS ARE SECONDARY TO ITS PHARMACOLOGICAL EFFECTS 311
H. INDUSTRY FAILURE TO REMOVE NICOTINE FROM TOBACCO DESPITE AVAILABLE TECHNOLOGY 318

PART THREE: REGULATORY OBJECTIVES 324

APPENDICES

1. Background on Nicotine Pharmacology
2. Corporate Relationship Between Brown and Williamson and British-American Tobacco Co.
3. FDA Letters to Tobacco Manufacturers
4. Bibliography of Industry-Funded Research
5. Marketing of Cigarettes and Smokeless Tobacco in the U.S.
6. Citizen Petitions and Submitted Comments
7. Statement by David A. 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, March 25, 1994
8. Statement by David A. 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, June 21, 1994
9. Remarks by David A. Kessler, M.D., Commissioner of Food and Drugs, The Samuel Rubin Program, the Columbia University School of Law, March 8, 1995
10. Additional Documents

INTRODUCTION

Part One of this document (Legal Analysis of Jurisdiction over Tobacco Products) consists of three main sections. Section I demonstrates that nicotine's addictive and other pharmacological properties are effects on the "structure or any function of the body" within the meaning of the Act's definition of a drug. Section II demonstrates that tobacco manufacturers intend their products to have these effects within the meaning of the Act because: these effects are widely known and foreseeable to the industry; most consumers use tobacco products to obtain these effects; and tobacco manufacturers understand that consumers use tobacco products to obtain nicotine's pharmacologic effects and design their products to be used for these effects. Section III explains why regulation of cigarettes and smokeless tobacco products as devices is most appropriate at this time.

Part Two of this document (Findings) consists of two main sections. Section I presents the scientific evidence of nicotine's addictive and other pharmacological effects. This section also explains how marketed tobacco products deliver pharmacologically active doses of nicotine, and how consumers use these products to obtain various drug effects. Section II describes the statements, extensive research, and other actions by tobacco manufacturers regarding nicotine's pharmacological effects. This section identifies the industry's numerous acknowledgments that nicotine in tobacco acts as a drug and is addictive, and the industry's extensive research on nicotine's drug effects on the body. Section II also describes the considerable industry research on supplying sufficient nicotine to provide "satisfaction," determining the minimum and maximum dose of nicotine required by consumers, and assessing how consumers "compensate" to achieve an adequate dose of

nicotine.

Section II provides further evidence that manufacturers intend to market these products for their pharmacological effects, including explanations of the industry's: product development research to ensure that their products deliver doses of nicotine adequate to achieve pharmacological effects; manipulation and control of nicotine in marketed products; development of nicotine substitutes and alternative products that provide nicotine's drug effects; knowledge that nicotine's sensory effects are secondary to its pharmacological effects; and failure to remove nicotine from tobacco despite the available technology to do so.

Part Three of this document (Regulatory Objectives) summarizes FDA's objectives in regulating cigarettes and smokeless tobacco products. This section explains why, despite the significant public health problem caused by cigarettes and smokeless tobacco products, it would not be appropriate to remove them from the market because approximately 40 million Americans are addicted to these products. The section summarizes the evidence that almost all tobacco use begins during childhood or adolescence, and that the prevalence of tobacco use by children and adolescents is increasing. Therefore, the goal of FDA's regulatory action will be to reduce tobacco use by children and teenagers and prevent future generations from becoming addicted to nicotine-containing tobacco products.

PART ONE: LEGAL ANALYSIS OF JURISDICTION OVER TOBACCO PRODUCTS

INTRODUCTION AND SUMMARY 2

I. CIGARETTES AND SMOKELESS TOBACCO PRODUCTS "AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY" BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION 6

II. TOBACCO MANUFACTURERS "INTEND" THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS 10
- A. OBJECTIVE INTENT IS THE APPROPRIATE STANDARD. 11
- B. THE EVIDENCE DEMONSTRATES INTENT TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY 21
  - 1. The Addictive, Psychoactive, and Other Pharmacological Effects of Nicotine Are Widely Known and Foreseeable by Any Reasonable Person in the Position of a Tobacco Manufacturer. 22
  - 2. Consumers Use Tobacco Products to Obtain the Pharmacological Effects of Nicotine and to Satisfy Their Addiction to Nicotine. 29
  - 3. Tobacco Manufacturers Know That Nicotine Has Pharmacological Effects and That Consumers Use Tobacco for Those Effects, and Have Acted to Facilitate That Use. 30
    - a. Tobacco Manufacturers' Studies and Statements Demonstrate Knowledge That Nicotine in Tobacco Is Addictive and Has Psychoactive Effects. 31
    - b. Tobacco Manufacturers Know That Consumers Use Tobacco Products for the Pharmacological Effects of Nicotine. 38
    - c. Tobacco Manufacturers Have Acted to Facilitate and Sustain the Consumer Use of Tobacco Products for Their Pharmacological Effects. 43
    - d. Smokeless Tobacco Manufacturers Manipulate Nicotine Delivery and Foster Graduation of Users From Low to High Nicotine Products. 56

III. NICOTINE-CONTAINING CIGARETTES AND SMOKELESS TOBACCO PRODUCTS ARE DRUG DELIVERY SYSTEMS THAT ARE APPROPRIATELY REGULATED AS DEVICES 60

CONCLUSION 65

APPENDIX TO LEGAL ANALYSIS 67

INTRODUCTION AND SUMMARY

FDA has jurisdiction over consumer products, including foods, drugs, medical devices, biologics, and cosmetics, under the Federal Food, Drug, and Cosmetic Act (FDCA or the Act), 21 U.S.C. §§ 301-394, a statute enacted to "safeguard the public health" and to "protect consumer welfare." H.R. Rep. No. 2139, 75th Cong. 3d Sess. 1-2 (1938).

The Act defines "drug" and "device" in a parallel manner. The term "drug" is defined, in relevant part, as an article "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" or "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(B), (C). The term "device" is defined as an instrument or other similar article "intended for use in the cure, mitigation, treatment or prevention of disease" or "intended to affect the structure or any function of the body." 21 U.S.C. § 321(h)(2), (3). These definitions are broad in scope and encompass a range of products wider than those ordinarily thought of as drugs or medical devices. Indeed, FDA has regulated such diverse, non-therapeutic products as narcotics without medical claims and tanning booths pursuant to these definitions. The question of whether a product is a drug or device is one that "the FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided [in the FDCA]." Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973); see id. at 652-54; CIBA Corp. v. Weinberger, 412 U.S. 640, 643-44 (1973); see also Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1377 (9th Cir. 1983).

Under the Act, FDA has jurisdiction over nicotine-containing cigarettes and smokeless tobacco products (hereafter "cigarettes and smokeless tobacco products") if they are intended to treat a disease or to affect the structure or any function of the body. As set forth in greater

detail below, the evidence now available to the agency demonstrates that cigarettes and smokeless tobacco products fall well within the definitions of drug and device.[1] It is well established that nicotine in tobacco is highly addictive, causes other psychoactive effects, such as relaxation and stimulation, and affects weight regulation. These responses to nicotine are effects on the structure or function of the body within the meaning of the Act.

The evidence before the agency also demonstrates that manufacturers intend to market and distribute products that affect the structure or function of the body within the meaning of the Act. Under the Act, Agency regulations, well-established case law, and longstanding Agency practice, discussed in detail below, "intended for use" and "intended to affect" can be demonstrated by evidence that: drug-like (pharmacological) effects in a large proportion of consumers are foreseeable by a reasonable manufacturer; consumers use the product predominantly and even nearly exclusively for its significant pharmacological effects; or manufacturers actually know that the product will be used for its significant pharmacological effects and have taken steps to encourage such use. In determining the intended use of a product, all relevant evidence may be considered, including the product's effect on consumers, consumer behavior and statements regarding the product, manufacturers' conduct and statements, results of scientific studies, and the other circumstances surrounding the distribution of the product.

In 1988, the U. S. Surgeon General issued a report formally recognizing that nicotine in cigarettes causes addiction. He had made a similar finding for smokeless tobacco products

[1] The 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 tobacco products. *See* LEGAL ANALYSIS § I.B.1., *infra,* p. 22.

in 1986. Today, nearly every major public health organization in this country and many experts who consult for the tobacco companies consider tobacco products containing nicotine to be addictive. In fact, recent major studies show that 75% to 90% of frequent smokers of tobacco are addicted. Thus, manufacturers of these products can reasonably be expected to foresee that their products are likely to lead to addiction in a large proportion of consumers.

This evidence also demonstrates that the vast majority of smokers and many smokeless tobacco consumers, because they are addicted to nicotine, use cigarettes and smokeless tobacco to satisfy nicotine dependence. Many of these consumers also use these products to affect mood and to control weight. Consumers use cigarettes predominantly and even "nearly exclusively" for their pharmacological effects.

Finally, internal tobacco industry documents demonstrate the industry's longstanding knowledge of and extensive research on the significant addictive and pharmacological effects of nicotine. Moreover, manufacturers of tobacco products have conducted product development research regarding the levels of nicotine necessary to produce pharmacological effects in tobacco users and also on methods of manipulating the amount of nicotine delivered by cigarettes. FDA's investigation has revealed that tobacco manufacturers actively control the amount and rate at which nicotine from marketed cigarettes and smokeless tobacco is delivered to consumers. Smokeless tobacco manufacturers both manipulate the amount of nicotine delivered by their products and promote the graduation of smokeless tobacco consumers from the lowest to the highest nicotine products, demonstrating an intention to facilitate nicotine dependence.

In summary, the evidence before the agency demonstrates that cigarettes and

smokeless tobacco products are intended to affect the structure and function of the body. Accordingly, the record[1a] before the agency demonstrates that cigarettes and smokeless tobacco products are drug delivery systems whose purpose is to deliver nicotine, a drug, and, hence, are devices under the Act. Given the current evidence, the nature of the products, and the nature of the regulatory framework, cigarettes and smokeless tobacco products should be regulated as devices under the Federal Food, Drug, and Cosmetic Act.

[1a]The phrase "record" as used throughout this document is not used as a term of art, but is used instead to refer to the accumulation of evidence gathered during FDA's investigation.

I. CIGARETTES AND SMOKELESS TOBACCO PRODUCTS "AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY" BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION

The definition of drug in the Food and Drugs Act of 1906 included only articles "intended to be used for the cure, mitigation, or prevention of disease." Pub. L. No. 59-384, 34 Stat. 768 § 6. Congress added section 201(g)(1)(C)[2] when it enacted the Federal Food, Drug, and Cosmetic Act of 1938 in order to expand the reach of the drug definition to encompass products that escaped regulation under the 1906 act. Section 201(g)(1)(C) and the parallel section 201(h)(3), governing devices, reach products that do not have therapeutic uses but have, or are promoted as having, significant pharmacological or physiological effects. As House Report 2139 explained:

> *[t]he definition of drug is expanded to include . . . articles other than food intended to affect the structure or any function of the body of man or other animals. These expansions are needed to give jurisdiction over a great number of drugs which are not amenable to control under the present law.*

H.R. Rep. No. 2139 at 3, reprinted in 6 Legislative History 300, 302 (emphasis added). The principal example given in the legislative history of products "intended to affect the structure or any function of the body" is weight management products. The "structure or any function" language was needed because obesity and extreme thinness were not considered diseases. Congress was concerned with both the egregious nature of the claims for some of these products as well as the health risks associated with their use. See 78 Cong. Rec. 8960 (73d Cong., 2d Sess., May 16, 1934) (prepared statement of Senator Copeland), reprinted in 2 Legislative History at 831.

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[2] Section 201 of the Federal Food, Drug, and Cosmetic Act is now codified at 21 U.S.C. § 321.

While Congress' primary focus in 1938 was on products intended for weight management, it adopted language that included all products that affect the structure or function of the body. This expansion of the drug definition was "needed to protect the consumer . . . against a multiplicity of abuses not subject to the [1906 act]." S. Rep. No. 646, 74th Cong. 1st Sess. 1, reprinted in 4 Legislative History at 93. As one court explained:

> *The legislative history of the 1938 Act discloses that . . . the law which broadened the drug definition was enacted in part, and perhaps in important part, to control fraudulent remedies for obesity and leanness. But it also discloses that the expansion of the drug definition was not aimed solely at these remedies. They were merely illustrative of a comprehensive class of preparations which were intended to affect the structure or function of the body to which the legislation was directed.*

United States v. Article Consisting of 36 Boxes . . . "Lineaway, Temporary Wrinkle Smoother", 284 F. Supp. 107, 110 (D. Del. 1968), aff'd, 415 F.2d 369 (3d Cir. 1969) (emphasis added) (citations omitted).

Consistent with the statutory language and Congress' intent to insure that FDA has the authority to regulate products with non-therapeutic, but pharmacological effects, FDA has interpreted the provisions to encompass products that intrinsically have pharmacological or physiological effects, even though they are not promoted for therapeutic purposes. Examples of such products are topical hormones, sunscreens, and tanning booths. See Appendix to Legal Analysis. Judicial constructions of sections 201(g)(1)(C) and 201(h)(3) are consistent with this interpretation. See, e.g., E.R. Squibb & Sons, Inc. v. Bowen, 870 F.2d 678, 683 (D.C. Cir. 1989) (summarizing cases); United States v. Undetermined Quantities of Cal-Ban 3000, 776 F. Supp. 249, 253 (E.D.N.C. 1991) ("[T]he term 'drug' should be interpreted broadly and not limited to only products which are commonly known as drugs.").

Courts have been careful to distinguish between remote physical effects which arguably might fall within the literal language of section 201(g)(1)(C) or section 201(h)(3) and significant effects on structure or function which clearly fall within the provisions' ambit. "[R]emote physical effect[s] on the body" are not covered by the structure or function provision. E.R. Squibb & Sons, 870 F.2d at 682. On the other hand, products intended to prevent pregnancy, thus affecting the reproductive function of the human body, fall within that definition. Id. at 682-83.

For example, a product intended to reduce the number of bacteria in an animal's digestive system and oral cavity is a drug within the meaning of section 201(g)(1)(C) because it "was intended to alter a function of the animal's body." United States v. Undetermined Quantities . . . "Pet Smellfree", 22 F.3d 235, 240 (10th Cir. 1994). Similarly, liquid solutions intended to cause hair growth and prevent hair loss are drugs within the meaning of section 201(g)(1)(C) because the hair growth process is a function of the human body. United States v. Kasz Enterprises, Inc., 855 F. Supp. 534, 540 (D.R.I. 1994), judgment modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994). Likewise, an apparatus containing oxygen that is intended to improve athletic performance by increasing a tired athlete's intake of oxygen falls within sections 201(g)(1)(C) and 201(h)(3) because enhanced oxygen absorption alters a bodily structure or function. United States v. Eighteen Units, More or Less Of An Article of Drug . . . "SPORTS OXYGEN . . .", Civ. No. 89-2085 (D.N.J. October 27, 1992), reprinted in Food, Drug, and Cosmetic Act Judicial Record, 1991-92 115. Cocaine and similar substances with parallel addictive and psychoactive effects also fall within the drug definition because

they "affect the structure or any function of the body."[3]

In each of these cases, a significant pharmacological effect on the body can bring a substance within the drug definition, even when the product has no therapeutic effect. On numerous other occasions, the Agency has reached similar conclusions and has taken regulatory action. See Appendix to Legal Analysis for examples. As is discussed at p. 22, et seq., it is now widely accepted that nicotine has pharmacological effects on both the structure and function of the central nervous system, particularly the brain. Addiction is a direct result of nicotine's effects on the structure and function of the body. Id. Based on the record before the agency, cigarettes and smokeless tobacco products "affect the structure or any function of the body" within the meaning of sections 201(g)(1)(C) and 201(h)(3).

[3] In fact, the Controlled Substances Act, 21 U.S.C. §§ 801-904, which prohibits the sale of drugs such as cocaine, defines "drug" by reference to section 201(g)(1) of the FDCA. 21 U.S.C. § 802(12).

II. TOBACCO MANUFACTURERS "INTEND" THAT THEIR PRODUCTS HAVE ADDICTIVE AND SIGNIFICANT PHARMACOLOGICAL EFFECTS.

The FDCA, FDA's regulations, and judicial decisions interpreting the Act and analogous provisions in other public welfare statutes all demonstrate that "intended to" and "intended for," as used in the Act, denote objective intent, as that term has become commonly understood by the courts. Objective intent may be determined by what a reasonable person would understand in the circumstances presented, or whether a "reasonable person would believe" that the defendant's conduct would lead to certain events. See, e.g. United States v. Articles of Banned Hazardous Substances . . . Baby Rattles, 614 F. Supp. 226, 231 (E.D.N.Y. 1985) ("[t]he only rational interpretation of the word 'intended' in the statute calls for an objective test of intent: whether a reasonable person would believe that the object is a toy"); W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 8, at 36 (5th ed. 1984) ("relying on circumstantial evidence, [one] may infer that the actor's state of mind was the same as a reasonable person's state of mind would have been").

The courts have also described objective intent in terms of foreseeability. For example, in United States v. Focht, the Third Circuit held that the intent requirement in the "intended to produce [banned] fireworks" language of the regulations implementing the Federal Hazardous Substance Act (FHSA) could be satisfied by a demonstration that it was "foreseeable" that the components sold by the defendant would be used to build banned products. 882 F.2d 55, 59-60 (3d Cir. 1989); see 15 U.S.C. § 1261(q). Similarly, in defining discriminatory intent in a voting rights case, the Fifth Circuit held that "[o]bjective intent . . . presumes that a person intends the natural and foreseeable consequences of his voluntary

actions." Lee v. Lee County Bd. of Ed., 639 F.2d 1243, 1267 (5th Cir. 1981).[4]

Subsection A, infra, demonstrates that an objective intent standard is the appropriate standard under the FDCA. The evidence in subsection B, infra, demonstrates that tobacco manufacturers "intend" cigarettes and smokeless tobacco products to affect the structure or any function of the body within the meaning of the FDCA.

A. OBJECTIVE INTENT IS THE APPROPRIATE STANDARD.

The FDCA is a consumer protection statute which has as its explicit purpose the "prohibit[ion of] the movement in interstate commerce of adulterated and misbranded foods, drugs, devices, and cosmetics." Pub. L. No. 75-717, 75th Cong. 3d. Sess. (1938); see also H.R. Rep. No. 2139 at 1-2, reprinted in 6 Legislative History at 300-01 ("this act seeks to set up effective provisions against abuses of consumer welfare"; "the old law . . . contains serious loopholes [and] is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions"; the 1938 Act "amplifies and strengthens the provisions [of the 1906 act] designed to safeguard the public health and prevent deception, and it extends the scope of the old law to include . . . certain drugs that now escape regulation").

Given the Act's focus on consumer welfare and public health protection, interpreting

[4] Subjective intent, on the other hand, considers the actual state of mind of the responsible actor. *See, e.g.*, Ellington v. Metropolitan Life Ins. Co., 696 F. Supp. 1237, 1242 (S.D. Ind. 1988) (a subjective intent test requires a determination that the defendant actually foresaw the result of his conduct and persisted nonetheless). This standard, which focuses on the actor's actual desires and knowledge, has been applied in certain areas of criminal law when the critical issue is the culpability of a particular actor. *See, e.g.*, Morisette v. United States, 342 U.S. 246, 250-52 (1952). It is not used as a standard of proof for intent in public health and welfare statutes such as the FDCA.

the phrases "intended for use" and "intended to affect" to require a showing of subjective intent -- which would limit the relevant evidence to what is in the mind of the manufacturer or vendor as shown by express representations, promotional claims, or otherwise -- would frustrate those legislative policy goals. As one court found, in determining that an objective intent standard is appropriate in construing a consumer protection statute: "[t]he subjective interpretation of intent urged by claimant could seriously diminish the effectiveness of FHSA [the Federal Hazardous Substances Act] because it would enable a manufacturer to introduce dangerous articles into commerce on the unreasonable but good faith belief that the articles would not be used by children." Baby Rattles, 614 F. Supp. at 232. The court further noted that "the language of the FHSA . . . nowhere speaks specifically of the manufacturer's subjective intent," and that a subjective intent standard could not possibly comport with Congress' intent in enacting the FHSA. Id. 231-32. The same reasoning extends to the Federal Food, Drug, and Cosmetic Act. The language and purposes of the FDCA support an objective intent standard that allows consideration of information about the foreseeable uses of the product for pharmacological purposes, as well as any statements or actions by the vendor that might show the vendor's actual purpose in marketing a product, or refute the vendor's claims regarding the product's intended use.

Although the FDCA is not primarily a criminal statute designed to punish law breakers, it does include criminal penalties to enforce its provisions. See, e.g., 21 U.S.C. § 333. It is relevant that the Act imposes a strict liability standard that is applicable to criminal prosecutions and assesses criminal liability even where there is no evidence of actual knowledge of the alleged conduct on the part of the corporate defendant. 21 U.S.C. § 331;

see United States v. Dotterweich, 320 U.S. 277, 280-81 (1943); United States v. Park, 421 U.S. 658, 670-73 (1975); see also Smith v. California, 361 U.S. 147, 152 (1959) (some penal statutes "dispense with any element of knowledge on the part of the person charged, food and drug legislation being a principal example . . . . The usual rationale for such statutes is that the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors -- in fact an absolute standard which will not hear the distributor's plea as to the amount of care he has used.").

Moreover, FDA's regulations interpreting sections 201(g)(1) and 201(h), which were adopted after notice and comment rulemaking, and therefore have the force and effect of law, explicitly adopt an objective intent standard. Those regulations, which were originally promulgated in 1952, describe the evidence relevant to determining intent to include:

> *such [manufacturers' or vendors'] expressions or . . . 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 [manufacturers or vendors] or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such [manufacturers or vendors] or their representative, offered and used for a purpose for which it is neither labeled nor advertised . . .*

21 C.F.R. § 201.128 (1994) (drugs) (emphasis added); see 21 C.F.R. § 801.4 (1994) (parallel provision for devices); see also 17 Fed. Reg. 6818 (July 24, 1952). Thus, under these regulations, evidence of objective intent is not limited to expressions in labeling or advertising, but may be based on the totality of the relevant evidence showing the seller's awareness of how its product is actually used and affects the structure or function of the body, regardless of how the product is labeled or advertised.

The foregoing interpretation of the statutory language is also consistent with FDA's

regulatory policy decisions and actions. As demonstrated in the Appendix to Legal Analysis, FDA has used both general knowledge and recognition of products' nature and effects, as well as their actual uses and effects, to determine whether products fall within the statutory definitions of drug or device.

FDA has used the known or inherent pharmacological effects of particular ingredients to determine that products are "intended to affect the structure or any function of the body," even where there are no public expressions by the seller that the product is to be used for those effects. See Appendix to Legal Analysis. For example, in the context of a proposed rule on vaginal products for over-the-counter use, the Agency stated:

> *If an active ingredient is present in a therapeutic concentration, the product is a drug, even if that product does not claim to produce the effect which will result from the action of the therapeutically effective ingredient.*

48 Fed. Reg. 46694, 46701 (October 13, 1983). In its tentative conclusion to comments on this issue, the Agency reiterated:

> *[t]he type and amount of ingredient(s) present in a product, even if that product does not make explicit drug claims, must be considered in determining its regulatory status. For example, the mere presence of a pharmacologically active ingredient could make a product a drug even in the absence of explicit drug claims. In these cases, the intended use would be implied because of the known or recognized drug effects of the ingredient (e.g., fluoride in a dentifrice).*

59 Fed. Reg. 5226, 5227 (February 3, 1994) (emphasis added).

Thus, products containing ingredients or components with known pharmacological effects, including fluoride and hormones, have -- on that basis alone and in the absence of express claims -- been determined to be "intended to affect the structure or function of the body" because they contained a pharmacologically active ingredient. See Appendix to Legal

Analysis. FDA has also regulated as devices products that affect the structure or function of the body, even when the vendor makes no claims regarding the products. For example, FDA regulates as devices noncorrective tinted contact lenses that are expressly promoted only for their cosmetic effect of enhancing eye color because they have physiological effects on the eye. See Appendix to Legal Analysis.

The courts have consistently held that the statutory language imposes an objective intent standard. United States v. Undetermined Quantities . . . "Pet Smellfree", 22 F.3d 235, 236, 239 (10th Cir. 1994) (referring to "objective intent" in the context of considering whether a product is a drug); United States v. Kasz Enterprises, Inc., 855 F. Supp. 534, 542 (D.R.I. 1994) ("it is the objective intent of the vendor, not the vendor's subjective explanations and disclaimers, which determines the intended use of a product") (emphasis added), judgment modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994); Clinical Reference Laboratory v. Sullivan, 791 F. Supp. 1499, 1506 n.8 (D. Kan. 1992) ("intended use . . . depends upon the objective intent of the persons responsible for its labeling") (emphasis added), aff'd in relevant part, rev'd in part on other grounds sub nom., United States v. An Undetermined Number of Unlabeled Cases, 21 F.3d 1026 (10th Cir. 1994); United States v. Two Plastic Drums, 761 F. Supp. 70, 72 (C.D. Cal. 1991) ("In determining . . . intended use . . . , the inquiry should focus on the vendor's objective intent") (emphasis added); United States v. Articles of Drug . . . Neptone, No. C-83-0864-EFL, CCH Food and Drug Reporter ¶ 38,240 at 39,294 (N.D. Cal. October 25, 1983) ("objective manifestations of intent are clearly sufficient").

The Environmental Protection Agency (EPA) and the Consumer Product Safety

Commission (CPSC) have also adopted an objective intent standard in construing similar provisions in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Hazardous Substances Act (FHSA), and courts have uniformly upheld those interpretations. See e.g., N. Jonas & Co. Inc. v. EPA, 666 F.2d 829, 833 (3d Cir. 1981); United States v. Focht, 882 F.2d 55, 58-60 (3d Cir. 1989); Baby Rattles, 614 F. Supp. at 231-32. Judicial constructions of those statutes demonstrate that evidence of actual consumer use, knowledge by the manufacturer of such actual use, general knowledge about the effectiveness of the product for a particular use, and other circumstances surrounding its distribution, can be used to determine the "intended use" of a product for purposes of a public welfare statute such as the FDCA.

In Jonas, the issue was whether "Scorch," a product labeled for swimming pool sanitation and maintenance, was a pesticide. The product's label contained a disclaimer stating: "Scorch is not to be used for daily disinfection or algae control of your pool." 666 F.2d at 831. The manufacturer contended that a product's intended use can be determined only from the company's express representations concerning the product. Id. at 832. EPA took the position that "intended use" should be based on the use to which a reasonable consumer would put the product based on "the collectivity of the circumstances." EPA also argued that "[t]he fact that the product may have other uses does not affect" whether it qualifies as a pesticide. Id. The court, relying in part on cases under the FDCA, agreed with EPA and held that the statutory phrase "intended use" refers to objective intent and, as a result, the manufacturer "intends those uses to which the reasonable consumer will put its products." Id. at 832-33.

In deciding whether sufficient evidence exists to support a finding of objective intent, the court in Jonas stated that "the inquiry cannot be restricted to a product's label and to the producer's representations." Id. at 833. Instead, the court determined that relevant evidence could come from, among other things, "general public knowledge" of the usefulness of similar products as pesticides, the "effectiveness" of the product for a pesticidal use (that is, its actual inherent effects), and the collectivity of all the circumstances. Id.

Similarly, in Baby Rattles, the court held that the phrase "any toy or other article intended for use by children" in 15 U.S.C. § 1261(f)(1)(D) requires application of an objective intent standard, and that this standard is met if evidence exists that "a reasonable person would believe that the object is a toy or article intended for use by children." 624 F. Supp. at 231. The court found that this standard was met with respect to a rattle marketed by the manufacturer as a "party favor" based on "evidence of its use as a toy and the common sense observation that children would be likely to use it as a toy." Id. at 231 n.9.

The court observed that even if it accepted the manufacturer's argument that the "intended use" language in the FHSA should be interpreted as requiring a subjective intent standard, such intent would have been established by evidence that the manufacturer knew that its rattles were used on babies' shoes and were given as gifts at baby showers: "[C]laimant could not possibly have ignored the possibility that children would use the rattles, regardless of whether he intended such use of the rattles and whether reasonably prudent parents would give such objects to their children." Id.

Finally, in Focht, component parts of fireworks sold by the Fochts were held to have been "intended to produce banned fireworks" under the FHSA, based on evidence that the

parts were likely to be used by consumers to make banned fireworks, and despite evidence that the components could also be used for numerous legal purposes. An expert testified at trial that 90% of consumers who purchased the components in question would use them to make illegal fireworks, and that, if the components were filled in the "traditional manner," they would contain over the legal limit of explosive. 882 F.2d at 59-60. The court held that "[i]ntended use . . . objectively defined, necessarily encompasses foreseeability" and that this testimony made it "foreseeable that the components in question will be used to build banned fireworks. Such knowledge must be attributed to the Fochts." Id. at 60. Accordingly, a finding that a product is intended to affect the structure or function of the body may be appropriately based on evidence that use of a product leading to such effects in a large proportion of consumers is foreseeable.

Objective intent may also be established by evidence, alone or in combination with other evidence, that consumers use a product for pharmacological purposes. See Action on Smoking and Health [ASH] v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980) (consumer use may be relevant source of evidence of intended use); National Nutritional Foods Assn [NNFA] v. Mathews, 557 F.2d 325, 333-34 (2d Cir. 1977) (product's use for therapeutic purposes was evidence of intended use); United States v. Two Plastic Drums, 761 F. Supp. 70, 72 (C.D. Cal. 1991) (consumer use is relevant to intended use); see also Medical Devices Amendments of 1976, H.R. Rep. 94-853, 94th Cong., 2d Sess. at 14 (1976) (in interpreting "intended for use" and "intended to affect," FDA "may consider the ultimate destination of a product . . . just as [it] may consider actual use of a product"); Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Proposed Rule, 58 Fed. Reg.

28194, 28204 (May 12, 1993) (objective evidence of intent may be derived from "the consumer's intent in using the product").

In ASH, the D.C. Circuit stated that "the near-exclusivity of consumer use of cigarettes with the intent 'to affect the structure or any function of the body of man,'" would be sufficient by itself to establish that cigarettes are drugs within the meaning of the FDCA. 655 F.2d at 240; see also NNFA, 557 F.2d at 336 (demonstration that high dosage vitamins were "taken 'almost exclusively' for therapeutic purposes" would show an objective intent that the products be used as drugs and be sufficient for a determination that the products are drugs within the FDCA's meaning).

Evidence of consumer use may also be used in combination with other evidence to establish intended use or intended effects. FDA has relied on evidence of consumer use to establish the intended use of a drug or device product, even though the extent of consumer use had not been quantified. For example, beginning in the early 1980's, FDA regulated as unapproved drugs imports of catha edulis, or "khat," a shrub whose leaves act as a stimulant narcotic that affects the central nervous system when chewed or used as tea, even though the Agency did not have any evidence that vendors represented the product as a stimulant. Instead, FDA relied on information about the product's use and effects from United Nations reports, and other sources of information that described international customs and practices related to the substance. See Appendix to Legal Analysis.

Similarly, physicians' use of a product to treat or diagnose patients or to affect the structure or function of patients' bodies may provide evidence of intended use. FDA has classified products as drugs or devices based on physician use of the product. For example,

FDA undertook an enforcement action against a metal tube containing a light bulb, round metal discs, and colored glass filters used by a medical practitioner in his office in the treatment of various eye malfunctions and conditions. A district court upheld the Agency's conclusion that this use made the tube a device, even though the practitioner made no claims for the product. United States v. An Article of Device . . . Labeled in Part: "Cameron Spitler Amblo-Syntonizer", 261 F. Supp. 243, 245 (D. Neb. 1966). In another example, FDA established a due diligence requirement regarding manufacturers' distribution of interferon, a biologic product composed of proteins. See 48 Fed. Reg. 52644 (Nov. 21, 1983). At the time, interferon could be used only for investigational purposes in laboratory animals and tests in vitro. However, interferon received wide media coverage as a potential "miracle cure" in the treatment of cancer and viral infections in humans. Because of its concern over diversion of interferon to unapproved uses, the Agency issued the notice to prevent use of interferon in humans.

Finally, a vendor's behavior or statements may also be used as evidence of objective intent. See, e.g. United States v. An Article . . . Consisting of 216 Cartoned Bottles . . . "Sudden Change", 409 F.2d 734, 739-741 (2d Cir. 1969) (lotion promoted on product box, leaflets, and advertising as providing a "face lift" is intended to affect the structure of the body and is a drug); "Pet Smellfree", 22 F.3d at 239-40 (compound labeled and marketed as eliminating odor from a pet's breath and waste material is intended to affect the animal's digestive and elimination functions and is a drug).

Awareness that a product will achieve pharmacological effects, actual use of the product for a pharmacological purpose, and the totality of circumstances surrounding

distribution of the product constitute "objective manifestations of intent [that] are clearly sufficient." Neptone, CCH Food and Drug Reporter at 39,294. Moreover, evidence that a manufacturer actually knows that its product is being widely used for pharmacological purposes, and has taken steps to facilitate that use, provides compelling evidence of "intended use."

As shown below, the evidence now available to FDA demonstrates that tobacco manufacturers "intend" that their products have addictive and pharmacological effects which make cigarettes and smokeless tobacco products drugs within the meaning of the Act.

B. THE EVIDENCE DEMONSTRATES INTENT TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY.

As demonstrated above, in order to establish that a product has an intended use that subjects it to FDA's jurisdiction, it is sufficient to demonstrate foreseeable drug uses or effects in a large proportion of users, predominant or "nearly exclusive" consumer use for drug effects, or the subjective intent of the manufacturer, as evidenced by behavior and statements, that the product be used as a drug. As shown below, the facts before the agency demonstrate, based on each of these three grounds, that tobacco products are intended to affect the structure or function of the body and are, therefore, "drugs" and "devices." Moreover, the combined evidence before the agency from all three categories plainly demonstrates that tobacco products are "drugs" and "devices" within the meaning of the Act.[5]

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[5] Since 1980, when the Agency last evaluated its legal authority to regulate cigarettes as drugs or devices and declined to do so, *see* Action on Smoking and Health [ASH] v. Harris, 655 F.2d 236 (1980), the evidence regarding intended use has changed dramatically. As discussed *infra*, since 1980, the Surgeon General of the United States and virtually every major public health organization have concluded that nicotine in tobacco products leads to addiction. Since that time, the Agency has also exercised

1. The Addictive, Psychoactive, and Other Pharmacological Effects of Nicotine Are Widely Known and Foreseeable by Any Reasonable Person in the Position of a Tobacco Manufacturer.

As summarized below, a large body of compelling and widely accepted scientific evidence now exists that establishes that nicotine is addictive. Nicotine's addictive properties and its other significant pharmacological effects are now so well documented and commonly understood that these effects on the structure or function of the body must be held to be foreseeable by any manufacturer of cigarettes or smokeless tobacco products that contain nicotine. Although the manufacturers' claimed purpose may be to provide "taste" or "smoking pleasure," manufacturers may nevertheless be held, under an objective intent standard, to intend the foreseeable consequences of consumers' use of nicotine-containing cigarettes and smokeless tobacco products.

a. Addictive Effects. Until the 1980's, nicotine was not widely appreciated to be an addictive drug.[6] Overwhelming scientific evidence and broad recognition that nicotine is an addictive or dependence-producing substance emerged in the 1980's. See p. 78. Almost all

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jurisdiction over alternative nicotine delivery systems such as "Favor," a plug impregnated with a nicotine solution inserted within a small tube corresponding in appearance to a conventional cigarette, and "Future Free," a roll-on transdermal applicator containing nicotine in the form of a liquified raw tobacco extract, nicotine gums, and nicotine transdermal patches. Finally, the Agency's investigation has identified a wealth of evidence consisting of industry statements, research and actions acknowledging nicotine's drug effects and the role of nicotine in the manufacture of cigarettes and smokeless tobacco. As the Court explicitly acknowledged in ASH, the FDCA "calls for case-by-case analysis," and an agency may "depart from its prior interpretations" so long as it "provide[s] a reasoned explanation for its action." 655 F.2d at 242 n. 10; *see also* Chevron, U.S.A., Inc. v. National Resources Defense Council, Inc. 467 U.S. 837, 842-845, (1984); Bell v. Goddard, 366 F. 2d 177, 181 (7th Cir. 1966) ("An interpretation of the statute prohibiting such new application of existing information would do violence to the paramount interest in protecting the public from unsafe drugs."). In this document, the Agency has provided such a reasoned explanation.

[6] While some evidence of the addictive nature of nicotine existed at the time FDA last considered the regulation of nicotine-containing cigarettes and smokeless tobacco products in the late 1970's, the evidence available to FDA since that time has grown exponentially. *See* FINDINGS § I.B.

the leading experts and public health organizations in the United States and in the international community, including the vast majority of scientists funded by the tobacco industry now recognize nicotine's addictive effects. In 1986, the Office of the U.S. Surgeon General published a finding that nicotine in smokeless tobacco is addictive. See p. 80. Two years later, the Surgeon General issued his landmark report concluding that: cigarettes and smokeless tobacco products are addicting; nicotine is the drug in tobacco that causes addiction; and the pharmacological and behavioral processes that cause tobacco addiction are similar to those that cause addiction to drugs such as heroin and cocaine. See p. 82.

Since 1980, nicotine has been recognized as addictive or dependence-producing[7] by the World Health Organization, the American Medical Association, the American Psychiatric 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. See p. 82. In a 1991 survey, the vast majority of scientists funded by the tobacco industry stated that they believe that cigarette smoking is addictive. See p. 83. Indeed, among the principal investigators of research projects funded by the tobacco industry in 1989, 83.3% strongly agreed and 15.3% agreed somewhat that cigarette smoking is addictive. See p. 83.

More recently, on August 2, 1994, FDA's Drug Abuse Advisory Committee concluded unanimously that cigarettes and other forms of tobacco are addicting and that nicotine is the drug in tobacco that causes addiction. See p. 83. The FDA Advisory Committee also

[7] The terms "addictive" and "dependence-producing" are generally used interchangeably; both refer to the persistent and repetitive intake of psychoactive substances despite evidence of harm and a desire to stop using the substance. *See* p. 78. The terms are used interchangeably in this document.

concluded that all currently marketed cigarettes contained addicting levels of nicotine. Id.

Tobacco use is also recognized as an addiction in the leading psychiatric manuals defining mental illnesses. The two most widely used clinical definitions of addiction in the United States are those in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) and World Health Organization's International Classification of Diseases (ICD). Nicotine has been recognized as dependence-producing under the DSM criteria since 1980. The ICD has recognized tobacco as dependence-producing since 1992. See pp. 84-85.

The current, scientifically accepted method of identifying addictive substances relies on the knowledge that there is a pharmacologic basis to addiction. See p. 79. Addictive substances achieve their addictive effects by exerting psychoactive (mood-altering) effects, and by producing chemical reactions in the brain that motivate repeated, compulsive use of the substance. See pp. 79-80. These pharmacologic effects create psychological or physiological dependence in the user. Id. Nicotine has been shown in animal and human studies to be a powerful psychoactive agent and to produce effects in the brain that are characteristic of other addictive substances, such as heroin and cocaine. See p. 94 et seq. Nicotine has also been shown to act as a "positive reinforcer," perhaps the most important hallmark of an addictive substance. See p. 96.

Current, widely accepted definitions of substance addiction place primary emphasis on: compulsive, regular use of the substance; inability to stop using the substance despite a desire to quit and/or harmful consequences; and the existence of tolerance and/or withdrawal symptoms (physiologic dependence). See p. 84. Using the contemporary definition of

addiction, evidence from epidemiological studies has now established that many cigarette smokers and smokeless tobacco users are addicted to nicotine.

Numerous studies have documented the characteristics of addiction among cigarette and smokeless tobacco users. First, consumers use tobacco regularly and compulsively. For example, 87% of people who smoke cigarettes smoke every day. See p. 86. Nearly two-thirds of smokers need their first cigarette within the first half-hour after awakening. Id.

Second, the failure rate of people who attempt to stop or reduce their smoking is dramatic, even in the face of life-threatening, tobacco-related illnesses. See pp. 86-87. Each year, nearly 15 million people -- almost one-third of all smokers -- try to quit smoking in the United States. Only about 3% of would-be quitters achieve long-term success. Indeed, cigarettes and smokeless tobacco products may be the only elective consumer product that a majority of users want to quit using, but cannot. In response to the 1993 National Health Information Survey, 70% of current smokers reported that they would like to completely stop smoking cigarettes. See p. 87. Sixty-eight percent of smokeless tobacco users in one study reported an average of four previous unsuccessful attempts to quit using smokeless tobacco. See p. 91. Moreover, tobacco use persists despite harmful and often deadly consequences. In one survey, 90% of smokers agreed with the general proposition that smoking is harmful to health, 65% believed that smoking had already adversely affected their health, and 77% believed that they could avoid or decrease serious health problems by quitting smoking. See p. 87. Almost half of the smokers who have surgery for lung cancer resume smoking. See p. 87. Even when smokers have their larynxes removed, 40% try smoking again. See p. 87.

Third, consumers who abstain from tobacco products experience withdrawal symptoms and nicotine has been shown to produce tolerance (the lessening of the desired effect over time or the need for higher doses to produce the same effect) among tobacco users. See pp. 88, 92, 99. For example, abstinence from smoking is often accompanied by powerful cravings for a cigarette, and the range of other symptoms produced by abstinence can disrupt personal life. Id. Among smokeless tobacco users, one study showed that of users 10 to 22 years old who had tried to quit, 93% had suffered withdrawal symptoms. See p. 93.

Accordingly, nicotine satisfies the classic criteria for an addictive substance. In fact, major recent clinical studies have demonstrated that between 75% and 90% of frequent smokers, and more than one-third of smokeless tobacco users are addicted to tobacco. See pp. 91, 115 et seq.. Further, cigarette users themselves recognize that cigarettes are addictive. According to a national household survey conducted by the U.S. Department of Health and Human Services in 1991-92, 83% to 87% of cigarette smokers who smoke more than 26 cigarettes a day believe they are addicted. See p. 87.

The success of nicotine replacement therapies provides further evidence of nicotine's addictive qualities. Nicotine replacement therapies (nicotine gum and nicotine patches) have been shown to be effective in assisting dependent tobacco users to quit. See p. 88 et seq. Nicotine replacement could only significantly increase the success of smoking cessation efforts if nicotine dependence were the major factor preventing tobacco users from quitting. Id.

To summarize, the widely known, well-publicized evidence of the addictive nature of nicotine and the very high frequency of addiction among frequent smokers, ranging, in major

recent studies, from 75% to 90%, has resulted in virtually universal acceptance that nicotine produces addiction.[8] Thus, nicotine's addictive effects are now undeniably foreseeable to manufacturers of cigarettes and smokeless tobacco products. Because it is also well known that nicotine addiction produces a physiological and psychological need for additional doses of nicotine, it is foreseeable that a large proportion of consumers will use tobacco to satisfy their addiction.

b. Other Pharmacological Effects. In addition to its addictive effects, nicotine produces a range of other significant pharmacological effects, which manufacturers of cigarettes and smokeless tobacco products can reasonably be expected to foresee. See p. 73 et seq. A large body of published evidence demonstrates that nicotine produces both stimulative and depressant effects on mood. See p. 75; see also p. 171. These psychoactive effects have been confirmed using electroencephalographic (EEG) analysis. Id. When smokers are in a stressful situation, smoking has a depressant effect on the EEG profile. When smokers are under conditions of low arousal, induced by mild sensory isolation, cigarette smoking has a stimulant effect. See pp. 75-76. In his 1988 report, the Surgeon General reviewed the epidemiological literature on the effects of smoking on mood. The report concluded:

> *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 . . . .*

[8] This evidence distinguishes nicotine from caffeine-containing beverages and alcohol. If beverages containing caffeine are addictive, they are addictive in a very small percentage of users. Griffiths RR. Editorial: Caffeine dependence should be kept in proper perspective. *JAMA* 1994;272(13):1065-66. Beverages containing alcohol are addictive in fewer than 15% of users. Id. at p. 1066; Grant BF, Harford T, et al. Prevalence of DSM-II-R Alcohol Abuse and Dependence in the U.S., 1988. Alcohol Health and Research World Epidemiologic Bulletin No. 27, 1991;15(1):91.

See p. 118.

In addition, nicotine is widely believed to regulate weight gain in smokers. See p. 119. The 1988 Surgeon General's Report summarized the large number of clinical studies establishing an inverse relationship between cigarette smoking and body weight and animal studies demonstrating that nicotine plays an important role in the relationship between smoking and body weight. Id. Numerous studies show that smokers believe that smoking keeps weight down and that weight control is a significant motivation for continued smoking. Id.

This evidence plainly satisfies the objective standard for "intended use" set forth above. The widespread knowledge and acceptance of the very significant pharmacological effects of nicotine establish that any reasonable person would know that marketing nicotine-containing cigarettes and smokeless tobacco products will result in these effects and lead to addiction in millions of users.

This evidence is at least as strong as the evidence that the courts found to be sufficient to establish intended use in Jonas, Baby Rattles, and Focht, supra. As discussed above, in each of those cases, the defendant had a plausible argument that its product could be used for purposes that fell outside the jurisdiction of the relevant statute (e.g., baby rattles as party favors, firework components for use in legal fireworks). Nevertheless, the courts in each case found that the product fell within the jurisdiction of the applicable regulatory agency based on evidence that a foreseeable use of the product fell within the ambit of the statute. The pharmacologic effects and uses of nicotine-containing cigarettes and smokeless tobacco products are at least as foreseeable as the uses of the products at issue in Jonas, Baby Rattles,

and Focht.

2. Consumers Use Tobacco Products to Obtain the Pharmacological Effects of Nicotine and to Satisfy Their Addiction to Nicotine.

As previously explained, the intent that a product be used as a drug may also be shown by evidence, alone or in combination with other evidence, that consumers use it for pharmacological purposes. Here, the evidence establishes that consumers use tobacco for three pharmacological purposes: to satisfy a nicotine addiction; to receive the accompanying psychoactive effects, such as relaxation and stimulation; and to control weight. Moreover, the evidence shows that consumers use cigarettes nearly exclusively for pharmacological purposes. As discussed above, under the most widely used definitions, major recent studies show that 75% to 90% of frequent cigarette users are addicted to cigarettes. See p. 26. Studies also reveal that a large proportion of consumers use tobacco for other pharmacological effects, including relaxation, reduction of negative feelings, and for controlling weight. See p. 118 et seq. Under ASH, 655 F.2d at 240, and NNFA, 557 F.2d at 336, the high percentage of smokers who use cigarettes for their pharmacological effects, particularly to satisfy an addiction, one of the most significant drug effects on the body possible, is sufficient by itself to classify cigarettes and smokeless tobacco products as drug delivery systems within the meaning of the Act.

Even if the evidence of consumer use of tobacco products to satisfy addiction and to obtain other pharmacological effects were not alone sufficient to establish the intended use of cigarettes and smokeless tobacco products, the evidence of consumer use, in combination with the other evidence presented here, provides compelling support for the determination

that these products are intended to be used for pharmacological purposes. Indeed, the nature of consumer use of these products underscores nicotine's classification as a drug. Because nicotine is an addictive product that the vast majority of consumers use on a daily basis for a period of years, if not a lifetime, to satisfy an addiction, nicotine unquestionably functions as a pharmacological product at the consumer level. See also LEGAL ANALYSIS § II.B.3, infra (tobacco manufacturers recognize and acknowledge that consumers use their products to obtain the pharmacological effects of nicotine).

In summary, consumers' use of cigarettes and smokeless tobacco products for nicotine's pharmacological effects, viewed in combination with the other evidence presented here, supplies more than sufficient evidence to show that nicotine-containing cigarette and smokeless tobacco products are drug delivery systems within the meaning of the Act.

3. Tobacco Manufacturers Know That Nicotine Has Pharmacological Effects and That Consumers Use Tobacco for Those Effects, and Have Acted to Facilitate That Use.

Nicotine's psychoactive and addictive effects on tobacco users are plainly foreseeable to tobacco manufacturers, not only because they are widely known and published in scientific, governmental, and lay publications, but because for over 30 years the manufacturers themselves have engaged in intensive research on nicotine's psychoactive and addictive effects. In addition, tobacco industry documents reveal numerous statements by both industry researchers and executives in which they express their own views that nicotine in tobacco products acts as a psychoactive and addictive drug. Tobacco manufacturers' own research also demonstrates that consumers use cigarettes to obtain the pharmacological effects of

nicotine. Finally, tobacco manufacturers have conducted numerous studies to identify the dose of nicotine that will elicit the psychoactive effects sought by tobacco users, and manipulate the amount of nicotine delivered by tobacco products.

a. Tobacco Manufacturers' Studies and Statements Demonstrate Knowledge That Nicotine in Tobacco Is Addictive and Has Psychoactive Effects.

(i.) Addiction. Over the last 35 years, the tobacco industry has conducted many studies that collectively demonstrate that nicotine has the properties of an addictive drug. As described in FINDINGS § I.A.2., infra, substances are shown to have addictive properties by studies of the substance in animals, studies of human reactions to the substance, and studies of effects on the brain caused by the substance.

Two kinds of animal studies are highly predictive of a substance's addictive properties: self-administration studies and drug discrimination studies. See pp. 94-97. A substance is considered a "positive reinforcer" that is highly likely to be addictive in humans if studies show that animals self-administer the substance. Id. In drug discrimination studies, potentially addictive substances are identified by comparing the effects of one substance to those of other psychoactive substances. Id.

As noted above, under the major definitions of addiction, a substance is recognized as producing addiction (dependence) on the basis of studies on human responses to the substance if:

- the substance is psychoactive; i.e., mood altering;
- patterns of use are regular and compulsive, despite attempts to quit and harmful consequences;

- it causes physical dependence characterized by a withdrawal syndrome; and/or
- tolerance develops, causing diminished effects after repeated use and increased intake.

See p. 79 et seq.

The tobacco industry has conducted or funded studies in both animals and humans showing that nicotine bears each of these hallmark properties of an addictive substance. Industry-conducted and sponsored research has shown that animals self-administer nicotine and that animals experience nicotine's psychoactive effects. See p. 180 et seq. Industry research also demonstrates that the human response to nicotine in tobacco meets generally accepted definitions of addiction. Tobacco industry research demonstrates that nicotine has psychoactive effects, see p. 171, that most tobacco consumers continue daily use of tobacco, despite serious attempts to quit and despite concerns about the adverse health consequences of tobacco use, see p. 206 et seq., and that abstinence from tobacco use produces a withdrawal syndrome. See pp. 146, 182. Tolerance to the pharmacological effects of nicotine has also been closely studied by the tobacco industry and demonstrated in both animals and humans. See p. 181. Finally, tobacco industry studies have shown that nicotine acts on the mesolimbic system in the brain and triggers the release of the chemical dopamine. See p. 170. It is believed that dopamine release is the mechanism by which several of the most significant drugs of abuse, including cocaine and amphetamines, exert their addictive effects. See p. 74. Thus, the tobacco industry's own research demonstrates that nicotine has all the properties of an addictive drug.

Numerous tobacco company documents contain statements by company researchers and executives acknowledging that nicotine is, in fact, addictive. See p. 143 et seq. More

than 30 years ago, a report was completed for British-American Tobacco Co. (BATCO)[9] that specifically addressed the mechanism of nicotine addiction in smokers. See p. 143. The researchers concluded that chronic intake of nicotine, such as that which occurs in regular smokers, creates a need for ever-increasing levels of nicotine to maintain the desired action: "[u]nlike other dopings, such as morphine, the rate of increasing demand for greater dose levels is relatively slow for nicotine." Id. The report continues:

> *A body left in this unbalanced state craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine.*

See p. 144.

Dr. Sidney J. Green, the director of research for BATCO for 20 years and a member of the company's board of directors, repeatedly acknowledged that nicotine is addictive. See p. 150. Dr. William L. Dunn, a senior scientist at Philip Morris similarly made repeated statements that reflect the view that nicotine has the properties of an addictive substance. See pp. 152-154.

On the basis of research that had been sponsored by the industry in the early 1960's, the general counsel to Brown and Williamson reached the conclusion that "[w]e are, then, in the business of selling nicotine, an addictive drug . . . ." See p. 150. There have been more recent acknowledgements by the industry that nicotine is addictive, although industry representatives have been much more reticent in the statements they have made about nicotine's addictive properties since the 1970's, when product liability concerns began to

[9] BATCO and Brown and Williamson Tobacco Corp, both part of the multi-national BAT Industries, PLC, shared both the funding and the results of their nicotine-related research. *See* Appendix 2.

mount. Throughout the 1970's and 1980's, industry-funded researchers have repeatedly stated that nicotine produces addiction, dependence, and withdrawal. See p. 145 et seq., 179-80. Moreover, in 1994, a recently retired CEO of a major tobacco company openly stated that tobacco is addictive and that its addictive properties are why people smoke. In an interview for an article in the Wall Street Journal, the former chief executive of RJR Nabisco, F. Ross Johnson, was asked about nicotine in cigarettes, and he responded, "Of course it's addictive. That's why you smoke . . ." See p. 155.

(ii.) Psychoactive Effects. The tobacco industry has conducted and funded, both as individual companies and through the jointly-operated Council for Tobacco Research (CTR),[10] hundreds of studies evaluating nicotine's pharmacological effects on the brain, including nicotine's specific physiological effects on brain structure and chemistry; its effects on mood, performance, and cognition; and its capacity to produce the characteristic features of addiction. See FINDINGS § II.B., infra, at p. 160 et seq.

Internal company documents reveal that the industry conducted and funded this research effort on the effects of nicotine on the brain because the tobacco manufacturers strongly suspected, as long as 30 years ago, that nicotine's drug effects were the basis for the world tobacco market. See p. 161. For example, in 1963, researchers for one company urged further study of nicotine because "nicotine is the key factor in controlling, through the central nervous system, a number of beneficial effects of tobacco smoke." See p. 161 (emphasis added). In the early 1960's, a prominent industry scientist, Sir Charles Ellis, the scientific

[10] The Council for Tobacco Research is an industry trade association that represents almost all of the major tobacco producers in the United States. *See* note 176, *infra*.

advisor to the board of directors of BATCO, explained that industry-sponsored research was underway "to elucidate the effects of nicotine as a beneficent alkaloid drug," and stated "we are in a nicotine rather than a tobacco industry." See p. 161. Indeed, the industry as a whole was sponsoring substantial research on nicotine pharmacology because of the shared belief that the drug effects of nicotine were central to tobacco use. See pp. 140-42.

Over the next 30 years, the tobacco industry conducted numerous studies on the drug effects of nicotine that appear similar to the studies conducted by pharmaceutical companies. Before marketing prescription drugs, 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 therapeutic or physiological effect). The tobacco industry has conducted and funded hundreds of studies on nicotine's pharmacokinetics, pharmacodynamics, and clinical effects. See p. 160 et seq. As a result, the tobacco industry appears to have an understanding of the pharmacological effects produced by the nicotine in tobacco analogous to that which a pharmaceutical company has in marketing a new drug.

For example, the tobacco industry has developed sophisticated techniques for determining, quantitatively and qualitatively, the presence of nicotine and its metabolites in blood, urine, and tissue. See p. 174. Studies sponsored by tobacco companies using these techniques have shown that nicotine from tobacco is absorbed into the bloodstream and delivered to the brain, see p. 176, and that, once delivered to the brain, nicotine acts on the

receptors in the brain that produce a range of significant effects on brain chemistry and metabolism. See pp. 164, 169.

The tobacco industry has also sponsored many studies on the ultimate psychoactive effects produced by nicotine. Studies sponsored by the tobacco industry have repeatedly demonstrated that nicotine induces moods changes, which, under different conditions, provide both stimulant and depressant (relaxant) effects. See pp. 171-72. Moreover, tobacco industry studies have shown that nicotine's effects on mood are correlated to EEG changes (a measurement of electrical activity in the brain that is indicative of pharmacological activity on the central nervous system). Id. The tobacco industry has also conducted many studies that attempt to show that nicotine improves performance efficiency. See p. 173.[11]

Internal tobacco company documents reveal that all of this research has convinced company researchers and executives that nicotine in tobacco functions as a drug with powerful psychoactive effects. For example, in 1962, even before much of this research had been completed, Sir Charles Ellis, of BATCO, expressed his view that nicotine in tobacco functions as a drug much like stimulants and tranquilizers:

> *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 tranquilising effect. You are all aware of the very great increase in the use of artificial controls, stimulants, tranquilisers, sleeping pills, and it is a fact that under modern conditions of life people find that they cannot depend just on their subconscious reactions to meet the various environmental strains with which they are confronted: they must have drugs available which they can take when they feel the need. Nicotine is not only a very fine drug, but the techniques of administration by smoking has considerable psychological advantages and a built-in control against excessive absorption.*

[11] In fact, these studies show only that tobacco users perform better on some cognitive tasks when they are given nicotine than when deprived of cigarettes or nicotine. The studies do not show that tobacco users perform better than non-tobacco users. *See* FINDINGS § II.A.2., *infra*.

See p. 139 (emphasis added). In the decades that followed this statement, BATCO and Brown and Williamson held many research conferences, some of which were devoted entirely to discussing nicotine's pharmacological effects. The records of these conferences demonstrate that, at almost every conference, tobacco company officials from around the world discussed the results of research on nicotine pharmacology and reached agreement that nicotine had been shown to have pharmacological effects on tobacco users. See p. 125 et seq.

Researchers and executives from the other major tobacco companies and associated with CTR have also made statements revealing their knowledge that nicotine is a psychoactive drug. For example, the authors of a research paper funded by CTR reporting on the "beneficial" pharmacological effects of nicotine in cigarettes said that "[n]icotine is recognized as the primary psychoactive compound in cigarette smoke." See p. 131.

Researchers at RJR have published studies in which they freely acknowledge the pharmacological effects of nicotine in tobacco. In one study, they concluded that "the beneficial effects of smoking on cognitive performance . . . are a function of nicotine absorbed from cigarette smoke upon inhalation." Another published RJR study discusses the "nicotine paradox": the effects of smoking that appear to be stimulating (e.g., increased heart rate) and to increase mental alertness are inconsistent with nicotine's calming and stress-reduction effects. See p. 129. As discussed in the following subsection, documents containing statements from Philip Morris officials and officials at U.S. Tobacco, the largest smokeless tobacco manufacturer, show that executives at these companies also believe that nicotine in tobacco is a psychoactive drug.

b. Tobacco Manufacturers Know That Consumers Use Tobacco Products for the Pharmacological Effects of Nicotine.

Industry documents show that tobacco manufacturers have thoroughly researched consumer use of tobacco products and understand that consumers use tobacco to obtain the pharmacological effects of nicotine. In fact, tobacco manufacturers believe that consumers will not accept cigarettes that contain insufficient levels of nicotine to produce pharmacological effects.

BATCO reports, research conference proceedings, and other internal documents from BATCO contain repeated assertions that consumers use tobacco largely to obtain nicotine's pharmacological effects. See p. 125 et seq. A BATCO Group R&D Smoking Behaviour-Marketing Conference held in 1984, which focused almost entirely on the role of nicotine pharmacology in smoking, included a presentation in which the following statement was made:

> *Smoking is then seen as 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.*

See pp. 126-27 (emphasis added). At a 1976 BATCO Smoking Behavior Conference, the conferees were so convinced that obtaining a dose of nicotine was the reason people smoke that they thought that other, non-pharmacological reasons for smoking might emerge only after the smoker had achieved a "maximum nicotine level" and had satisfied his desire for nicotine. See p. 194. Many other industry statements described in FINDINGS, § II.A.1 and C., infra, also show that the tobacco industry knows that the pharmacological effects of

nicotine are the primary reason consumers use cigarettes and smokeless tobacco products.

Industry documents also reveal that tobacco manufacturers appreciate that consumers will not accept individual tobacco products unless they provide a pharmacologically satisfying dose of nicotine. Dr. Helmut Wakeham of Philip Morris stated in 1961 that the pleasures of smoking derive at least in part from nicotine's pharmacological effects and that "nicotine is believed essential to cigarette acceptability." See p. 134. This view was later adopted and enlarged by William Dunn, Jr., another high-ranking Philip Morris official. In summarizing a 1972 conference sponsored by CTR, Dunn reported that "[t]he primary incentive to cigarette smoking is the immediate salutary effect of inhaled smoke upon body function." See p. 134. Dunn continued:

> *The majority of the conferees would go even further and accept the proposition that nicotine is the active constituent of cigarette smoke. Without nicotine, the argument goes, there would be no smoking. Some strong evidence can be marshalled to support this argument:*
>
> *1) No one has ever become a cigarette smoker by smoking cigarettes without nicotine.*
>
> *2) Most of the physiological responses to inhaled smoke have been shown to be nicotine-related.*
>
> *3) Despite many low nicotine brand entries in the market place, none of them have captured a substantial segment of the market . . . .*

See p. 135 (emphasis added).

Tobacco industry documents on "satisfaction" also demonstrate industry knowledge that delivery of a pharmacologically active dose of nicotine is essential to consumer acceptance of tobacco products, see FINDINGS § II.C.1., infra, and that "satisfaction" is a tobacco industry euphemism for the pharmacological response to nicotine that smokers seek

to obtain from smoking. See p. 185. For example, a BATCO scientist, in a 1969 presentation describing the research activities of BATCO Group Research & Development, stated that:

> *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" of smoking, using this term in the physiological rather than the psychological sense.*

See p. 186. An RJR Marketing Summary Report from 1983 similarly concludes that the primary reason people smoke "is probably the physiological satisfaction provided by the nicotine level of the product." See p. 186 (emphasis added). These and other industry statements set forth in FINDINGS § II.C.1., infra, further demonstrate the tobacco manufacturers' awareness that consumer "satisfaction" from tobacco products depends upon delivery of pharmacologically satisfying amounts of nicotine.

The industry's study of "compensation" behavior by smokers provides further telling evidence of the industry's awareness that consumers use tobacco to obtain a carefully titrated dose of nicotine. See FINDINGS § II.C.3., infra, p.198 et seq. "Compensation" refers to the behavior of smokers when given cigarettes that provide a lower nicotine yield than their regular brands (as measured by a smoking machine). When using lower-dose products, smokers often smoke more cigarettes or smoke the cigarette more intensely, for example, by taking larger or more puffs. Tobacco company documents reveal that the industry recognizes both that smokers compensate and that the purpose of compensation behavior is to allow smokers to achieve a dose of nicotine that satisfies their physiological need for nicotine. Id.

The tobacco industry has conducted studies on compensation that show that each smoker tends to obtain close to the same dose of nicotine from each cigarette, despite differences in the yield as measured by a smoking machine. See pp. 202-04. In other words,

industry studies show that tobacco users seek a specific dose of nicotine from tobacco and adjust their smoking behavior to obtain their customary dose of nicotine from cigarettes with different yields. For example, in 1974, BATCO researchers reported on a study that found that "the smoker adjusts his pattern to deliver his own nicotine requirements (about 0.8 mg per cigarette)." See p. 202. Thus, the tobacco industry's studies demonstrate that smokers use the cigarette as a nicotine delivery system and vary their smoking behavior to obtain specific doses of nicotine.

Tobacco company documents demonstrate not only the tobacco industry's awareness of the fundamental importance of nicotine's effects on the brain, but their knowledge that these effects motivate almost all smoking. A 1977 BATCO report entitled "Some 'Benefits' of Smoking" contained the following statement:

> *Some insights into the likely benefits of smoking follow from a consideration of the properties of nicotine, which is considered to be the reinforcing factor in the smoking habit of at least 80% of smokers . . . .*

See p. 132 (emphasis added). High-ranking officials agreed with this assessment. Dr. S.J. Green of BATCO, the Director of Research and member of the Board of Directors of BATCO, wrote in 1972 that the "[t]he tobacco smoking habit is reinforced or dependent upon the psycho-pharmacological effects mainly of nicotine." See p. 140.

The smokeless tobacco industry also recognizes that almost all consumers use tobacco products to obtain the pharmacological effects of nicotine. The senior vice-president for marketing of U.S. Tobacco wrote in a 1981 letter on new product development:

> *Flavorwise we should try for innovation, taste and strength, nicotine should be medium . . . Virtually all tobacco usage is based upon nicotine, "the kick," satisfaction.*

See pp. 186-87 (emphasis added).

The importance of nicotine delivery to consumer acceptance of tobacco products is so well-recognized by the tobacco industry that tobacco company officials themselves consider tobacco products to be nicotine delivery systems, i.e., vehicles for administering doses of nicotine. At the 1984 BATCO Smoking Behaviour-Marketing Conference, which focused heavily on the central role of nicotine's pharmacological effects in tobacco use, one of the presentations included a slide that read "in its simplest sense puffing behaviour is the means of providing nicotine dose [sic] in a metered fashion." See p. 159.

Tobacco company documents demonstrate that high-ranking tobacco company officials share the view that tobacco is a nicotine delivery system. See FINDINGS § II.A.3., infra, at p. 156 et seq. Dr. Green repeatedly asserted that tobacco is simply a vehicle for delivering nicotine. See p. 157. RJR executive Claude Teague, Jr. wrote:

> *In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects . . . . 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 products - and where possible our advertising - around nicotine delivery . . .*

See pp. 156-57.

In summarizing a 1972 conference sponsored by the CTR, William Dunn, of Philip Morris, characterized the cigarette 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.*

See p. 156.

Thus, tobacco company researchers and executives have not only acknowledged that nicotine's drug effects are central to the use of tobacco, but have also stated their intention that tobacco products be used as delivery systems to administer doses of nicotine.

c. Tobacco Manufacturers Have Acted to Facilitate and Sustain the Consumer Use of Tobacco Products for Their Pharmacological Effects.

The amount of nicotine that reaches the bloodstream of the smoker is determined by the nicotine content of the leaf, the chemical additives used during processing of the tobacco, and the design of the cigarette or smokeless tobacco product. FDA's investigation has revealed that tobacco manufacturers have conducted numerous studies to identify the dose of nicotine that will elicit the pharmacological effects sought by the products' users. See FINDINGS § II.C.2, infra, at p. 188 et seq. Furthermore, the investigation has shown that cigarette and smokeless tobacco companies manufacture their products to specifications that ensure that the final product will contain precise levels of nicotine. See FINDINGS § II.E., infra at p. 232 et seq. This evidence also demonstrates that tobacco manufacturers know and intend that the nicotine in their products have pharmacological effects on consumers.

(i.) Product Development Research. The tobacco industry is not only keenly aware that consumers use tobacco for nicotine's pharmacological effects, but has conducted product development research designed to ensure that tobacco products deliver a sufficient dose of nicotine to provide a pharmacological response that satisfies the users' need for nicotine. See FINDINGS §§ II.C.1. and 2., infra. The industry has developed sophisticated technology to

determine the amount of nicotine absorbed by tobacco users. See p. 191. Using this technology, tobacco manufacturers have shown that tobacco users have a "daily nicotine requirement." See p. 192. Industry research and statements also show that the industry has devoted substantial resources to determine what dose of nicotine must be delivered by each cigarette and has attempted to establish the "minimum dose of [ ] nicotine that can provide pharmacological satisfaction for the smoker." See p. 190. The tobacco industry has also focused a significant portion of its product development research on methods of ensuring that nicotine is delivered at levels that do not fall below a pharmacologically satisfying dose.

In 1972, William Dunn, Jr., of Philip Morris expressed the widely held industry view that there is a minimum level of nicotine that must be delivered in tobacco products to provide pharmacological effects, and that below that level there would be few, if any, tobacco sales:

> *[C]ritics 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. The physiological response to nicotine can be readily elicited by cigarettes delivering in the range of 1 mg of nicotine.*

See p. 189 (emphasis added).

The industry has conducted many studies designed to establish the daily dose of nicotine obtained by tobacco users and the amount of nicotine that individual tobacco products must deliver to the consumer to provide that dose. See FINDINGS § II.C.1. and 2., infra. For example, Project Wheat was a multi-part study intended to aid BATCO in developing cigarettes with increased consumer acceptance and, specifically, to establish smokers' preferred nicotine level in tobacco products. See pp. 183-84. Reports of the study

make clear that the research was designed to identify the dose of nicotine that would produce desired physiological responses, rather than to identify the correct level of nicotine for taste or flavor. One report states:

> *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 recognized.*

See p. 184 (emphasis added). The researchers offered cigarettes containing different levels of nicotine to smokers and studied their responses. The study report concludes that there was an optimum nicotine delivery for smokers. The study also found that there was a minimum level of nicotine necessary to satisfy all smokers and that cigarettes that provided nicotine below that level were unacceptable. See p. 189. Project Wheat and similar industry studies and statements, FINDINGS § II.C.1. and 2., infra, reveal that tobacco manufacturers know that tobacco products must deliver a pharmacologically active level of nicotine to maintain consumer acceptance, and that manufacturers have acted to identify that level.

Other tobacco industry research reveals that the tobacco industry has taken action to ensure that tobacco products in fact deliver pharmacologically satisfying doses of nicotine. See FINDINGS § II.D., infra, at p. 213 et seq. As described above, the industry is well aware that tobacco products must provide a certain level of nicotine to elicit the pharmacological effects sought by consumers and that consumers will not continue to purchase tobacco products that fall below that threshold. As a result, the industry has focused substantial attention on methods of manipulating nicotine delivery in marketed products. In particular, the industry has devoted considerable research to reducing tar while maintaining a level of

nicotine delivery that would satisfy consumers' desire for the pharmacological effects of nicotine. See FINDINGS § II.D.2., infra at p. 222 et seq. As stated in one industry patent:

> *Maintaining the nicotine content at a sufficiently high level to provide the desired physiological activity, taste, and odor . . . can thus be seen to be a significant problem in the tobacco art. The addition of nicotine to tobacco in such a way that it remains inert and stable in the product and yet is released in a controlled amount into the smoke aerosol when the tobacco is pyrolyzed, is a result which is greatly desirable.*

See p. 213-14 (emphasis added).

As early as 1965, a Brown and Williamson official reported to other Brown and Williamson executives that BATCO research was focused on "the smoking and health problem." The goal was "to find ways of obtaining maximum nicotine for minimum tar." See p. 225. Approaches being used include: (a) chemical treatment of filters; (b) nicotine fortification of cigarette paper; (c) addition of nicotine containing powders to tobacco; (d) alteration of blends." Id.

An abundance of industry studies and patents show that in the decades since 1965, the tobacco industry has invested substantial resources to develop methods and technologies, the declared purpose of which is to facilitate the design of cigarettes in which the tar has been lowered but the amount of nicotine delivered has been maintained or increased. See FINDINGS § II.D.2., infra. These methods and technologies include: increasing the nicotine content of tobaccos by, for example, adding commercial nicotine to the tobacco or other parts of the cigarette, see pp. 214-16; transferring nicotine from one tobacco to another or by adding tobacco extracts, see p. 217; adding chemicals to tobacco and filters to increase delivery of nicotine, without altering nicotine content, see p. 228; and altering the "puff-by-puff" delivery of nicotine, see p. 227.

Tobacco manufacturers have also attempted to help smokers compensate for lower nicotine yields, that is to obtain more nicotine from a cigarette than its machine-tested yield, by designing cigarettes with "elasticity." See p. 229 et seq. ("Elasticity" refers to the ability of a cigarette, whatever its machine-measured nicotine yield, to deliver enough smoke to permit a smoker to obtain the amount of nicotine he needs, for example, through more or longer puffs, or by covering ventilation holes.) BATCO researchers described corporate policy on compensation and elasticity at a 1984 conference:

> *Compensation by modifying smoking regime [increasing or decreasing puff volume, duration, puff frequency, amount inhaled] is a topic which is being explored at GR & DC 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.*

See p. 230 (emphasis added). BATCO documents reflect numerous examples of research on different methods to improve elasticity. See p. 230.

In summary, the tobacco industry's product development research confirms that: tobacco manufacturers know that consumers use tobacco for its pharmacological effects; have acted to establish the dose that consumers require to obtain pharmacological satisfaction from tobacco products; and have worked to develop technology that will ensure that marketed products deliver a pharmacologically satisfying dose of nicotine.

(ii.) Control Over Nicotine Levels. Tobacco manufacturers also deliberately control the level of nicotine in cigarettes by monitoring and adjusting nicotine levels at each stage of the manufacturing process. The ultimate objective of these efforts is to ensure that the finished cigarette delivers the desired level of nicotine.[12]

Perhaps the best example of manufacturers' control of nicotine levels is the effort that the companies make to ensure that low-tar cigarettes deliver an adequate amount of nicotine. As described in the preceding subsection, tobacco industry research activities have focused on developing technologies for maintaining and increasing nicotine levels as tar is reduced. FDA's investigation has also shown that tobacco manufacturers actually use a number of techniques to ensure that nicotine levels in marketed products do not fall below a certain level, such as incorporating high nicotine tobaccos to ensure "adequate" levels of nicotine and using chemical additives to enhance nicotine delivery.

Tobacco manufacturers have a sophisticated understanding of the nicotine levels in various types of tobacco and in the various parts of the tobacco plant. By monitoring nicotine levels in the tobacco they purchase and by blending the tobaccos in accordance with their nicotine levels, tobacco companies are able to manufacture tobacco products with nicotine levels that vary only minimally within cigarette packs and from pack to pack. See p. 271.

Officials at R.J. Reynolds and Brown and Williamson have confirmed the importance

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[12] A number of techniques of cigarette production and manufacture can be used to lower nicotine levels. Probably the most significant technique is the design of low-tar cigarettes which lower nicotine levels when they lower tar levels. The filters that are used in 95% of cigarettes sold in the United States remove a certain amount of nicotine. The techniques described in FINDINGS § II.E., *infra*, are used by the tobacco industry to offset these reductions in nicotine levels and ensure that each cigarette delivers an amount of nicotine necessary to ensure consumer "satisfaction," i.e., to provide an adequate dose of nicotine to produce desired pharmacological effects.

of nicotine levels in leaf growing and purchasing. See p. 243. At least one company has actually developed a high-nicotine tobacco to use in manufacturing low-tar cigarettes. Brown and Williamson used a combination of conventional and advanced genetic breeding techniques to develop a high-nicotine, flue-cured tobacco plant, named "Y-1," that has approximately twice the nicotine level of American-grown flue-cured tobacco. Brown and Williamson used Y-1 tobacco in its cigarettes. See p. 239 et seq.

Once purchased, tobacco leaves are blended to attain target levels of nicotine. In fact, nicotine content is maintained at levels that would represent a high degree of control for a conventional drug manufactured from synthetic, homogeneous materials. See pp. 246-47. This level of control is remarkable for a product such as cigarettes, which are made from biological materials with a highly variable content.

Where design features aimed at reducing tar levels have also lowered nicotine levels, the manufacturer can use tobacco leaves with higher nicotine content to increase the nicotine level. For example, filters that are designed to reduce tar can also reduce nicotine. Yet, the industry is known to use proportionally greater amounts of higher nicotine-containing tobaccos in the tobacco blends of the lowest-tar varieties of cigarettes to maintain a higher nicotine level in those products. See p. 247. For example, "Y-1," Brown and Williamson's high-nicotine tobacco, was developed as a "blending tool" to permit the company to reduce tar and yet maintain nicotine delivery in its low-tar cigarettes. See p. 240.

Chemical additives are also used to enhance nicotine delivery. A major American tobacco company's 1991 handbook on leaf blending and product development identified ammonia as being effective to increase the amount of nicotine delivered to the smoker.

According to the handbook, ammonia in cigarette smoke "can liberate free nicotine from the blend, which is associated with increases in impact and 'satisfaction' reported by smokers." See p. 249. American tobacco companies often use ammonia in reconstituted tobacco; when cigarettes containing this type of tobacco are burned, the reconstituted tobacco serves as a source of ammonia in the cigarette smoke. See p. 250.

Tobacco companies also use a number of other chemicals to optimize nicotine delivery. Nicotine has a naturally harsh taste. To maintain sufficiently high levels of nicotine in tobacco products, manufacturers moderate nicotine's harshness by adding flavors such as sugar, licorice, cocoa, menthol, and other alcohol-based aromic substances to tobacco. According to one industry expert, the major contribution of the tobacco flavor specialist is to "help provide a rich, clean, full-bodied tobacco flavor, to keep to a minimum hotness and irritation in the mouth, and to ensure high satisfaction from an adequate level of nicotine per puff[,] requirements that guarantee the consumer a pleasurable smoke." See p. 251. In addition, glycerine/glycol in aerosol formulation is used to enhance "smoothness," ensuring that smoke will be inhaled into the lungs, thereby facilitating rapid and complete absorption of nicotine. See p. 253.

To a remarkable degree, the cigarette industry has accomplished the task of delivering sufficiently high levels of nicotine in low-tar products. A 1983 study showed that cigarettes advertised as having a low-nicotine yield contain as much nicotine as high-yield cigarettes. See p. 262. Moreover, all marketed cigarettes deliver sufficient nicotine to produce pharmacological effects on smokers. See p. 108 et seq. These findings are consistent with FDA's findings that the industry employs a number of methods to boost nicotine delivery to

compensate for nicotine losses from the application of tar-reducing designed modifications. Without the use of such methods, the techniques used to reduce tar should result in corresponding nicotine reductions. Instead, studies by FDA and others have demonstrated that the nicotine yield of cigarettes, as defined by the Federal Trade Commission (FTC) smoking machine tests, correlates inversely with nicotine concentrations in the tobacco, i.e., that some of the lowest-tar cigarettes have the highest concentrations of nicotine. See p. 262 FDA's analysis of FTC data also reveals an apparent increase in the sales-weighted FTC nicotine delivery ratings since 1982 (the earliest year for which the computer database is available), i.e., an overall increase in nicotine delivery from U.S. cigarettes. See p. 266.

Tobacco manufacturers' actions to manipulate nicotine deliveries from marketed cigarettes further demonstrate that nicotine is the central component of tobacco products, and that tobacco manufacturers have taken deliberate steps to maintain the level of nicotine that smokers receive.

(iii.) Alternative Product Research. Tobacco manufacturers have researched and developed alternatives to conventional tobacco products and to nicotine, largely in response to concerns about the health effects of conventional tobacco products. See FINDINGS § II.F., infra, p. 289 et seq. Industry documents explaining the nature and purpose of these alternative products provide confirmation that tobacco manufacturers: 1) understand that nicotine's pharmacological effects on the brain are essential to the successful marketing of tobacco products, and 2) have taken actions to ensure that alternative tobacco products will continue to provide these pharmacological effects.

Internal documents from both Philip Morris, Inc., and Brown and Williamson show

that these companies have had substantial research programs to identify "nicotine analogues," chemicals that are closely related to nicotine. See FINDINGS § II.F.1., infra. Company documents reveal that both Philip Morris and Brown and Williamson were seeking analogues that would produce effects on the central nervous system similar to nicotine, that could be substituted for nicotine if nicotine-containing tobacco became regulated or unattractive to consumers, and that could be added to currently marketed products to enhance the effects of nicotine. See p. 289. These programs were also designed to identify substances that shared nicotine's "desired" effects on the central nervous system, without producing its undesirable effects on the cardiovascular system. See p. 290.

The industry's nicotine analogue research programs were expressly based on the companies' view that "[s]hould nicotine become less attractive to smokers, the future of the tobacco industry would become less secure . . . . A commercial threat would arise if either an alternative [nicotine] product became acceptable or the effect of nicotine was changed [by an antagonist to nicotine]." See p. 292. In 1968, BATCO researchers, acknowledging the critical importance of nicotine in tobacco, recommended that the industry search for nicotine substitutes with the "desired" pharmacological effects on the brain:

> *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. The possibility that nicotine and other substances together may exert effects larger than either separately (synergism) should be studied and if necessary the attention of Marketing Departments should be drawn to these possibilities.*

See p. 290 (emphasis added). Various BATCO documents show that the company had an extensive program to identify nicotine analogues. See FINDINGS § II.F.1., infra.

Internal documents from Philip Morris' nicotine analogue program reveal that this company also sought nicotine analogues with pharmacological effects on the central nervous system, including effects associated with addiction. See p. 293 et seq. Philip Morris documents state explicitly that the purpose of the research on nicotine analogues was to find nicotine substitutes that were behaviorally active and had the same "reinforcing properties" in animals as nicotine. In an internal report on Philip Morris research, a section entitled "Nicotine Analogues" includes the following "research objectives":

1. *Determine if behaviorally active nicotine analogues can be directly substituted for nicotine in rats for which nicotine is functioning as an intravenously delivered positive reinforcer.*

2. *Establish nicotine analogues as an intravenously delivered positive reinforcer.*

3. *Compare the potencies of nicotine analogues to nicotine in producing positive reinforcing effects.*

See p. 296. As described in FINDINGS § I.B., infra, it is well established that the ability of a substance to act as a "positive reinforcer" is one of the hallmarks of an addictive substance. Philip Morris documents show that the company also tested nicotine analogues using "prostration" studies and "drug discrimination" studies. See p. 295. These studies provide evidence about whether a substance acts on the brain in the same manner as nicotine and has properties of an addictive substance. See FINDINGS § I.B., infra.

Philip Morris has also conducted pharmacological and behavioral research on another constituent of cigarette smoke, acetaldehyde, that was believed to have reinforcing effects. See FINDINGS § II.F.2, infra. This research was intended to find a combined dose of acetaldehyde and nicotine in cigarettes that would produce "maximal reinforcing effects."

See p. 298. The reinforcing efficacy of a substance is a measure of its ability to cause addiction in users. Id. In undertaking research on how to maximize the reinforcing effects of cigarettes, Philip Morris demonstrated its understanding of the addictive nature of cigarettes and its intention to produce, and even increase, these effects in tobacco users.

These company documents show that tobacco manufacturers have sought substitutes for nicotine that had psychoactive effects and other recognized characteristics of an addictive substance. At least one company conducted research on how to increase the reinforcing properties of cigarettes. This evidence compellingly shows that manufacturers intend tobacco products to have pharmacological effects and result in addiction.

Tobacco companies have also developed a number of cigarette alternatives. See FINDINGS § II.F.3., infra. In developing cigarette alternatives, the companies have sought to eliminate many of the traditional components and characteristics of cigarettes and cigarette smoke, such as tar and carbon monoxide. Tobacco companies have consistently recognized, however, that cigarette alternatives must deliver adequate amounts of nicotine to satisfy consumers. As a result, most of the alternative cigarette products developed by tobacco companies are simply nicotine delivery systems. For example, R.J. Reynolds has developed two "smokeless cigarettes," Premier and Eclipse. See p. 302 et seq. Nicotine is virtually the only compound (other than the paper and the filter) that is contained in these products in quantities similar to conventional cigarettes. Although these alternative products are very different from one another, they are strikingly the same in their ability to administer a consistent level of nicotine. Industry documents and patents show that other tobacco companies' cigarette alternatives are also intended to be nothing more than nicotine delivery

systems. See pp. 305-07. For example, BATCO developed cigarette alternatives that it characterized as "devices for the controlled administration of nicotine." See p. 307.

A 1970 BATCO R&D conference included a telling illustration of the tobacco industry's recognition of the central importance of nicotine in cigarette alternatives:

> *It was agreed that, if and when total cigarette consumption declined, great opportunities for supplying the demands of other socially acceptable habits could follow. Discussion followed on those opportunities which might arise. Amongst those discussed were a) chewing products, and b) wet snuff [both of which are smokeless tobacco products]. It was felt that this whole area, much of which is already in the tobacco industry, should be examined more thoroughly. Particular attention should be given to buccal administration of nicotine and other physiologically active ingredients. At the same time, it was re-affirmed that we would not contemplate the incorporation of nicotine in edible products.*

See p. 308 (emphasis added). As this passage makes clear, tobacco manufacturers understand that the common feature of cigarettes and smokeless tobacco products is the ability to administer nicotine to consumers, and that the purpose of the nicotine is to produce pharmacological effects in the consumer.

Thus, company documents related to the development of alternatives to both nicotine and conventional tobacco products establish tobacco manufacturers' knowledge that nicotine's psychoactive effects are critical to maintaining a successful market for cigarettes and smokeless tobacco, and that consumers use these products primarily for nicotine's pharmacological effects. The fact that the tobacco industry considers alternative cigarettes that are simply nicotine delivery systems to be functionally equivalent to traditional cigarettes demonstrates that tobacco companies intend their currently marketed tobacco products to be used for pharmacological purposes by consumers.

d. Smokeless Tobacco Manufacturers Manipulate Nicotine Delivery and Foster Graduation of Users From Low to High Nicotine Products.

Smokeless tobacco manufacturers control the delivery of nicotine from smokeless tobacco through a variety of additives and design features. Manufacturers use these additives and features to produce lines of smokeless products that deliver nicotine in increasing amounts. Evidence exists that smokeless tobacco manufacturers employ a "graduation process" to market these products. Low-nicotine products are marketed to new users of smokeless tobacco. After these new users become tolerant to the low-nicotine products, manufacturer marketing encourages smokeless tobacco consumers to "graduate" to higher nicotine products. The goal of the graduation process is to establish and maintain a market for the smokeless tobacco products with the highest nicotine delivery. Smokeless tobacco manufacturers' deliberate manipulation of levels of nicotine delivery, and the marketing of low-nicotine products to new users and high-nicotine products to experienced users, demonstrates the manufacturers' intent to facilitate nicotine addiction. This evidence establishes that smokeless tobacco manufacturers intend to affect the structure and function of the body.

Until the 1970's, smokeless tobacco companies in the United States marketed only products with high nicotine delivery that were not well tolerated by new users and the number of consumers using their products was steadily diminishing. See pp. 279-80. Evidence from the files of smokeless tobacco companies shows that, in the late 1960's or early 1970's, these companies began to entice new users of smokeless tobacco. Id. To do so, they decided to develop low-nicotine products in teabag-like pouches to encourage people to begin using smokeless tobacco. See pp. 280-81. Company documents also reveal that manufacturers

deliberately set out to produce a range of products with low, medium, and high nicotine delivery, see p. 281, and that they understood that nicotine's pharmacological effects were essential to the success of their products. As noted above, the senior vice president for marketing of the largest smokeless tobacco company wrote in a memorandum on new product development that "virtually all tobacco usage is based upon nicotine, 'the kick,' satisfaction." See pp. 186-87.

Analyses, by FDA and others, of current smokeless tobacco products show that smokeless tobacco companies have successfully developed product lines with graduated nicotine deliveries. See p. 276. Abundant evidence exists that manufacturers deliberately manipulate smokeless tobacco products to provide these graduated nicotine deliveries. Smokeless tobacco manufacturers do so primarily by adding various acidic or buffered compounds to the tobacco to alter its "pH," i.e., its relative acidity or alkalinity. See pp. 273-275. By increasing the pH of a product, manufacturers increase the amount of nicotine that is transformed from the "salt" or "bound" form of nicotine into "free nicotine." Only free nicotine can be readily absorbed through the mouths of smokeless tobacco users into the bloodstream. Small adjustments in pH can dramatically raise delivery of free nicotine. For example, raising the salivary pH from 7 to 8 increases the percentage of free nicotine from 10% to 50%, a five-fold increase. See p. 274. Analyses of currently marketed smokeless tobacco products reveal that the "starter" products have a pH in the range of 5 to 7, while the products for experienced users, like Copenhagen, have a pH of 8 or more. The amount of free nicotine delivered from these products correspondingly ranges from 5% to 20% for the starter products and 50% to 80% for the high-end products. See p. 276.

Other features of these products are also designed to lower nicotine absorption at the low (starter) end of the product range and to raise nicotine absorption at the top end. For example, humectants are added to the products to increase moisture content. See p. 279. High moisture content and other design features of smokeless tobacco have the effect of providing an intense "bolus" dose of nicotine to the user when the user first places a wad of tobacco in the mouth. See p. 278. On the other hand, "starter products" like Skoal Bandits are often packaged in a miniature pouch designed to be placed in the user's mouth; the pouch serves to limit the amount of snuff that is placed in the mouth and to create a barrier that decreases the rate of nicotine release from the product. See p. 277. Thus, starter products like Bandit deliver less total nicotine at a slower rate than the high-nicotine products offered by the same companies.

Internal documents from United States Tobacco Co. (UST), the largest smokeless tobacco producer in the United States, demonstrate that the company developed low nicotine snuff products for the specific purpose of creating "starter" products for new users who could not tolerate products with more nicotine. These low-nicotine products were then aggressively marketed to new users through advertising and by offering free samples at college campuses and sports events. See p. 282 et seq. UST documents, including internal memoranda and advertising, demonstrate that smokeless tobacco manufacturers know and intend that their customers will "graduate" upward through the range of nicotine products to the highest nicotine products. For example, a chart prepared by UST's marketing department is labeled "graduation process" and shows a hierarchy of products, with arrows going from Skoal Bandits, to Happy Days and Skoal Long Cuts, and culminating with Copenhagen. See p. 284.

This "graduation" corresponds exactly to the progression of the nicotine levels delivered by the listed products.

The product development and marketing strategies for smokeless tobacco have been extremely successful at recruiting new users. Use of smokeless tobacco products has risen substantially since the 1970's: overall, moist snuff sales almost tripled from 1972 through 1991, while use by male adolescents aged 18 to 19 increased almost 1,500% between 1970 and 1991. See p. 287.

The deliberate marketing of products that deliver graduated amounts of nicotine demonstrates that smokeless tobacco manufacturers know that their products are used to satisfy consumers' desire for increasing amounts of nicotine. The evidence of manipulation of nicotine delivery in smokeless tobacco shows that manufacturers have taken steps to create and sustain the need for nicotine. This evidence is more than sufficient to demonstrate that smokeless tobacco manufacturers intend consumers to become tolerant to, and addicted to, the nicotine in smokeless tobacco. Both tolerance and addiction are effects on the structure and function of the body produced by nicotine. Accordingly, smokeless tobacco products are intended to affect the structure or function of the body.

III. NICOTINE-CONTAINING CIGARETTES AND SMOKELESS TOBACCO PRODUCTS ARE DRUG DELIVERY SYSTEMS THAT ARE APPROPRIATELY REGULATED AS DEVICES.

Nicotine-containing cigarettes and smokeless tobacco products are "intended to affect the structure or any function of the body" within the meaning of the Act's drug and device definitions. 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). Based on the agency's analysis of the evidence before it: (1) the nicotine in cigarettes and smokeless tobacco products is a drug, achieving its effect through chemical action within the body; (2) cigarettes and smokeless tobacco are drug delivery systems whose purpose is to deliver nicotine in a manner in which it can be most readily absorbed by the consumer, and are, therefore, devices; and (3) cigarettes and smokeless tobacco products are combination products that the agency has the discretion to regulate using drug authorities, device authorities, or a combination of both authorities. 21 C.F.R. § 3.2(e) (1994). The record before the agency supports regulation of cigarettes and smokeless tobacco products pursuant to the Act's device authorities.

FDA considers device-like products, such as instruments, implements, machines, contrivances, implants, or other similar or related articles, 21 U.S.C. § 321(h), whose primary purpose is delivery of a drug, and that are distributed with a drug product, to be drug delivery systems. Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health § VII.A.1.(b)(October 31, 1991)("Intercenter Agreement"). Examples include contrivances containing drugs, such as pre-filled syringes, transdermal patches, and metered-dose inhalers. Id. Cigarettes and smokeless tobacco products 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.

Specifically, a cigarette is analogous to a metered-dose inhaler, an instrument that converts a drug into an aerosolized form for inhalation and delivery to the lungs for absorption into the bloodstream. Indeed, a cigarette is not simply tobacco, paper, and a filter. It is "a highly engineered product." FDA Docket No. 94P-0069, Response of R.J. Reynolds Tobacco Company, Appendix D, p. 1 (November 2, 1994). A device is an instrument or related article that "does not achieve its primary 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 its primary intended purposes." 21 U.S.C. § 321(h).

The primary purpose of parts of the cigarette, each of which is a device or device component within the Act's meaning, and the cigarette itself, a consciously engineered instrument, is to effectuate the delivery of a carefully controlled amount of the 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 in the lungs, yields on average approximately 1.0 mg of nicotine. As the evidence discussed above reveals, cigarettes are drug delivery systems and, accordingly, are devices within the meaning of the Act.

Smokeless tobacco products function like infusion devices or transdermal patches that

deliver a controlled continuous amount of nicotine to the cheek tissue for 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.[13] The tobacco also delivers chemicals added during the manufacturing process, primarily alkalines, that increase the pH within the oral cavity and affect the rate at which the nicotine is absorbed into the body. See FINDINGS § II.E.2.

Because cigarettes and smokeless tobacco products are drug-device combination products, FDA may regulate them as drugs, devices, or both. See 56 Fed. Reg. 58754, 58754-55 (November 21, 1991); Intercenter Agreement § VII.A.1(b). Based on the record before the agency, regulation of cigarettes and smokeless tobacco products pursuant to the Act's device authorities is most appropriate at this time.[14] The alternative, regulating the products

[13] The fact that smokeless tobacco material is largely organic does not remove it from the definition of a device. FDA regulates many organic substances as devices, as well as liquids and gases. For example, FDA regulates as devices: injectable collagen, hemodialysis fluids, lubricants and lubricating jellies, preservation solutions for organ/tissue transport, absorbable sponges and wound dressings, gas mixtures for pulmonary function tests, spray-on dressings, liquids functioning through physical action applied to the body to cool or freeze tissues, and sodium hyaluronate or hyaluronic acids for use as a surgical aid. See Intercenter Agreement § VII.C.

[14] This decision is similar to the determination of the Department of Health, Education, and Welfare (HEW), before authority over biologic drugs was transferred to FDA, regarding radioactive biologic products. Radioactive biologic products are both biologics under the Public Health Service Act (PHSA), 42 U.S.C. § 262, as well as drugs and new drugs, 21 U.S.C. § 321(g), (p), that may be regulated pursuant to the drug provisions of the FDCA. HEW determined that a drug would not be subject to the new drug provisions of the FDCA if it is a drug regulated as a biologic product pursuant to the licensure provisions of the PHSA. 40 Fed. Reg. 31311, 31312 (July 25, 1975); see 21 C.F.R. § 310.4.

pursuant to the Act's drug authorities, might result in the removal of these products from the market. Over 40 million Americans are currently addicted to cigarettes and smokeless tobacco products. Prohibiting the sale of these products, which could be required if FDA were to apply the Act's new drug authorities to them, could have significant health consequences for a substantial number of these nicotine-addicted consumers. In the unique setting of highly addictive products that have already been marketed for a sufficient period to addict a large number of Americans, application of requirements that could result in the abrupt removal of the products from the market is not the most appropriate regulatory response.

By contrast, the Act's device authorities provide flexible tools that allow FDA to establish and move towards the public health protection goals that are most practicable for cigarettes and smokeless tobacco products. Therefore, FDA is proposing a set of regulatory requirements for these products pursuant to the Act's device authorities.

The Medical Device Amendments of 1976, while having as their objective the ultimate assurance of the safety and effectiveness of marketed devices, contain provisions designed to permit a staged, multi-tiered approach to assuring the safety and effectiveness of long-marketed products. The authorities available under the Act's device provisions may be used to help eliminate or greatly reduce the addiction of the next generation of American children and teenagers to cigarettes and smokeless tobacco products.

Based on the record before the agency, all cigarettes and smokeless tobacco products distributed in the United States are drug-device combination products subject to regulation as devices. The record before the agency includes evidence that these products are intended to

affect the structure or any function of the body, based in part on nicotine's well-established pharmacological and addictive effects and the widespread consumer use of cigarettes and smokeless tobacco for pharmacological purposes. These factors are relevant to establishing the intended use of all brands of cigarettes and smokeless tobacco products distributed in the United States.

The Agency has obtained evidence concerning the knowledge of cigarette and smokeless tobacco product manufacturers about the pharmacological and addictive effects of nicotine in cigarettes and smokeless tobacco, and their manipulation of nicotine delivery to satisfy users' physiological need for nicotine, from the major manufacturers of these products and from CTR. Products from these manufacturers account for the vast majority of the U.S. cigarette and smokeless-tobacco market and probably account for close to 100% of that market. Under FDA's traditional approach to device classification, it is appropriate to classify all marketed cigarettes and smokeless tobacco products as drug delivery devices based on the cumulative evidence obtained from manufacturers.

CONCLUSION

The Food and Drug Administration has conducted an extensive investigation and has engaged in comprehensive analysis regarding the agency's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. The results of that inquiry and analysis support a finding at this time that nicotine in cigarettes and smokeless tobacco products is a drug, and that these products are drug delivery devices within the meaning of the Federal Food, Drug, and Cosmetic Act. Nonetheless, because the agency recognizes the unique importance of the jurisdictional issue as well as the factual justification for any proposed rule in this area, the agency invites comment on these matters. Comments will receive full and serious consideration.

APPENDIX TO LEGAL ANALYSIS

Examples of FDA's Regulation of Products as Drugs or Devices Based on the Product's Inherent Nature, Actual Use, or Its Effect on the Structure or Function of the Body

FDA has, on a number of occasions, asserted jurisdiction over a product even though the product's labeling and the vendor's advertising or other express representations did not establish that the product was a drug or a device within the meaning of the Act. The agency has found "intended use" and "intended effects" based on the inherent nature of the product, its actual use or effects, or a combination of these factors. Some examples follow:

1. Stimulant Narcotic Chewed or Used as Tea: Beginning in the early 1980's, FDA regulated as unapproved drugs imports of catha edulis, or "khat," a shrub whose leaves act as a stimulant narcotic that affects the central nervous system when chewed or used as tea, even though the agency did not have any information about or claims by vendors. FDA Import Alert 66-23 (March 26, 1982, revised April 2, 1986, and February 9, 1993). FDA issued an import alert for the product, deeming it a drug in the absence of any labeling or other material that would establish intended use. See FDA Import Alert 66-23 (March 26, 1982). FDA initiated a seizure of "khat" in Buffalo in 1985 and the product was ultimately forfeited and destroyed. FDA Import Alert 66-23 (April 2, 1986 revision). Knowledge of khat's use came from United Nations reports and other general sources of information about customs and practices regarding the use of khat. Id.

2. Imitation Cocaine: FDA took numerous enforcement actions in the 1980's against "caine" products that were used to imitate cocaine. "Caine" contained bulk anesthetic powders, such as lidocaine or mannitol, and was often sold as "incense" or "novelty cocaine."

Memorandum from Chief, Prescription Drug Compliance Branch (August 4, 1982), reprinted in Rx Drug Study Bulletin #258. The agency used laboratory analyses of the products, the manner in which the products were offered and sold, such as through magazines not associated with the legitimate drug industry (e.g. the National Enquirer, High Times, Soldier of Fortune, and Easy Rider) and at headshops with other drug paraphernalia, and "street" information that the products provide a "cheap high" to determine the products' intended use. See id. In 1984, the government seized a "caine" product from Golden Rod Music in Dayton, OH. FDC 64350, Case No. C-3-84-686 (S.D. Ohio). The product consisted of more than 25 percent ephedrine, as determined by laboratory analysis. Id. Also in 1984, FDA issued a regulatory letter to Mid-America Drug Co., Evansville, IN., concerning marketing of "caine" products. FDA Administrative File for Mid-America Drug Co., regulatory letter 84-DT-12. The firm voluntarily discontinued sales of the products, as did several other firms that received regulatory letters at about the same time. Id., response to regulatory letter 84-DT-12; see also, 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 odorizer but in fact containing lidocaine. Case No. 94 CR 20040-BC (E.D. Mich.).

3. Hormones in Topical Preparations: The agency has formally taken the position that any statement in the labeling indicating that "hormones" are present in topical products will be considered to be an implied claim for therapeutic purposes, or to affect the structure or

function of the body, and will make the product a drug, even in the absence of more specific claims. 58 Fed. Reg. 47611, 47612 (September 9, 1993); Drug Study Bulletin No. 67 (March 28, 1994); see also 54 Fed. Reg. 40618, 40619 (October 2, 1989). The agency has also taken the position that even in the absence of labeling indicating that "hormones" are present in the product, the mere presence of hormones at levels that affect the structure or any function of the body, or the inclusion of certain hormones that do not have any legitimate cosmetic uses, would be sufficient for a determination that the product is a drug. 58 Fed. Reg. at 47611.

4. Fluoride in Dentifrice Products: FDA considers dentifrice products containing fluoride to be drugs, irrespective of whether any claims are made, because fluoride is widely accepted as an anti-cavity agent by the dental products industry and consumers, and because fluoride affects the structure of the tooth. See 59 Fed. Reg. 6084, 6088 (February 9, 1994); see also 50 Fed. Reg. 39854 (September 30, 1985).

5. Thyroid in Food Supplements: In 1984, the government seized and destroyed a thyroid-containing product that had been marketed as a food supplement by an Arkansas firm. FDC 64270, Case No. B-C-84-61 (E.D. Ark.). FDA had concluded that the product was a drug, based on the recognized effects of thyroid products on the structure and function of the human body.

6. Interferon: In 1983, FDA established a due diligence requirement regarding manufacturers' distribution of interferon, a biologic product composed of proteins. See 48 Fed. Reg. 52644 (November 21, 1983). At the time, interferon could be used only for investigational purposes in laboratory animals and tests in vitro. However, interferon received wide media coverage as a potential "miracle cure" in the treatment of cancer and viral infections in humans.

Because of its concern over diversion of interferon to unapproved uses, the Agency issued the notice to prevent use of interferon in humans.

7. Eye Ailment Device: In the 1960's, FDA undertook an enforcement action against a metal tube containing a light bulb, round metal discs, and colored glass filters used by a medical practitioner in his office in the treatment of various eye malfunctions and conditions. A district court upheld the Agency's conclusion that this use made the tube a device, even though the practitioner made no claims for the product. United States v. An Article of Device . . . Labeled in Part: "Cameron Spitler Amblo-Syntonizer", 261 F. Supp. 243, 245 (D. Neb. 1966).

8. Novelty Condoms: In early 1994, FDA took the position that "novelty condoms" that are usable as condoms would be regulated as condoms even in the absence of express claims (e.g., for birth control or to prevent sexually transmitted diseases). Letter from Ronald Johnson, Director, Office of Compliance, CDRH, to Manufacturers, Distributors, and Importers of Condoms, February 23, 1994. The agency's position was based on the belief that, because of the inherent nature and exclusive use of the article, people would actually use the condoms for prophylactic purposes even though they were not so labeled. The Agency stated that "[l]abeling a functional condom as a novelty is not sufficient" to escape the regulatory requirements applicable to condoms specifically and medical devices in general. Instead, a manufacturer would have to render the product completely unusable as a condom. Id.

9. Noncorrective Tinted Contact Lenses: The agency has taken the position that tinted contact lenses that do not correct or improve vision and are promoted to enhance eye color are medical devices. This position is based on the fact that all contact lenses, including neutral lenses, have a physiological effect on the eye. In 1986, the government obtained a consent

decree of permanent injunction against the sale of a system used to make noncorrective tinted contact lenses on the ground that the system causes adulteration of a medical device, the lenses. FDA INJ 1145, United States v. International Hydron Corp., No. 87-2129 (E.D.N.Y.).

10. Sunscreens: Between 1940 and the 1970's, FDA changed its position regarding the degree to which sunscreens were drugs under the Act. See 58 Fed. Reg. 28194 (May 12, 1993). FDA had stated in a 1940 advisory opinion that a product promoted for the prevention of damage from the sun was a drug while a product promoted for acquiring an even tan was a cosmetic. Id. at 28204. FDA changed its view of the latter category of products, however, because "[s]ince 1940 . . . there has been a significant body of information developed on the harmful effects of the sun on human health and a significant change has occurred in consumer perception of the purpose of suntanning products." Id. FDA explained that sunscreen products affect the structure and function of the body by "altering the normal physiological response to solar radiation," and that consumers expect protection from such products irrespective of the way in which such products are promoted. Id.

11. Tanning Booths: FDA has taken the position that tanning booths are devices under the Act because, by exposing the body to ultraviolet rays, they are intended to affect the structure or function of the body. Based on this position, the Agency has initiated seizure actions in recent years against various tanning booths, including, among others, those in the possession of Chic Wig Boutiques, Clarksville, Indiana. FDC 66099, Case No. NA 91-64-C (N.D. Ind.). The Indiana firm signed a consent decree with regard to this device. Id.; see also FDC 66224 (Chic Tanning Studio, Tampa, Florida), Case No. 92-CV-70829-DT (M.D. Fl.); FDC 65453 (Sunburst Sun Spa, Anchorage, Alaska), Case No. A-87-625-CIV (D. Alaska).

PART TWO: FINDINGS

I. NICOTINE HAS DRUG EFFECTS ON THE BODY 73
- A. NICOTINE HAS PHYSIOLOGICAL AND CENTRAL NERVOUS SYSTEM EFFECTS 74
- B. NICOTINE IS ADDICTIVE 78
  - 1. Major Public Health Groups and Leading Experts Concur 78
  - 2. Epidemiological Data Establishes That Tobacco Users Display the Clinical Symptoms of Addiction 86
  - 3. Laboratory Studies Establish That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Substances 94
  - 4. Nicotine's Sensory Effects Are Secondary to its Psychoactive Effects 102
  - 5. Other Factors Associated with Tobacco Use Are Secondary 106
- C. MARKETED TOBACCO PRODUCTS DELIVER PHARMACOLOGICALLY ACTIVE DOSES OF NICOTINE 108
  - 1. Amount of Nicotine Necessary to Produce a Physiological Response in the Central Nervous System 108
  - 2. Nicotine Delivery From Currently Marketed Tobacco Products ... 110
- D. CONSUMERS USE TOBACCO PRODUCTS FOR DRUG EFFECTS ... 115
  - 1. To Satisfy Addiction 115
  - 2. To Affect Mood and Control Weight 118

II. STATEMENTS, RESEARCH, AND ACTIONS BY TOBACCO COMPANIES 121
- A. INDUSTRY STATEMENTS ON NICOTINE'S DRUG EFFECTS 122
  - 1. Statements That Nicotine's Drug Effects Are Essential to Tobacco Use 123
  - 2. Statements Recognizing That Nicotine Is Addictive 143
  - 3. Statements That Tobacco Products Are Nicotine Delivery Systems 156
- B. INDUSTRY RESEARCH ON THE DRUG EFFECTS OF NICOTINE .. 160
  - 1. Industry Research on Nicotine's Effects on the Brain 164
  - 2. Industry Research on Nicotine Delivery to the Blood and Brain ... 174
  - 3. Industry Research Establishes That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Drugs 179
- C. INDUSTRY RESEARCH ON THE CONSUMER'S NEED FOR AN ADEQUATE DOSE OF NICOTINE 183
  - 1. Industry Research on Importance of Supplying Sufficient Nicotine to Provide Consumer Acceptance and "Satisfaction" 183
  - 2. Industry Research to Determine the Minimum and Maximum "Dose" of Nicotine Required by Consumers of Tobacco 188
  - 3. Industry Research on How Consumers "Compensate" to Achieve an Adequate Dose of Nicotine 198

4. Industry Research and Knowledge of Tobacco Users' Inability to Quit 206
D. INDUSTRY PRODUCT DEVELOPMENT RESEARCH TO ENSURE AN ADEQUATE DOSE OF NICOTINE 213
1. Industry Emphasis on Nicotine in Product Development Research 213
2. Industry Research on Maintaining Adequate Nicotine Delivery When Lowering Tar 222
E. INDUSTRY MANIPULATION AND CONTROL OF NICOTINE DELIVERY IN MARKETED TOBACCO PRODUCTS 232
1. Industry Manipulation and Control of Nicotine in Cigarettes 232
2. Industry Manipulation and Control of Nicotine in Smokeless Tobacco 273
F. INDUSTRY ALTERNATIVE TOBACCO PRODUCTS 289
1. Industry Development of Nicotine Substitutes That Mimic Nicotine's Drug Effects 289
2. Industry Research on Acetaldehyde As a Reinforcer 298
3. Industry Development of Alternative Cigarettes That Deliver Nicotine 302
G. INDUSTRY KNOWLEDGE THAT NICOTINE'S SENSORY EFFECTS ARE SECONDARY TO ITS PHARMACOLOGICAL EFFECTS 311
H. INDUSTRY FAILURE TO REMOVE NICOTINE FROM TOBACCO DESPITE AVAILABLE TECHNOLOGY 318

I. NICOTINE HAS DRUG EFFECTS ON THE BODY

Nicotine is a psychoactive drug that affects the brain, the skeletal muscles, the cardiovascular system, and other systems throughout the body.[15] Psychoactive is defined as having the ability to alter mood, anxiety, behavior, cognitive processes, or mental tension.[16] There is widespread agreement within the scientific community that nicotine causes substantial pharmacological effects, including those that lead to addiction in the majority of users. This section will briefly review: 1) the physiological and central nervous system effects of nicotine; 2) the data that support the conclusion that nicotine is an addictive agent; 3) the evidence that the amount of nicotine in commercially available products is sufficient to cause addiction; and 4) the evidence that consumers use tobacco products for their drug effects.

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[15] U.S. Department of Health and Human Services. *The Health Consequences of Smoking: Nicotine Addiction. Report of the U.S. Surgeon General, 1988.* U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Health Promotion and Education, Office on Smoking and Health. DHHS Publication No. (CDC) 88-8406, 1988. Pages 13-14, 79-124, 410, 596-601. (Hereafter cited as Surgeon General's Report. 1988. *Nicotine Addiction.*)

[16] Hensyl WR, ed. *Stedman's Medical Dictionary.* 25th ed. Baltimore, MD: Williams and Wilkins; 1990:1284.

A. NICOTINE HAS PHYSIOLOGICAL AND CENTRAL NERVOUS SYSTEM EFFECTS

The physiological and central nervous system effects of nicotine involve effects on both the structure and the function of the brain. When it is inhaled in cigarette smoke, nicotine is absorbed into the lungs and then rapidly enters the bloodstream. In smokeless tobacco, it is absorbed through tissues of the mouth or nose and then enters the bloodstream. Once it is in the bloodstream, nicotine crosses the blood-brain barrier and is rapidly distributed to the brain.[17] It is estimated that, once inhaled in cigarette smoke, nicotine reaches the brain in 11 seconds or less.[18] Nicotine generates its effects by binding to receptors in the brain that are intended to receive the neurotransmitter acetylcholine. These receptors, when activated by nicotine, cause the release of other chemicals in the brain that produce effects on mood, alertness, and perhaps cognition. Continued nicotine use causes an increase in the number of receptors that can bind nicotine, and changes the electrical and metabolic activity of the brain.

Nicotine's rewarding effects are the result of its action on a part of the brain called the mesolimbic system, which is also affected by many other addictive drugs.[19] Nicotine, like amphetamine and cocaine, produces its rewarding or reinforcing effects by stimulating the

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[17] Surgeon General's Report. 1988. *Nicotine Addiction.* Page 13.

[18] Benowitz NL. Clinical Pharmacology of Inhaled Drugs of Abuse: Implications in Understanding Nicotine Dependence. *Research Monograph 99.* National Institute on Drug Abuse. 1990. Page 17.

[19] *See:*
Wise RA, Rompre PP. Brain dopamine and reward. *Ann Rev Psychol.* 1989;40:191-225.

Clarke PBS. Mesolimbic dopamine activation--the key to nicotine reinforcement? *The Biology of Nicotine Dependence.* Wiley, Chichester (Ciba Foundation Symposium 152) 1990;153-168.

release of dopamine, a chemical produced in the mesolimbic system. Dopamine plays a major role in regulating pleasurable sensations.[20] (See Appendix 1 for a summary of the studies indicating that nicotine acts on the mesolimbic dopaminergic system.)

Nicotine produces a range of other complex pharmacological effects that are related to its dose and/or bioavailability. For example, at low doses, nicotine stimulates the cardiovascular system, producing an increase in blood pressure and heart rate. At higher doses or more rapid administration, nicotine slows the heart rate.[21]

Depending on the circumstances, nicotine delivered by cigarette smoking can have an arousal-increasing or arousal-reducing effect.[22] These effects have been confirmed using electroencephalographic (EEG) analysis.[23] When smokers are placed in a stressful situation,

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[20] *See:*
Pomerleau OF, Pomerleau CS. Neuroregulators and the reinforcement of smoking: towards a biobehavioral explanation. *Neurosci Biobehav Rev.* 1984;8:503-513.

Wise and Rompre, note 19, *supra,* at pp. 191-225.

Clarke, note 19, *supra,* at pp. 153-168.

[21] Henningfield JE, Miyasato K, Jasinski DR. Abuse liability and pharmacodynamic characteristics of intravenous and inhaled nicotine. *J. Pharmacol Exp Ther.* 1985;234:1-12.

[22] Norton R, Brown K, Howard R. Smoking, nicotine dose and the lateralisation of electrocortical activity. *Psychopharmacology.* 1992;108:473-479.

[23] *See:*
Pritchard WS, Gilbert DG, Duke DW. Flexible effects of quantified cigarette-smoke delivery on EEG dimensional complexity. *Psychopharmacology.* 1993;113:95-102.

Pritchard WS. Electroencephalographic effects of cigarette smoking. *Psychopharmacology.* 1991;104:485-490.

Golding JF. Effects of cigarette smoking on resting EEG, visual evoked potentials and photic driving. *Pharmacology Biochemistry and Behavior.* 1988;29:23-32.

smoking can have a depressant effect on the EEG profile.[24] When smokers are under conditions of low arousal induced by mild sensory isolation, cigarette smoking can have a stimulant effect.[25] In other words, smoking appears to have a relaxing effect in stressful situations and a stimulating effect in otherwise nonstimulating circumstances.

Smoking or the administration of nicotine appears to have mixed results in its effects on sustained attention.[26] The tobacco industry has conducted several studies on nicotine's effect on performance and cognition. While some studies showed increased performance and response,[27] others showed little or no effect.[28] Many of these studies were conducted with nicotine-deprived subjects, and the results may reflect the reversal of deficiencies caused by nicotine withdrawal. The 1988 Surgeon General's Report concluded that "[a]fter smoking cigarettes or receiving nicotine, smokers perform better on some cognitive tasks . . . than they do when deprived of cigarettes or nicotine. However, smoking and nicotine do not improve general learning."[29] (An extensive discussion of the physiological and central nervous system

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[24] *See* Pritchard, note 23, *supra,* at pp. 485-490.

[25] Golding J, Mangan GL. Arousing and de-arousing effects of cigarette smoking under conditions of stress and mild sensory isolation. *Psychophysiology.* 1982;19(4):449-56.

[26] Heishman SJ, Taylor RC, Henningfield JE. Nicotine and smoking: A review of effects on human performance. *Experimental and Clinical Psychopharmacology.* 1994;2(4):345-395.

[27] *See:*
Wesnes K, Warburton DM. Effects of smoking on rapid information processing performance. *Neuropsychobiology.* 1983;9:223-229.

Wesnes K, Warburton DM. Effects of scopolamine and nicotine on human rapid information processing performance. *Psychopharmacology.* 1984;82:147-150.

[28] *See* Heishman et al, note 26, *supra.*

[29] Surgeon General's Report. 1988. *Nicotine Addiction.* Page 441.

effects of nicotine is available in the 1988 Surgeon General's Report.[30])

[30] *Id.* at pp. 381-458.

B. NICOTINE IS ADDICTIVE

1. Major Public Health Groups and Leading Experts Concur

Until the 1980's, nicotine was not widely appreciated to be an addictive drug. Within the past 15 years, however, broad international agreement has developed within the scientific community that nicotine in tobacco is a highly addictive or dependence-producing substance. The terms "addictive" and "dependence-producing" are generally used interchangeably; both terms refer to the persistent and repetitive intake of psychoactive substances despite evidence of harm and a desire to quit.[31] Some scientific organizations have replaced the term "addictive" with "dependence-producing" to shift the focus to dependent patterns of behavior and away from the moral and social issues associated with addiction.[32] Both terms are equally relevant for purposes of understanding the drug effects of nicotine, and in this section, the terms will be used interchangeably. The current broad recognition that nicotine is an addictive substance has been due to: 1) an evolution in the understanding of the science of addiction (e.g., the recognition that a substance does not have to be intoxicating when used at addictive levels);[33] 2) epidemiological evidence establishing the high percentage of tobacco

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[31] Surgeon General's Report. 1988. *Nicotine Addiction*. Page 7.

[32] *Id.* at p. 11.

[33] U.S. Public Health Service. *Smoking and Health. Report of the Advisory Committee to the Surgeon General of the Public Health Service.* U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control. PHS Publication No. 1103, 1964. (Hereafter cited as Surgeon General's Report. 1964. *Smoking and Health.*) The 1964 Surgeon General's Report considered nicotine to be "habituating" rather than addictive because it did not appear to produce intoxication or cause physical dependence, and its users did not tend to increase the dose. These were considered to be the features of addictive drugs.

At that time, cocaine and amphetamines were also regarded as not causing physical dependence. *See:* Wesson DR, Smith DE. Cocaine: Its Use for Central Nervous System Stimulation Including Recreational

users who display the clinical symptoms of addiction; and 3) the accumulation of evidence in the last two decades demonstrating, in both laboratory animals and humans, that nicotine is a psychoactive drug that produces pharmacological effects similar to those seen with other addictive substances.

Scientists' understanding of addiction has evolved over the past 30 years. Earlier definitions of addiction suggested that addiction was predominately the result of weakness in the personality of the user rather than the result of the pharmacological effects of the addicting substance.[34] More recently, animal and human research has revealed the pharmacological basis of addiction.[35] It has been shown that addictive substances produce

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and Medical Uses. In: Cocaine: 1977. NIDA Research Monograph. DHEW Publication Number (ADM) 77-471. Department of Health, Education, and Welfare. Rockville, MD. 1977. Page 145.

Winkler A. The Etiology of Opioid Dependence. In: Opioid Dependence: Mechanisms and Treatment. Winkler A (ed). 1980. Plenum Press. New York, NY. Page 26.

Winkler A. The Problems of Drug Dependence. In: Opioid Dependence, *supra*, at p. 13.

[34] *See:*
The Committee on Nomenclature and Statistics of the American Psychiatric Association. 1952. *Diagnostic and Statistical Manual, Mental Disorders with Special Supplement on Plans for Revision.* American Psychiatric Association. Washington, DC. Page 39.

Surgeon General's Report. 1964. *Smoking and Health.* Page 351.

Surgeon General's Report. 1988. *Nicotine Addiction.* Page 248.

[35] *See:*
Hanson HM, Ivester CA, Morton BR. Nicotine self-administration in rats. In: *Cigarette Smoking as a Dependence Process, NIDA Research Monograph 23.* U.S. Department of Health, Education, and Welfare. 1979. Pages 70-90.

Goldberg SR, Spealman RD, Goldberg DM. Persistent behavior at high rates maintained by intravenous self-administration of nicotine. *Science.* 1981;214:573-575.

Griffiths RR, Henningfield JE, Bigelow GE. Human cigarette smoking: manipulation of number of puffs per bout, interbout interval and nicotine dose. *J Pharmacol Exp Ther.* 1981;220(2):256-265.

definable chemical effects in the brain that reinforce continued use of these substances and cause physiological and/or psychological dependence on these substances.[36] The contemporary understanding of addiction also places a major emphasis on the intrinsic pharmacological ability of a substance to cause compulsive, regular use and on the inability of users to stop using the substance, even when they are strongly motivated to do so.[37]

In 1986, the Office of the U.S. Surgeon General issued a report concluding that nicotine in smokeless tobacco is addictive.[38] In 1988, the Surgeon General issued an additional report concluding that nicotine in cigarettes and other forms of tobacco is addictive.[39]

The landmark 1988 report by the Surgeon General ("the 1988 report") noted that the

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Griffiths RR, Henningfield JE. Pharmacology of cigarette smoking behavior. *Trends Pharmacol Sci.* 1982;3:260-263.

Henningfield JE, Goldberg SR. Nicotine as a reinforcer in human subjects and laboratory animals. *Pharmacol Biochem Behav.* 1983;19(6):989-992.

[36] Surgeon General's Report. 1988. *Nicotine Addiction.* Pages 170-279.

[37] *See:*
American Psychiatric Association. 1994. *Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition).* American Psychiatric Association. Washington, DC. Page 176. (Hereafter cited as American Psychiatric Association. 1994. *DSM IV.*)

World Health Organization. 1992. *The ICD-10 Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines.* World Health Organization. Geneva, Switzerland. Page 76. (Hereafter cited as World Heath Organization. 1992. *ICD-10.*)

Surgeon General's Report. 1988. *Nicotine Addiction.* Pages 248-250.

[38] U.S. Department of Health and Human Services. *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General, 1986.* U.S. Department of Health and Human Services, Public Health Service, Bethesda, MD. NIH Publication No. 86-2874, April 1986. Pages 144-145, 166. (Hereafter cited as Surgeon General's Report. 1986. *Smokeless Tobacco.*)

[39] Surgeon General's Report. 1988. *Nicotine Addiction.* Page 9.

main features of the definitions of addiction used by groups throughout the world are highly consistent. The 1988 report adopted a set of criteria based on the common criteria of these definitions. The primary criteria for drug dependence relied on in the Surgeon General's Report were:

1. highly controlled or compulsive use (even despite a desire, or repeated attempts, to quit);
2. psychoactive ("mood altering") effects produced by the action of the drug substance on the brain; and
3. drug-motivated behavior caused by "reinforcing" effects of the psychoactive substance.[40]

The 1988 report identified the following additional criteria for identifying drug dependence:

- repetitive and stereotyped patterns of use;
- persistent use despite adverse physical, social or psychological effects;
- quitting episodes followed by relapse;
- recurrent cravings for the drug, especially during abstinence;
- development of tolerance (diminished responsiveness to the drug's effects, sometimes accompanied by increased intake);
- withdrawal symptoms that can motivate further use of the drug; and
- pleasant (euphoriant) effects produced by the drug.[41]

The 1988 report exhaustively reviewed the available data on the effects of nicotine on the body, the metabolism of nicotine within the body, the dependence-producing properties of

[40] *Id.* at p. 7.

[41] *Id.* at pp. 7-8.

nicotine, tobacco use compared to other drug dependencies, the pharmacological effects of nicotine that promote tobacco use, and treatment of tobacco dependence. Applying the criteria for drug dependence listed above to these data, the 1988 Surgeon General's Report concluded that:

1. Cigarettes and other forms of tobacco are addicting;

2. Nicotine is the drug in tobacco that causes 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.[42]

Major public health organizations and leading experts have concluded that nicotine is an addictive or dependence-producing substance.

- The World Health Organization, the American Medical Association, the American Psychiatric Association, the American Psychological Association, the Royal Society of Canada, and the Medical Research Council in the United Kingdom have all recognized that nicotine is an addictive or dependence-producing drug.[43]

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[42] *Id.* at pp. 6-9.

[43] *See:*

World Health Organization. 1974. *World Health Organization Technical Report Series No. 551. WHO Expert Committee on Drug Dependence, Twentieth Report.* World Health Organization. Geneva, Switzerland. Pages 15-16.

World Health Organization. 1992. *ICD-10.* Page 324.

American Medical Association. *1993 AMA Policy Compendium. Ethyl alcohol and nicotine as addictive drugs.* American Medical Association. 1993.

American Psychiatric Association. 1980. *Quick Reference to the Diagnostic Criteria from DSM-III.* American Psychiatric Association. Washington, DC. Page 99.

American Psychological Association. Statement of the American Psychological Association before the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment on the subject of The 1988 Surgeon General's Report, *The Health Consequences of*

- On August 2, 1994, FDA's Drug Abuse Advisory Committee, an independent group composed primarily of experts on addiction science, concluded that cigarettes and other forms of tobacco are addicting, and that nicotine is the drug in tobacco that causes addiction. The FDA advisory committee also concluded that all currently marketed cigarettes contained addicting levels of nicotine.
- In a 1991 survey, the vast majority of scientists funded by the tobacco industry stated that they believed that cigarette smoking is addictive.[44] According to this report, among the principal investigators of research projects funded by the tobacco industry in 1989, 83.3% strongly agreed and 15.3% agreed somewhat that cigarette smoking is addictive.[45]

Furthermore, the medical community has, since the early 1980's, come to recognize that nicotine addiction is a clinical disorder. The Diagnostic and Statistical Manual of Mental Disorders (DSM), published by the American Psychiatric Association, and the International Statistical Classification of Disease and Related Health Problems (ICD), published by the

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Smoking: Nicotine Addiction. July 29, 1988. Page 1.

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. August 31, 1989. Pages 8-9.

Medical Research Council. The Basis of Drug Dependence. *MRC Field Review.* Medical Research Council. 1994. Page 11.

[44] Cummings KM, Sciandra R, Gingrass A, Davis R. What scientists funded by the tobacco industry believe about the hazards of cigarette smoking. *Am. J of Pub Health.* 1991;81(7)894.

[45] *Id.* at p. 895.

World Health Organization, use very similar criteria to identify dependence.[46] Like the criteria specified by the U.S. Surgeon General, these criteria emphasize the ability of a substance to produce compulsive use, withdrawal and/or tolerance, inability to control or terminate drug use despite efforts to quit or reduce use, and continued use despite harmful effects. (See Appendix 1 for a description and history of the criteria for identifying addiction.)

Nicotine has been recognized as dependence-producing under the DSM criteria since 1980. The most recent version of DSM (DSM-IV) recognizes two substance use disorders

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[46] The most recent version of DSM (DSM-IV) defines "substance dependence" as substance use that produces three or more of the following symptoms in users:

- marked tolerance;
- a withdrawal syndrome and/or the substance is taken to relieve or avoid withdrawal symptoms;
- the substance is often taken in larger amounts over a longer period of time than intended;
- persistent desire or unsuccessful efforts to cut down or control substance use;
- a great deal of time spent in activities necessary to obtain the substance, use the substance (e.g., chain smoking), or recover from its effects;
- important social, occupational, or recreational activities are given up or reduced because of substance use; and
- 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.

DSM-IV explains how the following criteria are apparent in nicotine dependence: tolerance, withdrawal, desire to quit, great deal of time using, and continued use despite medical problems. American Psychiatric Association. 1994. *DSM IV.* Pages 181, 243.

"Dependence syndrome" is characterized under the ICD-10 as a cluster of effects after repeated use of a substance resulting in three or more of the following symptoms:

- a strong desire or sense of compulsion to take the substance;
- an impaired capacity to control substance-taking behavior in terms of its onset, termination, or levels of use;
- substance use with the intention of relieving withdrawal symptoms and with awareness that this strategy is effective;
- a physiological withdrawal state;
- evidence of tolerance such that the increased doses of the substance are required in order to achieve effects originally produced by lower doses;
- progressive neglect of alternative pleasures or interests in favor of the substance; and
- persisting with substance use despite clear evidence of overtly harmful consequences.

World Health Organization. 1992. *ICD-10.* Pages 75-76, 321.

associated with nicotine: nicotine dependence and nicotine withdrawal.[47]

The ICD has included tobacco as a dependence-producing substance since 1992. Previously, the ICD recognized the existence of tobacco dependence, but tobacco was treated separately from other addictive drugs because tobacco differed in its psychotoxic effects[48] when used at usual doses. With the publication of ICD-10 in 1992, however, tobacco was included with the other addictive drugs.[49]

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[47] *See* American Psychiatric Association. 1994. *DSM IV,* note 37, *supra,* at p. 99. An individual is classified as having physiologic (in addition to psychological) dependence on a substance under DSM-IV if there is evidence of tolerance to or withdrawal from the substance. *Id.*

[48] World Health Organization. 1978. *Mental Disorders: Glossary and Guide to Their Classification in Accordance with the Ninth Revision of the International Classification of Diseases.* World Health Organization. Geneva, Switzerland. Page 43.

[49] World Health Organization. 1992. *ICD-10.* Page 75.

2. Epidemiological Data Establishes That Tobacco Users Display the Clinical Symptoms of Addiction

a. Studies Documenting Symptoms of Addiction in Smokers

Population studies of smokers conducted in recent years clearly demonstrate that nicotine produces regular, compulsive use, that such use is persistent despite both attempts to quit and an appreciation of cigarette's harmful effects, and that abstinence from nicotine produces withdrawal symptoms:

Regular, compulsive use:

- 87% of people who smoke cigarettes smoke every day;[50] and
- Nearly two-thirds of smokers have their first cigarette within the first half-hour after they wake up.[51]

Use persists despite attempts to quit or reduce use:

- In one study, 84.3% of those who smoked a pack or more per day had unsuccessfully tried to reduce the number of cigarettes smoked.[52]
- A smoker who makes a serious attempt to stop smoking has a less than 5% chance of being off cigarettes a year later;[53]
- Each year in the United States, 15 million people try to quit smoking, but less than 3%

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[50] Centers for Disease Control. *1991 National Health Interview Survey.* Atlanta, GA. U.S. Department of Health and Human Services, 1991.

[51] Centers for Disease Control. *1987 National Health Interview Survey.* Atlanta, GA. U.S. Department of Health and Human Services, 1987.

[52] Henningfield JE, Clayton R, Pollin W. Involvement of tobacco in alcoholism and illicit drug use. *British Journal of Addiction.* 1990;85:280.

[53] Sachs DPL, Leischow SJ. Pharmacologic Approaches to Smoking Cessation. *Clinics in Chest Medicine.* 1991;12(4):788.

have long-term success;[54]

- In one study, 70% of current smokers reported they would "like to completely stop smoking";[55] and
- 83% to 87% of cigarette smokers who smoke more than 26 cigarettes a day believe they are addicted.[56]

Use persists despite harmful consequences:

- In one survey, 90% of smokers agreed with the general proposition that smoking is harmful to health, 65% believed that smoking had already affected their health, and 77% believed that they could avoid or decrease serious health problems by quitting smoking;[57]
- Almost half of the smokers who undergo surgery for lung cancer resume smoking;[58] and
- Even after smokers have had their larynxes removed, 40% try smoking again.[59]

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[54] Centers for Disease Control. *Morbidity and Mortality Weekly Report.* "Cigarette Smoking Among Adults-United States, 1993." December 23, 1994. Page 927.

[55] *Id.*

[56] Substance Abuse and Mental Health Services Administration. *1991/1992 National Household Survey on Drug Abuse.* U.S. Department of Health and Human Services.

[57] Thomas RM, Larsen MD. *Smoking prevalence, beliefs, and activities by gender and other demographic indicators.* Princeton, NJ. The Gallup Organization, Inc. 1993.

[58] Davison G, Duffy M. Smoking habits of long term survivors of surgery for lung cancer. *Thorax.* 1982;37:331-333.

[59] West R, Himbury S. Smoking habits after laryngectomy. *Br Med J.* 1985;291:514-515.

Abstinence produces withdrawal symptoms:

- Abstinence from smoking is often accompanied by powerful cravings for a cigarette;[60]
- Smokers in a position to compare the effects of nicotine with the effects of other addictive drugs say they are comparable;[61] and
- Nicotine replacement therapy significantly reduces withdrawal symptoms in smokers who are attempting to quit.[62]

Data from clinical research evaluating nicotine replacement therapy (nicotine gum and patches) as aids in smoking cessation support the conclusion that a high proportion of smokers are addicted. The studies, submitted to the FDA as part of new drug applications for nicotine replacement products, were conducted in male and female smokers who smoked about a pack to a pack and a half of cigarettes (about 20 to 30 cigarettes) per day. The subjects were recruited from the general population by advertisement, from primary health care settings, and from medically based smoking cessation programs.[63]

Participants in these studies clearly demonstrated addiction to nicotine delivered from cigarettes. All reported symptoms of nicotine addiction at trial entry, and all suffered withdrawal symptoms after smoking cessation. These withdrawal symptoms were relieved

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[60] *See:*
Benowitz NL. Cigarette smoking and nicotine addiction. *Medical Clinics of North America.* 1992;76(2):423.

West R, Schneider N. Craving for Cigarettes. *British Journal of Addiction.* 1987;82:407.

[61] Henningfield JE, Miyasato K, Jasinski DR. Abuse liability and pharmacodynamic characteristics of intravenous and inhaled nicotine. *J Pharmacol Exp Ther.* 1985;234(1):4-5.

[62] 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).

[63] *Id.,* NDA's for Habitrol (Ciba), ProStep (Elan), and Nicoderm (Alza).

entirely or partly by medical administration of nicotine.

Smokers using the above nicotine replacement products (in the dosage range of 14 to 24 mg/nicotine per day) had an initial quit rate of about 50%, twice that of smokers receiving placebo. This two-fold difference was maintained throughout a full year of follow-up, and was associated with reductions in craving, withdrawal symptoms, and the desire to smoke.[64] In studies in which nicotine replacement therapy was provided for a year or more, relapse rates were nearly half those of studies in which nicotine replacement was halted after a fixed interval (usually about 6 to 12 weeks).[65]

Data from these studies demonstrate how tenacious nicotine addiction is, even for adults who express a strong desire to quit smoking and who receive optimal medical care. Only half of the patients studied were able to stop smoking for as long as 1 week, and the long-term failure rate was more than 80% after patients were withdrawn from nicotine replacement. The fact that nicotine replacement therapy in smokers reduces relapse rates provides strong evidence that it is the nicotine in tobacco products that creates and sustains addiction to cigarettes.

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[64] *See:*
Fiore MC, Smith SS, Jorenby DE, Baker TB. The effectiveness of the nicotine patch for smoking cessation: a meta-analysis. *JAMA*. 1994;271(24):1940-47.

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).

[65] *Id.*

b. Studies Documenting Symptoms of Addiction in Smokeless Tobacco Users

Smokeless tobacco users can also develop a dependence on nicotine similar to that experienced by cigarette smokers.[66] The Surgeon General's 1986 report concluded that smokeless tobacco is addictive.[67] This is not surprising, since smokeless tobacco users can absorb at least as much nicotine as smokers.[68] The 1986 report states that:

> *. . . given the nicotine content of smokeless tobacco, its ability to produce high and sustained blood levels of nicotine, and the well-established data implicating nicotine as an addictive substance, one may deduce that smokeless tobacco is capable of producing addiction in users.*[69]

Studies have shown that smokeless tobacco is associated with compulsive use,[70] persistent use despite efforts to quit,[71] persistent use despite harmful consequences,[72] and

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[66] Benowitz NL. Pharmacology of smokeless tobacco use: nicotine addiction and nicotine-related health consequences. In: *Smokeless Tobacco or Health, An International Perspective.* Smoking and Tobacco Control, Monograph 2. U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. NIH Publication No. 93-3461. 1993. Page 227.

[67] Surgeon General's Report.1986. *Smokeless Tobacco.* Pages 182-183.

[68] Surgeon General's Report. 1994. *Preventing Tobacco Use Among Young People.* Page 40.

[69] *Id.* at p. 141.

[70] *See* Benowitz, note 66, *supra,* at p. 223.

[71] *See:*
Ary DV, Lichtenstein E, Severson HH, Weissman W, Seeley JR. An in-depth analysis of male adolescent smokeless tobacco users: interview with users and their fathers. *J. Behavioral Medicine.* 1989;12:449-467.

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. U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. NIH Publication No. 93-3461. 1993. Pages 281-282.

[72] Connolly GN, Winn DM, Hecht SS, Henningfield JE, Hoffman D, Walker B. The re-emergence of smokeless tobacco. *N. Engl J. Med.* 1986;314(16):1020-1026.

withdrawal symptoms when use is discontinued.[73,74]

Fewer clinical and epidemiological data are available on the prevalence of addiction among smokeless tobacco users than among smokers. However, some users of smokeless tobacco products do meet addiction criteria.[75] A 1986 report of the Office of the Inspector General of the Department of Health and Human Services found that 37% of young users of smokeless tobacco (also called "spit" tobacco) continue use because they are addicted.[76] In a study involving 675 men enrolled in a cessation program, 68% reported an average of four unsuccessful attempts to quit.[77] Other studies of smokeless tobacco cessation programs reveal that many users continue consuming the product despite their desire to quit.[78] Glover reported a 2.3% quit rate at 6 months and concluded that smokeless tobacco may be more addicting than cigarette smoking.[79] Other researchers have found that over one-third of the current

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[73] Hatsukami D, Gust W, Keenan R. Physiologic and subjective changes from smokeless tobacco withdrawal. *Clin Pharmacol Ther.* 1987;41(1):103-107.

[74] *Id.*

See also Severson, note 71, *supra,* at p. 282.

[75] Benowitz NL. Pharmacology of Smokeless Tobacco Use: Nicotine Addiction and Nicotine-Related Health Consequences. In: *Smokeless Tobacco or Health,* Smoking and Tobacco Control Monograph 2. U.S. Department of Health and Human Services.1993. Page 224.

[76] U.S. Department of Health and Human Services. *Spit Tobacco and Youth.* Washington DC. U.S. Department of Health and Human Services, Office of the Inspector General. 1992. Page 7.

[77] *See* Severson, note 71, *supra,* at pp. 281-282.

[78] *See:*
Glover ED. Conducting smokeless tobacco cessation clinics. *Am. J. Pub. Health.* 1986;76(2):207.

Hatsukami D, Nelson R, Jensen J. Smokeless tobacco: Current status and future directions. *Brit. J. of Addiction.* 1991;86:559-563.

[79] *See:*
Glover ED, Glover PN. Smokeless tobacco cessation and nicotine reduction therapy. In: *Smokeless*

smokeless tobacco users report an unsuccessful attempt to quit, despite the fact that 92% of those surveyed believed that there are health risks associated with smokeless tobacco use.[80]

Studies suggest that tolerance to nicotine develops with prolonged smokeless tobacco use. One study noted that a higher percentage of older users of smokeless tobacco used brands with a higher nicotine content compared with younger users.[81] A World Health Organization study group reported on another study that showed a positive relationship between the number of years of smokeless tobacco use, the number of minutes per day of reported use, and urinary nicotine and cotinine[82] levels. These relationships are consistent with the development of tolerance and physical dependence.[83]

Biglan and coworkers demonstrated that nicotine reinforces smokeless tobacco use. In one study that describes the drug-reinforcing behavior of the product, smokeless tobacco users were found to titrate the level of nicotine in their bodies by adjusting use to maintain a specified level of nicotine. In another study in which men used both snuff and cigarettes, the subjects smoked more cigarettes when smokeless tobacco use was restricted, and consumed

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Tobacco or Health, An International Perspective. Smoking and Tobacco Control, Monograph 2. U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. NIH Publication No. 93-3461. 1993. Pages 291-295.

Glover, note 78, *supra,* at p. 207.

[80] *See* Ary, note 71, *supra.*

[81] Browson RC, DiLorenzo TM, Van Tuinen M, Finger WW. Patterns of cigarette and smokeless tobacco use among children and adolescents. *Preventive Medicine.* 1990;19:170-180.

[82] Cotinine is a major metabolite of nicotine and an indicator of nicotine absorption.

[83] World Health Organization. 1988. *WHO Technical Report Series No 773. Smokeless Tobacco Control: Report of a WHO Study Group.* World Health Organization. Geneva, Switzerland. Page 36.

more smokeless tobacco when cigarette use was restricted.[84]

Smokeless tobacco users who are addicted experience withdrawal symptoms similar to those reported by smokers.[85] One study found that among daily smokeless tobacco users ages 10 to 22 who had previously tried to quit, 93.3% experienced at least one symptom of nicotine withdrawal.[86] It has been concluded that "dependence on smokeless tobacco may be no less tenacious than dependence on cigarettes."[87] (See Appendix 1 for a more complete discussion of the definition of addiction and rates of dependence.)

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[84] *See* Benowitz, note 66, *supra,* at pp. 223-224.

[85] *See:*
Hatsukami, note 73, *supra,* at pp.103-107.

Severson, note 71, *supra,* at p. 282.

[86] U.S. Department of Health and Human Services, Public Health Service, 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. *MMWR.* 1994;43(41):745-750.

[87] Jarvis MJ. Dependence on smokeless tobacco. In: *Smokeless Tobacco or Health, An International Perspective.* Smoking and Tobacco Control, Monograph 2. U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. NIH Publication No. 93-3461. 1993. Page 243.

3. Laboratory Studies Establish That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Substances

Evidence gathered in the last two decades demonstrates, in both laboratory animals and humans, that nicotine is a psychoactive drug that produces pharmacological effects similar to those of other addictive substances. Many of the advances in the understanding of the psychopharmacological and addictive aspects of nicotine have come from recent laboratory studies using both animals and human volunteers.

Animal studies have the advantage of being able to assess the pharmacological actions of a potentially addictive substance, independent of such factors as the taste of the substance, the personality of the user, or social factors such as peer pressure. Studies using human volunteers have the advantage of allowing the subject to directly inform the researcher of the subjective effects of the drug being studied.

Two kinds of studies are used to determine whether a substance may be an addictive drug: "drug discrimination" studies and "self-administration" studies. There is a strong correlation between the results of these studies in animals and humans. Substances that animals identify as similar to known psychoactive drugs in drug discrimination studies and substances that animals self-administer in self-administration studies are highly likely to be addictive in humans. With very few exceptions, substances that are addictive in humans are self-administered by animals.[88]

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[88] Gardner EL. Brain Reward Mechanism. In: *Substance Abuse, A Comprehensive Textbook.* 2nd ed. Baltimore, MD: Williams and Wilkins; 1992:70.

a. Animal studies

An impressive number of animal studies have demonstrated that nicotine has pharmacological properties common to many other addictive drugs. These studies establish that nicotine, like other addictive drugs, has psychoactive properties that exert control over behavior.

(i) Drug Discrimination Studies

Drug discrimination studies are used to evaluate the subjective effects (discriminative stimulus properties) of a drug and to make direct comparisons of these effects to known dependence-producing drugs.[89] The ability of a substance to produce discriminative stimulus effects is one characteristic of an addictive substance. In drug discrimination studies, animals identify nicotine as having a highly specific discriminative stimulus profile and some similarity with the discriminative stimulus effects of cocaine and amphetamine.[90] (See

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[89] Balster RL. Drug abuse potential evaluation in animals. *Br J Addiction.* 1991; 86:1549-1588.

[90] *See:*

Takada K, Swedberg MDG, Goldberg SR, Katz JL. Discriminative stimulus effects of intravenous l-nicotine and nicotine analogs or metabolites in squirrel monkeys. *Psychopharmacology.* 1989;99:208-212.

Pratt JA, Stolerman IP, Garcha HS, Giardini V, Feyerabend C. Discriminative stimulus properties of nicotine: Further evidence for mediation at a cholinergic receptor. *Psychopharmacology.* 1983;81:54-60.

Goldberg SR, Risner ME, Stolerman IP, Reavill C, Garcha HS. Nicotine and some related compounds: effects on schedule-controlled behaviour and discriminative properties in rats. *Psychopharmacology.* 1989;97:295-302.

Chance WT, Murfin D, Krynock GM, Rosecrans JA. A description of nicotine stimulus and tests of its generalization to amphetamine. *Psychopharmacology.* 1977;55:19-26.

Stolerman IP, Garcha HS, Pratt JA, Kumar R. Role of training dose in discrimination of nicotine and related compounds by rats. *Psychopharmacology.* 1984;84:413-419.

Appendix 1 for a summary of the studies documenting nicotine's discriminative stimulus effects and the site of these actions.)

(ii) Self-Administration

The self-administration model is widely used to assess a drug's ability to induce and maintain drug-seeking behavior in animals.[91] Self-administration studies determine whether animals will press a lever to give themselves repeated doses of the test substance. The ability of a substance to cause self-administration in animals demonstrates that the substance is a positive reinforcer; i.e., that it induces continued, compulsive use.[92] As noted above, having a positive reinforcing effect in animals is one of the key pieces of predictive evidence that a substance will produce addiction in humans.

Like many addictive drugs, such as cocaine, opiates, and hypnotics, nicotine has now been demonstrated through self-administration studies to be an effective positive reinforcer in animals.[93] This property of nicotine was not consistently demonstrated until the 1980s, when

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Stolerman IP. Discriminative stimulus effects of nicotine in rats trained under different schedules of reinforcement. *Psychopharmacology*. 1989;97:131-138.

[91] *See:*
Schuster CR, Thompson T. Self-administration of behavioral dependence on drugs. *Annual Rev of Pharm.* 1969;9:483-502.

Griffiths RR, Bigelow GE, Henningfield JE. Similarities in animal and human drug-taking behavior. *Advances in Substance Abuse*. 1980;1:1-90.

[92] *See*:
Schuster, note 91, *supra,* at pp. 483-502.

Griffiths, note 91, *supra,* at pp. 1-90.

[93] *See:*
Cox BM, Goldstein A, Nelson WT. Nicotine self-administration in rats. *British Journal of*

it was discovered that the reinforcing efficacy of nicotine is highly dependent on the schedule by which the drug is made available to the animals and the specific amount administered.[94] Intermittent availability of nicotine, which parallels the pattern of cigarette smoking, will induce self-administration in animals, while continuous administration (which was used in the earlier studies) is far less likely to do so. (See Appendix 1 for a summary of the studies establishing that nicotine is a positive reinforcer in animal self-administration studies.)

b. Studies in Human Volunteers

In addition to the extensive population-based epidemiological studies described above, a growing body of evidence gathered from laboratory and clinical settings using human volunteers, is providing further evidence of the addictive effects of nicotine.

Pharmacology. 1984;83:49-55.

Goldberg, note 35, *supra,* at pp. 573-575.

Slifer BL, Balster RL. Intravenous self-administration of nicotine: with and without schedule-induction. *Pharmacol. Biochem. Behav.* 1985;22:61-69.

Corrigall WA, Franklin KBJ, Coen KM, Clarke PBS. The mesolimbic dopaminergic system is implicated in the reinforcing effects of nicotine. *Psychopharmacology*. 1992;107:285-289.

[94] *See*:
Goldberg, note 35, *supra,* at pp. 573-575.

Henningfield, note 35, *supra,* at pp. 989-992.

(i) Evaluation of Subjective Effects

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.[95] Using a common measure of the subjective effects of addictive drugs (the Addiction Research Center Inventory), nicotine produced a dose-related increase in the "euphoria" scale (also known as the morphine-benzedrine group scale).[96] This study shows that nicotine produces subjective effects that are similar to those of other addictive drugs. (See Appendix 1 for a summary of the studies on the subjective effects of nicotine.)

(ii) Self-Administration Studies

Human self-administration of nicotine has been demonstrated under controlled laboratory conditions. Smokers were provided the opportunity to give themselves injections of nicotine in test sessions where they were not allowed to smoke.[97] The subjects self-administered nicotine in a regular, orderly pattern, giving themselves roughly the same amount of nicotine as they were accustomed to getting from their cigarette smoking.[98] (See Appendix 1 for a summary of the studies establishing that nicotine is a positive reinforcer in

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[95] *See:*
Surgeon General's Report. 1988. *Nicotine Addiction.* Pages 177-178.

Henningfield et al, note 21, *supra.*

[96] *Id.*

[97] Henningfield JE, Miyasato K, Jasinski DR. Cigarette smokers self-administer intravenous nicotine. *Pharm Biochem Behav.* 1983;19:887-890.

[98] *Id.*

human self-administration studies.)

c. Studies on Tolerance and Withdrawal

"Tolerance" is produced by a substance when the effects of the substance, at a given dose, become less intense over time, or when an increasing dose over time is necessary to cause an effect or response of a specified intensity. It is well documented that nicotine produces tolerance in users. For example, novice smokers usually experience nicotine-related effects such as dizziness, nausea, vomiting, and headaches.[99] These effects are not produced in experienced smokers because they rapidly develop a tolerance to nicotine. Eventually, smokers increase the amount that they will smoke, always ensuring that the level of nicotine intake will fall below the level at which they would suffer undesirable physical effects and above the level at which they would begin to experience withdrawal symptoms.[100] Tolerance to nicotine is not complete, because even the heaviest smokers can experience symptoms, such as nausea and vomiting, when they suddenly increase their smoking rates.[101] Additionally, the amount of nicotine needed to maintain an addiction may plateau. (See Appendix 1 for a summary of studies demonstrating tolerance to nicotine.)

Clinical studies on nicotine withdrawal have demonstrated that physiological effects

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[99] Surgeon General's Report. 1994. *Preventing Tobacco Use Among Young People*. Page 138.

[100] Rose JE, Behm FM, Levin ED. The role of nicotine dose and sensory cues in the regulation of smoke intake. *Pharm Biochem and Behav.* 1993;44:891-900.

[101] *See:*
Danaher BG. Research on rapid smoking: Interim summary and recommendations. *Addictive Behaviors.* 1977;2:151-166.

Surgeon General's Report. 1988. *Nicotine Addiction*. Page 50.

occur as a result of tobacco deprivation. These effects include decreased heart rate, decreased arousal evidenced by diminished alertness, central nervous system changes, decreases in blood pressure, and disruptions in sleep patterns.[102] 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 following nicotine withdrawal.[103]

After several weeks of nicotine exposure, users who are deprived of nicotine for more than a few hours develop withdrawal symptoms. The most common self-reported withdrawal symptoms in nicotine-deprived smokers and smokeless tobacco users are increased irritability, anxiety, difficulty concentrating, restlessness, impatience, and insomnia.[104] Withdrawal symptoms after quitting tobacco use can persist for months.[105] Although nicotine withdrawal is not as severe as withdrawal from heroin or alcohol, it is comparable to withdrawal from other stimulants such as cocaine, and can be highly disruptive to personal

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[102] *See:*
West RJ, Jarvis MJ, Russell MAH, Caruthers ME, Feyerabend C. Effect of nicotine replacement on the cigarette withdrawal syndrome. *British Journal of Addiction.* 1984;79(2):215-219.

Hughes JR, Hatsukami D. Signs and symptoms of tobacco withdrawal. *Arch Gen Psychiatry.* 1986;43:289-294.

[103] *See:*
Wack JT, Rodin J. Smoking and its effect on body weight and the systems of caloric regulation. *The American Journal of Clinical Nutrition.* 1982;35(2):366-380.

Glauser SC, Glauser EM, Reidenberg MM, Reisy BF, Tallarida RJ. Metabolic changes associated with the cessation of cigarette smoking. *Archives of Environmental Health.* 1970;20:377-381.

[104] *See* Hughes, note 102, *supra,* at pp. 289-294.

[105] Ryan FJ. Cold Turkey in Greenfield, Iowa: A Follow-up Study. In: Dunn WL, ed. *Smoking Behavior: Motives and Incentives.* Washington, DC: VH Winston & Sons; 1973:231- 234.

life.[106]

[106] Benowitz NL. Cigarette smoking and nicotine addiction. *Medical Clinics of N. America.* 1992;76(2):415-437.

4. Nicotine's Sensory Effects Are Secondary to its Psychoactive Effects

Nicotine is an irritant to the throat and upper respiratory system.[107] Its effects in the throat contribute to the harshness of tobacco smoke reported by smokers.[108] Many beginning smokers report that the taste of cigarettes is unpleasant.[109] Despite these facts, those who continue to smoke report that they enjoy the taste of commercial tobacco products.[110] In some studies, low-nicotine or nicotine-free products that replicate the taste, flavor, or throat and chest sensations of cigarette smoking can, in the very short term, reduce certain nicotine withdrawal symptoms, including craving for cigarettes.[111] Significantly, however, many of the positively perceived aspects of the harsh taste and flavor of commercial tobacco products are due to "secondary reinforcement." This is a phenomenon by which smokers associate the irritant effects of nicotine in the mouth and throat with desired psychoactive effects that occur immediately thereafter.[112] These irritant effects are then judged favorably, because they are

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[107] *See* Rose, note 100, *supra.*

[108] Rose JE, Sampson A, Levin ED, Henningfield JE. Mecamylamine Increases Nicotine Preference and Attenuates Nicotine Discrimination. *Pharm Biochem and Behav.* 1989;32:933-938.

[109] Surgeon General's Report. 1994. *Preventing Tobacco Use Among Young People.* Page 138.

[110] *Id.*

[111] *See:*
Rose JE, Behm F. Refined cigarette smoke as a method for reducing nicotine intake. *Pharmacology Biochemistry and Behavior.* 1987;28:305-310.

Levin ED, Rose JE, Behm F. Development of a citric acid aerosol as a smoking cessation aid. *Drug and Alcohol Dependence.* 1990;25:273-279.

Rose JE, Behm FM. Inhalation of vapor from black pepper extract reduces smoking withdrawal symptoms. *Drug and Alcohol Dependence.* 1994;34:225-229.

[112] *See:*
Rose, note 100, *supra.*

associated with the delivery of the psychoactive properties of nicotine. The conditioning process is similar to that which occurs for other dependence-producing drugs in which effects that are disliked upon initial exposure come to be associated with desired psychoactive effects.[113] Experienced smokers can use the irritant effects of nicotine to assess how much nicotine they are delivering to themselves while they are smoking.[114]

Data indicate that long-term smoking is continued not because of the taste characteristics of tobacco but because of other factors, specifically the pharmacological effects of nicotine.[115] Evidence gathered from nicotine replacement products supports this position. As noted, two nicotine dosage forms are on the market for treatment of nicotine withdrawal as an aid to smoking cessation (nicotine polacrilex gum and nicotine transdermal patches). FDA is reviewing a New Drug Application (NDA) for a third dosage form, an aqueous nicotine nasal spray. The nicotine nasal spray was the subject of an August 1994 FDA Drug Abuse Advisory Committee meeting because of its possible addiction liability. Among subjects who used the spray for a year during one of the trials, several reported that they felt dependent on the spray, displayed withdrawal symptoms upon stopping the spray,

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Levin ED, Behm F, Rose JE. The use of flavor in cigarette substitutes. *Drug and Alcohol Dependence.* 1990;26:115-160.

Rose JE, Tashkin DP, Ertle A, Zinser MC, Lafer R. Sensory blockade of smoking satisfaction. *Pharmacology Biochemistry and Behavior.* 1985;23:289-293.

[113] Surgeon General's Report. 1988. Nicotine Addiction. Pages 264-265, 309.

[114] *See* Rose, note 100, *supra.*

[115] *See:*
Rose, Tashkin, et al, note 112, *supra.*

Rose, note 100, *supra.*

and sometimes used the spray in larger quantities and more frequently than was required by the study protocol -- all despite the fact that use of the spray was unpleasant and caused nasal ulcers and other medical problems for some participants.[116]

The ability of nicotine nasal spray to produce some of the classic characteristics of addiction to nicotine supports the position that tobacco users seek nicotine primarily for its systemic pharmacological effects, and not for its acute sensory effects. The spray vehicle and dispensing system of the nicotine nasal spray are rudimentary; it is merely nicotine in water forced through an aspirator to make a nasal mist. 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, can impart a very unpleasant taste if it runs down the nose and into the throat, 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 continued use of the spray, the spray was used to maintain nicotine dependence for many of the participants in its clinical trials.[117]

The dependence upon nicotine nasal spray illustrates a physical need for nicotine's pharmacological effects, not merely in the absence of any pleasurable sensory effects that may be associated with nicotine in cigarette smoke, but even in the face of rather unpleasant

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[116] E. Douglas Kramer, M.D. Testimony before the Drug Abuse Advisory Committee. August 1, 1994. Drug Abuse Advisory Committee Meeting Transcript. Pages 58-63. Nicotine nasal spray is unique among nicotine replacement therapies in that it produces peak blood levels of nicotine almost as quickly as inhalation of cigarette smoke.

[117] FDA Drug Abuse Advisory Committee Background Information. August 1, 1994. Joint Abuse Liability Review of Nicotine Nasal Spray.

and even painful sensations. This provides strong evidence that nicotine is sought by tobacco users who are dependent upon it for reasons other than its pleasurable, acute sensory effects in the mouth, nose, and throat.

5. Other Factors Associated with Tobacco Use Are Secondary

There are other factors that play a role in the decisions to begin and continue the use of tobacco.[118] For example, social and psychological factors play a role in the initiation of smoking and, to a lesser extent, the maintenance of tobacco use.[119] In particular, parents, peers, and older siblings greatly influence the likelihood that a young person will smoke cigarettes.[120] There is also evidence that adolescents begin to smoke because it promotes sociability, plays a part in establishing friendships, and because it makes them feel mature.[121] Tobacco advertising also plays a role in the decision to start using tobacco.[122] It is recognized

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[118] Tate JC, Pomerleau CS, Pomerleau OF. Pharmacological and non-pharmacological smoking motives: a replication and extension. *Addiction*. 1994;89:322.

[119] *See:*
Surgeon General's Report. 1994. *Preventing Tobacco Use Among Young People.* Pages 124-140.

Stepney R. Smoking behaviour: A psychology of the cigarette habit. *Br J Dis Chest.* 1980;74:325-344.

[120] *See:*
Bewley BR, Bland JM, Harris R. Factors associated with the starting of cigarette smoking by primary school children. *Brit J Prev Soc Med.* 1974;28:37-44.

Murray M, Cracknell A. Adolescents' views on smoking. *J Psychosom Res.* 1980;24:248-249.

Banks MH, Bewley BR, Bland JM, Dean JR, Pollard V. Long-term study of smoking by secondary schoolchildren. *Arch Disease in Childhood.* 1978;53:14-16.

[121] *See:*
Bewley, note 120, *supra.*

Bewley BR, Bland JM. Academic performance and social factors related to cigarette smoking by schoolchildren. *Brit J Prev Soc Med.* 1977;31:18-24.

Surgeon General's Report. 1994. *Preventing Tobacco Use Among Young People.* Page 124.

[122] *See:*
Surgeon General's Report. 1994. *Preventing Tobacco Use Among Young People.* Pages 191-192.

Cocores JA. Smokeless Tobacco. In: Cocores JA, ed. *The Clinical Management of Nicotine Dependence.* New York, NY: Springer-Verlag; 1991:49.

that many of the mannerisms and processes associated with smoking may, in the perception of the smoker, become pleasurably linked with tobacco use. These mannerisms or processes may deliver some element of pleasure to the smoker, independent of the inhalation of tobacco smoke.[123]

It is widely accepted, however, by medical and public health groups that the maintenance of tobacco use is due primarily to the addictive properties of nicotine and not solely to these social and psychological factors.

[123] Christen AG, Glover ED. Psychological satisfactions derived from smoking cigarettes in fifty-seven dental patients. *J Drug Educ*. 1983;13(1):95-102.

C. MARKETED TOBACCO PRODUCTS DELIVER PHARMACOLOGICALLY ACTIVE DOSES OF NICOTINE

Scientific studies demonstrate that tobacco products currently marketed in the United States contain and deliver sufficient levels of nicotine to produce pharmacological effects on the central nervous system.[124]

1. Amount of Nicotine Necessary to Produce a Physiological Response in the Central Nervous System

In a recent study, the minimal dose of nicotine that was calculated to produce pharmacological effects on the central nervous system in humans was 0.18 mg.[125] In another study, based on nicotine nasal sprays, the minimal pharmacological dose was reported to be 0.2 mg for the average adult.[126]

Changes in the electroencephalogram (EEG) of smokers, indicative of central nervous system effects of nicotine, have been seen with plasma nicotine increases of 10 ng/ml, an amount easily obtainable from one cigarette.[127] Other studies have shown that EEG effects emerge after the first puff of cigarette and become pronounced and statistically significant by

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[124] *See:*
Armitage AK, Dollery CT, George CF, Houseman TH, Lewis PJ, Turner DH. Absorption and metabolism of nicotine from cigarettes. *British Medical Journal.* 1975;4:313-316.

Stepney, note 119, *supra.*

[125] Yanagita T, Kiyoshi A, Wakasa Y, Shimada A. Behavioral and biochemical analysis of the dependence properties of nicotine. *Advances in Pharmacological Sciences.* (1995) (in press).

[126] KA Perkins. Statement in support of presentation by Jack Henningfield, Ph.D., to FDA Drug Abuse Advisory Committee Meeting. August 2, 1994.

[127] Kadoya C, Domino EF, Matsuoka S. Relationship of electroencephalographic and cardiovascular changes to plasma nicotine levels in tobacco smokers. *Clin Pharmacol Ther.* 1994;55:370-377.

the fourth puff.[128]

Even a single U.S. cigarette delivers enough nicotine to cause EEG changes indicative of pharmacological effects on the central nervous system.[129]

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[128] *See:*

Knott V. Neuroelectric correlates of smoking behavior. In: Adlkofer F, Thurau, eds. *Effects of Nicotine on Biological Systems Advances in Pharmacological Sciences.* Boston, MA: Birkhauser; 1991:491-500.

Knott V. Dynamic EEG changes during cigarette smoking. *Neuropsychobiology.* 1988;19:54-60.

Knott V. Effects of low-yield cigarettes on electroencephalographic dynamics. *Neuropsychobiology.* 1989;21:216-222.

[129] *See:*

Pickworth WB, Heishman SJ, Henningfield JE. Relationships between EEG and performance during nicotine withdrawal and administration. In: Domino EF, ed. *Brain Imaging of Nicotine and Tobacco Smoking.* Ann Arbor, MI: NPP Books; 1995:1-11.

Pritchard WS, Gilbert DG, Duke DW. Flexible effects of qualified cigarette-smoke delivery on EEG dimensional complexity. *Psychopharmacology.* 1993;113:95-102.

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.

2. Nicotine Delivery From Currently Marketed Tobacco Products

a. Laboratory Studies

Currently marketed cigarettes contain, on average, 8 to 9 mg of nicotine in the tobacco rod.[130] FDA laboratory analysis demonstrates that currently marketed smokeless tobacco products contain between 8.8 and 26.4 mg of nicotine, per 2-gram sample of a typical "pinch."[131]

Currently marketed cigarettes typically deliver about 1 mg of nicotine to the bloodstream of smokers, with individual intake ranging from 0.3 to 3.2 mg of nicotine per cigarette.[132] Even members of the tobacco industry appear to agree that current cigarettes provide a pharmacologically active dose of nicotine. A senior industry researcher summarizing the views of industry scientists at a 1972 conference said that "[t]he physiological response to nicotine can be readily elicited by cigarettes delivering in the range of 1 mg of nicotine."[133]

Several studies reveal that with regular use throughout the day, the levels of nicotine

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[130] *See* Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. *N Engl J Med.* 1994;331:123-125.

[131] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Drug Analysis Laboratory. *Study of Smokeless Tobacco Products: pH and Free Base Nicotine*. November 4, 1994, memorandum from Henry Drew, Chief, Drug Monitoring Branch, to Elizabeth Berbakos, Office of the Commissioner, FDA, and Frederick L. Fricke, FDA.

[132] Benowitz, note 130, *supra.*

[133] Dunn WL. Motives and incentives in cigarette smoking. Summary of CTR-sponsored conference in St. Martin. 1972. Philip Morris Research Center, Richmond, VA. (Summary of January 1972 St. Martin Conference referred to in preface of Dunn WL, ed. *Smoking Behavior: Motives and Incentives.* Washington, DC: VH Winston & Sons; 1973).

in the blood of smokeless tobacco users are similar to those observed in cigarette smokers.[134] In one study, the nicotine blood levels during ad libitum use of oral snuff (avg. 15.6 gm/day) or chewing tobacco (avg. 72.9 gm/day) were similar to those observed with cigarette smokers (avg. 36.4 cigarettes/day). In addition, the total daily levels of cotinine produced by various marketed tobacco products were similar, averaging 48.5, 48.25, and 46.17 μmol/L/hr for oral snuff, chewing tobacco, and cigarette tobacco, respectively.[135]

It has been shown that a single U.S. cigarette boosts plasma nicotine to as much as 23 ng/ml.[136] It also has been shown that a single "pinch" of smokeless tobacco produces peak plasma nicotine concentrations as high as 33 ng/ml and 21 ng/ml for oral snuff and chewing tobacco, respectively.[137]

b. The Federal Trade Commission Method

Another method to gauge nicotine delivery from cigarettes is based on levels published by the Federal Trade Commission (FTC). According to the FTC machine tests, the

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[134] *See:*
Benowitz NL, Porchet HP, Sheiner L, Jacob P. Nicotine absorption and cardiovascular effects with smokeless tobacco use: comparison with cigarettes and nicotine gum. *Clin Pharmacol Ther.* 1988;44:23-28.

Holm H, Jarvis MJ, Russell MAH, Feyerabend C. Nicotine intake and dependence in Swedish snuff takers. *Psychopharmacology.* 1992;108:507-511.

[135] Benowitz NL, Jacob P, Yu L. Daily use of smokeless tobacco: systemic effects. *Ann Int Med.* 1989;111:112-116.

[136] *See* Benowitz, note 134, *supra.*

[137] *Id.* at p. 25.

See also Gritz ER, Baer-Weiss V, Benowitz NL, Van Vunakis H, Jarvik ME. Plasma nicotine and cotinine concentrations in habitual smokeless tobacco users. *Clin Pharmacol Ther.* 1981;30(2):201-209.

mean nicotine yield for cigarettes on a sales-weighted basis in 1991 was 0.94 mg of nicotine. Individual yields ranged from 0.1 to 1.9 mg, with 95% of all cigarettes sold falling in the narrower range of 0.32 to 1.56 mg of nicotine.[138] FTC yields for individual brands do not predict actual nicotine intake. Each cigarette rod contains significantly more nicotine than the amount "inhaled" by the smoking machine. Consequently, smokers may absorb more nicotine than the FTC machine, depending on the number and intensity of the puffs they take and whether their lips or fingers block the ventilation holes that can dilute the smoke from "low tar" and "ultra low tar" cigarettes.[139] Whether the tar and nicotine levels measured by the FTC test provide appropriate and useful information to smokers was the subject of a December 5-6, 1994, conference held by the National Cancer Institute at the request of the FTC and the then chairman of the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce. The conferees concluded, among other things, that "actual human smoking behavior is characterized by wide variations in smoking patterns which result in wide variations in tar and nicotine exposure. Smokers who switch to lower tar and nicotine cigarettes frequently change their smoking behavior which may negate potential health benefits."[140]

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[138] U.S. Federal Trade Commission. *Tar, Nicotine, and Nicotine/Tar Ratios by Year* (Weighted by Sales). U.S. Department of Commerce. 1994.

[139] Mueller M. Overview of the 1980-1994 Research Findings Relating to the Standard FTC Test Method For Cigarette Smoking (and studies cited therein). Prepared by ROW Sciences, Inc. for the National Cancer Institute Conference on the FTC Test Method for Determining Tar, Nicotine, and Carbon Monoxide Levels in Cigarettes, December 5-6, 1994. Smoking and Tobacco Control Program, National Cancer Institute. Bethesda, MD.

[140] Ad Hoc Committee of the President's Cancer Panel. Statement from the Ad Hoc Committee of the President's Cancer Panel to Consider the FTC Test Method for Determining Tar, Nicotine, and Carbon Monoxide Levels in Cigarettes. December 6, 1994.

It has been shown, for example, that smokers who switch to cigarettes with lower nicotine yields "compensate" by smoking the lower-nicotine cigarette more intensely and that the published FTC nicotine yield is not a good predictor of the amount of nicotine absorbed by smokers.[141] One study demonstrated that the actual intake of nicotine by smokers falls within a much narrower range than the published yields would suggest, and that the nicotine yield figures at the "low-yield" end of the spectrum significantly underestimate true rates of nicotine absorption.[142] This study found that while FTC nicotine yields in tested cigarettes ranged from 0.1 to 1.6 mg, actual nicotine intake by smokers ranged from 0.75 to 1.25 mg/cigarette. The study further confirms that U.S. cigarettes actually deliver in the range of 1.0 mg per cigarette.

To summarize, multiple studies show that marketed cigarettes and smokeless tobacco products deliver, on average, about 1 mg of nicotine.[143] Additionally, studies show that the

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[141] *See:*
Benowitz NL, Hall SM, Herning RI, Jacob P III, Jones RT, Osman AL. Smokers of low-yield cigarettes do not consume less nicotine. *N Engl J Med.* 1983;309(3):139-142.

Kozlowski LT, Frecker RC, Khouw V, Pope MA. The misuse of "less-hazardous" cigarettes and its detection: hole-blocking of ventilated filters. *Amer J Public Health.* 1980;70(11):1202-1203.

Herning RI, Jones RT, Benowitz NL, Mines AH. How a cigarette is smoked determines blood nicotine levels. *Clin Pharm Ther.* 1983;33:84-90.

Herning RI, Jones RT, Bachman J, Mines AH. Puff volume increases when low-nicotine cigarettes are smoked. *Br Med J.* 1981;283:187-189.

[142] Gori GB, Lynch CJ. Analytical cigarette yields as predictors of smoke bioavailability. *Regulatory Toxicology and Pharmacology.* 1985;5:314-326.

[143] *See:*
Benowitz NL, Jacob P. Daily intake of nicotine during cigarette smoking. *Clin Pharmacol Ther* 1984;35(4):499-504.

Benowitz NL, Jacob P, Yu L. Daily use of smokeless tobacco: systemic effects. *Ann of Int*

amount of nicotine necessary to have pharmacological effects is much lower, in the range 0.2 mg.[144] Thus, currently marketed cigarettes and smokeless tobacco products deliver pharmacologically active doses of nicotine.

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*Med.*1989;111:112-116.

Benowitz, note 134, *supra.*

Gori et al, note 142, *supra.*

[144] *See* Perkins, note 126, *supra.*

D. CONSUMERS USE TOBACCO PRODUCTS FOR DRUG EFFECTS

1. To Satisfy Addiction

Nicotine, at levels present in commercially marketed tobacco products, is addictive to most users. Most people who use tobacco products do so to maintain their addiction.

A number of studies have been conducted to determine the prevalence of tobacco or nicotine dependence among smokers according to accepted definitions of dependence. Major recent studies conclude that at least 75% and as many as 90% of frequent smokers meet the criteria for addiction established by major public health organizations.[145]

In a 1987 paper by Hughes et al.[146] the authors reported on their efforts to determine the prevalence of tobacco dependence using several diagnostic measures. The study participants included 1,006 middle-aged men in the Minneapolis-St. Paul metropolitan area.[147] The mean number of cigarettes smoked per day in this sample was 28, and the mean number of years smoked was 33. Forty-two percent (n=423) of the subjects had made at least three prior attempts at quitting; 61% (n=614) had made at least one unsuccessful attempt to stop

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[145] Hughes JR, Gust SW, Pechacek TF. Prevalence of tobacco dependence and withdrawal. *Am J Psychiatry*. 1987;144(2):205-208. The precise number of tobacco users found to meet the criteria for nicotine dependence varies depending on the population studied and the study methods used. *See* Appendix 1.

[146] *Id.*

[147] Although utilizing a sample of men only may raise questions about the generalizability of these findings, as the authors point out, previous studies have found that age and sex have little or no effect on tobacco dependence and withdrawal. *See:*

Shiffman SM. The tobacco withdrawal syndrome. In: Krasnegor NA, ed. *Cigarette Smoking as a Dependence Process*. NIDA Research Monograph 23. DHEW Publication No. ADM 79-800. Washington, DC: U.S. Government Printing Office. 1979.

Hughes JR, Hatsukami D. Signs and symptoms of tobacco withdrawal. *Arch Gen Psychiatry* 1986;43:289-294.

smoking. The investigators concluded that 90% (n=905) of the smokers fulfilled the DSM-III criteria for tobacco dependence.

Hale et al. surveyed 201 residents of Burlington, VT. Using the DSM-III-R criteria for drug dependence, the researchers concluded that 80% of the current tobacco users were dependent (Male=91%, Female=71%). The most commonly met criteria were unsuccessful attempts to control use despite a persistent desire to quit (93%) and experiencing withdrawal symptoms when stopping or cutting down (74%).[148]

In another study, Cottler compared the various DSM and ICD diagnostic criteria for nicotine dependence among persons who reported smoking or using tobacco daily for 1 month or more during their lives. Sixty-three percent of the sample included patients from substance abuse treatment programs; 37% of the sample was drawn from the general population. Among the 677 nicotine users who fulfilled the smoking or tobacco use requirement, 77% were deemed dependent under the DSM-III diagnostic criteria. Eighty percent met the criteria for dependence according to the DSM-III-R criteria. Under the old ICD-10 criteria, 92% were found to be dependent, compared with 86% under the new ICD-10 criteria.[149]

Woody et al. analyzed the responses of 1,100 subjects who had identified themselves as having used tobacco six or more times during their lives. Subjects were all between 18 and

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[148] Hale KL, Hughes JR, Oliveto AH, et al. Nicotine dependence in a population-based sample: problems of drug dependence, 1992. Proceedings of the 54th Annual Scientific Meeting of the College on Problems of Drug Dependence. NIDA Research Monograph 132. NIH Publication No. 93-3505. Washington, DC. U.S. Government Printing Office. 1993.

[149] Cottler LB. Comparing DSM-III-R and ICD-10 substance use disorders. *Addiction.* 1993;88:689-696.

44 years of age. The researchers found that 87% of those who used tobacco six or more times were dependent under the DSM-III-R criteria.[150] These studies show that a consistently high percentage of smokers are dependent on nicotine, despite the different measuring tools used to evaluate dependence.

As described on p. 90 et seq., studies have also shown that a significant proportion of smokeless tobacco users are addicted.

[150] Woody GE, Cottler LB, Cacciola J. Severity of dependence: data from the DSM-IV field trials. *Addiction*. 1993;88:1573-1579.

2. To Affect Mood and Control Weight

a. Mood

Surveys show that people use tobacco to achieve a relaxing effect, both in stressful situations and to enhance pleasure.[151] For example, one survey found that 65% to 75% of adults believed that smoking reduced nervous irritation.[152] Similarly, a recent survey of young people aged 10 to 22 found that of daily smokers, 72.8% said that smoking relaxed them. Of daily smokeless tobacco users, 53.8% reported that smokeless tobacco relaxed them.[153] Studies also have shown that smokers use cigarettes in an attempt to reduce negative feelings.[154]

The 1988 Surgeon General Report reviewed the epidemiological literature on the effects of smoking on mood and concluded:

> *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 . . . .These data do not necessarily indicate that the various functions characterize different types of smokers; rather, they suggest that most functions are salient to an individual but are operative at different times or in*

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[151] Surgeon General's Report. 1988. *Nicotine Addiction.* Pages 394-399.

[152] *See:*
McKennell AC. Smoking motivation factors. *Br J of Soc and Clin Psych.* 1970;49(1):8-22.

Surgeon General's Report. 1988. *Nicotine Addiction.* Page 399.

[153] *See* CDC, note 86, *supra.*

[154] *See:*
Horn D. Some factors in smoking and its cessation. In: Borgatta EF, Evans RR, eds. *Smoking Health and Behavior.* Chicago, IL: Aldine Publishing Co.; 1968:12-21.

Ikard FF, Green DE, Horn D. A scale to differentiate between types of smoking as related to the management of affect. *Int J Addict.* 1969;4(4):649-59.

different situations."[155]

b. Weight Control

Numerous studies show that smokers believe that smoking keeps weight down and that weight control is a significant motivation to continue smoking.[156] In two surveys of young people, between a third and one-half of smokers offered weight control as a reason for smoking.[157] It has also been suggested that weight gain that occurs after smoking cessation causes many smokers to relapse to smoking.[158]

Research indicates that smoking may play a role in regulating weight. 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 weigh less than nonsmokers and that people who quit smoking gain weight.*[159]
>
> *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 who did not receive nicotine].*

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[155] Surgeon General's Report. 1988. *Nicotine Addiction*. Page 399.

[156] *See:*

Pomerleau CS, Ehrlich E, Tate JC, Marks JL, Flessland KA, Pomerleau OF. The female weight-control smoker: a profile. *J Substance Abuse*. 1993;5:391-400.

Feldman W, Hodgson C, Corber S. Relationship between higher prevalence of smoking and weight concern amongst adolescent girls. *Canadian Journal of Public Health*. 1985;76(3):205-206.

Surgeon General's Report. 1988. *Nicotine Addiction*. Pages 414-432.

[157] Surgeon General's Report. 1988. *Nicotine Addiction*. Page 438.

[158] *Id.* at pp. 414, 438-441.

[159] *Id.* at p. 431.

Recent research on nicotine polacrilex gum with humans corroborates the role of nicotine in body weight effects.[160]

It is clear from the evidence that consumers use tobacco products for several well-defined and well-documented drug effects. Most significantly, consumers use tobacco products to maintain their addiction to nicotine. Consumers also use tobacco for a variety of ancillary drug effects. These include the effects of nicotine on mood and weight control.

[160] *Id.* at p. 432.

II. STATEMENTS, RESEARCH, AND ACTIONS BY TOBACCO COMPANIES

The evidence presented in this section describes the statements, research activities, and actions of the tobacco industry related to the role of nicotine in cigarettes and smokeless tobacco. Industry statements show that tobacco company officials at the highest levels are aware that nicotine's drug effects are the primary reason people use their products. The tobacco industry's research shows that it has knowledge of the pharmacological role of nicotine in tobacco use, including its ability to affect brain function and behavior and to produce dependence. The industry has also conducted research to determine what constitutes an adequate dose of nicotine. The tobacco industry's actions show that it has manipulated nicotine delivery in marketed products and attempted to develop products to provide a dose of nicotine that satisfies consumers' desire for the pharmacological effects of nicotine.

A. INDUSTRY STATEMENTS ON NICOTINE'S DRUG EFFECTS

Recently disclosed industry documents contain explicit statements, made by high-ranking tobacco company officials over more than three decades, acknowledging nicotine's drug effects and the central role those effects play in tobacco use. These documents also include research reports and conference summaries describing the specific pharmacological and physiological effects of nicotine, including, in some cases, its addictive properties. Covering a period of more than 30 years, these company documents show that tobacco companies have long recognized that nicotine in tobacco is a drug, that nicotine is the primary reason people use cigarettes and smokeless tobacco, and that cigarettes and smokeless tobacco are nicotine delivery systems. Internal statements of company officials and researchers reflect the industry's true knowledge and real intentions. The internal statements contained in these documents confirm that tobacco manufacturers intend nicotine-containing cigarettes and smokeless tobacco to be used as drugs. The extent of these statements was not known to FDA at the time of its earlier determinations about the intended use of tobacco.

1. Statements That Nicotine's Drug Effects Are Essential to Tobacco Use

Tobacco company researchers have, for more than 30 years, studied the effects of nicotine on the body. Industry documents reveal that the manufacturers' research has convinced the industry that nicotine in tobacco produces pharmacological effects in tobacco users and that these effects are the major reason that consumers use tobacco products. These documents reveal further that tobacco company executives and senior officials share these convictions about the central role of nicotine's drug effects in tobacco use.

a. Tobacco Company Researchers' Views

A wide range of industry documents reveals that tobacco company researchers have known for several decades that nicotine in tobacco functions as a drug and that nicotine's drug effects are the central reason that consumers use tobacco.

More than 30 years ago, in 1962-63, BATCO received the results of its Project HIPPO study (HIPPO I and HIPPO II), the aim of which was to "understand some of the activities of nicotine -- those activities that could explain why smokers are so fond of their habit."[161] A second purpose of the Project HIPPO study was to compare the effects of nicotine with those of then-new tranquilizers, "which might supersede tobacco habits in the near future."[162] Thus,

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[161] *See:*
Hersch J, Libert O, Rogg-Effront C. *Final Report on Project HIPPO I.* Battelle Memorial Institute. International Division. Geneva, Switzerland. January 1962. (Hereafter cited as Final Report on Project HIPPO I.)

Haselbach CH, Libert O. *Final Report on Project HIPPO II.* Battelle Memorial Institute. International Division. Geneva, Switzerland. March 1963. Pages 1-3. (Hereafter cited as Final Report on Project HIPPO II.)

[162] *Id.* Final Report on Project HIPPO II. Page 1.

these researchers believed that nicotine-containing tobacco and tranquilizers were used for the same purposes by consumers. The researchers concluded that, despite some similarities, nicotine has different drug effects than tranquilizers:

> *both kinds of drugs [nicotine and tranquilizers] act quite differently, and [] nicotine may be considered (its cardiovascular effects not being contemplated here) 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.*[163] [Emphasis added.]

In the final conclusion of the HIPPO study, the researchers discuss the effect of nicotine in the "stress reaction":

> *The understanding and thorough investigation of this effect seems of the greatest importance: it is by this very effect that nicotine acts as a 'tranquilliser.'*[164]

The Project HIPPO reports were disseminated to officials of Brown and Williamson (B&W).[165] The exchange of information between BATCO and B&W is important because it

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[163] Final Report on Project Hippo II. Page 2. Based on studies of rats, the Project HIPPO I researchers also concluded:

> *We have been in a position to show a definite enhancing effect of nicotine in the normal mechanism of defence [sic] against stress, i.e., in the stimulation of the release of the pituitary corticotropic hormone (ACTH).*

Final Report on Project HIPPO I. Page 2.

[164] Final Report on Project HIPPO I. Page 48.

[165] These reports were also circulated to various other U.S. tobacco companies, and the Tobacco Industry Research Committee, the forerunner to the Council for Tobacco Research (Little, CC. "Report of the Scientific Director," 1963, at p. 5), demonstrating that at least some of the industry's nicotine research was shared. *See, e.g.*:

June 28, 1963, letter from Sir Charles Ellis, Scientific Advisor to the Board of BATCO to A. Yeaman of B&W.

August 5, 1963, letter from A. Yeaman to E.J. Jacob of R.J. Reynolds Tobacco Co.:

demonstrates B&W's awareness of the results of studies such as Project HIPPO,[166] which was just one of a number of studies commissioned by BATCO to study the physiological and pharmacological effects of nicotine. For example, a 1980 report addresses the critical role of nicotine's drug effects:

> *Nicotine is an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical, and physiological responses in vivo . . . In some instances, 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.*[167]

The BATCO documents include not only some of the research reports themselves, bu also summaries or minutes of numerous BATCO research and development (R&D) meetings at which nicotine's drug effects and importance to the industry were discussed. These papers demonstrate both the consistency and the extent of industry's interest in and knowledge of

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> *I suggest to you and Henry that it is now timely to release these reports to the S.A.B. [Scientific Advisory Board of the Tobacco Institute Research Council].*

June 19, 1963, note for Mr. Cutchins of B&W, noting that Sir Charles Ellis had sent Mr. Cutchins reports of research that BATCO had sponsored at Battelle :

> *. . . . showing the beneficial effects of nicotine . . . . BAT decided to make this research available to the T.R.C. [Tobacco Research Council of the U.K.] . . . .Todd, of T.R.C. is to-day sending copies to T.I.R.C. [Tobacco Industry Research Committee of the U.S.] with a request that they consider whether it would help the U.S. industry for these reports to be passed on to the Surgeon General's Committee.*

[166] Appendix 2 contains a detailed description of how the research was shared between B&W and BATCO. The B&W/BATCO documents that recently were made public offer an extraordinary glimpse into the workings of the third largest U.S. tobacco company. Although the five other leading U.S. tobacco companies received requests from FDA on July 11, 1994, for similar documentary evidence, to date the companies have failed to provide the requested information. *See* Appendix 3. Tobacco industry material is cited throughout the Legal Analysis and Findings sections of this document that refers to the workings of the five U.S. tobacco companies. This material constitutes just a representative sample of the internal information still in the possession of those companies.

[167] BATCO Group R &.D. Southampton, England. *Method for Nicotine and Cotinine in Blood and Urine.* Report No. RD.1737-C. May 21, 1980. Page 2.

nicotine as the primary pharmacological agent in tobacco. For example, at a 1974 BATCO Group R&D Meeting, it was noted that:

> *Nicotine (which has been assumed to be the main pharmacologically active component in smoke) may act in a bi-phasic manner, either as a stimulant (CNV increase) or depressant (CNV decrease).*[168]

In addition, a 1977 report concerning an International Smoking Behavior Conference includes the following statements about nicotine's effects:

> *Nicotine was the focal point of the conference. In many cases, psychological and physiological changes observed in subjects . . . . were shown to be due to nicotine.*
>
> *Most researchers conclude that the nicotine effect is biphasic and dosage dependent; small doses stimulate and large doses depress.*[169]

Subsequent BATCO research conferences offer equally revealing statements about the drug effects of nicotine. A BATCO Group R&D Smoking Behaviour-Marketing Conference held in 1984 focused almost entirely on the role of nicotine pharmacology in smoking. Summaries of the presentations at that conference include numerous references to the pharmacological effects of nicotine and the importance of these effects in maintaining tobacco use. For example, one presentation included the following observation:

> *Smoking is then seen as 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*

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[168] BATCO Group R&D. Southampton, England. *Interaction of Smoke and the Smoker, Part 3: The Effect of Cigarette Smoking on the Contingent Negative Variation.* Report No. RD.1164-R. December 12, 1974. Page 1.

[169] BATCO International Smoking Behavior Conference: Trip Report. Chelwood Vachery, England. November 27-30, 1977. Pages 1-2.

themselves as changes in human performance and psychological well-being.[170] [Emphasis added.]

Reporting on a study testing the hypothesis that extroverts smoke for nicotine and introverts smoke for the motor activity provided by smoking, another presentation concluded:

> *Extraverts [sic] relied principally on nicotine and did not pay attention to the motor aspects of smoking except to gain nicotine and so did not show well developed motor potentials preceding the motor act. However, the effect of nicotine is to enhance the extravert's motivation to act, and this increases motor activity rate after smoking (as was shown in the tapping rate recorded for extraverts after smoking) . . . . For preparatory smokers (extraverts): Smoking functions as a kind of portable, stationary generator inducing the effects of activity on the CNS [central nervous system] without the usual requirement of stressful activity to achieve those effects.*[171]

Finally, another BATCO conference focusing on nicotine was held in 1984. One of the presentations was characterized by a Brown and Williamson official:

> *The presentation was concerned with summarising and outlining the central role of nicotine in the smoking process and our business generally. . . There are two areas of nicotine action that are of primary importance: (i.) to identify to what extent the pharmacological properties or responses to nicotine are influenced by blood and tissue levels of nicotine. (ii) what is the significance and role of nicotine in eliciting the impact response and upper respiratory tract responses . . .* [Emphasis added.][172]

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[170] Ferris RP. *The role of smoking behavior in product development: some observations on the psychological aspects of smoking behaviour.* In: Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Page 79.

[171] Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Slides. Pages BW-W2-02772-02775.

[172] Ayres CI. Notes from the GR&DC [Group Research and Development Centre] Nicotine Conference June, 1984. Page 62. The conference was devoted predominantly to nicotine's pharmacological effects. The conference's seven sessions are listed as follows:

> *Session I - Nicotine Dose Requirement - Background; Session II - Nicotine Dose Estimation; Session III - Sensory and Psychological Effects of Nicotine; Session IV - Effect of Nicotine - Interaction with the Brain (Pharmacology); Session V - Effects of Nicotine - Interaction with Peripheral Tissues (Physiology);Session VI - Product Modification for Maximal Nicotine Effects Session VII - General Session.* Pages BW-W2-02639, 12641-46.

See also:

As described in FINDINGS § II.B., infra, comparable research on the pharmacological effects of nicotine has been conducted or sponsored by all the major tobacco companies. For example, researchers at the R.J. Reynolds Tobacco Co. have published studies in which they freely acknowledge the pharmacological effects of nicotine in tobacco and the importance of those effects to smokers:

> *The beneficial effects of smoking on cognitive performance . . . are a function of nicotine absorbed from cigarette smoke upon inhalation.*[173]

BATCO R&D Conference. Hilton Head, SC. September 24-30, 1968. Page 3. The conferees recognized "that the reasons why people smoke are partly pharmacological and partly psychological."

BATCO R&D Conference. Montreal, Canada. October 25, 1967. Page 6. The conferees concluded:
> *While recognizing the importance of psychological factors in smoking and the possibility that some smokers would accept non-nicotine cigarettes, it was felt that nicotine is important for the majority of smokers and that the form of nicotine can be significant.* [Emphasis added.]

BATCO R&D Conference. Kronberg, Germany. June 2-6, 1969. Page 7 of summary:
> *The Conference agreed that all the evidence continues to demonstrate the importance of nicotine to the smoker, and again emphasises the importance of keeping separate TPM and nicotine figures.* [Emphasis added.]

BATCO Group R&D report. Southampton, England. *Preparation and Properties of Nicotine Analogues.* Report No. RD 953-R. November 9, 1972.

BATCO Group R&D Conference on Smoking Behavior. Southampton, England. October 11-12, 1976. Pages BW-W2-02145-02149, BW-W2-02150-02165, BW-W2-02292-02311.

February 9, 1984, letter from C.I. Ayres to E.E. Kohnhorst (both of Brown and Williamson) summarizing the August 30-September 3, 1982, BATCO R&D Conference. Montebello, Canada.

[173] 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;108:471.

See also Pritchard WS, Robinson JH, Guy TD (R.J. Reynolds Tobacco Co.). Enhancement of continuous performance task reaction time by smoking in non-deprived smokers. *Psychopharmacology.* 1992;108:437-442.

Pritchard WS, Gilbert DG, Duke DW (R.J. Reynolds Tobacco Co.). Flexible effects of quantified cigarette smoke delivery on EEG dimensional complexity. *Psychopharmacology.* 1993;113:95-102.

> *An enduring question regarding human cigarette smoking is the basis of the so-called "nicotine paradox." Although the peripheral effects of smoking appear to be stimulatory (e.g., increased heart rate, especially for the initial cigarette of the day [citation omitted]) and many smokers say that smoking increases their mental alertness, other smokers report that smoking helps them to function in the face of environmental stress by having a calming effect on their mood [citation omitted].*[174]
>
> *We recognize that nicotine plays an important role in smoking behavior for many people.*[175] [Emphasis added.]

Philip Morris researchers conducted extensive research on nicotine pharmacology from the late 1960's until at least the mid-1980's. See note 240a, infra. The nature and magnitude of the research, as well as statements made in internal documents, show that the Philip Morris researchers strongly believed that nicotine has potent psychoactive effects and that these effects provide a primary motivation for smoking. For example, in 1969, a Philip Morris researcher proposed a study whose purpose was to show that cigarette smoking is more likely in stressful situations. The researcher stated that such a study would demonstrate "one of the advantages of smoking, its use as an anxiety reducer."[175a] In 1974, Philip Morris researchers began a study designed to test their theory that hyperkinetic children take up

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[174] Pritchard WS (R.J. Reynolds Tobacco Co.). Electroencephalographic effects of cigarette smoking. *Psychopharmacology.* 1991;104:485-490. Page 00033640. (Smokers who inhale lightly appear to use tobacco to achieve "mental activation and performance enhancement" while those who inhale more deeply achieve effects in the portion of their brains that is associated with anxiety reduction after administration of benzodiazepines. *Id.* at p. 00033643. [Benzodiazepines are drugs used as sedatives and to treat anxiety.])

See also Gibert DG, Robinson JH, Chamberlin CL (R.J. Reynolds Tobacco Co.), and Spielberger, CD. Effects of smoking/nicotine on anxiety, heart rate, and lateralization of EEG during a stressful movie. *Psychophysiology.* 1989;26(3):311-319. (High-nicotine cigarettes associated with reductions in anxiety and activation of the right hemisphere of the brain.)

[175] Robinson J, Pritchard W. The role of nicotine in tobacco use. *Psychopharmacology.* 1992;108:405.

[175a] Memorandum to W.L. Dunn from F.J. Ryan. Proposed Research Project: Smoking and Anxiety. December 23, 1969. *In* 141 Cong. Rec. H7648 (daily ed. July 25, 1995).

smoking in adolescence because nicotine may perform the same pharmacological function as prescription medications used to treat hyperkinesis:

> *It has been found that amphetamines, which are strong stimulants, have the anomalous effect of quieting these children down . . . Many children are therefore regularly administered amphetamines throughout grade school years . . . . 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 in the third grade.*[175b] [Emphasis added.]

In 1976, a Philip Morris researcher wrote a memo explaining why people smoke. In his memo, he reported on a survey in which smokers were asked why they smoked. The researcher concluded that

> *the circumstances in which smoking occurs may be generalized as follows:*
> *1. As a narcotic, tranquilizer, or sedative. Smokers regularly use cigarettes a times of stress.*
> *2. At the beginning or ending of a basic activity . . . .*
> *3. Automatic smoking behavior. . .*[175c] [Emphasis added.]

In a research paper funded by the Council for Tobacco Research, U.S.A. (CTR),[176]

[175b] Dunn WL. 1600/Smoker Psychology/May 1-31, 1974 [Monthly Report]. June 10, 1974.
See also:
Memorandum from W.L. Dunn to P.A. Eichorn. Quarterly Report- February-March, 1972. April 4, 1972. This memo reports on a study conducted by Philip Morris comparing the "arousal response" produced by nicotine, caffeine, and placebo. The researchers reported that the "arousal response was clearly present with nicotine" and that the caffeine response was nearer to placebo. *In* 141 Cong. Rec. H7651 (daily ed. July 25, 1995).

[175c] Memorandum from A. Udow, Philip Morris, New York, NY, to Mr. J.J. Morgan. Why People Start to Smoke. June 2, 1976. *In* 141 Cong. Rec. H7664 (daily ed. July 25, 1995).

[176] In January, 1954, 14 presidents of tobacco manufacturers, growers, and warehousemen organized the forerunner organization to CTR, known as the Tobacco Industry Research Committee (TIRC), to sponsor a research program into questions of tobacco use and health. (By-laws of the Tobacco Industry Research Committee, subscribed and adopted on January 1, 1954.) TIRC was founded in response to growing concern by tobacco executives over the appearance of published articles claiming an established relationship between cigarette smoking and lung cancer.

reporting on the "beneficial" pharmacological effects of nicotine in cigarettes, the authors said:

> *Nicotine is recognized as the primary psychoactive compound in cigarette smoke.*[177]

Many other industry documents refer to the central role of nicotine's drug effects for smokers and, therefore, for the industry.[178] Nicotine is repeatedly identified as a primary

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The driving force behind the creation of TIRC was Paul M. Hahn, President of the American Tobacco Company. Other original signers of the TIRC by-laws were Timothy V. Hartnett, President of Brown and Williamson Tobacco Corp., Herbert A. Kent, Chairman of P. Lorillard & Co., O. Parker McComas, President of Philip Morris & Co., E.A. Darr, President of R. J. Reynolds Tobacco Co., J.W. Peterson, President of U.S. Tobacco Co., and Joseph F. Cullman, President of Benson & Hedges. (Minutes of the Meeting of the Presidents of the Leading Tobacco Companies at the Hotel Plaza, December 15, 1953. Page 1.)

By 1963, grants had been made to 140 scientists from $6,250,000 appropriated by TIRC from its member companies. In January, 1964, TIRC changed its name to the Council for Tobacco Research (CTR), its current name. The current members of CTR include Philip Morris, R.J. Reynolds, Brown and Williamson, American Tobacco, Lorillard Corp., and U.S. Tobacco. By 1993, CTR had funded more than $223 million in research. Annual Reports issued by CTR reveal that the organization has provided extensive funding to research on nicotine pharmacology. *See* note 195, *infra.*

[177] Levin ED, Briggs SJ, Christopher NC, Rose JE. Persistence of chronic nicotine-induced cognitive facilitation. *Behavioral and Neural Biology*. 1992;58:152-158.

[178] For example, the American Tobacco Company (ATC) published a document entitled *A Summary of Biological Research on Tobacco Supported in Whole or in Part by the American Tobacco Company* (April 1962). In a chapter entitled "Role of Nicotine in the Cigarette Habit," ATC referred to a 1945 study and stated that "[t]he authors concluded that with some individuals, nicotine becomes a major factor in their cigarette habit." Page 66. (*See* Finnegan JK, Larson PS, Haag B. The role of nicotine in the cigarette habit. *Science*. 1945;102:94.)

See also:

Willey LC, Kellett ND (for Imperial Tobacco Group Ltd.). *Effects of Nicotine on the Central Nervous System*. Huntingdon Research Centre. 1971. Page 9:

> *We aim, by using various different schedules of behavioural training, and by comparing the effects of many different drugs on these schedules, to be able to classify the effect of nicotine, when given intermittently in smoking doses, as similar to a known class of drug acting on the central nervous system. Alternatively, it may, perhaps, act like one type of drug in some tests and at some doses and like another type in other tests.*

U.S. Patent No. 4,340,072. Bolt AJ, Chard B. *Smokable Device*. Imperial Group Ltd. 1982. C1:

> *Among the reasons why most people smoke conventional cigarettes is that they wish to*

reason consumers smoke or use other nicotine-containing products. A "Proposal for Low Delivery Project for B&W" prepared by a marketing firm hired by B&W in the late 1970's contained the following statement that a sufficient dose of nicotine is essential to sell cigarettes and, implicitly, to maintain market share based on nicotine addiction:

> *Current market trends clearly indicate a major trend toward low-tar brands although current "ultra" low "tar" brands, have had limited success because of their failure to deliver satisfaction/maintain an adequate nicotine level. An ancillary concern relative to nicotine delivery is that if a satisfying, low-nicotine cigarette were to be developed, it could represent an effective means of withdrawal . . . with severe implications for long-term market growth.* [Emphasis added.][179]

Finally, a 1976 BATCO Conference on Smoking Behavior underscores tobacco industry researchers' awareness of the fundamental importance (to the huge majority of smokers) of nicotine's effects on the brain:

> *Some insight into the likely benefits of smoking follows from a consideration of the properties of nicotine, which is considered to be the reinforcing factor in the smoking habit for at least 80% of smokers* . . . [Emphasis added.][180]

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inhale an aerosol containing nicotine.

Note from S.J. Green (BATCO R&D) to Dr. G. Hook (BATCO R&D). June 11, 1974.

[179] Lisher & Company Inc. memo. Proposal for Low Delivery Project for B&W. On the copy of this proposal, lines 3 - 7, beginning with "maintain an adequate nicotine level," are crossed out. The unedited quote makes clear that the term "satisfaction" is a euphemism used by the industry to refer to satisfaction of the desire for nicotine.

[180] BATCO Group R&D Conference on Smoking Behavior. Group Research and Development Centre. Southampton, England. October 11-12, 1976. "*Benefits" of Smoking.* (Pages BW-W2-02152 and 02153). The summary of a presentation at this conference also notes that all types of tobacco usage -- smoking, chewing and snuffing -- allow nicotine to go directly into the blood and to the brain. The speaker observed that nicotine is not ingested, a route that converts nicotine to a pharmacologically inactive metabolite, cotinine, before it can affect the brain. The summary then notes:

> *It would therefore be surprising if nicotine, which is known to be pharmacologically active in the brain (unlike cotinine), and which is obtained in the ways most likely to enable it to reach the brain unchanged, were not involved in the reasons why people smoke.*

Id., Session II: Current Views on the Role of Nicotine in Smoking Behaviour. Page BW-W2-02145.

b. Tobacco company executives' and senior officials' views

Internal and published documents demonstrate that tobacco company executives and senior officials have also long understood that nicotine is a drug and that nicotine's pharmacological effects are essential to consumer satisfaction.

In 1988, during the case Cipollone v. Liggett, Joseph Cullman III, former CEO of the Philip Morris Tobacco Company, testified as follows:

Q: Let me ask you the question, then, Mr. Cullman. Is nicotine a drug?

A: Well it's so described in every book on pharmacology.

Q: So then you agree that it's a drug?

A: I have no reason to disagree with books on pharmacology.[181]

In 1981, the Tobacco Advisory Council, representing the United Kingdom tobacco manufacturers[182] (including BATCO), published a monograph on nicotine pharmacology and toxicology that expressly treats nicotine as a drug delivered by tobacco.[183] The monograph states that "nicotine is regarded as the most pharmacologically-active compound in tobacco smoke" and states that nicotine's main effects, "at doses absorbed by inhalers (i.e. 1 mg approx per cigarette)" are:

> *central stimulation and/or depression (which vary with the individual), transient hyperpnoea, peripheral vasoconstriction (usually associated with a rise in systolic pressure), suppression of appetite, stimulation of peristalsis and, at larger nicotine intakes, nausea of central origin, associated with*

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[181] *Transcript of proceedings in* Cipollone v. Liggett Group, Inc., at p. 3290 (D.N.J. Feb. 23, 1988). (Civil Action No. 83-2864 (SA)).

[182] 1981 document of the Tobacco Advisory Council (corrections sheet).

[183] Cohen AJ, Roe FJC. *Monograph on the pharmacology and toxicology of nicotine*. Tobacco Advisory Council. Occasional paper 4. 1981. Page 1.

vomiting.[184]

More than three decades ago, in 1961, a presentation by Dr. Helmut Wakeham, a senior Philip Morris research scientist, to the company's Research and Development Committee noted that:

> *Low nicotine doses stimulate, but high doses depress functions . . . It is also recognised that smoking produces pleasurable reactions or tranquility, and that this is due at least in part to nicotine . . . .*[185]

Dr. Wakeham also noted that "nicotine is believed essential to cigarette acceptability,"[186] a view later restated by William Dunn, Jr., another high-ranking Philip Morris official. In summarizing a 1972 conference sponsored by the Council for Tobacco Research, Dr. Dunn reported:

> *Most of the conferees would agree with this proposition: The primary incentive to cigarette smoking is the immediate salutary effect of inhaled smoke upon body function.* [Emphasis added.][187]

After describing "the physiological effect" as "the primary incentive" for smoking, Dr. Dunn continued:

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[184] *Id.* at p.17.

[185] Wakeham H. *Tobacco and Health -- R&D Approach.* In: 3.10 Tobacco Products Liability Reporter (TPLR) 8.129. *See also* Wakeham H. Presentation to R & D Committee at meeting held in New York Office on November 15, 1961.

Later, when Wakeham was a Vice President at Philip Morris, his introduction to a tobacco industry symposium included the following acknowledgment that nicotine produces psychoactive effects: "Tobacco and other psychoactive plants have probably been part and parcel of our cultural baggage for thousands of years..." Wakeham H. *Tobacco Smoke: Its Formation and Composition.* 31st Tobacco Chemists Research Conference. October 5-7, 1977. Greensboro, NC. In: *Recent Advances in Tobacco Science.* 1977;3:iii.

[186] *Id.*, TPLR 8.129.

[187] Dunn, note 133, *supra,* at p. 3.

> *The majority of the conferees would go even further and accept the proposition that nicotine is the active constituent of cigarette smoke. Without nicotine, the argument goes, there would be no smoking. Some strong evidence can be marshalled to support this argument:*
>
> *1) No one has ever become a cigarette smoker by smoking cigarettes without nicotine.*
>
> *2) Most of the physiological responses to inhaled smoke have been shown to be nicotine-related.*
>
> *3) Despite many low nicotine brand entries in the market place, none of them have captured a substantial segment of the market . . .* [Emphasis added.][188]

In 1969, Dr. Wakeham, then Vice President for Research and Development, briefed the Philip Morris Board of Directors on why people smoke. A draft of his remarks, which contains the notation "delivered with only minor changes," includes several unequivocal statements that cigarettes are smoked for the pharmacological effects of nicotine:

> *[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.*[188a]

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[188] *Id.* at p. 4.

[188a] Ryan/Dunn Alternate -Third version of Board presentation. Fall, 1969. *In* 141 Cong. Rec. H7648 (daily ed. July 25, 1995).
See also:
Memorandum to P.A. Eichorn from W.L. Dunn. Five-year Objectives and Plans for Project 1600. September 25, 1970. *In* 141 Cong. Rec. H7650, *supra.* This document details Philip Morris' plans to study the "short-term psychological and psychophysiological" effects of smoking "as manifested through changes in autonomic, perceptual, cognitive and central nervous system processes and motor performance." The author goes so far toward presuming the essential role of nicotine as to propose that research be undertaken to answer the question: "Can the smoking habit be sustained in the absence of nicotine?"

Dunn WL. 1600/Smoker Psychology/January 1- January 31, 1973 [Monthly Report]. February 9, 1973. *In* 141 Cong. Rec. H7650, *supra.* This report shows that several studies were underway at Philip Morris

A 1974 annual report on the Behavioral Research program at Philip Morris approved by Thomas Osdene (later Vice President for science and technology) and distributed to Dr. Wakeham, also reflects the view that cigarettes are drugs consumed for pharmacological effects. The report states that a person regulates smoke intake "to achieve his habitual quota of the pharmacological action [of the components of smoke]." [188b]

In the following year, the annual report on the "Behavioral Research" program explicitly acknowledged that nicotine is a stimulant drug. Describing a theory concerning the effect of an individual's CNS arousal level on performance efficiency, the report says that while one way to increase the CNS arousal level is to seek out stimulating situations, another way is to:

consume socially approved chemicals which would have a similar effect on the

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to determine the effects of nicotine on the central nervous system and on performance, including studies on the effects of smoking on: electrical activity in the brain, the "arousal mechanisms of the central nervous system," and "spare mental capacity."

Philip Morris Research Center. Behavioral Research Annual Report (Part II). November 1, 1974. *In* 141 Cong. Rec. H7658, *supra.* The report lists the following "working hypotheses" of Philip Morris researchers:

> *IA. Cigarette smoke improves efficiency in the performance of complex psychological tasks.*
> *1B. Cigarette smoking attenuates, modulates or otherwise influences emotional arousal such as to be gratifying or rewarding to the smoker, thus reinforcing the smoking act.*
> . . . .
> *IIA. Dose-control continues even after the puff of smoke is drawn into the mouth.*

Dunn WL, Ryan FJ, Martin P. Behavioral Research Annual Report. July 18, 1975. *In* 141 Cong. Rec. H7658, *supra.* This report describes a study being undertaken by Philip Morris, entitled "Nicotine as a Modulator of CNS Arousal." The study was to be conducted because the researchers believed that previous studies had provided evidence that nicotine reduces emotional responsiveness:

> *[Previous] observations imply the influence of nicotine upon some control mechanism governing affective responsivity, the net effect upon overt behavior being to reduce the intensity of the emotionally-toned response, or raise the threshold for the elicitation of that response.*

[188b] Philip Morris Research Center. Behavioral Research Annual Report, Part II. Approved by T.S. Osdene. November 1, 1974. *In* 121 Cong. Rec. H7660 (daily ed. July 25, 1995).

body--such as the stimulant drugs caffeine and nicotine.[188c]

Two years later, William Dunn provided a detailed description of the pharmacological effects produced by nicotine that cause smokers to continue smoking:

> *[T]he doses of nicotine inhaled produce definite, mild, and transient neuropsychopharmacological effects which are positively reinforcing and thus promote repetition of smoking. These effects include: (a) modulation of conditioned behavior; (b) mixed depression and facilitation of the neural substrates of reward; (c) transient (in minutes) EEG and behavioral arousal crudely reminiscent of d-amphetamine but pharmacologically quite different; and at the same time (d) skeletal muscle relaxation.*[188d]

Finally, a memorandum from a Philip Morris official in 1980 confirms the company's view that nicotine's pharmacological effects on the central nervous system are critical to the tobacco industry's success:

> *Nicotine is a powerful pharmacological agent with multiple sites of action and*

[188c] Dunn WL, Ryan FJ, Martin P. Behavioral Research Annual Report. July 18, 1975. *In* 141 Cong. Rec. H7655 (daily ed. July 25, 1995). The same report states that the authors have proposed an international industry conference on "the regulatory influence of nicotine upon behavior."

[188d] Memorandum to T.S. Osdene from W.L. Dunn. Rationale for Investigating the Effects of Smoking upon Electroencephalographic Phenomena. December 22, 1976. [Citing Domino EF, in Dunn (ed.). Smoking Behavior: Motives and Incentives. 1973.] *In* 141 Cong. Rec. H7665 (daily ed. July 25, 1995).
See also:
Philip Morris. Research and Development Five Year Plan-1979-1983. September 1978. *In* 141 Cong. Rec. H7668 (daily ed. July 25, 1995):

> *Nicotine may be the physiologically active component of smoke having the greatest consequence to the consumer.*

Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1980. January 7, 1980. *In* 141 Cong. Rec. H7671 (daily ed. July 25, 1995). The author reports:

> *Cigarette smoking results in EEG changes associated with arousal, while smoke deprivation results in . . . [brain] waves associated with drowsiness . . . . [S]moke appears to have opposite effects on visual and auditory evoked potentials . . . [N]icotine, rather than being a general stimulant, may be exerting a selective influence on brain structures.* [Emphasis added.]

The same document describes a new research program underway at Philip Morris intended to study, among other things, "how . . . cigarette smoking can have psychosocial consequences through its . . . central-nervous-system-mediated effects upon the coping abilities of the smoking social participant." [Emphasis added.] *Id.*

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' and theories have been advanced for 'nicotine titration' by the smoker. Nicotine is known to have effects on the central and peripheral nervous system as well as influencing memory, learning, pain perception, response to stress and level of arousal. [Emphasis added.][189]

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[189] Philip Morris Interoffice Correspondence from J.L. Charles to Dr. R.B. Seligman. Nicotine Receptor Program-University of Rochester. March 18, 1980. Other Philip Morris documents contain similar statements. *See, e.g.:*

Wakeham H. *Smoker Psychology Research. Presented to the PM Board of Directors, November 26, 1969.* Page 11:

> *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.*

Ryan, FJ. Philip Morris Research Center Special Report. *Exit-Brand Cigarettes: A Study of Ex-smokers.* March 1978. Page 2.

> *We think that most smokers can be considered nicotine seekers, for the pharmacological effect of nicotine is one of the rewards that comes from smoking. When the smoker quits, he foregoes his accustomed nicotine. The change is very noticeable, he misses the reward and so he returns to smoking.*

Philip Morris employee (almost certainly W.L. Dunn). *Smoker Psychology Program Review.* Date not specified. Page 5. This paper states the theory that the reinforcing effects of smoking are

> *likely to be found among the chemical compounds being introduced into the bloodstream . . . Without the chemical compound, the cigarette market would collapse, P.M. would collapse, and we'd all lose our jobs and our consulting fees.*

The same paper later says that the research program at Philip Morris is based on "*a strong conviction about the central role of the pharmacologic effects of inhaled smoke.*" Page 8.

Ryan, FJ, Jones, BW, Martin, PG, Dunn, WL. Behavioral Research Annual Report. July 18, 1975. Pages 18-22, 25.

Memo to H. Wakeham from W.L. Dunn. *Stating the Risk Study Problem.* July 29, 1969. (Tobacco is used by consumers to modulate arousal level, and to avoid withdrawal.)

Memo to W.L. Dunn from T.R. Schori. *Smoking and Caffeine: A Comparison of Physiological Arousal Effects.* May 17, 1972. This memo attaches a report of the same name by Schori and B.W. Jones, which concludes that caffeine and nicotine, which is generally "administered by smoking," both have stimulant effects, but that the effects of caffeine are more like those of placebo than those of smoking. Pages 1, 7 of report.

Memo to T.S. Osdene from W.L. Dunn. Plans and Objectives - 1982. November 5, 1981. Memo says that Philip Morris is conducting research on the effects of nicotine on electrical activity in the brain "*on the premise that events which reinforce the smoking act are central nervous system events.*" Page 4.

BATCO documents also make clear that top company officials recognize nicotine's drug effects and recognize that the company's sales are tied to those effects. In a July 1962 meeting, Sir Charles Ellis, who served as the science advisor to the BATCO board, gave a presentation in which he affirmed the central role of nicotine in tobacco use and enthusiastically endorsed its pharmacological benefits to smokers as similar to those provided by stimulants and tranquilizers:

> *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 tranquilising effect. You are all aware of the very great increase in the use of artificial controls, stimulants, tranquilisers, sleeping pills, and it is a fact that under modern conditions of life people find that they cannot depend just on their subconscious reactions to meet the various environmental strains with which they are confronted: they must have drugs available which they can take when they feel the need. Nicotine is not only a very fine drug, but the techniques of administration by smoking has considerable psychological advantages and a built-in control against excessive absorption.*[190] [Emphasis added.]

Dr. Sidney J. Green, a BATCO board member as well as the firm's director of research, frequently acknowledged, in internal documents, the central role of nicotine's pharmacological effects in tobacco use. In a 1967 memo on BATCO research needs, Dr. Green pointed out that:

> *There has been significant progress in understanding why people smoke and opinion is hardening in medical circles that the pharmacological effects of nicotine play an important part and that these effects on balance may be beneficial.* [Emphasis added.][191]

In a paper on future research policy entitled "B.A.T. Group Research" (1968), Dr. Green wrote

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Dunn, WL. *Smoking as a Possible Inhibitor of Arousal.* Submitted to Philip Morris Manuscript Review Board on August 16, 1976.

[190] BATCO Research Conference. Southampton, England. Presentation by Sir Charles Ellis entitled *The Smoking and Health Problem.*1962. Pages 15-16.

[191] Green SJ. March 2, 1967, memorandum to D.S.F. Hobson entitled *Smoking and Health: Some Recent Findings.* Appendix I, page 1. In the same document at Appendix II, page 1, Dr. Green also wrote that "[t]here is now no doubt that nicotine plays a large part in the action of smoking for many smokers."

that there were four motives for smoking, at least three of which depend on the pharmacological and addictive effects of nicotine:

> *There appear to be four recognisable types of smoking behaviour:*
> *1. Habitual*
> *2. Addictive*
> *3. Enhancing desirable emotions and feelings such as enjoyment or excitement.*
> *4. Decreasing undesirable emotions and feelings such as anger, fear and shame.*[192]

In another paper a few years later, Dr. Green wrote more forcefully:

> *The tobacco smoking habit is reinforced or dependent upon the psycho-pharmacological effects mainly of nicotine.*[193]

Attorneys for some of the major U.S. tobacco manufacturers have asserted that the "benefits" of smoking include a range of significant pharmacological effects. For example, attorneys for R.J. Reynolds Tobacco Company described the following pharmacological benefits of smoking in a court filing:

> *[S]atisfaction; stress reduction; relaxation; stimulation; aided concentration; increased memory retention; alleviation of boredom and fatigue; avoidance of loss of vigilance in repetitive and sustained tasks. . .*[194]

CTR has also supported research on the psychopharmacology of nicotine and has concluded that nicotine's drug effects play an important role in why people use tobacco. CTR's annual report for 1966-67 described reports of smokers that they liked or needed to smoke

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[192] Green SJ. Lecture notes of Chelwood talk. BATCO Group Research Conference. Chelwood Vachery, England. September 4, 1968. Pages 1, 2.

[193] Green SJ. *The Association of Smoking and Disease.* July 26, 1972. Page 1.

[194] Reply to Interrogatories, *Gilboy v. American Tobacco Co. et al.,* No. 314002 (La. 19th Jud. Dist. Ct.). Attorneys for Lorillard Tobacco Company similarly characterized the pharmacological effects of smoking in a Reply to Interrogatories filed in *Covert v. Lorillard et al,* No. 88-1018-B (M.D. La):

> *Some of the benefits that are commonly reported by various smokers are. . .relaxation; relief of anxiety and stress; reduction of boredom; increased alertness; improvement in concentration. . .*

because smoking gave them a "pickup" or relaxed them.[195] The report went on to say

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[195] Report of the Scientific Director, 1966-67. Council for Tobacco Research. 1967. Page 12. CTR's annual reports disclose that the organization has funded research on nicotine's effects on the central nervous system continuously since the 1960's. *See, e.g.:*

Report of the Scientific Director, 1964-65. Council for Tobacco Research-U.S.A. Page 22:
Systematic study of the mode of action of nicotine at various synapses has been continued. Meanwhile increasing emphasis has been placed upon the psychopharmacology of nicotine . . . . Specific actions on the central nervous system have been described and the effects of these upon behavior are being sought.

Report of the Scientific Director, 1968-1969. Council for Tobacco Research-U.S.A. Page 14:
Some of the bases for human use of tobacco . . . might also be found in the realm of psycho-pharmacology, that is, in the effects of smoking and/or nicotine on the central nervous system . . . . The effects of nicotine on the brain are not always the same. Depending on the state of the nervous system and on the dosage, an "arousal" or "wake-up" effect may occur which is reflected both in brain waves and in behavior . . . . In larger doses or in a different state of the nervous system, a peculiar steady state of longer duration is produced . . . [which] has been described as a "tranquilizer effect."

Report of the Scientific Director, 1969-1970. Council for Tobacco Research-U.S.A. Page 13.
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.

Annual Report of The Council for Tobacco Research - U.S.A., Inc. 1971. Pages 16-17, 59 *passim.*

Report of The Council for Tobacco Research - U.S.A., Inc. 1972. Page 11.
The Council is currently supporting five studies in the field of psychopharmacology that are directed toward further elucidating the paradoxical arousal and tranquilizing effects of nicotine and its facilitation of the learning process in animals. . . . Because human smokers ordinarily receive nicotine chronically . . . a new emphasis has developed concerning habituation effects on the psychopharmacological responses to nicotine.

Report of The Council For Tobacco Research-U.S.A., Inc. 1973. Pages 13-14, 52 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1974. Page 43 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1975. Page 47 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1977. Page 45 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1978. Page 49 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1979. Page 39 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1981. Page 65 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1982. Page 60 *passim.*

that the study of nicotine in the "new field" of psychopharmacology was providing scientific substantiation for smokers' subjective views that tobacco could both "arouse the lethargic and calm the agitated."[196]

Thus, industry documents reveal that tobacco company researchers and top officials understand and unequivocally state that nicotine is a drug and that consumers of tobacco products use them for the pharmacological effects of nicotine.

Report of the Council for Tobacco Research-U.S.A., Inc. 1983. Page 80 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1984. Page 83 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1985. Page 89 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1986. Page 68 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1987. Page 85 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1988. Page 88 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1990. Page 101 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1991. Page 90 *passim.*

Report of the Council for Tobacco Research-U.S.A., Inc. 1992. Page 97 *passim.*

[196] *See id.*, Report of the Scientific Director, 1966-67, at p. 13.

2. Statements Recognizing That Nicotine Is Addictive

Tobacco company documents show that company researchers and executives not only have acknowledged that nicotine's pharmacological effects play a central role in consumer satisfaction with tobacco products, but have recognized nicotine's addictive properties. These documents demonstrate that tobacco companies understand that nicotine addiction is one of the major reasons that consumers use their products.

a. Tobacco Company Researchers' Views

In 1963, a report was completed for BATCO that specifically addressed the mechanism of nicotine addiction in smokers. The report, dated May 30, 1963, and titled "A Tentative Hypothesis on Nicotine Addiction,"[197] describes nicotine's effects on the brain, specifically through hypothalamo-pituitary stimulation. The report states that initially, small doses of nicotine are sufficient to trigger this mechanism, which helps people to cope with stress. However, chronic intake of nicotine, such as occurs with regular smokers, creates a situation where:

> *ever-increasing dose levels of nicotine are necessary to maintain the desired action. Unlike other dopings, such as morphine, the demand for increasing dose levels is relatively slow for nicotine.* [Emphasis added.][198]

After noting that when chronic smokers are deprived of nicotine, their endocrine system becomes unbalanced, the report states:

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[197] Haselbach C, Libert O. BATCO R&D. *A Tentative Hypothesis on Nicotine Addiction.* Southampton, England. May 30, 1963. Pages 1-3. A copy of this report was personally sent by Sir Charles Ellis of BATCO to Addison Yeaman, the General Counsel of B&W. *See* letter from Ellis to Yeaman, dated June 28, 1963.

[198] *Id.,* Haselbach et al, at p. 1.

> *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.* [Emphasis added.][199]

The report concludes:

> *In conclusion, a tentative hypothesis for the explanation of nicotine addiction would be that of an unconscious desire to restore the normal physiological equilibrium of the corticotropin releasing system in a body in which the normal functioning of the system has been weakened by chronic intake of nicotine.* [Emphasis added.][200]

In the decades that followed this report, tobacco industry researchers repeatedly recognized nicotine's addictive properties.[201] In an article reporting on a study supported by a grant from the Tobacco Industry Research Committee (TIRC), the researcher stated that smoking is addictive:

> *Addiction to smoking is found to be consistently greater among men in military service than in civilian life, irrespective of peace or war, and greater in veterans than in nonveterans.* [Emphasis added.][202]

Similarly, a report prepared for Liggett & Myers in anticipation of the 1964 Surgeon General's Report implicitly acknowledged that nicotine dependence and withdrawal are the reasons smokers have difficulty quitting:

> *If reliance is to be placed on stopping cigarette smoking by men with warnings of high*

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[199] *Id.* at p. 2.

[200] *Id.* at p. 3.

[201] Recognition of nicotine's addictive properties apparently extended to the smokeless tobacco industry. In a Wall Street Journal article, Larry D. Story, a former U.S. Tobacco Co. (UST) chemist, was quoted as saying, "There used to be a saying at UST that 'There's a hook in every can' . . . [a]nd that hook is nicotine." Freedman AM. Juiced up: how a tobacco giant doctors snuff brands to boost their 'kick'. Wall Street Journal. October 26, 1994:A.

[202] Seltzer CC. Why people smoke. *Atlantic Monthly*. July 1962. Page 42. In a TIRC memo to the Scientific Advisory Board from R.C. Hockett, "Papers by grantees of the Tobacco Industry Research Committee," Carl Seltzer was identified as a recipient of a TIRC grant-in-aid.

> *mortality, then heavy research is badly needed . . . on means enabling such smokers to stop smoking more easily and effectively. Use of declining doses of injected nicotine or orally administered nicotine analogs during withdrawal were reported as providing some benefit . . .* [203]

In Project Wheat,[204] a study of smoking behavior conducted by BATCO, researchers concluded that consumer preferences for different cigarette types could be predicted using only two factors: 1) "Inner Need," a measure of the extent to which a smoker uses cigarettes for drug-type uses (to relieve stress, to aid concentration, as a substitute for food); and 2) concern for health. The researchers felt their conclusion to be:

> *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.*[205]

Nicotine addiction/dependence is also acknowledged in a number of other BATCO studies and other documents.[206]

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[203] L&M Littlefield. January 17, 1963, memo from Harry B. Wissman to C.J. Kensler.

[204] *See:*
BATCO. Project Wheat - Part 1: Cluster profiles of U.K. male smokers and their general smoking habits. Southampton, England. July 10, 1975.

BATCO. Project Wheat - Part 2: U.K. male smokers: their reactions to cigarettes of different nicotine delivery as influenced by inner need. Southampton, England. January 30, 1976. (Project Wheat is described in greater detail in FINDINGS § II.C., *infra.*)

[205] *Id.*, Part 2, at p. 49.

[206] *See:*
Proceedings of the BATCO Smoking Behaviour-Marketing Conference. Session III. July 9-12, 1984. Ferris slides (BW-W2-02737-02759). One chart (BW-W2-02750), entitled *Role of Nicotine: Hypotheses*, states: "If smokers are ADDICTED to nicotine then . . . 1. The nicotine smokers get from cigarettes may be replaced by nicotine from alternative sources. 2. Cigarettes of different strengths should be smoked differently, e.g., smokers given a low/reduced delivery cigarette should smoke it more intensively (and vice versa)." [Emphasis in original.] Subsequent slides show both that nicotine replacement reduced smokers intake of cigarettes, and that cigarette consumption increased as nicotine yields decreased. Pages BW-W2-02751-02759.

In addition, a Philip Morris researcher who studied a group of smokers in a small town that had gone through a cold turkey campaign described at length the withdrawal symptoms of those who had quit smoking. Even after eight months quitters were apt to report symptoms such as feeling depressed, being restless and tense, being ill-tempered, having a loss of energy, being apt to doze off.[207] They were further troubled by constipation and weight gains which averaged about five pounds per quitter.[208] The researcher stated:

> *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*

Armitage AK. *Appraisal of Report: "The Fate of Nicotine in the Body."* August 28, 1963. Armitage wrote:

> *The authors themselves admit (p.27) that the present results offer no conclusive evidence for any particular mechanism involved in tolerance to nicotine, nor do they indicate a lead to the phenomenon of addiction. This important problem was, I imagine, the main object of the research.*

Final Report on Project HIPPO II, note 161, *supra,* at page 4:

> *A quantitative investigation of the relations with time of nicotine - and of some possible brain mediators - on adreno-corticotrophic activity could give us the key to the explanation of both phenomena of tolerance and of addiction, in showing the symptoms of withdrawal.*

In the Minutes of the BATCO R&D Conference in Montreal (October 24, 1976), the list of "assumptions" includes the statement: "Smoking is an addictive habit attributable to nicotine." (The word "addictive" has been crossed out.) Page 2.

A report of the BATCO Group R&D Conference Part I, February 5-9, 1979, attended by Sanford and Reynolds of Brown and Williamson, under the heading "Behavioral Research," states: "With regard to dependence [the researcher] wants to study the nature and effect of dependence on smoking behavior and break smokers down into dissonant and consonant smokers." Page BW-W2-03526.

A report of the BATCO Group R&D Psychology Research (1984-86) states:

> *Activity continues in the area of researching the functional significance of smoking in everyday life, current emphasis being placed on the role of personality in relation to nicotine dependance [sic] and personal requirements of the product.* Page BW-W2-02004.

[207] Ryan FJ (Philip Morris). *Bird-1, A study of the Quit-Smoking campaign in Greenfield, Iowa, in Conjunction with Movie, Cold Turkey.* 1971. Summary, pages 30-33. *See* FINDINGS § II.C.4, *infra.*

[208] *Id.*

> *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.*[209]

In his report, the Philip Morris researcher also observed that some smokers "need" tobacco, and that this need may be correlated with use of high-nicotine cigarettes.[210] In 1976, the same Philip Morris researcher elaborated on his view that smokers smoke many cigarettes to satisfy their physiological "need" for a specific level of nicotine in the blood:

> *Although nicotine intake appears a critical mainstay of tobacco consumption, not all people smoke for nicotine on all occasions . . . . All . . . cigarettes contribute to the total nicotine in the system, so that a cigarette smoked out of habit will delay the time until a cigarette is smoked out of need.*[210a]

A BATCO report, as well as a report by the American Tobacco Company, also implicitly acknowledge that nicotine produces withdrawal/physical dependence.[211]

Nicotine's capacity to produce "tolerance," often cited as a defining feature of addiction, see p. 81, is also acknowledged in several internal documents. For example, the BATCO-commissioned report "Fate of Nicotine in the Body" acknowledges that nicotine produces tolerance and/or addiction:

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[209] *Id.* at p. 33.

[210] *Id.* at p. 20.

[210a] Ryan FJ. Habit and Need Cigarettes. *In* Dunn WL. 1600/Smoker Psychology/October 1-31, 1977 [Monthly Report]. November 11, 1977. *In* 141 Cong. Rec. H7665 (daily ed. July 25, 1995).

[211] *See:*
BATCO R&D. *Relative Contributions of Nicotine and Carbon Monoxide to Human Physiological Response.* Report No. RD.839-R. November 15, 1971. Page 20:

> *All the regular smokers in this trial were required not to smoke for at least half an hour before the trials, which may have caused an additional stress factor, shown as a stimulation due to the ending of a period of forced abstinence. . .*

The American Tobacco Company, note 178, *supra,* at p. 66.

> *In addition, the alkaloid [nicotine] appears to be intimately connected with the phenomena of tobacco habituation (tolerance) and/or addiction.*

Notes from a BATCO Nicotine Conference[212] include a chart titled "Session IV -- Effects of Nicotine-interaction with the Brain (Pharmacology)." The chart includes the statement "Nicotine and smoke exposure causes adaptation of the nicotine receptor," a change that has been recognized as being associated with tolerance.

Perhaps the most telling admissions that nicotine is addictive come from marketing research studies prepared for tobacco companies. In these documents, the market researchers candidly assert nicotine's addictiveness, in a manner that appears to assume that the tobacco company recipients of the reports will not find the assertion unusual or controversial. For example, in a market research report prepared for Imperial Tobacco Ltd., on attitudes of adolescent smokers, the authors state:

> *until a certain nicotine dependence has been developed [taste] is somewhat less important than other things . . ."*[213]

Another market research firm refers to attitudes of adolescents "[o]nce addiction does take place . . ."[214] and states that "addicted they do indeed become."[215] The same firm, discussing its research on smokers' attempts to quit, reported that:

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[212] *See* Ayres note 172, *supra,* at p. BW-W2-02643.

[213] Spitzer, Mills & Bates. *The Player's Family: A Working Paper.* Report prepared for Imperial Tobacco Ltd. March 25,1977. Page 12.

[214] Kwechansky Marketing Research. *Project Plus/Minus*, in "Study Highlights." Report prepared for Imperial Tobacco Ltd. May 7, 1982.

[215] *Id.* at p. 26. This same documents notes that: "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." *Id.* in "Study Highlights."

> *Recidivism has several causes . . . . Another is 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 save face for an interim period, to pretend to oneself and to others that addiction is no longer present, which is nonsense.* [216]

A market research report that was widely circulated in Britain included the following editorial comment, contained in a description of smokers' views of the role played by tar and nicotine in smoking-related health problems:

> *Another idea was that nicotine and tar combined to have a harmful effect upon health (i.e., quite apart from nicotine's addictive function).*[217] [Emphasis added.]

Later in the same study, the researchers reported under the heading "Nicotine's addictive function" that:

> *Most respondents, with a bias towards men, realised that nicotine was the attribute in cigarettes causing addiction. It was also usually seen as the component providing satisfaction.*[218] [Emphasis added.]

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[216] *Id.* at p. 36-37. The same document also says, at page ii:

> *It is likely more difficult to break the ritualistic aspects of smoking than it is to overcome the physical withdrawal.*

See also an advertising strategy document prepared for Imperial Tobacco which recommends the following advertisement:

> *The chosen scene should ideally depict a pause or moment of relaxation before, during or after the activity. This moment should correspond to the physiological need for smoking.*

Publicite BCP. *Player's Filter '81 Creative Guidelines.* January 25, 1980. [Emphasis added.]

[217] *Attitudes Towards Smoking and Health.* Page 11. Transmitted by letter dated July 26, 1979, to Dr. H.E. Bentley, Imperial Tobacco Ltd., from A.H. Johnston, Market Research Manager, Carreras Rothmans Ltd.

[218] *Id.* at p. 12.

b. Tobacco Company Executives' and Senior Officials' Views

High-ranking tobacco company officials have also acknowledged that nicotine is addictive and that this is the reason why people use tobacco.[219]

For example, in the aforementioned July 1962 tobacco industry meeting, BATCO board science advisor Sir Charles Ellis stated:

> *Smoking is a habit of addiction.*[220]

In an internal memo, the general counsel to Brown and Williamson makes the same point in clear, simple language:

> *Moreover, nicotine is addictive . . . . We are, then, in the business of selling nicotine, an addictive drug* . . . [Emphasis added.][221]

Dr. Green, the director of research for BATCO, also repeatedly stated his view that some portion of smoking behavior was due to its addictive effects.[222] In a note to Dr. G. Hook, another scientist at BATCO, Dr. Green wrote, "If you consider Russell's study on cigarette dependence and his five types of smoking you can conceive a pattern as follows . . ." The note follows with a hand-drawn triangle symbolizing the reasons for smoking, with the three points of the triangle labeled "sensory rewards," "psychosocial rewards," and "pharmacological rewards." In the corner of the triangle near "pharmacological rewards" are

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[219] One tobacco company, which markets a cigarette brand called "Death Cigarettes," now states on the package that "cigarettes are addictive." FDA was informed on December 23, 1994, by John D. Slade, M.D., that "Death Cigarettes" stands for "Daring Enterprises Against Tobacco Hypocrisy." The company, owned by Charles and Amelie Southwood, has a post office box in Venice, CA, and an office in Marina Del Ray, CA.

[220] Ellis C. *The Smoking and Health Problem*. BATCO Research Conference. Smoking and Health-Policy on Research. Southampton, England. 1962. Page 4.

[221] Yeaman, A. Implications of Battelle Hippo I and II and the Griffith Filter. July 17, 1963. Page 4.

[222] *See* Green, note 191, *supra,* at Appendix I.

the words "addictive smoking."[223]

In a handwritten note about the likely continued success of the tobacco industry, Dr. Green wrote:

> *The main factor ensuring the continuation of the habit is the dependency induced in smokers. . . . Certainly large numbers of people will continue to smoke because they are unable to give it up. If they could they would do so. They can no longer be said to make an adult choice. And many new smokers become dependent.*[224] [Emphasis added.]

In a handwritten paper entitled "Marketing Cigarettes in the 80's," Dr. Green again stated that addiction is a major reason that people smoke. Noting various failures and constraints in the marketing of cigarettes, including a "close down in advertising" and "the U.K. tar premium,"[225] he writes:

> *Nevertheless smokers will continue - addiction . . .*
>
> *Perhaps 50-60% dissonant smokers [smokers who continue despite desire and motivation to quit] . . .*
>
> *Regard cig[arettes] as catering for addicts.*

Finally, in a paper stating that there was adequate evidence that smoking causes disease, written shortly after he retired from BATCO, Dr. Green wrote that, while it may be up to the individual, "if he is able," to decide whether to accept the "considerable risk" from smoking:

> *on behalf of those unable to make judgments such as children and addicted smokers, the social apparatus must be used to exercise value judgments on the*

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[223] Green SJ. Note to Hook G. BATCO R&D. Southampton, England. June 11, 1974. Also in the end of the triangle marked "pharmacological rewards" were "stimulation smoking" and "tranquilisation smoking."

[224] Green SJ. Transcript of handwritten note. Undated. Attached to documents, Green SJ, *Cigarette Smoking and Causality,* and Green SJ, *Smoking, Associated Diseases and Causality.*

[225] The U.K. tar premium is a tax imposed on products on the basis of tar content.

acceptability of the risks.[226] [Emphasis added.]

In 1961, Dr. Wakeham of Philip Morris noted in a presentation to the company's Research and Development Committee that "continued usage [of nicotine] develops tolerance."[227]

William Dunn, a senior scientist at Philip Morris, made numerous statements reflecting the position that nicotine has the properties of an addictive drug. In 1969, Dunn wrote a memorandum to his supervisor, entitled "Objectives and Plans - 1600," describing the research Philip Morris planned to undertake in the coming year. One of the planned research projects were designed to investigate the addictive properties of nicotine, by teaching rats:

> *to seek the inhalation of cigarette smoke . . . . ultimately through the reinforcing effect of the psychopharmacological effects of the inhaled smoke.*[227a]

As described in § I.B.3., supra, the ability of a substance to function as "positive reinforcer" in animals is one of the most significant pieces of evidence that the substance will be addictive in humans. By 1980, Dunn reported that Philip Morris researchers had successfully demonstrated that rats will self-administer nicotine,

> *making it quite clear that nicotine can function as a positive reinforcer for rats.*[227b]

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[226] Green, note 224, *supra,* at p. 92238.

[227] Wakeham, note 185, *supra.*

[227a] Dunn WL and Eichorn PA. Objectives and Plans - 1600. January 8, 1969. *In* 141 Cong. Rec. H7646 (daily ed. July 25, 1995). A second research project planned for 1969 was intended to discover "any product that can potentially replace the cigarette in need-gratification."

[227b] Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives - 1981. November 26, 1980. *In* 141 Cong. Rec. H7682 (daily ed. July 25, 1995). Philip Morris undertook a range of animal studies on nicotine that constitute the classic methods for assessing the addictive properties of drugs, including self-administration, tolerance, and discrimination studies:

Other statements are equally revealing. A 1974 annual research report from the Behavioral Research program at Philip Morris, which was approved by Thomas Osdene (later Philip Morris' Vice President for science and technology) and distributed to the Vice President for research and development, states that people continue to smoke because the "pharmacologically active components of smoke" are "reinforcing":

> *A general premise in our model of the cigarette smoker is that the smoking habit is maintained by the reinforcing effect 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.*[227c]

The report goes on to acknowledge that stopping smoking produces a withdrawal syndrome like that of other habit-forming drugs. Commenting on a proposed study to test the hypothesis that smoking decreases aggressivity, the researchers note that any increase in

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> *Nicotine discrimination, self-administration, and tolerance studies will enable us to examine the cueing and reinforcing properties of nicotine and nicotine analogues in rats. These are the state-of-the-art bioassays for central nervous system activity which we believe will serve as useful models of human smoking behavior.* [Emphasis added.]

Memorandum to T.S. Osdene from J.I. Seeman et al. Nicotine Program: Specific Implementation. March 31, 1978. *In* 141 Cong. Rec. H7668, *supra*. In 1980, Philip Morris decided to perform yet another study of "the rewarding properties of nicotine" using a technique developed to study the similar properties of morphine:

> *Mucha and Van der Kooy (1979) have reported that a place preference paradigm may be used to demonstrate the rewarding properties of morphine. We plan to use a similar paradigm to examine the rewarding properties of nicotine.*

Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1980. January 7, 1980. *In* 141 Cong. Rec. H7671, *supra*.

[227c] Philip Morris Research Center. Behavioral Research Annual Report (Part II). *In* 141 Cong. Rec. H7660 (daily ed. July 25, 1995). Approved by T.S. Osdene and distributed to H. Wakeham et al. November 1, 1974. Philip Morris officials consistently held the view that the reinforcing properties of cigarette smoking have a pharmacological basis, as shown by a document written six years later, in which the following statement appears:

> *It is our belief that the reinforcing properties of cigarette smoking are directly relatable to the effects that smoking has on the electrical and chemical events within the central nervous system.*

Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1981. November 26, 1980. *In* 141 Cong. Rec. H7681, *supra*.

aggressivity following deprivation

> *may be as readily explained as the emergence of reactions to [cigarette] deprivation, not unlike those to be observed upon withdrawal from any of a number of habituating pharmacological agents.*[227d]

A Philip Morris research report written by Dunn again acknowledged that cigarette deprivation produces a withdrawal syndrome in 1980, and stated that those smokers who suffered withdrawal in the absence of sufficient nicotine showed "nicotine dependence." The report began by stating the Philip Morris had attempted to identify

> *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 . . . . Now we may have two extra tools to use: PM cigarettes of ultra low tar and nicotine, and salivary nicotine concentrations . . . . 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.*[227e] [Emphasis added.]

CTR documents also refer to the addictive properties of nicotine. In a section of its annual report for 1966-67 entitled "Nicotine and the Central Nervous System," CTR described research in which monkeys self-administered nicotine.[228]

Much more recently, tobacco companies have attempted to rely on the "common

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[227d] Behavioral Research Annual Report, Part II. Approved by T.S. Osdene. November 1, 1974. *In* 141 Cong. Rec. H7660 (daily ed. July 25, 1995).

[227e] Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1980. January 7, 1980. *In* 141 Cong. Rec. H7672 (daily ed. July 25, 1995).

[228] *See* Report of the Scientific Director, 1966-67, note 195, *supra,* at pp. 12-13. As discussed earlier, it is well-established that self-administration of a substance by animals, under laboratory conditions, demonstrates that the substance is a "positive reinforcer," one of the hallmark properties of addictive drugs. *See* p. 96.

knowledge" that nicotine is addictive to defend against product liability cases brought by smokers. For example, in Rogers v. R.J. Reynolds et al., attorneys for Philip Morris, R.J. Reynolds, the American Tobacco Co., and the Liggett Group argued that the plaintiff could not claim that her deceased husband was not adequately warned that cigarettes were addictive, because their addictive properties are so well known:

> *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. [Footnote omitted.] 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.*[229]

Finally, F. Ross Johnson, the former chief executive of RJR Nabisco, has openly acknowledged that tobacco is addictive and that its addictive properties are why people smoke. In an interview for an article in the Wall Street Journal, Mr. Johnson was asked about tobacco. He responded:

> *Of course it's addictive. That's why you smoke . . .*[230]

Accordingly, it is clear that high-ranking officials of tobacco companies have long known that nicotine is an addictive drug and, more importantly, that the market for tobacco products in large part depends on the addictive effects of nicotine.

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[229] Rogers v. R.J. Reynolds et al (Sup.Ct. Ind.)(No. 49A02-8904 CV 164)(1990), Appellees Brief in Reply to Appellants' Opposition to Petition for Transfer, at pp. 7-8.

[230] Shapiro E. Big spender finds new place to spend. *The Wall Street Journal.* October 6, 1994.

3. Statements That Tobacco Products Are Nicotine Delivery Systems

Internal and published documents also show that top-ranking tobacco industry officials intend to offer tobacco products to consumers as nicotine delivery systems. In summarizing the 1972 conference sponsored by CTR, William Dunn, Jr., of Philip Morris characterized the cigarette as a nicotine delivery system:

> *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:*
> *1) It is readily prepped for dispensing nicotine.*
> *2) Its rate of combustion meters the dispensing rate, setting an upper safe limit for a substance that can be toxic in large doses.*
> *3) Dispensing is unobtrusive to most ongoing behavior.*
>
> *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 and the cigarette the most optimized dispenser of smoke.*[231]

In a document entitled "RJR confidential research planning memorandum on the nature of the tobacco business and the crucial role of nicotine therein," quoted in the New York Times, RJR executive Claude Teague, Jr. wrote:

> *In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a*

[231] *See* Dunn Summary, note 133, *supra*. (Indeed, when interviewed by FDA officials in May 1994, Dunn stated that he was known as "the Nicotine Kid" at Philip Morris. See handwritten notes summarizing meeting May 10, 1994, between FDA and Dr. W.L. Dunn.)

variety of physiological effects.[231a]

The memo goes on:

> *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 products - and where possible our advertising - around nicotine delivery rather than around tar delivery or flavor.*[231b]

As noted above, Sir Charles Ellis, BATCO's scientific advisor, considered smoking a method of administering nicotine as early as 1962:

> *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.*[232]

Dr. S.J. Green, BATCO board member and research director, also viewed the cigarette as a vehicle for delivering nicotine. In a document describing BATCO's research needs, he made the following statement:

> *It may be useful, therefore, to look at the tobacco industry as if for a large part its business is the administration of nicotine (in the clinical sense).*[233]

In a draft of another document entitled "A Blueprint for B.A.T. Scientific Departments," Green repeated this belief:

[231a] Hilts PJ. U.S. Convenes Grand Jury to Look at Tobacco Industry. *New York Times.* July 26, 1995.

[231b] *Id.*

[232] Ellis C. *The Smoking and Health Problem.* BATCO Research Conference. Smoking and Health-Policy on Research. Southampton, England. 1962. Page 16.

[233] Green, note 191, *supra,* at Appendix II.

See also Green, note 192, *supra,* at p. 2:

> *[w]hile other factors cannot be ignored and their influence is not completely understood, it seems a good assumption that nicotine plays a predominant role for many smokers. So that a good part of the tobacco industry is concerned with the administration of nicotine to consumers . . . . [T]hus a large part of our research problem can be identified as the improvement in quality by improving the administration of nicotine . . .*

We must assume that the main objective is the administration of nicotine . . . [234]

In a handwritten chart, attached to a paper entitled "The Association of Smoking and Disease," Green described all forms of tobacco as different methods of nicotine administration.[235]

The 1981 monograph on nicotine pharmacology and toxicology published by the British Tobacco Advisory Council expressly states that nicotine is a drug and that tobacco is simply a vehicle for its administration.[236] After setting forth the purpose of the monograph -- to help medical authorities decide whether smoking-related illness should be handled by eliminating smoking altogether, by progressively reducing smoke deliveries, or by developing a cigarette that delivers "an adequate dose of nicotine without the necessity of inhaling large doses of toxic vehicle" -- the introduction states succinctly:

> *In a nutshell our approach has been to regard nicotine as a "drug" to which man is exposed in various "vehicles" and by various routes.*[237]

A presentation at the 1984 BATCO Smoking Behaviour-Marketing Conference included the following slides:

Relationship Between Smoking Behaviour and Nicotine Intake

> *Is there any commonalty [sic] in the process [of smoking]:*
> *- broad similarities in wholebody nicotine dose of nicotine across smoking groups*
> *- strong indirect evidence of smokers smoking for nicotine*
> *- is this cause and effect or a reflection for something else*

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[234] Undated draft of *A Blueprint for B.A.T. Scientific Departments.* Page 4.

[235] *See* Green, note 193, *supra.* Handwritten chart attached.

[236] Cohen, note 183, *supra,* at p. 1.

[237] *Id.* at p. 1. (Emphasis added.)

What is the Significance of this Observation:

> *-underlying smoking maintenance through nicotine, and as a consequence probably provides the basis of smoking satisfaction - in its simplest sense puffing behaviour is the means of providing nicotine dose in a metered fashion* [Emphasis added.][238]

Finally, in a list of expected changes in cigarettes over the next several years, a BATCO official suggested that cigarettes could become delivery systems for drugs in addition to nicotine:

> *"Increases in the use of drugs other than nicotine. Potential legalisation of the use of marijuana. Possible introduction of caffeine."* [Emphasis added.][239]

Thus, tobacco company executives have both recognized that nicotine's drug effects are central to the use of tobacco and stated their clear understanding that cigarettes are being sold to and used by smokers as nicotine delivery systems. On the basis of this evidence, these products are intended to affect the structure or function of the body.

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[238] Proceedings of the BATCO Smoking Behaviour-Marketing Conference. Session I. July 9-12, 1984. Slides.

[239] FH [Initials of BATCO employee]. BATCO R&D. *Technical and Product Developments Envisaged Over the Next Five Years.* January 22, 1974. Page 1.

B. INDUSTRY RESEARCH ON THE DRUG EFFECTS OF NICOTINE

The tobacco industry has conducted and funded extensive research to characterize nicotine's addictive potential and properties. This research includes studies on nicotine's absorption into the bodies of tobacco users, its effects on behavior, and its effects on the brain and endocrine systems.[240] Sections II.B., C., and D. detail the extensive research conducted and funded by the tobacco industry on: 1) nicotine's pharmacological effects, § II.B., infra; 2) how consumers use tobacco products to obtain an adequate dose of nicotine, § II.C., infra; and 3) how to manipulate nicotine delivery from tobacco to provide an adequate dose to consumers, § II.D., infra.[240a]

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[240] The long history of tobacco and nicotine use for pharmacological purposes is also well known to the tobacco industry. Larson PS, Silvette H. Medical uses of tobacco (past and present), (funded by a grant from the Tobacco Industry Research Committee and presented at industry-sponsored symposium). In: VonEuler, ed. *Tobacco Alkaloids and Related Compounds.* New York, NY: Pergamon Press; 1965:3-11.

See also Cohen, note 183, *supra,* at p. 1.

[240a] The extent of the industry's research on nicotine pharmacology is very likely to be even greater than that reflected in this section. According to a recent report in the New York Times, Philip Morris conducted internal research on nicotine's pharmacological effects on smokers from the late 1960's to the mid-1980's. The Times reported that Charles Wall, a Philip Morris lawyer, confirmed that company documents showed that Philip Morris carried out extensive research on nicotine over many years. Hilts PJ. "Documents Disclose Philip Morris Studied Nicotine's Effect on Body." *New York Times.* June 8, 1995. Documents later disclosed by Congress provide detailed evidence of Philip Morris' long-term research on nicotine pharmacology, including studies to isolate and characterize nicotine receptors in the central nervous system, the effects of nicotine/smoking on the electrical activity of the brain, the effects of nicotine on human and animal behavior, self-administration of nicotine by rats, nicotine discrimination in rats, nicotine tolerance, and the effects of nicotine administration on human physiologic function, including the relationship between blood nicotine levels and central nervous system activity. 141 Cong. Rec. H7470-76 (daily ed. July 24, 1995); 141 Cong. Rec. H7646-83 (daily ed. July 25, 2995). Philip Morris has not contested the authenticity of these documents. R.J. Reynolds, too, appears to have conducted extensive research on nicotine pharmacology that is not fully reflected here. In response to questions about that company's research on nicotine, a spokeswoman for R.J. Reynolds Tobacco Company stated that "[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. We're extremely proud of the quality and number of the studies." Collins G. "Legal Attack on Tobacco Intensifies." *New York Times.* June 9, 1995.

It is important to understand why the tobacco industry has conducted this research. Tobacco industry documents show that the industry research described in the following sections was undertaken because industry officials strongly suspected, more than 30 years ago, that nicotine's pharmacological effects were vital to the successful marketing of tobacco. For example, internal BATCO documents disclose that the major BATCO-sponsored nicotine studies completed or underway in the early 1960's were undertaken "to elucidate the effects of nicotine as a beneficent alkaloid drug"[241] because of the belief of Sir Charles Ellis, the leading BATCO scientist, that "we are in a nicotine rather than a tobacco industry."[242]

Another nicotine study commissioned by BATCO in the early 1960's similarly reveals that industry research on nicotine's pharmacological effects was undertaken because of the industry's understanding that consumers use tobacco to obtain those effects:

> *There is increasing evidence that nicotine is the key factor in controlling, through the central nervous system, a number of the beneficial effects of tobacco smoke . . . . Detailed knowledge of these effects of nicotine in the body*

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[241] *See* Ellis, note 232, *supra,* at p. 16. On the same page Ellis describes upcoming 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."

[242] Johnson RR. *Comments on nicotine.* June 30, 1963. Pages 10-11. This document goes on to reveal that these studies on nicotine's pharmacological effects were part of a broader research initiative that was being conducted by the industry and included altering nicotine delivery:

> *The Southampton group is going to be doing a large amount of work on nicotine, and for some good reasons. To summarize:*
> *Project ARIEL [a cigarette alternative developed by BATCO] - This is dormant for the moment. The first samples tried gave a tremendous kick, even though the nicotine delivery was quite small. It would appear that the project will be reinitiated within a few months.*
> *Dr. S.R. Evelyn is presently investigating the absorption of extractable and non-extractable nicotine in the mouth . . . .*
> *Dr. J.D. Backhurst is setting up an analysis for pH of whole smoke on a puff-by-puff basis. This correlates with his previous interest in extractable nicotine.*
> *Mr. H.G. Horsewell continues to work with alkaline filter additives which selectively increase nicotine delivery.*

of a smoker is therefore of vital importance to the tobacco industry.[243]

An annual report from the Council for Tobacco Research discloses that the research it funded on nicotine's pharmacology was designed to elucidate the effects of nicotine on the smoker's central nervous system:

> *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.*[244]

The studies of nicotine's pharmacokinetics and pharmacodynamics described in § II.B., infra, were undertaken to assist the industry in marketing products that would satisfy tobacco users' nicotine requirements. This information relating to how nicotine acted in the body was needed by the industry for additional studies specifically designed to establish the dose of nicotine required by consumers, § II.C., infra. As noted in the report of one study whose purpose was to validate a method for assaying nicotine and a metabolite in urine:

> *It can be concluded from the comparative studies that analysis of nicotine and cotinine in urine is likely to be a good indicator of whole body nicotine dose in man. This technique has an immediate and direct relevance for . . . human behavioural studies in the assessment of an individuals' [sic] nicotine dose in response to modification in cigarette design.* [Emphasis added.][245]

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[243] Geissbuhler H, Haselbach C. *The Fate of Nicotine in the Body*. Battelle Memorial Institute. Geneva, Switzerland. May 1963. Page 1. Report prepared by Battelle for BATCO. (Hereafter cited as: BATCO. *The Fate of Nicotine in the Body*.).

[244] Report of the Scientific Director, 1969-1970. Council for Tobacco Research-U.S.A. Page 13.

[245] BATCO Group R&D Centre. *Nicotine Studies: A Second Report. Estimation of Whole Body Nicotine Dose By Urinary Nicotine and Cotinine Measurement*. Report No. RD.1792. March 31, 1981. Page 1.

Industry documents related to other basic research studies on nicotine show a similar nexus with product development. For example, the report from a 1974 Brown and Williamson study of nicotine's brain effects states that:

> *The development of new products and the modification of existing ones requires that we have some knowledge of the smoker toward whom these efforts are directed. The work described in this report is focused on the acute, or immediate physiological response of*

Thus, this research demonstrates the tobacco industry's fundamental interest in the dose of nicotine absorbed into the systemic circulation of the tobacco user (rather than simply the amount of nicotine necessary to deliver sensory effects to the mouth of the user.)

The ultimate purpose of the tobacco industry's studies on nicotine was to better understand the nicotine requirements of tobacco users and to develop products that delivered the desired pharmacological effects of nicotine. Philip Morris officials stated that the rationale for the company's extensive research program on nicotine pharmacology was that the information would

> *strengthen Philip Morris R&D capability in developing new and improved smoking products.*[245a]

Accordingly, the industry-sponsored studies described in the following sections provide further evidence that tobacco manufacturers intend to market their products to deliver the pharmacological effects of nicotine to consumers.[246]

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smokers.
Brotzge RF, Kennedy JE. Brown and Williamson. *Human Smoking Studies: Acute Effect of Cigarette Smoke on Brain Wave Alpha Rhythm - First Report.* October 31, 1974. Report No. 74-20. Page 1.

Similarly, a 1974 BATCO study on nicotine's effects on brain electrical activity was intended to "help elucidate the mode of action of nicotine during smoking" so as to better understand smoker behavior in response to nicotine. BATCO Group Research & Development. Comer AK, Thornton RE. *Interaction of Smoke and the Smoker Part 3: The Effect of Cigarette Smoking on the Contingent Negative Variation.* Report No. RD.1164-R. December 12, 1974. Page 2.

[245a] Memorandum from W.L. Dunn to T.S. Osdene-Plans and Objectives-1979. December 6, 1978. *In* 141 Cong. Rec. H7669 (daily ed. July 25, 1995).

[246] The full citations for the references in notes 247 through 279 can be found in Appendix 4. Entries under the heading "OTHER" include studies sponsored by the Smokeless Tobacco Research Council (whose members include U.S. tobacco companies), Swedish Tobacco Co. (which has corporate relationships with both Pinkerton and U.S. Tobacco Co.), Svenska Tobaks (a subsidiary of Swedish Tobacco Co.), the Tobacco Advisory Council and the Tobacco Research Council of the U.K. (whose members included British-American Tobacco Co.), Imperial Tobacco Co. (which has corporate relationships with British-American Tobacco Co., and manufactures cigarettes that are marketed in the U.S.), Carreras Rothmans Ltd. (whose affiliated companies manufacture cigarettes that are marketed in the U.S.), Swiss Association of Cigarette Manufacturers (whose members include affiliates of U.S. tobacco companies, and the Canadian Tobacco Manufacturers Council (whose members include affiliates of U.S. tobacco companies).

1. Industry Research on Nicotine's Effects on the Brain

The tobacco industry has extensively studied, in its own laboratories and through grants or contracts to other laboratories, the effects of nicotine on the brain and other parts of the central nervous system, including the sites in the brain on which nicotine acts.[247]

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[247] COUNCIL FOR TOBACCO RESEARCH-USA

Abood. Comparison of the binding of optically pure (-)- and (+)-[3H]nicotine to rat brain membranes

Abood. Electrophysiological, behavioral, and chemical evidence for a noncholinergic, stereospecific site for nicotine in rat brain

Abood. Receptor binding characteristics of a 3H-labeled azetidine analogue of nicotine

Abood. Tritiated methylcarbamylcholine a new radioligand for studying brain nicotinic receptors

Abood. Evidence for a noncholinergic site for nicotine's action in brain: Psychopharmacological, electrophysiological and receptor binding studies

Abood. Acute and chronic effects of nicotine in rats and evidence for a non-cholinergic site of action

Andersson. Involvement of D1 dopamine receptors in the nicotine-induced neuro- endocrine effects and depletion of diencephalic catecholamine stores in the male rat

Andersson. Effects of acute central and peripheral administration of nicotine on hypothalamic catecholamine nerve terminal systems and on the secretion of adenohypophyseal hormones in the male rat

Andersson. Interactions of nicotine and pentobarbitone in the regulation of telencephalic and hypothalamic catecholamine levels and turnover and of adenohypophyseal hormone secretion in the normal male rat

Andersson. Effects of single injections of nicotine on the ascending dopamine pathways in the rat

Andersson. Mecamylamine induced blockade of nicotine induced inhibition of gonadotrophin and TSH secretion and of nicotine induced increases of catecholamine turnover in the rat hypothalamus

Andersson. 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 adenohypophyseal hormones

Andersson. 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

Andersson. 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 adenohypophyseal hormones and corticosterone

Andersson. Effects of chronic exposure to cigarette smoke on amine levels and turnover in various hypothalamic catecholamine nerve terminal systems and on the secretion of pituitary hormones in the male rat

Andersson. Mecamylamine pretreatment counteracts cigarette smoke induced changes in hypothalamic catecholamine neuron systems and in anterior pituitary function

Bhagat. Effects of chronic administration of nicotine on storage and synthesis of noradrenaline in rat brain

Bhagat. Influence of chronic administration of nicotine on the turnover and metabolism of noradrenaline in the rat brain

Bhagat. Effect of chronic administration of nicotine on the concentrations of adrenal enzymes involved in the synthesis and metabolism of adrenaline

Bhattacharya. Influence of acute and chronic nicotine administration on EEG reactivity to drugs in rabbits: 2. Prychoactive agents

Chance. A comparison of nicotine and structurally related compounds as discriminative stimuli

Chang. Effect of chronic administration of nicotine on acetylcholinesterase activity in the hypothalamus and medulla oblongata of the rat brain An ultrastructural study

Davies. Evidence for a noncholinergic nicotine receptor on human phagocytic leukocytes

Domino. Electroencephalographic and behavioral arousal effects of small doses of nicotine: A neuropsychopharmacological study

Erwin. Nicotine alters catecholamines and electrocortical activity in perfused mouse brain

Essman. Changes in cholinergic activity and avoidance behavior by nicotine in differentially housed mice

Fuxe. Increases in dopamine utilization in certain limbic dopamine terminal populations after a short period of intermittent exposure of male rats to cigarette smoke

Fuxe. Neurochemical mechanisms underlying the neuroendocrine actions of nicotine: focus on the plasticity of central cholinergic nicotinic receptors

Grenhoff. Selective stimulation of limbic dopamine activity by nicotine

Grenhoff. Chronic continuous nicotine treatment causes decreased burst firing of nigral dopamine neurons in rats partially hemitransected at the meso-diencephalic junction

Harfstrand. Distribution of nicotinic cholinergic receptors in the rat tel- and diencephalon: a quantitative receptor autoradiographical study using [3H]-acetylcholine, [alpha-125I]bungarotoxin and [3H]nicotine

Harsing. Dopamine efflux from striatum after chronic nicotine: evidence for autoreceptor desensitization

Huganir. Phosphorylation of the nicotinic acetylcholine receptor regulates its rate of desensitization

Kawamura. Differential actions of m and n cholinergic agonists on the brainstem activating system

Knapp. Action of nicotine on the ascending reticular activating system

Kramer. The effect of nicotine on catecholaminergic storage vesicles

Lapin. Dopamine-like action of nicotine: lack of tolerance and reverse tolerance

Lapin. Action of nicotine on accumbens dopamine and attenuation with repeated administration

Lindstrom. Structural and functional heterogeneity of nicotinic receptors

London. Glucose metabolism: An index of nicotine action in the brain

Lowy. Antagonism by cholinergic drugs of behavioural effects in cats of an anticholinergic psychotomimetic drug and enhancement by nicotine

Lukas. Heterogeneity of high-affinity nicotinic [3H]acetylcholine binding sites

Lukas. Pharmacological distinctions between functional nicotinic acetylcholine receptors on the PC12 rat pheochromocytoma and the TE671 human medulloblastoma

Marks. Characterization of nicotine binding in mouse brain and comparison with the binding of alpha-bungarotoxin and quinuclidinyl benzilate

Martin. Nicotine binding sites and their localization in the central nervous system

Marty. Effects of nicotine on beta-endorphin, alpha MSH, and ACTH secretion by isolated perfused mouse brains and pituitary glands, in vitro

Mitchell. Increases in tyrosine hydroxylase messenger RNA in the locus coeruleus after a single dose of nicotine are followed by time-dependent increases in enzyme activity and noradrenaline release

Mitchell. Role of the locus coeruleus in the noradrenergic response to a systemic administration of nicotine

Naftchi. Acute reduction of brain substance P induced by nicotine

Nelsen. Chronic nicotine treatment in rats: 2. Electroencephalographic amplitude and variability changes occurring within and between structures

Owman. Chronic nicotine treatment eliminates asymmetry in striatal glucose utilization following unilateral transection of the mesostriatal dopamine pathway in rats

Pradhan. Effects of nicotine on self-stimulation in rats

Rosecrans. Noncholinergic Mechanisms involved in the behavioral and stimulus effects of nicotine, and relationships to the process of nicotine dependence

Rosecrans. Nicotine as a discriminative stimulus: a neurobehavioral approach to studying central cholinergic mechanisms

Schaeppi. Nicotine treatment of selected areas of the cat brain: effects upon EEG and autonomic system

Sershen. Effect of nicotine and amphetamine on the neurotoxicity of N-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP) in mice

Sershen. Noncholinergic, saturable binding of (+/-)-[3H]nicotine to mouse brain

Sershen. Nicotinic Binding Sites in the brain: properties, regulation, and putative endogenous ligands

Siegel. Rapid and discrete changes in hypothalamic catecholamine nerve terminal systems induced by audiogenic stress, and their modulation by nicotine-relatinship to neuroendocrine function

Silvette. The actions of nicotine on central nervous system functions

Sorenson. The reducing agent dithiothreitol (DTT) does not abolish the inhibitory nicotinic response recorded from rat dorsolateral septal neurons

Stadnicki. Nicotine changes in EEG and behavior after intravenous infusion in awake unrestrained cats

Stadnicki. Nicotine infusion into the fourth ventricle of unrestrained cats: changes in EEG and behavior

Stitzer. Effects of nicotine on fixed-interval behavior and their modification by cholinergic antagonists

Sugiyama. [3H]Nicotine binding sites in developing fetal brains in rats

Svensson. Effect of nicotine on dynamic function of brain catecholamine neurons

Toth. Effect of nicotine on extracellular levels of neurotransmitters assessed by microdialysis in various brain regions: role of glutamic acid

Toth. Effect of nicotine on levels of extracellular amino acids in regions of the rat brain in vivo

Tung. Peripheral induction of burst firing in locus coeruleus neurons by nicotine mediated via excitatory amino acids

Vincek. Synthesis of 4,4-ditritio-(+)-nicotine: comparative binding and distribution studies with natural enantiomer

Westfall. Effect of nicotine and related substances upon amine levels in the brain

Whiting. Expression of nicotinic acetylcholine receptor subtypes in brain and retina

Wong. Pharmacology of nicotinic receptor-mediated inhibition in rat dorsolateral septal neurones

Wong. A direct nicotinic receptor-mediated inhibition recorded intracellularly in vitro

Yamamoto. Nicotine-induced EEG and behavioral arousal

COUNCIL FOR TOBACCO RESEARCH - USA, Literature Review
Edwards. Smoking, nicotine and electrocortical activity

Fuxe. Neuroendocrine actions of nicotine and of exposure to cigarette smoke: medical implications

PHILIP MORRIS TOBACCO COMPANY
DeNoble. Behavioral effects of intraventricularly administered (-)-nicotine on fixed ratio schedules of food presentation in rats

Sahley. Antinociceptive effects of central and systemic administrations of nicotine

Vezina. The effect of acute and repeated nicotine injections on brain dopamine activation: Comparisons with morphine and amphetamine

R. J. REYNOLDS COMPANY
Bjercke. Anti-idiotypic antibody probes of neuronal nicotinic receptors

Brazell. 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

Collins. Modulation of Nicotine Receptors by Chronic Exposure to Nicotinic Agonists and Antagonists

Gilbert. Effects of smoking/nicotine on anxiety, heart rate, and lateralization of EEG during a stressful movie

Lippiello. The Role of Desensitization in CNS Nicotinic receptor function

Lippiello. Characterization of nicotinic receptors on cultured cortical neurons using anti-idiotypic antibodies and ligand binding

Lippiello. The binding of L-[3H]nicotine to a single class of high affinity sites in rat brain membranes

Lippiello. Identification of putative high affinity nicotinic receptors on cultured cortical neurons

Lippiello. Kinetics and mechanism of L-[3H]nicotine binding to putative high affinity receptor sites in rat brain

Marks. Downregulation of nicotinic receptor function after chronic nicotine infusion

Mitchell. Nicotine-induced catecholamine synthesis after lesions to the dorsal or ventral noradrenergic bundle

Mitchell. Regionally specific effects of acute and chronic nicotine on rates of catecholamine and 5-hydroxytryptamine synthesis in rat brain

Prince. Actions of the general anesthetic propofol (2,6- diisopropylphenol) on the binding of [3H] nicotine to rat cortical membranes

Pritchard. Flexible effects of quantified cigarette-smoke delivery on EEG dimensional complexity

Smith. Effects of chronic and subchronic nicotine on tyrosine hydroxylase activity in noradrenergic and dopaminergic neurones in the rat brain

Wonnacott. Presynaptic actions of nicotine in the CNS

BROWN AND WILLIAMSON TOBACCO CORPORATION, Unpublished
Brotzge. Human smoking studies: acute effect of cigarette smoke on brain wave alpha rhythm-first report

BRITISH-AMERICAN TOBACCO COMPANY, LTD.
Golding. Arousing and de-arousing effects of cigarette smoking under conditions of stress and mild sensory isolation

Golding. Effects of cigarette smoking on resting EEG, visual evoked potentials and photic driving

BRITISH-AMERICAN TOBACCO COMPANY, LTD., Unpublished
Ayres. Notes from the GR & DC Nicotine Conference

Comer. Interaction of smoke and the smoker part 3: the effect of cigarette smoking on the contingent negative variation

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Funded – Unpublished Battelle Studies
Haselbach. Final report on project HIPPO II

Haselbach. A tentative hypothesis on nicotine addiction

Hersch. Final report on project HIPPO I

Libert. Report no 1 regarding project HIPPO II

Willey. Effects of nicotine on the central nervous system

INDUSTRY SUPPORTED AMA/EDUCATIONAL AND RESEARCH FOUNDATION (ERF) STUDIES:
Murphree. Elecroencephalographic changes in man following smoking

Rosecrans. Brain area nicotine levels in male and female rats with different levels of spontaneous activity

Rosecrans. Effects of nicotine on behavioral arousal and brain 5-hydroxytryptamine function in female rats selected for differences in activity

Rosecrans. Brain area nicotine levels in male and female rats of two strains

Schechter. Behavioral evideace for two types of cholinergic receptors in the C.N.S.

Schechter. Effect of mecamylamine on discrimination between nicotine- and arecoline- produced cues

Schechter. Nicotine as a discriminative cue in rats: inability of related drugs to produce a nicotine-like cueing effect

Schechter. Nicotine as a discriminative stimulus in rats depleted of norepinephrine or 5-hydroxytryptamine

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Pharmacological basis for the tobacco smoking habit

Armitage. Some recent observations relating to the absorption of nicotine from tobacco smoke

Armitage. Effects of nicotine on electrocortical activity and acetylcholine release from the cat cerebral cortex

Armitage. Nicotine, Smoking and cortical activation

Armitage. The effects of nicotine on the electrocorticogram and spontaneous release of acetylcholine from the cerebral cortex of the cat

Armitage. Effects of nicotine and some nicotine-like compounds injected into the cerebral ventricles of the cat

Armitage. Further evidence relating to the mode of action of nicotine in the central nervous system

Balfour. A possible role for the pituitary-adrenal system in the effects of nicotine on avoidance behaviour

Bhagat. The effects of nicotine and other drugs on the release of injected 3H-norepinephrine and on endogenous norepinephrine levels in the rat brain

Hall. Effects of nicotine and tobacco smoke on the electrical activity of the cerebral cortex and olfactory bulb

Morrison. A comparison of the effects of nicotine and physostigmine on a measure of activity in the rat

Wesnes. Effects of scopolamine and nicotine on human rapid information processing performance

Wesnes. The separate and combined effects of scopolamine and nicotine on human information processing

OTHER
Adem. Distribution of nicotinic receptors in human thalamus as visualized by 3H-nicotine and 3H-acetylcholine receptor autoradiography

Adem. Quantitative autoradiography of nicotinic receptors in large cryosections of human brain hemispheres

Andersson. 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

Cohen. Monograph on the pharmacology and toxicology of nicotine and its role in tobacco smoking

Copeland. A comparison of the binding of nicotine and nornicotine stereoisomers to nicotinic binding sites in rat brain cortex

Mechanisms of action: receptors, neurotransmitters, and hormones. The tobacco industry has supported sophisticated studies to identify the sites and mechanisms of nicotine's actions, as well as how the structure of the brain itself is altered by nicotine's effects on nicotinic receptors. These studies have identified the receptors in the central nervous system on which nicotine acts; shown that nicotinic receptors present in the brain of both animals and man mediate the behavioral effects of nicotine; and sought to define the location and functional properties of these nicotinic receptors in the central nervous system.[248]

Falkeborn. Chronic nicotine exposure in rat: a behavioural and biochemical study of tolerance

Fuxe. On the action of nicotine and cotinine on central 5-hydroxytryptamine

Fuxe. Reduction of [3H]nicotine binding in hypothalamic and cortical membranes by dopamine D1 receptors

Fuxe. Regulation of endocrine function by the nicotinic cholinergic receptor

Grenhoff. Nicotinic effects on the firing pattern of midbrain dopamine neurons

Hasenfratz. Smoking-related subjective and physiological changes: pre- to postpuff and pre- to post cigarette

Hasenfratz. Post-lunch smoking for pleasure seeking or arousal maintenance?

Knott. Effects of cigarette smoking on subjective and brain evoked responses to electrical pain stimulation

Larsson. Comparative analysis of nicotine-like receptor-ligand interactions in rodent brain homogenate

Larsson. In vitro binding of 3H-acetylcholine to nicotinic receptors in rodent and human brain

Nisell. Systemic nicotine-induced dopamine release in the rat nucleus accumbens is regulated by nicotinic receptors in the ventral tegmental area

Nordberg. Effect of long-term nicotine treatment on [3H]nicotine binding sites in the rats brain

Nordberg. Effect of acute and subchronic nicotine treatment on cortical acetylcholine release and on nicotinic receptors in rats and guinea-pigs

Nordberg. Studies of muscarinic and nicotinic binding sites in brain

Perez de la Mora. Neurochemical effects of nicotine on glutamate and GABA mechanisms in the rat brain

Slotkin. Developmental Effects of Nicotine

Slotkin. Effects of prenatal nicotine exposure on neuronal development: selective actions on central and peripheral catecholaminergic pathways

Svensson. Effect of nicotine on single cell activity in the noradrenergic nucleus locus coeruleus

Zhang. Effects of chronic treatment with (+)- and (-)- nicotine on nicotinic acetylcholine receptors and N-methyl-D-aspartate receptors in rat brain

OTHER, Literature Review
Edwards. Smoking, nicotine and electrocortical activity

[248] COUNCIL FOR TOBACCO RESEARCH-USA
Abood. Comparison of the binding of optically pure (-)- and (+)-[3H]nicotine to rat brain membranes

Abood. Electrophysiological, behavioral, and chemical evidence for a noncholinergic, stereospecific site for nicotine in rat brain

Abood. Evidence for a noncholinergic site for nicotine's action in brain: Psychopharmacological, electrophysiological and receptor binding studies

Abood. Tritiated methylcarbamylcholine a new radioligand for studying brain nicotinic receptors

Andersson. Intravenous injections of nicotine induce very rapid and discrete reductions of hypothalamic catecholamine levels associated with increases of ACTH, vasopressin and prolactin secretion

Andersson. Effects of acute central and peripheral administration of nicotine on hypothalamic catecholamine nerve terminal systems and on the secretion of adenohypophyseal hormones in the male rat

Andersson. 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 adenohypophyseal hormones

Andersson. Effects of single injections of nicotine on the ascending dopamine pathways in the rat Evidence for increases of dopamine turnover in the mesostriatal and mesolimbic dopamine neurons

Andersson. 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

Britto. Immunohistochemical localization of nicotinic acetylcholine receptor subunits in the mesencephalon and diencephalon of the chick (Gallus gallus)
Chance. A comparison of nicotine and structurally related compounds as discriminative stimuli

Davies. Evidence for a noncholinergic nicotine receptor on human phagocytic leukocytes

Fuxe. Neuroendocrine actions of nicotine and of exposure to cigarette smoke: medical implications

Fuxe. Neurochemical mechanisms underlying the neuroendocrine actions of nicotine: focus on the plasticity of central cholinergic nicotinic receptors

Harfstand. Distribution of nicotinic cholinergic receptors in the rat tel- and diencephalon: a quantitative receptor autoradiographical study using [3H]-acetylcholine, [alpha-125I]bungarotoxin and [3H]nicotine

Huganir. Phosphorylation of the nicotinic acetylcholine receptor regulates its rate of desensitization

Lapin. Action of nicotine on accumbens dopamine and attenuation with repeated administration

Lindstrom. Structural and functional heterogeneity of nicotinic receptors

Lukas. Heterogeneity of high-affinity nicotinic [3H]acetylcholine binding sites

Lukas. Pharmacological distinctions between functional nicotinic acetylcholine receptors on the PC12 rat pheochromocytoma and the TE671 human medulloblastoma

Marks. Characterization of nicotine binding in mouse brain and comparison with the binding of alpha-bungarotoxin and quinuclidinyl benzilate

Martin. Nicotine binding sites and their localization in the central nervous system

Mitchell. Increases in tyrosine hydroxylase messenger RNA in the locus coeruleus after a single dose of nicotine are followed by time- dependent increases in enzyme activity and noradrenaline release

Mitchell. Role of the locus coeruleus in the noradrenergic response to a systemic administration of nicotine

Owman. Chronic nicotine treatment eliminates asymmetry in striatal glucose utilization following unilateral transection of the mesostriatal dopamine pathway in rats

Pradhan. Effects of nicotine on self-stimulation in rats

Rosecrans. Nicotine as a discriminative stimulus: a neurobehavioral approach to studying central cholinergic mechanisms

Rosecrans. Noncholinergic Mechanisms involved in the behavioral and stimulus effects of nicotine, and relationships to the process of nicotine dependence

Schaeppi. Nicotine treatment of selected areas of the cat brain: effects upon EEG and autonomic system

Sershen. Nicotinic Binding Sites in the brain: properties, regulation, and putative endogenous ligands

Sershen. Noncholinergic, saturable binding of (+/-)-[3H]nicotine to mouse brain

Sorenson. The reducing agent dithiothreitol (DTT) does not abolish the inhibitory nicotinic response recorded from rat dorsolateral septal neurons

Stitzer. Effects of nicotine on fixed-interval behavior and their modification by cholinergic antagonists

Sugiyama. [3H]Nicotine binding sites in developing fetal brains in rats

Svensson. Effect of nicotine on dynamic function of brain catecholamine neurons

Toth. Effect of nicotine on levels of extracellular amino acids in regions of the rat brain in vivo

Whiting. Expression of nicotinic acetylcholine receptor subtypes in brain and retina

Wong. A direct nicotinic receptor-mediated inhibition recorded intracellularly in vitro

Wong. Pharmacology of nicotinic receptor-mediated inhibition in rat dorsolateral septal neurones

COUNCIL FOR TOBACCO RESEARCH-USA, Literature Review
Fuxe. 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

R. J. REYNOLDS COMPANY
Bjercke. Anti-idiotypic antibody probes of neuronal nicotinic receptors

Collins. Modulation of Nicotine Receptors by Chronic Exposure to Nicotinic Agonists and Antagonists

Lippiello. The Role of Desensitization in CNS Nicotinic receptor function

Lippiello. Characterization of nicotinic receptors on cultured cortical neurons using anti-idiotypic antibodies and ligand binding

Lippiello. Identification of putative high affinity nicotinic receptors on cultured cortical neurons

Lippiello. Properties of putative nicotine receptors identified on cultured cortical neurons

Lippiello. Kinetics and mechanism of L-[3H]nicotine binding to putative high affinity receptor sites in rat brain -

Lippiello. The binding of L-[3H]nicotine to a single class of high affinity sites in rat brain membranes

Marks. Downregulation of nicotinic receptor function after chronic nicotine infusion

Prince. Actions of the general anesthetic propofol (2,6-diisopropylphenol) on the binding of [3H] nicotine to rat cortical membranes

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Unpublished
Ayres. Notes from the GR & DC Nicotine Conference

PHILIP MORRIS TOBACCO COMPANY, Unpublished
DeNoble. Brain Sites Involved in the Mediation of the Behavioral Effects of Intraventricularly Administered (-)-nicotine

DeNoble. Manuscript--Brain Sites Involved in the Mediation of the Behavioral Effects of Intraventricularly Administered (-)-nicotine

INDUSTRY SUPPORTED AMA/ERF STUDIES
Hirschhorn. Studies on the time course and the effect of cholinergic and adrenergic receptor blockers on the stimulus effect of nicotine

Schechter. Behavioral evidence for two types of cholinergic receptors in the CNS

Schechter. Effect of mecamylamine on discrimination between nicotine- and arecoline- produced cues

Schechter. Nicotine as a discriminative stimulus in rats depleted of norepinephrine or 5-hydroxytryptamine

TOBACCO RESEARCH COUNCIL LABS., U.K.
Wesnes. The separate and combined effects of scopolamine and nicotine on human information processing

Wesnes. Effects of scopolamine and nicotine on human rapid information processing performance

OTHER
Adem. Quantitative autoradiography of nicotinic receptors in large cryosections of human brain hemispheres

Adem. Distribution of nicotinic receptors in human thalamus as visualized by 3H-nicotine and 3H-acetylcholine receptor autoradiography

Copeland. A comparison of the binding of nicotine and nornicotine stereoisomers to nicotinic binding sites in rat brain cortex

Neurotransmitters. Tobacco industry studies have shown that nicotine and its metabolites produce neurochemical and metabolic effects in the brain.[249]

Fuxe. On the action of nicotine and cotinine on central 5-hydroxytryptamine

Fuxe. Reduction of [3H]nicotine binding in hypothalamic and cortical membranes by dopamine D1 receptors

Larsson. In vitro binding of 3H-acetylcholine to nicotinic receptors in rodent and human brain

Larsson. Comparative analysis of nicotine-like receptor-ligand interactions in rodent brain homogenate

Nisell. Systemic nicotine-induced dopamine release in the rat nucleus accumbens is regulated by nicotinic receptors in the ventral tegmental area

Nordberg. Effect of long-term nicotine treatment on [3H]nicotine binding sites in the rats brain

Nordberg. Effect of acute and subchronic nicotine treatment on cortical acetylcholine release and on nicotinic receptors in rats and guinea-pigs

Nordberg. Studies of muscarinic and nicotinic binding sites in brain

Slotkin. Developmental Effects of Nicotine

Svensson. Effect of nicotine on single cell activity in the noradrenergic nucleus

Zhang. Effects of chronic treatment with (+)- and (-)- nicotine on nicotinic acetylcholine receptors and N-methyl-D-aspartate receptors in rat brain

[249] COUNCIL FOR TOBACCO RESEARCH-USA

Andersson. 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

Andersson. Mecamylamine pretreatment counteracts cigarette smoke induced changes in hypothalamic catecholamine neuron systems and in anterior pituitary function

Andersson. Intravenous injections of nicotine induce very rapid and discrete reductions of hypothalamic catecholamine levels associated with increases of ACTH, vasopressin and prolactin secretion

Andersson. 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

Andersson. Interactions of nicotine and pentobarbitone in the regulation of telencephalic and hypothalamic catecholamine levels and turnover and of adenohypophyseal hormone secretion in the normal male rat

Andersson. Effects of acute central and peripheral administration of nicotine on hypothalamic catecholamine nerve terminal systems and on the secretion of adenohypophyseal hormones in the male rat

Andersson. Effects of single injections of nicotine on the ascending dopamine pathways in the rat: Evidence for increases of dopamine turnover in the mesostriatal and mesolimbic dopamine neurons

Andersson. 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 adenohypophyseal hormones

Andersson. Mecamylamine induced blockade of nicotine induced inhibition of gonadotrophin and TSH secretion and of nicotine induced increases of catecholamine turnover in the rat hypthalamus

Andersson. 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 adenohypophyseal hormones and corticosterone

Andersson. Effects of chronic exposure to cigarette smoke on amine levels and turnover in various hypothalamic catecholamine nerve terminal systems and on the secretion of pituitary hormones in the male rat

Bhagat. Influence of chronic administration of nicotine on the turnover and metabolism of noradrenaline in the rat-brain

Bhagat. Effect of chronic administration of nicotine on the concentrations of adrenal enzymes involved in the synthesis and metabolism of adrenaline

Bhagat. Effects of chronic administration of nicotine on storage and synthesis of noradrenaline in rat brain

Chang. Effect of chronic administration of nicotine on acetylcholinesterase activity in the hypothalamus and medulla oblongata of the rat brain An ultrastructural study

Chiou. The ability of various nicotinic agents to release acetylcholine from synaptic vesicles

Erwin. Nicotine alters catecholamines and electrocortical activity in perfused mouse brain

Essman. Changes in cholinergic activity and avoidance behavior by nicotine in differentially housed mice

Fuxe. Increases in dopamine utilization in certain limbic dopamine terminal populations after a short period of intermittent exposure of male rats to cigarette smoke

Grenhoff. Chronic continuous nicotine treatment causes decreased burst firing of nigral dopamine neurons in rats partially hemitransected at the meso-diencephalic junction

Grenhoff. Selective stimulation of limbic dopamine activity by nicotine

Harsing. Dopamine efflux from striatum after chronic nicotine: evidence for autoreceptor desensitization

Knapp. Action of nicotine on the ascending reticular activating system

Lapin. Dopamine-like action of nicotine: lack of tolerance and reverse tolerance

Lapin. Action of nicotine on accumbens dopamine and attenuation with repeated administration

Lowy. Antagonism by cholinergic drugs of behavioural effects in cats of an anticholinergic psychotomimetic drug and enhancement by nicotine

Marty. Effects of nicotine on beta-endorphin, alpha MSH, and ACTH secretion by isolated perfused mouse brains and pituitary glands, in vitro

Mitchell. Increases in tyrosine hydroxylase messenger RNA in the locus coeruleus after a single dose of nicotine are followed by time-dependent increases in enzyme activity and noradrenaline release

These studies show that nicotine exerts its behavior modifying effects, in part, through the cascade of effects that are produced through nicotine's actions on existing brain chemicals. Industry-supported studies show that nicotine, like other addictive drugs, acts on dopaminergic receptors[250] in the mesolimbic system to release

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Mitchell. Role of the locus coeruleus in the noradrenergic response to a systemic administration of nicotine

Naftchi. Acute reduction of brain substance P induced by nicotine

Siegel. Rapid and discrete changes in hypothalamic catecholamine nerve terminal systems induced by audiogenic stress, and their modulation by nicotine-relationship to neuroendocrine function

Toth. Effect of nicotine on extracellular levels of neurotransmitters assessed by microdialysis in various brain regions: role of glutamic acid

Toth. Effect of nicotine on levels of extracellular amino acids in regions of the rat brain in vivo

Tung. Peripheral induction of burst firing in locus coeruleus neurons by nicotine mediated via excitatory amino acids

Westfall. Effect of nicotine and related substances upon amine levels in the brain

Westfall. Effect of nicotine and other drugs on the release of 3H-norepinephrine and 3H-dopamine from rat brain slices

R. J. REYNOLDS COMPANY
Brazell. 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

Mitchell. Nicotine-induced catecholamine synthesis after lesions to the dorsal or ventral noradrenergic bundle

Mitchell. Regionally specific effects of acute and chronic nicotine onrates of catecholamine and 5-hydroxytryptamine synthesis in rat brain

Smith. Effects of chronic and subchronic nicotine on tyrosine hydroxylase activity in noradrenergic and dopaminergic neurones in the rat brain

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Unpublished
Haselbach. Tentative Hypothesis on Nicotine Addiction

Haselbach. Final Report on Project HIPPO II

INDUSTRY SUPPORTED SYMPOSIA
Joseph. Possible mechanisms underlying beneficial effects of nicotine in cognitive function

Nordberg. Assessment of cholinergic neuronal activity in the brain

INDUSTRY SUPPORTED AMA/ERF STUDIES
Rosecrans. Effects of nicotine on behavioral arousal and brain 5-hydroxytryptamine function in female rats selected for differences in activity

Schechter. Nicotine as a discriminative stimulus in rats depleted of norepinephrine or 5-hydroxytryptamine

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Effects of nicotine on electrocortical activity and acetylcholine release from the cat cerebral cortex

Armitage. The effects of nicotine on the electrocorticogram and spontaneous release of acetylcholine from the cerebral cortex of the cat

Armitage. Further evidence relating to the mode of action of nicotine in the central nervous system

Balfour. A possible role for the pituitary-adrenal system in the effects of nicotine on avoidance behaviour

Bhagat. The effects of nicotine and other drugs on the release of injected 3H-norepinephrine and on endogenous norepinephrine levels in the rat brain

OTHER
Fuxe. Regulation of endocrine function by the nicotinic cholinergic receptor

Fuxe. On the action of nicotine and cotinine on central 5-hydroxytryptamine neurons

Grenhoff. Nicotinic effects on the firing pattern of midbrain dopamine neurons

Nisell. Systemic nicotine-induced dopamine release in the rat nucleus accumbens is regulated by nicotinic receptors in the ventral tegmental area

Nordberg. Effect of acute and subchronic nicotine treatment on cortical acetylcholine release and on nicotinic receptors in rats and guinea-pigs

Perez de la Mora. Neurochemical effects of nicotine on glutamate and GABA mechanisms in the rat brain

Slotkin. Effects of prenatal nicotine exposure on neuronal development: selective actions on central and peripheral catecholaminergic pathways

OTHER, Literature Review
Edwards. Smoking, nicotine and electrocortical activity

[250] **COUNCIL FOR TOBACCO RESEARCH-U.S.A**
Abood. Receptor binding characteristics of a 3H-labeled azetidine analogue of nicotine

Andersson. Mecamylamine induced blockade of nicotine induced inhibition of gonadotrophin and TSH secretion and of nicotine induced increases of catecholamine turnover in the rat hypothalmus

Andersson. 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 adenohypophyseal hormones and corticosterone

Andersson. Effects of single injections of nicotine on the ascending dopamine pathways in the rat. Evidence for increases of dopamine turnover in the mesostriatal and mesolimbic dopamine neurons

Andersson. 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

Andersson. Interactions of nicotine and pentobarbitone in the regulation of telencephalic and hypothalamic catecholamine levels and turnover and of adenohypophyseal hormone secretion in the normal male rat

Andersson. Effects of acute central and peripheral administration of nicotine on hypothalamic catecholamine nerve terminal systems and on the secretion of adenohypophyseal hormones in the male rat

Erwin. Nicotine alters catecholamines and electrocortical activity in perfused mouse brain

dopamine, a chemical in the brain associated with pleasurable feelings.

Mood modification and EEG effects. In tobacco industry-sponsored trials, nicotine has been shown to induce both behavioral arousal and calming effects.[251] These effects have been correlated with

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Fuxe. Increases in dopamine utilization in certain limbic dopamine terminal populations after a short period of intermittent exposure of male rats to cigarette smoke

Grenhoff. Selective stimulation of limbic dopamine activity by nicotine

Harsing. N-type calcium channels are involved in the dopamine releasing effect of nicotine

Lapin. Action of nicotine on accumbens dopamine and attenuation with repeated administration

Lapin. Dopamine-like action of nicotine: lack of tolerance and reverse tolerance

Westfall. Effect of nicotine and other drugs on the release of 3H-norepinephrine and 3H-dopamine from rat brain slices

R. J. REYNOLDS COMPANY
Lippiello. The role of desensitization in CNS nicotinic receptor function

Marks. Downregulation of nicotinic receptor function after chronic nicotine infusion

INDUSTRY SUPPORTED SYMPOSIA
Joseph. Possible mechanisms underlying beneficial effects of nicotine in cognitive function

OTHER
Adem. Quantitative autoradiography of nicotinic receptors in large cryosections of human brain hemispheres

Andersson. 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

Fuxe. Regulation of endocrine function by the nicotinic cholinergic receptor

Grenhoff. Nicotinic effects on the firing pattern of midbrain dopamine neurons

Nisell. Systemic nicotine-induced dopamine release in the rat nucleus accumbens is regulated by nicotinic receptors in the ventral tegmental area

[251] COUNCIL FOR TOBACCO RESEARCH-USA
Domino. Electroencephalographic and behavioral arousal effects of small doses of nicotine: A neuropsychopharmacological study

Heimstra. The effects of deprivation of cigarette smoking on psychomotor performance

Marks. Genetics of nicotine response in four inbred strains of mice

Nelsen. Improvement of performance on an attention task with chronic nicotine treatment in rats

Pradhan. Effects of nicotine on several schedules of behavior in rats

Schaeppi. Nicotine treatment of selected areas of the cat brain: effects upon EEG and autonomic system

Stadnicki. Nicotine infusion into the fourth ventricle of unrestrained cats: changes in EEG and behavior

Stadnicki. Nicotinic changes in EEG and behavior after intravenous infusion in awake unrestrained cats

Yamamoto. Nicotine-induced EEG and behavioral arousal

COUNCIL FOR TOBACCO RESEARCH-USA, Literature Review
Silvette. The actions of nicotine on central nervous system functions

R. J. REYNOLDS COMPANY
Lippiello. Properties of putative nicotine receptors identified on cultured cortical neurons

Pritchard. Electroencephalographic effects of cigarette smoking

Robinson. The role of nicotine in tobacco use

BRITISH-AMERICAN TOBACCO COMPANY, LTD.
Golding. Arousing and de-arousing effects of cigarette smoking under conditions of stress and mild sensory isolation

Mangan. The effects of cigarette smoking on vigilance performance

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Unpublished
Comer. Interaction of Smoke and the Smoker Part 3: The Effect of Cigarette Smoking on the Contingent Negative Variation

Thornton. Some "Benefits" of Smoking

INDUSTRY SUPPORTED SYMPOSIA
Joseph. Possible mechanisms underlying beneficial effects of nicotine in cognitive function

Wesnes. The effects of cigarette smoking and nicotine tablets upon human attention

INDUSTRY SUPPORTED AMA/ERF STUDIES
Rosecrans. Effects of nicotine on behavioral arousal and brain 5-hydroxytryptamine function in female rats selected for differences in activity

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Effects of nicotine on electrocortical activity and acetylcholine release from the cat cerebral cortex

Armitage. Nicotine, smoking and cortical activation

Hall. Effects of nicotine and tobacco smoke on the electrical activity of the cerebral cortex and olfactory bulb

Morrison. Antagonism by antimuscarinic and ganglion-blocking drugs of some of the behavioural effects of nicotine

Morrison. The occurrence of tolerance to a central depressant effect of nicotine

Warwick. Experimental studies of the behavioural effects of nicotine

OTHER

electroencephalogram/electrocorticogram changes in electrical activity in the brain.[252] Whether nicotine provides a stimulating or calming effect depends on the dose of nicotine taken, the time elapsed since the last dose, and other factors.[253]

Cohen. Monograph on the "Pharmacology and Toxicology of Nicotine and its Role in Tobacco Smoking Draft

Edwards. Evidence of more rapid stimulus evaluation following cigarette smoking

Golding. Effects of cigarette smoking on measures of arousal, response suppression, and excitation/inhibition balance

Nordberg. Effect of nicotine on passive avoidance behaviour and motoric activity in mice

[252] COUNCIL FOR TOBACCO RESEARCH-USA
Domino. Electroencephalographic and behavioral arousal effects of small doses of nicotine: A neuropsychopharmacological study

Erwin. Nicotine alters catecholamines and electrocortical activity in perfused mouse brain

Kawamura. Differential actions of m and n cholinergic agonists on the brainstem activating system

Marty. Effects of nicotine on beta-endorphin, alpha MSH, and ACTH secretion by isolated perfused mouse brains and pituitary glands, in vitro

Nelsen. Chronic nicotine treatment in rats 2 Electroencephalographic amplitude and variability changes occurring within and between structures

Schaeppi. Nicotine treatment of selected areas of the cat brain: effects upon EEG and autonomic system

Stadnicki. Nicotine infusion into the fourth ventricle of unrestrained cats: changes in EEG and behavior

Stadnicki. Nicotinic changes in EEG and behavior after intravenous infusion in awake unrestrained cats

Yamamoto. Nicotine-induced EEG and behavioral arousal

COUNCIL FOR TOBACCO RESEARCH-USA, Literature Review
Silvette. The actions of nicotine on central nervous system functions

PHILIP MORRIS TOBACCO COMPANY
Mangan. Relationships between photic driving, nicotine and memory

(One Philip Morris document explains why the company decided to conduct nicotine-related EEG research: "We are establishing an EEG laboratory in search of the reinforcing event. Brain waves are neuro-physiological phenomena, but they are legitimate subject matter for us in that brain events underlie behavioral events. Smoke-related changes in brain waves can give us clues as to smoke-related psychological changes." Philip Morris employee (almost certainly W.L. Dunn). *Smoker Psychology Program Review*. October 19, 1977. Page 9.)

R. J. REYNOLDS COMPANY
Gilbert. Effects of smoking/nicotine on anxiety, heart rate, and lateralization of EEG during a stressful movie

Pritchard. Flexible effects of quantified cigarette-smoke delivery on EEG dimensional complexity

Pritchard. Electroencephalographic effects of cigarette smoking

Robinson. Psychopharmacological effects of smoking a cigarette with typical "tar" and carbon monoxide yields but minimal nicotine

BROWN AND WILLIAMSON TOBACCO CORPORATION, Unpublished
Brotzge. Human smoking studies: acute effect of cigarette smoke on brain wave alpha rhythm-first report

BRITISH-AMERICAN TOBACCO COMPANY, LTD.
Golding. Effects of cigarette smoking on resting EEG, visual evoked potentials and photic driving

Golding. Arousing and de-arousing effects of cigarette smoking under conditions of stress and mild sensory isolation

Golding. Effects of cigarette smoking on measures of arousal, response suppression, and excitation/inhibition balance

BRITISH-AMERICAN TOBACCO COMPANY, LTD, Unpublished
Comer. Interaction of smoke and the smoker. Part 3: The effect of cigarette smoking on the contingent negative variation

Willey. Effects of nicotine on the central nervous system

INDUSTRY SUPPORTED AMA/ERF STUDIES
Murphree. Elecroencephalographic changes in man following smoking

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Effects of nicotine on electrocortical activity and acetylcholine release from the cat cerebral cortex

Armitage. The effects of nicotine on the electrocorticogram and spontaneous release of acetylcholine from the cerebral cortex of the cat

Armitage. Pharmacological basis for the tobacco smoking habit

Ashton. The use of event-related slow potentials of the brain as a means to analyse the effects of cigarette smoking and nicotine in humans

Hall. Effects of nicotine and tobacco smoke on the electrical activity of the cerebral cortex and olfactory bulb

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Edwards. Smoking, nicotine and electrocortical activity

Knott. Effects of cigarette smoking on subjective and brain evoked responses to electrical pain stimulation

Knott. Reaction time, noise distraction and autonomic responsivity in smokers and non-smokers

[253] INDUSTRY SUPPORTED AMA/ERF STUDIES
Rosecrans. Effects of nicotine on behavioral arousal and brain 5-hydroxytryptamine function in female rats selected for differences in activity

R. J. REYNOLDS COMPANY
Robinson. Psychopharmacological effects of smoking a cigarette with typical "tar" and carbon monoxide yields but minimal nicotine

BRITISH-AMERICAN TOBACCO COMPANY, LTD.
Mangan. The effects of cigarette smoking on vigilence performance

Effects on performance and behavior. Industry-funded scientists have conducted research to characterize nicotine's effects on behavioral performance and cognitive function.[254]

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[254] COUNCIL FOR TOBACCO RESEARCH-USA
Domino. Electroencephalographic and behavioral arousal effects of small doses of nicotine: A neuropsychopharmacological study
Marks. Genetics of nicotine response in four inbred strains of mice
Pradhan. Effects of nicotine on several schedules of behavior in rats
Yamamoto. Nicotine-induced EEG and behavioral arousal

TOBACCO RESEARCH COUNCIL LABS, U.K.
Warwick. Experimental studies of the behavioral effects of nicotine

COUNCIL FOR TOBACCO RESEARCH-USA
Bhagat. Effect of nicotine on the swimming endurance of rats
Heimstra. The effects of deprivation of cigarette smoking on psychomotor performance
Levin. Memory enhancing effects of nicotine
Marks. Genetics of nicotine response in four inbred strains of mice
Nelsen. Chronic nicotine treatment in rats
Nelsen. Protection by nicotine from behavioral disruption caused by reticular formation stimulation in the rat
Nelsen. Improvement of performance on an attention task with chronic nicotine treatment in rats

COUNCIL FOR TOBACCO RESEARCH-USA, Literature Reviews
Essman. Drug effects and learning and memory processes
Silvette. The actions of nicotine on central nervous system functions

PHILIP MORRIS TOBACCO COMPANY
Colrain. Effects of post-learning smoking on memory consolidation.
DeNoble. Behavioral effects of intraventricularly administered (-)-nicotine on fixed ratio schedules of food presentation in rats
Mangan. Relationships between photic driving, nicotine and memory
Woodson. Effects of nicotine on the visual evoked response

R. J. REYNOLDS COMPANY
Pritchard. Enhancement of continuous performance task reaction time by smoking in non-deprived smokers
Pritchard. Electroencephalographic effects of cigarette smoking

BRITISH-AMERICAN TOBACCO COMPANY, LTD.
Mangan. The effects of cigarette smoking on vigilance performance
Mangan. The effects of smoking on memory consolidation

INDUSTRY SUPPORTED AMA/ERF STUDIES
Schechter. C.N.S. effect of nicotine as the discriminative stimulus for the rat in a T-maze

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Pharmacological basis for the tobacco smoking habit
Balfour. A possible role for the pituitary-adrenal system in the effects of nicotine on avoidance behaviour
Morrison. Effects of nicotine on motor co-ordination and spontaneous activity in mice
Morrison. The effects of nicotine on punished behaviour
Warwick. Experimental studies of the behavioral effects of nicotine
Wesnes. Effects of nicotine on stimulus sensitivity and response bias in a visual vigilance task
Wesnes. The separate and combined effects of scopolamine and nicotine on human information processing
Wesnes. Effects of scopolamine and nicotine on human rapid information processing performance
Wesnes. Effects of smoking on rapid information processing performance

TOBACCO RESEARCH COUNCIL, UK, Literature Reviews
Hall. New evidence for a relationship between tobacco smoking, nicotine dependence, and stress
Wesnes. Smoking, nicotine and human performance

OTHER
Andersson. Effects of cigarette smoking on incidental memory
Battig. The effect of pre- and post-trial application of nicotine on the 12 problems of the Hebb-Williams-test in the rat
Driscoll. Effects of nicotine on the shuttlebox behavior of trained guinea pigs
Hasenfratz. Action profiles of smoking and caffeine: Stoop effect, EEG, and peripheral physiology
Hasenfratz. Can smoking increase attention in rapid information processing during noise?
Knott. Reaction time, noise distraction and autonomic responsivity in smokers and non-smokers
Knott. Noise and task induced distraction effects on information processing: Sex differences in smokers and non-smokers
Nordberg. Effect of nicotine on passive avoidance behaviour and motoric activity in mice
Roth. Smoking deprivation in "early" and "late" smokers and memory functions

Neuroendocrine effects. Tobacco industry-supported studies have demonstrated that nicotine affects hormone secretion and several endocrine functions involved in modulation of mood and behavior. These studies showed that nicotine stimulates the secretion of corticosteroids and catecholamines and decreases the secretion of thyroid stimulating hormone, leutinizing hormone, and prolactin.[255]

2. Industry Research on Nicotine Delivery to the Blood and Brain

The tobacco industry has studied the bioavailability of nicotine in tobacco products and how nicotine is distributed throughout the body, after absorption into the bloodstream. This has led to the industry's development of sophisticated techniques for determining, quantitatively and qualitatively, the presence of nicotine and its metabolites in body fluids.[256]

Wesnes. The effects of cigarettes of varying yield on rapid information processing

[255] COUNCIL FOR TOBACCO RESEARCH-USA
Andersson. Involvement of D1 dopamine receptors in the nicotine-induced neuro-endocrine effects and depletion of diencephalic catecholamine stores in the male rat

Andersson. 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 rat

Andersson. 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 adenohypophyseal hormones

Andersson. Mecamylamine induced blockade of nicotine induced inhibition of gonadotrophin and TSH secretion and of nicotine induced increases of catecholamine turnover in the rat hypothalamus

Andersson. 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 adenohypophyseal hormones and corticosterone

Andersson. 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

Andersson. Effects of acute central and peripheral administration of nicotine on hypothalamic catecholamine nerve terminal systems and on the secretion of adenohypophyseal hormones in the male rat

Fuxe. Neuroendocrine actions of nicotine and of exposure to cigarette smoke: medical implications

Fuxe. Neurochemical mechanisms underlying the neuroendocrine actions of nicotine: focus on the plasticity of central cholinergic nicotinic receptors

Fuxe. 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

Marty. Effects of nicotine on beta-endorphin, alpha MSH, and ACTH secretion by isolated perfused mouse brains and pituitary glands, in vitro
Rubin.
Nicotine-induced stimulation of steroidogenesis in adrenocortical cells of the cat

Siegel. Rapid and discrete changes in hypothalamic catecholamine nerve terminal systems induced by audiogenic stress, and their modulation by nicotine-relatinship to neuroendocrine function

Westfall. 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

Westfall. Specificity of blockade of the nicotine-induced release of 3H-norepinephrine from adrenergic neurons of the guinea-pig heart by various pharmacological agents

R. J. REYNOLDS COMPANY
Mitchell. Regionally specific effects of acute and chronic nicotine on rates of catecholamine and 5-hydroxytryptamine synthesis in rat brain

TOBACCO RESEARCH COUNCIL LABS., U.K.
Balfour. A possible role for the pituitary-adrenal system in the effects of nicotine on avoidance behaviour

OTHER
Fuxe. Regulation of endocrine function by the nicotinic cholinergic receptor

[256] AMERICAN TOBACCO COMPANY
Castro. Nicotine antibodies: comparison of ligand specificities of antibodies produced against two nicotine conjugates

COUNCIL FOR TOBACCO RESEARCH-USA
Castro. Nicotine enzyme immunoassay

Castro. Radioimmunoassays of drugs of abuse in humans: a review

Haines. Radioimmunoassay of plasma nicotine in habituated and naive smokers

McNiven. Determination of nicotine in smokers' urine by gas chromatography

Monji. Plasma nicotine pharmacokinetics in dogs after intravenous administration: determination by radioimmunassay

R. J. REYNOLDS COMPANY
Caldwell. Characterization of the glucuronide conjugate of cotinine: a previously unidentified major metabolite of nicotine in smokers' urine

Nicotine pharmacokinetics. Numerous publications document the tobacco industry's involvement in investigating all aspects of the pharmacokinetics of nicotine. (Pharmacokinetics is the study of the absorption, distribution, metabolism, and elimination of drugs in the body.) Areas that the industry has researched include:

- general pharmacokinetics of nicotine (absorption, distribution, metabolism, elimination);[257]

Davis. The determination of nicotine and cotinine in plasma

Kyerematen. Radiometric high performance liquid chromatographic assay for nicotine and twelve of its metabolites

Kyerematen. Pharmacokinetics of nicotine and 12 metabolites in the rat

Langone. Idiotype-anti-idiotype hapten immunoassays: assay for cotinine

McManus. A new quantitative thermospray LC-MS method for nicotine and its metabolites in biological fluids

BRITISH-AMERICAN TOBACCO COMPANY, Unpublished
Backhurst. Further work on extractable nicotine

Isaac. The absorption and effects of nicotine from inhaled tobacco smoke

Read. Method for nicotine and cotinine in blood and urine

Read. Nicotine studies: A second report. Estimation of whose body nicotine dose by urinary nicotine and contine measurement

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Funded -- Battelle Unpublished Studies
Geissbuhler. The fate of nicotine in the body

Haselbach. A tentative hypothesis on nicotine addiction

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. The transfer of endogenous and exogenous radioisotopically labelled nicotine to mainstream cigarette smoke and its absorption into the blood of anaesthetized cats

Beckett. Analysis of nicotine-1-N-oxide in urine, in the presence of nicotine and cotinine, and its application to the study of in vivo nicotine metabolism in man

OTHER
Biber. Determination of nicotine and cotinine in human serum and urine: an interlaboratory study

Isaac. Cigarette smoking and plasma levels of nicotine

Schievelbein. Nicotine Workshop

Schmiterlow. Distribution of Nicotine in the Central Nervous System

Schmiterlow. Tissue distribution of C14-nicotine and Related Compounds

Szuts. Long-term fate of [14C]nicotine in the mouse: retention in the bronchi, melanin-containing tissues and urinary bladder wall

[257] **COUNCIL FOR TOBACCO RESEARCH-USA**
Becker. Studies on nicotine absorption during pregnancy

Haines. Radioimmunoassay of plasma nicotine in habituated and naive smokers

Hibberd. Enzymology of the metabolic pathway from nicotine to cotinine, in vitro

Kershbaum. Cigarette, cigar, and pipe smoking. Some differences in biochemical effects

Monji. Plasma nicotine pharmacokinetics in dogs after intravenous administration: determination by radioimmunoassay

Rama. Distribution and Retention of nicotine and its major metabolite cotinine in the rat as a function of time

COUNCIL FOR TOBACCO RESEARCH-USA, Literature Reviews
Larson. Tobacco -- Experimental and Clinical Studies

Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature -- Supplement I

Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature -- Supplement II

Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature --Supplement III

AMERICAN TOBACCO COMPANY
Haag. Studies on the fate of nicotine in the body I: The effect of pH on the urinary excretion of nicotine by tobacco smokers

Larson. Studies on the fate of nicotine in the body VI: Observations on the relative rate of elimination of nicotine by the dog, cat, rabbit and mouse

Larson. Studies on the fate of nicotine in the body II: On the fate of nicotine in the dog

Larson. Studies on the fate of nicotine in the body IV: Observations on the chemical structure of an end product of nicotine metabolism

McKennis. N-methylation of nicotine and cotinine in vivo

Owen. Studies on the fate of nicotine in the animal body. VIII: Observations on the number and chemical nature of nicotine metabolites in the dog and cat

Weatherby. Rate of elimination of nicotine by the rabbit

R. J. REYNOLDS COMPANY
Caldwell. Characterization of the glucuronide conjugate of cotinine: a previously unidentified major metabolite of nicotine in smokers' urine

Caldwell. Intragastric nitrosation of nicotine is not a significant contributor to nitrosamine exposure

deBethizy. Chemical and biological studies of a cigarette that heats rather than burns tobacco

deBethizy. Absorption of nicotine from a cigarette that does not burn tobacco

- factors affecting the absorption of nicotine into the bloodstream, including route of administration;[258]
- distribution of nicotine to the brain;[259] and

Hammond. Metabolism of nicotine by rat liver cytochromes P-450: Assessment utilizing monoclonal antibodies to nicotine and cotinine

Kyerematen. Pharmacokinetics of nicotine and 12 metabolites in the rat

Kyerematen. Disposition of nicotine and eight metabolites in smokers and nonsmokers: Identification in Smokers of two metabolites that are longer lived than cotinine

BROWN AND WILLIAMSON TOBACCO CORPORATION, Unpublished
Brotzge. Human smoking studies: acute effect of cigarette smoke on brain wave alpha rhythm - first report

BRITISH-AMERICAN TOBACCO COMPANY, LTD., Funded - - Unpublished Battelle Studies
Geissbuhler. The fate of nicotine in the body

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Absorption and metabolism of nicotine from cigarettes

Armitage. Absorption of nicotine in cigarette and cigar smoke through the oral mucosa

Armitage. The transfer of endogenous and exogenous radioisotopically labelled nicotine to mainstream cigarette smoke and its absorption into the blood of anaesthetized cats

Beckett. Effect of smoking on nicotine metabolism in vivo in man

Beckett. Analysis of nicotine-1-N-oxide in urine, in the presence of nicotine and cotinine, and its application to the study of in vivo nicotine metabolism in man

Beckett. Buccal absorption of basic drugs and its application as an in vivo model of passive drug transfer through lipid membranes

Jenner. Species variation in the metabolism of R-(+)- and S-(-)-nicotine by alpha-C- and N-oxidation in vitro

Jenner. Factors affecting the in vitro metabolism of R-(+)- and S-(-)-nicotine by guinea-pig liver preparations

OTHER
Cholerton. Sources of inter-individual variability in nicotine pharmacokinetics

Cohen. Monograph on the Pharmacology and Toxicology of Nicotine and its Role in Tobacco Smoking

Hasenfratz. Development of central and peripheral smoking effects over time

Pilotti. Studies on the identification of tobacco alkaloids, their mammalian metabolites and related compounds by gas chromatography- -mass spectrometry

Schievelbein. Nicotine Workshop

Schmiterlow. Tissue distribution of C14-nicotine

Schmiterlow. Distribution of nicotine in the central nervous system

Szuts. Long-term fate of [14C]nicotine in the mouse: retention in the bronchi, melanin-containing tissues and urinary bladder wall

[258] **COUNCIL FOR TOBACCO RESEARCH-USA**
Haines. Radioimmunoassay of plasma nicotine in habituated and naive smokers

Kershbaum. Cigarette, cigar, and pipe smoking. Some differences in biochemical effects

R. J. REYNOLDS COMPANY
deBethizy. Chemical and biological studies of a cigarette that heats rather than burns tobacco

deBethizy. Absorption of nicotine from a cigarette that does not burn tobacco

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Unpublished
Backhurst. Further Work on Extractable Nicotine

Evelyn. Retention of nicotine and phenols in the human mouth

Evelyn. Transfer of nicotine from smoke into blood using a perfused canine lung

Evelyn. Absorption of nicotine via the mouth: studies using animal models

Isaac. The absorption and effects of nicotine from inhaled tobacco smoke

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Absorption of nicotine by man during cigar smoking [proceedings]

Armitage. Absorption of nicotine from small cigars

Armitage. The transfer of endogenous and exogenous radioisotopically labelled nicotine to mainstream cigarette smoke and its absorption into the blood of anaesthetized cats

Armitage. Absorption of nicotine in cigarette and cigar smoke through the oral mucosa

OTHER
Hasenfratz. Development of central and peripheral smoking effects over time

Schievelbein. Nicotine workshop: Absorption of nicotine under various conditions (an introductory review)

[259] **COUNCIL FOR TOBACCO RESEARCH-USA**
Hatchell. The influence of genotype and sex on behavioral sensitivity to nicotine in mice

Vincek. Synthesis of 4,4-ditritio-(+)-nicotine: comparative binding and distribution studies with natural enantiomer

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Unpublished
Creighton. Relative contributions of nicotine and carbon monoxide to human physiological response

Creighton. Further studies on the effect of nicotine on human physiological response

- plasma profiles of nicotine and its metabolites.[260]

Nicotine metabolism. The industry has investigated the metabolic fate of nicotine, including the metabolites (breakdown products) of nicotine.[261] Studies have also been done on the enzymatic systems involved in nicotine

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Isaac. The Absorption and Effects of Nicotine from Inhaled Tobacco Smoke

INDUSTRY SUPPORTED AMA/ERF STUDIES
Rosecrans. Brain area nicotine levels in male and female rats with different levels of spontaneous activity

Rosecrans. Brain area nicotine levels in male and female rats of two strains

OTHER
Cholerton. Sources of inter-individual variability in nicotine pharmacokinetics

Schmiterlow. Distribution of Nicotine in the Central Nervous System

OTHER, Literature Review
Edwards. Smoking, nicotine and electrocortical activity

[260] **COUNCIL FOR TOBACCO RESEARCH-USA**
Castro. Nicotine enzyme immunoassay

Haines. Radioimmunoassay of plasma nicotine in habituated and naive smokers

Monji. A Plasma nicotine pharmacokinetics in dogs after intravenous administration: Determination by radioimunassay

Rama. Distribution and Retention of nicotine and its major metabolite cotinine, in the rat as a function of time

AMERICAN TOBACCO COMPANY
Castro. Nicotine antibodies: comparison of ligand specificities of antibodies produced against two nicotine conjugates

R. J. REYNOLDS COMPANY
Davis. The determination of nicotine and cotinine in plasma

deBethizy. Absorption of nicotine from a cigarette that does not burn tobacco

Kyerematen. Pharmacokinetics of nicotine and 12 metabolites in the rat Application of a new radiometric high performance liquid chromatography assay

Kyerematen. Radiometric high performance liquid chromatographic assay for nicotine and twelve of its metabolites

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Unpublished
Isaac. The absorption and effects of nicotine from inhaled tobacco smoke

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Absorption and metabolism of nicotine from cigarettes

Armitage. Absorption of nicotine by man during cigar smoking [proceedings]

Armitage. Absorption of nicotine from small cigars

Armitage. The transfer of endogenous and exogenous radioisotopically labelled nicotine to mainstream cigarette smoke and its absorption into the blood of anaesthetized cats

Stepney. Behavioural regulation of nicotine intake in cigarette smokers presented with a 'shortened' cigarette [proceedings]

OTHER
Isaac. Cigarette smoking and plasma levels of nicotine

Isaac. Blood levels of nicotine and physiological effects after inhalation of tobacco smokeIsaac. Blood levels of nicotine and physiological effects after inhalation of tobacco smoke

Schievelbein. Nicotine Workshop

[261] **COUNCIL FOR TOBACCO RESEARCH-U.S.A**
Abood. Specific binding and metabolism of (-)- and (+)-[3H]-nicotine in isolated rat hepatocytes and hepatocyte membranes

Hibberd. Nicotine delta 1' (5)' iminium ion: a reactive intermediate in nicotine metabolism

Vincek. Synthesis of 4,4-ditritio-(+)-nicotine: comparative binding and distribution studies with natural enantiomer

AMERICAN TOBACCO COMPANY
Bowman. Studies on the metabolism of (-)-cotinine in the human

Bowman. Disposition and fate of (-)-cotinine-H3 in the mouse

Hucker. Studies on the metabolism of nornicotine in the dog

Larson. Studies on the fate of nicotine in the body III: On the pharmacology of some methylated and demethylated derivatives of nicotine

Larson. Studies on the fate of nicotine in the body IV: Observations on the chemical structure of an end product of nicotine metabolism

McKennis. Gamma-(3-pyridyl)-gamma-methylaminobutyric acid as a urinary metabolite of nicotine

McKennis. The excretion and metabolism of nicotine

McKennis. Mammalian degradation of (-)-nicotine to 3-pyridylacetic acid and other compounds

McKennis. Demethylation in the metabolism of (-)-nicotine

McKennis. Metabolic release of methyl groups from a series of N-methylpyridinium compounds

McKennis. Metabolism of nicotine to (+)-gamma-(3-pyridyl)-gamma- methylaminobutyric acid

McKennis. Demethylation of cotinine in vivo

McKennis. Metabolites of nicotine and a synthesis of nornicotine

metabolism.[262] Industry-supported research shows that smokers metabolize nicotine faster than non-smokers because one or more of the substances in cigarette smoke increases the production of the enzymes that metabolize nicotine.[263] Industry-funded studies have also shown that there may be gender differences in the metabolism of nicotine.[264]

Nicotine pharmacodynamics. The tobacco industry has studied a wide range of factors related to the pharmacodynamics of nicotine and nicotine delivery systems. (Pharmacodynamics is the study of a drug's effects on the body over time. A pharmacodynamic study would involve, for example, administering a drug and then evaluating its behavioral and physiological effects over time.) The industry has funded research on:

- factors affecting the onset and duration of nicotine's physiological effects on the body;[265]

McKennis. Demethylation in the metabolism of (-)-nicotine in vivo

McKennis. N-methylation of nicotine and cotinine in vivo

McKennis. The Metabolic Formation of Gamma-(3-Pyridyl)-Gamma- Hydroxybutyric Acid and Its Possible Intermediary Role in the Mammalian Metabolism of Nicotine

McKennis. The isolation and structure of a ketoamide formed in the metabolism of nicotine

Meacham. Additional routes in the metabolism of nicotine to 3-pyridylacetate

Miller. Observations on the metabolism of nicotine by tissue slices

Owen. Studies on the fate of nicotine in the animal body VIII: Observations on the nubmer and chemical nature of nicotine metabolites in the dog and cat

Schwartz. Studies on the degradation of the pyrrolidine ring of (-)-nicotine in vivo

Schwartz. Mammalian degradation of (-)-demethylcotinine

R. J. REYNOLDS COMPANY
Caldwell. Characterization of the glucuronide conjugate of cotinine: a previously unidentified major metabolite of nicotine in smokers' urine

Kyerematen. Disposition of nicotine and eight metabolites in smokers and nonsmokers: Identification in smokers of two metabolites that are longer lived than cotinine

TOBACCO RESEARCH COUNCIL LABS., U.K.
Jenner. Factors affecting the in vitro metabolism of R-(+)- and S-(-)-nicotine by guinea-pig liver preparations

Jenner. Species variation in the metabolism of R-(+)- and S-(-)-nicotine by alpha-C- and N-oxidation in vitro

OTHER
Fuxe. On the action of nicotine and cotinine on central 5-hydroxytryptamine

[262] COUNCIL FOR TOBACCO RESEARCH-U.S.A
Hibberd. Enzymology of the metabolic pathway from nicotine to cotinine, in vitro

Wilson. Nicotine-like actions of cis-metanicotine and trans-metanicotine

R. J. REYNOLDS COMPANY
Hammond. Metabolism of nicotine by rat liver cytochromes P-450: Assessment utilizing monclonal antibodies to nicotine and cotinine

[263] COUNCIL FOR TOBACCO RESEARCH-U.S.A
Hatchell. The influence of genotype and sex on behavioral sensitivity to nicotine in mice

Jusko. Role of tobacco smoking in pharmacokinetics

TOBACCO RESEARCH COUNCIL LABS., U.K.
Beckett. The effect of smoking on nicotine metabolism in vivo in man

[264] COUNCIL FOR TOBACCO RESEARCH-U.S.A
Jusko. Role of tobacco smoking in pharmacokinetics

TOBACCO RESEARCH COUNCIL LABS., U.K.
Beckett. The effect of smoking on nicotine metabolism in vivo in man

OTHER
Cohen. Monograph on the Pharmacology and Toxicology of Nicotine and its Role in Tobacco Smoking

[265] COUNCIL FOR TOBACCO RESEARCH-USA
Domino. Electroencephalographic and behavioral arousal effects of small doses of nicotine: A neuropsychopharmacological study

Hoff. Neurophysiological aspects of the action of nicotine

Lapin. Dopamine-like action of nicotine: lack of tolerance and reverse tolerance

Stitzer. Effects of nicotine on fixed-interval behavior and their modification by cholinergic antagonists

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. Absorption of nicotine in cigarette and cigar smoke through the oral mucosa

- the relationship of nicotine's physiological effects on the body to nicotine blood levels;[266] and
- physiological effects of nicotine on the brain and their time-course.[267]

3. Industry Research Establishes That Nicotine Produces Pharmacological Effects Similar to Those of Other Addictive Drugs

The tobacco industry has conducted or sponsored studies which demonstrate that nicotine produces pharmacological effects similar to those of other addictive substances. See FINDINGS § I.B., supra, for a discussion of the properties of addictive substances. Indeed, a number of industry-funded studies state that

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COUNCIL FOR TOBACCO RESEARCH-USA, Literature Reviews
Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature -- Supplement I

Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature -- Supplement II

Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature --Supplement III

OTHER
Battig. Smoke yield of cigarettes and puffing behavior in men and women

Nordberg. Pharmacodynamic effects of nicotine and acetylcholine biosynthesis in mouse brain

[266] COUNCIL FOR TOBACCO RESEARCH-U.S.A
Hatchell. The influence of genotype and sex on behavioral sensitivity to nicotine in mice

Westfall. Influence of nicotine on catecholamine metabolism in the rat

R.J. REYNOLDS COMPANY
Pritchard. Flexible effects of quantified cigarette-smoke delivery on EEG dimensional complexity

BRITISH-AMERICAN TOBACCO COMPANY, LTD. Unpublished
Isaac. The absorption and effects of nicotine from inhaled tobacco smoke

OTHER
Isaac. Blood levels of nicotine and physiological effects after inhalation of tobacco smoke

[267] COUNCIL FOR TOBACCO RESEARCH-U.S.A
Abood. Comparison of the binding of optically pure (-)- and (+)-[3H]nicotine to rat brain membranes

Andersson. 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

Andersson. 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 adenohypophyseal hormones and corticosterone

Bhagat. Influence of chronic administration of nicotine on the turnover and metabolism of noradrenaline in the rat brain

Fuxe. Increases in dopamine utilization in certain limbic dopamine terminal populations after a short period of intermittent exposure of male rats to cigarette smoke

Fuxe. 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

Tung. Peripheral induction of burst firing in locus coeruleus neurons by nicotine mediated via excitatory amino acids

Wong. Pharmacology of nicotinic receptor-mediated inhibition in rat dorsolateral septal neurones

Yamamoto. Nicotine-induced EEG and behavioral arousal

R.J. REYNOLDS COMPANY
Byrd. Evidence for urinary excretion of glucuronide conjugates of nicotine, cotinine, and trans-3'-hydroxycotinine in smokers

INDUSTRY SUPPORTED SYMPOSIA
Binnie. The effect of cigarette smoking on the contingent negative variation (CNV) and eye movement

INDUSTRY SUPPORTED AMA/ERF STUDIES
Hirschhorn. Studies on the time course and the effect of cholinergic and adrenergic receptor blockers on the stimulus effect of nicotine

Rosecrans. Brain area nicotine levels in male and female rats with different levels of spontaneous activity

TOBACCO RESEARCH COUNCIL LABS., U.K.
Armitage. The effects of nicotine on the electrocorticogram and spontaneous release of acetylcholine from the cerebral cortex of the cat

Wesnes. Smoking, nicotine and human performance

OTHER
Fuxe. On the action of nicotine and cotinine on central 5-hydroxytryptamine neurons

Hasenfratz. Development of central and peripheral smoking effects over time

Hasenfratz. Can smoking increase attention in rapid information processing during noise? Electrocortical, physiological and behavioral effects

Perez de la Mora. Neurochemical effects of nicotine on glutamate and GABA mechanisms in the rat brain

OTHER, Literature Review
Edwards. Smoking, nicotine and electrocortical activity

nicotine is an addictive/dependence-producing drug.[268]

Nicotine psychoactivity and discrimination studies. Industry studies have shown that nicotine is psychoactive and produces clearly discriminable stimulus effects[269] in both animals and humans.[270]

Nicotine reinforcement/self-administration studies. The industry has examined nicotine's ability to serve as a positive reinforcer in self-administration studies involving rats and monkeys. For example, Philip Morris conducted studies in rats demonstrating that nicotine is self-administered by rats and has other hallmark properties of addictive susbstances.[271] The industry-supported research on monkeys led prominent drug addiction researchers Deneau and Inoki to conclude in a paper published in 1967 that nicotine "may be one of

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[268] COUNCIL FOR TOBACCO RESEARCH-U.S.A
Bosse. Age and addiction to smoking

Martin. Tobacco Smoking and Nicotine: A Neurobiological Approach

Rosecrans. Noncholinergic Mechanisms involved in the behavioral and stimulus effects of nicotine, and relationships to the process of nicotine dependence

Rosecrans. Nicotine as a discriminative stimulus: a neurobehavioral approach to studying central cholinergic mechanisms

Svensson. Effect of nicotine on dynamic function of brain catecholamine neurons

Tung. Peripheral induction of burst firing in locus coeruleus neurons by nicotine mediated via excitatory amino acids

Williams. Stability of a factor-analytic description of smoking behavior

TOBACCO RESEARCH COUNCIL LABS., U.K.
Hall. New evidence for a relationship between tobacco smoking, nicotine dependence, and stress

OTHER
Andersson. 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

Nisell. Systemic nicotine-induced dopamine release in the rat nucleus accumbens is regulated by nicotinic receptors in the ventral tegmental area

[269] These effects are evaluated in animals using drug discrimination techniques which enable direct comparisons of the effects of different drugs. Such studies evaluate whether an animal experiences a psychoactive effect from a drug and facilitate comparisons of the effect of the study drug with the effect of other psychoactive drugs. Industry-funded studies have shown that animals can distinguish (discriminate) nicotine from other drugs or a placebo, and can communicate their identification of nicotine (as distinct from other drugs) to the investigator by pressing a bar or providing other behavioral signals. These studies also provide information on the similarity of nicotine's effects to effects of other dependence-producing drugs, including the degree to which nicotine mimics the psychoactive effects of those other drugs. *See* p. 95.

[270] INDUSTRY SUPPORTED AMA/ERF STUDIES
Hirschhorn. Studies on the time course and the effect of cholinergic and adrenergic receptor blockers on the stimulus effect of nicotine

Schechter. Behavioral evidence for two types of cholinergic receptors in the C.N.S.

Schechter. Behavioral tolerance to an effect of nicotine in the rat

Schechter. Effect of mecamylamine on discrimination between nicotine- and arecoline- produced cues

Schechter. Nicotine as a discriminative cue in rats: inability of related drugs to produce a nicotine-like cueing effect

Schechter. Nicotine as a discriminative stimulus in rats depleted of norepinephrine or 5-hydroxytryptamine

Schechter. C.N.S. effect of nicotine as the discriminative stimulus for the rat in a T-maze

COUNCIL FOR TOBACCO RESEARCH-U.S.A
Chance. A comparison of nicotine and structurally related compounds as discriminative stimuli

Rosecrans. Nicotine as a discriminative stimulus: a neurobehavioral approach to studying central cholinergic mechanisms

PHILIP MORRIS TOBACCO COMPANY
Kallman. Nicotine as a discriminative stimulus in human subjects

TOBACCO RESEARCH COUNCIL LABS., U.K.
Morrison. Nicotine injections as the conditioned stimulus in discrimination learning

[271] PHILIP MORRIS TOBACCO COMPANY, Unpublished
DeNoble. Manuscript: Nicotine as a Positive Reinforcer for Rats: Effects of Infusion Dose and Fixed Ratio Size

See also pp. 278-79, *infra*.

INDUSTRY SUPPORTED AMA/ERF STUDIES
Deneau. Nicotine self-administration in monkeys

the substances in tobacco smoke which is responsible for man's use of tobacco."[272] The industry has also funded studies demonstrating that nicotine could enhance the rewarding effects of electrical brain stimulation.[273] A book resulting from The International Smoking Behaviour Conference held at Chelwood Vachery, Sussex, England, in 1978, which was edited by a senior scientist at British-American Tobacco, included a "Conference Overview" stating: "At this stage, we hypothesize that nicotine (possible [sic] interacting with tar) is the main reinforcing agent in cigarettes . . . "[274] Moreover, as noted earlier, the industry has conducted studies showing that nicotine is active in the same dopaminergic pathways that modulate cocaine's effects. These studies are relevant to understanding how nicotine causes addiction.

Tolerance to nicotine. Tolerance to the physiological and behavioral effects of nicotine has been thoroughly studied by the tobacco industry and has been demonstrated to occur in animals as a result of nicotine use.[275]

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[272] **INDUSTRY SUPPORTED AMA/ERF STUDIES**
Deneau. Nicotine self-administration in monkeys

[273] **COUNCIL FOR TOBACCO RESEARCH-U.S.A.**
Olds. Comparision of muscarinic and nicotinic cholinergic agonists on self-stimulation behavior

Pradan. Effects of nicotine on self-stimulation in rats

[274] **INDUSTRY SUPPORTED SYMPOSIA**
Jarvik. Smoking Behaviour -- Physiological and psychological influences. 31. Conference overview

[275] **COUNCIL FOR TOBACCO RESEARCH-U.S.A**
Abood. Acute and chronic effects of nicotine in rats and evidence for a non-cholinergic site of action

Abood. Behavioral and biochemical studies in rats after chronic exposure to nicotine

Andersson. 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

Cronan. Effects of chronically administered nicotine and saline on motor activity in rats

Domino. Tolerance to the effects of daily nicotine on rat bar pressing behavior for water reinforcement

Fuxe. 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

Lapin. Dopamine-like action of nicotine: lack of tolerance and reverse tolerance

Nelsen. Improvement of performance on an attention task with chronic nicotine treatment in rats

Rosecrans. Noncholinergic Mechanisms involved in the behavioral and stimulus effects of nicotine, and relationships to the process of nicotine dependence

Stitzer. Effects of nicotine on fixed-interval behavior and their modification by cholinergic antagonists

Wenzel. Studies on the acute and chronic depressor actions of nicotine in the rat

Westfall. Studies on the mechanism of tolerance to nicotine-induced elevations of urinary catecholamines

R. J. REYNOLDS COMPANY
Bjercke. Anti-idiotypic antibody probes of neuronal nicotinic receptors

Collins. Modulation of nicotine receptors by chronic exposure to nicotinic agonists and antagonists

Marks. Downregulation of nicotinic receptor function after chronic nicotine infusion

PHILIP MORRIS TOBACCO COMPANY, Unpublished
DeNoble. Manuscript: Development of behavioral tolerance following chronic nicotine administration.

INDUSTRY SUPPORTED AMA/ERF STUDIES
Schechter. Behavioral tolerance to an effect of nicotine in the rat

TOBACCO RESEARCH COUNCIL LABS., U.K.
Morrison. The occurrence of tolerance to a central depressant effect of nicotine

OTHER
Larsson. Subchronic treatment of rats with nicotine: effects on tolerance and on [3H]acetylcholine and [3H]nicotine binding in the brain

Nordberg. Effect of acute and subchronic nicotine treatment on cortical acetylcholine release and on nicotinic receptors in rats and guinea-pigs

Nordberg. Effect of long-term nicotine treatment on [3H]nicotine binding sites in the rats brain

Nicotine's withdrawal effects. Scientists funded by the tobacco industry have conducted research on various aspects of withdrawal, including potential neurochemical mechanisms[276] and the effects of withdrawal on performance.[277] Symptoms of withdrawal may include craving, irritability, nervousness, tension, emotional strain, depression, inability to concentrate, sleep disturbance, sweating, gastrointestinal changes, drop in blood pressure and pulse rate, impaired performance, and changes in the electroencephalogram.[278]

The industry has also funded studies showing that tobacco users report "craving" for tobacco.[279]

Continued use of tobacco despite attempts to quit. As described in § II.C.4., infra, the tobacco industry has conducted a number of studies documenting the large percentage of tobacco users who have attempted to quit using tobacco and the very small percentage who have succeeded.

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[276] **COUNCIL FOR TOBACCO RESEARCH-U.S.A**
Andersson. 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

Fuxe. 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

Rosecrans. Noncholinergic Mechanisms involved in the behavioral and stimulus effects of nicotine, and relatinships to the process of nicotine dependence

COUNCIL FOR TOBACCO RESEARCH-U.S.A., Literature Reviews
Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature -- Supplement II

Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature --Supplement III

AMERICAN TOBACCO COMPANY
Finnegan. The role of nicotine in the cigarette habit

[277] **COUNCIL FOR TOBACCO RESEARCH-U.S.A**
Heimstra. The effects of deprivation of cigarette smoking on psychomotor performance

Heimstra. Effects of smoking upon sustained performance in a simulated driving task

COUNCIL FOR TOBACCO RESEARCH-U.S.A., Literature Reviews
Fuxe. Neuroendocrine actions of nicotine and of exposure to cigarette smoke: medical implications

Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature --Supplement III

OTHER
Hasenfratz. Psychophysiological reactions during active and passive stress coping following smoking cessation

[278] **COUNCIL FOR TOBACCO RESEARCH-U.S.A., Literature Reviews**
Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature -- Supplement II

Larson. Tobacco -- Experimental and Clinical Studies -- A Comprehensive Account of the World Literature --Supplement III

AMERICAN TOBACCO COMPANY
Finnegan. The role of nicotine in the cigarette habit

[279] **R. J. REYNOLDS COMPANY**
Robinson. The meaning of addiction: reply to West

OTHER
Hasenfratz. Development of central and peripheral smoking effects over time

Hasenfratz. Post-lunch smoking for pleasure seeking or arousal maintenance?

C. INDUSTRY RESEARCH ON THE CONSUMER'S NEED FOR AN ADEQUATE DOSE OF NICOTINE

1. Industry Research on Importance of Supplying Sufficient Nicotine to Provide Consumer Acceptance and "Satisfaction"

The industry has conducted extensive research establishing that smokers require a certain level of nicotine from their cigarettes and that tobacco "satisfaction" is attributable to nicotine's systemic effects after absorption, rather than to its immediate sensory effects in the mouth, nose, and throat.[280]

In the mid 1970's, BATCO Group Research & Development conducted Project Wheat, a study whose purpose was to identify the different motivations for smoking and correlate those motivations with what BATCO characterized as a smoker's "Inner Need level."[281] The researchers established smokers' "Inner Need level" by identifying the extent to which they smoked to relieve stress, to aid concentration, and as a food substitute to avoid weight gain.[282] In other words, a smoker's "Inner Need" was defined by the extent to which the smoker used cigarettes for the drug effects of nicotine. (See description of the effects of nicotine on mood and weight in FINDINGS § I.D., supra.) The researchers hypothesized that the "Inner Need

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[280] BATCO Group Research & Development Centre. Research Conference. Southampton, England. September, 1984. Page 1. Proposed Revisions for 1985-87:

> *Specific attention will be focussed on nicotine to identify its contribution to product attributes, particularly acceptability and satisfaction. A range of de-nicotinised tobacco blends, supplemented with varying levels of nicotine, will be prepared. These will be used in studies aimed at assessing the specific sensory properties of nicotine and the relationship between tar and nicotine in terms of product acceptability. The studies will provide an initial opportunity to separate immediate product acceptability from longer-term satisfaction.*

[281] *See* Project Wheat - Part 1, note 204, *supra,* at p. 1; Project Wheat - Part 2, note 204, *supra,* at p. 1.

[282] *See* Project Wheat - Part 1, note 204, *supra,* at pp. 5, 10-11, 16-25.

level" would correlate with the smoker's preferred nicotine delivery, and that smokers with higher "Inner Need" would prefer cigarettes that delivered higher nicotine levels.

Project Wheat was intended to help BATCO develop cigarettes that were more acceptable to consumers.[283] The Project Wheat researchers emphasized the importance of nicotine delivery over all other product features (including taste) in achieving an acceptable and satisfying cigarette:

> *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.*[284] [Emphasis added.]

The researchers found that "Inner Need" correlated positively with daily cigarette consumption, depth of inhalation, and anticipated difficulty in giving up smoking; i.e., a higher "Inner Need" smoker would smoke more cigarettes, inhale more deeply, and anticipate greater difficulty in quitting smoking than a lower "Inner Need" smoker.[285] The researchers concluded that "Inner Need" defined a requirement for nicotine by the smoker.[286]

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[283] *See* Project Wheat - Part 1, note 204 *supra,* at p.1.

[284] *See* Project Wheat - Part 1, note 204 *supra,* at p. 3.

[285] *Id.* at p. 2.

[286] BATCO Group R&D *Conference on Smoking Behavior.* October 11-12, 1976, at p. BW-W2-02295.

The Project Wheat researchers also found that smokers of low nicotine delivery cigarettes derive less satisfaction from their cigarettes than smokers of medium or high nicotine cigarettes.

> *Compared with the other two categories of smoker [medium and high], those respondents who smoke low nicotine cigarettes (less than 1.0 mg per cigarette) see their brand as milder, smoother, less satisfying and with not quite such a good taste, comments which are of course perfectly logical.*

Project Wheat - Part 2, note 204, *supra,* at p. 10.

Tobacco industry documents show that smoker "satisfaction" is one of the key attributes of consumer acceptance of tobacco products. These documents also make clear that "satisfaction" is a tobacco industry euphemism that refers to the pharmacological response to nicotine that smokers seek to obtain from smoking.[287] A BATCO scientist, in a 1969 presentation describing the research activities of BATCO Group Research & Development, stated that:

> *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.*

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[287] Wood DJ. BATCO Group Research & Development. "Aspects of the R&DE Function. Notes for a talk given at Chelwood. September, 1969." (The document bears the date July 20, 1970). Page 7.

See also:
Proceedings of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session I. July 9-12, 1984. Session I discusses nicotine's whole body dose and its relationship to smoker satisfaction. *See*, e.g., p. BW-W2-03242: nicotine underlies smoking maintenance "and as a consequence probably provides the basis of smoking satisfaction"; at p. 03243: nicotine's "whole body response [is] associated with satisfaction." Session II discusses methods for assessing smoker response to changing deliveries:

> *German butt analysis [testing of cigarette butts to determine smokers' nicotine uptake] and switching experiments [exposing smokers to cigarettes with varying deliveries] were used to indicate the capacity of external studies [as opposed to laboratory measures of smokers' nicotine uptake] to indicate . . . measurement of smokers changing the way they smoke in order to satisfy their needs.*

Ferris, RP. Notes from the Proceedings of the Smoking Behaviour-Marketing Conference. July 9-12, 1984. Page 21.

Imperial Tobacco. Matinee Marketing Strategy. 1971. Page 11. "A cigarette that delivers physiological satisfaction, yet is low in tar and nicotine, must surely be a major objective..."

BATCO Structured Creativity Conference. Southampton, England. June 25-28, 1984. The purpose of this conference was "to stimulate genuinely innovative product-based project ideas." Moist snuff was proposed as an alternative to cigarettes so as "[t]o capitalise on the potential downtrend of the smoking habit as the only means to achieve nicotine satisfaction by participating in a parallel product market free of social/health concerns and with attractive profitability." [Emphasis added.]

BATCO Group R & D. Research Conference. Rio de Janeiro, Brazil. August 22-26, 1983, at p. BW-W2-01838.

BATCO Group R & D. Nicotine Conference Outline. Southampton, England. June 6-8, 1984, at p. BW-W2-01977.

> *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" of smoking, using this term in the physiological rather than the psychological sense.*[288]

The proceedings to the 1983 BATCO Group R&D Research Conference in Rio de Janeiro state that:

> *The basic assumption is that nicotine, which is almost certainly the key smoke component for satisfaction, is fully released to the body system before exhalation takes place.* [Emphasis added].[289]

A 1984 BATCO Nicotine Conference similarly concluded that:

> *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.*[290]

An RJR-MacDonald Marketing Summary Report from 1983 concludes that the primary reason people smoke "is probably the physiological satisfaction provided by the nicotine level of the product."[291]

The term "satisfaction" is also used by the smokeless tobacco industry to refer to the physiological effects of nicotine on the user. The senior vice president for marketing of the U.S. Tobacco Co. wrote in a memo on new product development:

> *Flavorwise we should try for innovation, taste and strength, nicotine should be medium . . . Virtually all tobacco usage is based upon nicotine, "the kick."*

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[288] *See* Wood, note 287, *supra*, at p. 7.

[289] *See* BATCO Group R & D Research Conference, Rio de Janeiro, 1983, note 287, *supra*, at p. 10.

[290] *See* BATCO Conference Outline, 1984, note 287, *supra*, at p. BW-W2-01977.

[291] *RJR-MacDonald v. Canada*, 5.3 TPLR 4.26.

satisfaction. [Emphasis added.][292]

These documents show that tobacco companies know that tobacco "satisfaction" is provided by nicotine's pharmacological effects on the brain and that the industry strives to offer products that meet this need.

[292] Deposition of Per Erik Lindqvist, *Marsee v. U.S. Tobacco*, Civil Action No. 84-2777R (W.D. Ok. 1986). Transcript of Jury Trial Proceedings at p.1662. In: 1.7 TPLR 3.216.

2. Industry Research to Determine the Minimum and Maximum "Dose" of Nicotine Required by Consumers of Tobacco

The tobacco industry has focused extensive research efforts on methods to assay systemic nicotine absorption so that it may estimate nicotine doses obtained and required by smokers.[293] Tobacco company documents reveal that the primary purposes of these efforts are to better understand the relationship between nicotine dose and nicotine's pharmacological effects in smokers, and to establish the level of nicotine that must be provided in tobacco to produce these effects. Better knowledge of nicotine's dose-response effect in smokers results in a better understanding of how smokers respond to cigarettes with varying nicotine deliveries and how different doses of nicotine may affect smoker satisfaction.

As early as 1970, the tobacco industry had investigated and attempted to determine the

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[293] *See e.g.*:
BATCO. *Fate of Nicotine in the Body*. 1963.

BATCO R&D. *Relation Between 'Extractable Nicotine' Content of Smoke and Panel Response*. March 17, 1967.

BATCO R&D. *Nicotine in Smoke and Human Physiological Response*. March 26, 1970.

BATCO. *Relative Contributions of Nicotine and Carbon Monoxide to Human Physiological Response*. November 15, 1971.

BATCO Group R&D *Further Studies of the Effect of Nicotine on Human Physiological Response*. June 5, 1973.

Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference. Session I. July 9-12, 1984. Page 16 (slides).

See Ayres, note 172, *supra*.

BATCO Group R&D *Nicotine Studies: A Second Report. Estimation of Whole Body Nicotine Dose by Urinary Nicotine and Cotinine Measurement*. March 31, 1981. Page 3.

Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session I (1984):21, slide at p. BW-W2-03243; *Session II* (1984):21, slide at p. BW-W2-02406.

minimum level of nicotine necessary for consumer acceptance. At a BATCO R&D Conference held that year, the conferees agreed that:

> *Nicotine is important, and there is probably a minimum level necessary for consumer acceptance in any given market.*[294]

A 1972 Philip Morris document from a Council for Tobacco Research conference addressing why people smoke reveals the basis of the industry's concern about maintaining nicotine levels above a defined minimum:

> *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. The physiological response to nicotine can readily be elicited by cigarettes delivering in the range of 1 mg of nicotine.* [Emphasis added.][295]

Similarly, the 1984 BATCO Group R & D Nicotine Conference concluded:

> *Cigarettes which have a delivery of less than 0.7 mg of nicotine per cigarette as measured on a smoking machine, do not achieve large volume sales.*[296]

In Project Wheat, discussed in § II.C.1., supra, a 0.7 mg nicotine test cigarette was found to be unacceptable by smokers regardless of the smokers' relative nicotine requirements; the low-dose product was rejected by smokers with both high and low nicotine requirements.[297]

An internal Philip Morris document from 1978, detailing plans to study cigarettes wit

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[294] BATCO Group R&D *Summary Conclusions: Group Research Conference.* St Adele, Canada. September 11, 1970. Page 1.

[295] *See* Dunn, note 133, *supra,* at p. 4.

[296] BATCO Conference Outline, 1984, note 287 *supra,* at p. BW-W2-01977.

[297] *See* Project Wheat - Part 2, note 204, *supra,* at p. 47.

different levels of nicotine at a given tar level, shows that Philip Morris, too, conducted studies to find the minimum level of nicotine delivery necessary to satisfy smokers' need for nicotine:

> *Question 4. Tar delivery delivery being the same, what are the behavioral consequences of smoking low nicotine rather than high nicotine cigarettes?*
> *This question will be answered by conducting a series of shift studies using cigarettes of similar low tar but differential nicotine deliveries. The low nicotine delivery will ensure that the total nicotine in the system remains at or near the nicotine need threshold, thus maximizing the proportion of the day's cigarette consumption which is smoked out of need . . .*
> *The results may shed light on the manner by which nicotine control is achieved.*[297a] [Emphasis added.]

Demonstrating the industry's continuing interest in determining the minimum dose of nicotine that must be contained in a cigarette to provide satisfaction, the BATCO "Group R&D Research Programme, 1984: Proposed revisions for 1985-87," states that studies would be done by the industry

> *to establish the minimum dose of smoke nicotine that can provide pharmacological satisfaction for the smoker.* [Emphasis added.][298]

One key to identifying the minimum and maximum doses of nicotine was the development of a method to accurately measure nicotine in the human body. A 1976 Council for Tobacco Research Annual Report identifies a need for better methods to measure nicotine levels in human smokers:

> *. . .an expansion of information on the actual ranges or durations of plasma nicotine levels attained by human smokers (and users of other forms of tobacco) under actual conditions of life should be attainable . . . Sensitive, specific and rapid assays for plasma nicotine and its major metabolites have*

[297a] Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives - 1979. December 6, 1978. *In* Cong Rec. H7670 (daily ed. July 25, 1995).

[298] *See* BATCO, note 280, *supra,* at p. 2.

long been needed.[299]

Another series of studies conducted by Philip Morris was designed to discover the relationship between the dose of nicotine provided by a cigarette, the level of nicotine in the bloodstream following that cigarette, and the length of time before the nicotine in the bloodstream fell to the point that the smoker experienced the urge for another cigarette. This required Philip Morris to develop an assay for nicotine and saliva and correlate salivary nicotine with blood nicotine:

> *Our theorizing on the role of nicotine suggests that cigarettes will be smoked whenever body nicotine content drops below a certain (unknown) level . . . .*
>
> *We are engaged in systematic investigation of the changes in salivary nicotine content as a function of the time since smoking and magnitude of intake . . . .*
>
> *Assuming that salivary nicotine concentrations will reflect blood nicotine concentrations, we can then proceed to a fourth stage in the research, relating the easily obtained salivary concentrations to the urge to smoke.*[299a] [Emphasis added.]

A 1980 BATCO Group R&D study report, "Method for Cotinine and Nicotine in Blood and Urine," describes an improved analytical method for the simultaneous measurement of nicotine and cotinine (nicotine's major metabolite in man) in samples of blood and urine.[300]

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[299] Report of the Council for Tobacco Research - U.S.A., Inc. Annual Report 1976. Page 12.

[299a] Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives - 1980. January 7, 1980. *In* Cong Rec. H7672 (daily ed. July 25, 1995).

[300] Read GA, Anderson IGM. BATCO Group R&D *Method for Nicotine and Cotinine in Blood and Urine.* Report No. RD 1737-C. May 21, 1980. Page 12 (established and validated an assay for nicotine and cotinine in blood and urine that is sufficiently sensitive to determine changes in ". . . plasma levels of nicotine achieved in response to varying concentrations of or different dose levels of nicotine").

See also New Cigarette Prototypes that Heat Instead of Burn Tobacco. Winston-Salem, NC: R.J. Reynolds Tobacco Co. 1988:457-557. Comparative study of humans smoking the NEW CIGARETTE and a Reference Cigarette. (Compared nicotine pharmacokinetics in smokers smoking the New (heated tobacco) cigarette and a regular burning cigarette to determine whether the New cigarette provided a nicotine dose comparable to a regular burning cigarette. Researchers measured smokers' plasma and urine

The method was developed to better study the systemic effects of nicotine and the extent to which those effects influence smoking behavior and smoker satisfaction. The report states:

> *In some instances, 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. [Emphasis added.]*[301]

> *Naturally, during any study of the biological effect of nicotine it is of paramount importance to accurately assess the dose of nicotine absorbed . . . [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.* [Emphasis added.][302]

A 1981 BATCO Group R&D study developed a rat model to estimate "whole body nicotine dose" by measuring urinary nicotine and cotinine levels. The researchers concluded that the model would likely be a good predictor of nicotine dose in humans and, therefore, would aid in understanding the relationship between nicotine delivery and smokers' choice of particular brands:

> *These results strongly suggest that the whole body dose of nicotine can be predicted from urinary levels of nicotine and cotinine. The findings have immediate and obvious significance to both animal toxicity and human behavioural studies. They are particularly relevant to the development of an understanding of an individual smoker's daily nicotine requirement and the relationship between nicotine dose and smoking behaviour under conditions of brand switching/delivery modification.* [Emphasis added.][303]

A presentation at a 1983 BATCO Smoking Behavior Conference describes how to

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concentrations of nicotine to compare nicotine doses.)

[301] *See* Read, note 300, *supra*, at p. 2.

[302] *Id.* at pp. 2-3.

[303] BATCO Group R&D *Nicotine Studies: A Second Report. Estimation of Whole Body Nicotine Dose by Urinary Nicotine and Cotinine Measurement.* March 3, 1981, at pp. 9-10.

design and execute a study of plasma cotinine as a function of cigarette nicotine delivery.[304] It establishes that there is a linear relationship between plasma cotinine and nicotine delivery. 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 estimates [sic] of nicotine dose and to identify the significance of those measures for the smoker and product design." It was concluded that:

> *[u]nder appropriate conditions plasma nicotine and cotinine measures can be used to estimate daily nicotine intake.*[305]

Using assay methods such as those discussed above, tobacco companies have discovered that smokers obtain a fairly consistent dose of nicotine from tobacco. Moreover, tobacco companies are aware that smokers obtain this dose to maintain a desired blood level of nicotine throughout the day, and that achieving this dose results in smoker satisfaction.[306] For example, following a presentation on the role of nicotine in smoking behavior at the 1976 BATCO Conference on Smoking Behavior, it was observed "that smokers may be people suffering from a nicotine disorder and needed a certain dose level per day."[307] The speaker agreed and referred to a Battelle study which found that the nicotine level of smokers remained constant during the day, dropped during the night, and was restored to near its

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[304] Deines WH. BATCO. *Smoking Behaviour Conference: Overview.* 1983. (Attended by eight B&W employees). Page BW-W2-03280.

[305] Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session I. July 9-12, 1984. Montreal, Canada. Slide at p. BW-W2-02641, "Nicotine Dose Estimation."

[306] Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session I. July 9-12, 1984. Slides at pp. BW-W2-03243, BW-W2-03236: "whole body response: associated with satisfaction . . . [whether] dose of nicotine is adequate or inadequate."

[307] Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference. (Mrs. A.K. Comer, speaker.) Discussion on paper No. 2. October 1976. Southampton, England. Page BW-W2-02150.

daytime constant level by the first cigarette of the day.[308] The conferees then speculated that there may be a maximum dose of nicotine and that after this dose is achieved smokers may use cigarettes for reasons other than obtaining nicotine:

> *A further question in this area was whether there is a maximum nicotine level in smokers and, when this has been achieved, does the smoker smoke for reasons other than to obtain nicotine?*[309]

A paper presented at the 1977 BATCO International Smoking Behaviour Conference concluded that smokers adjust their smoking rate, depending on psychological factors and even diet, to maintain a certain body nicotine content.[310]

Relying on plasma nicotine/cotinine measurements, a 1984 BATCO Nicotine Conference concluded that:

> *[such] measurements can give reliable estimates of the nicotine uptake by groups of smokers, and with suitable precautions, by an individual smoker. Many smokers appear to obtain 12-14 mg of nicotine per day from their cigarettes.*[311]

A BATCO presentation from the 1984 BATCO Smoking Behaviour-Marketing Conference entitled "Current Status and Future Direction of Smoking Behavior Research" contains a discussion of whole body dose and whole body pharmacological properties of nicotine in relation to smoking satisfaction.[312] A chart accompanying the presentation plots a

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[308] *Id.* at p. BW-W2-02151.

[309] *Id.* at p. BW-W2-02151.

[310] BATCO International Smoking Behaviour Conference. Chelwood Vachery, England. 1977. Page 2.

[311] *See* BATCO Conference Outline, 1984, note 287, *supra,* at p. BW-W2-01977.

[312] Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session I. Montreal, Canada. July 9-12, 1984. Page BW-W2-03236.

24-hour nicotine blood level curve, with peaks representing the nicotine dose obtained from cigarettes smoked during the day. Each peak actually represents a series of smaller peaks that indicate the dose of nicotine delivered by each puff. Each puff is characterized as a "pulsed high concentration bolus dose of nicotine."[313]

The report states that among smokers there is broad consistency in the whole body nicotine doses obtained by different groups and types of smokers.[314] This is so despite the fact that smoking products have a wide range of nicotine deliveries and despite wide variations in smoking behavior, such as puff duration, puff intensity, puff volume, puff interval, and depth of inhalation. The report states that the fact that widely disparate smoking behavior nonetheless results in fairly consistent whole body nicotine doses (12-14 mg per day) across a broad range of smokers demonstrates that nicotine underlies smoking maintenance.[315] Smokers maintain a fairly consistent whole body dose or blood level and self-administer additional nicotine doses when total body nicotine dose declines due to metabolism of nicotine. Therefore, the report concludes, the dose of nicotine "probably provides the basis for smoking satisfaction"[316] as it restores the whole body dose to the desired level.

The smokeless tobacco industry has also investigated the dose of nicotine that is absorbed into the blood and bodies of smokeless tobacco users. Pharmacokinetic studies

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[313] *Id.* at p. BW-W2-03238.

[314] *Id.* at p. BW-W2-03241.

[315] *Id.* at p. BW-W2-03241-42.

[316] *Id.* at p. BW-W2-03242.

performed by the U.S. Tobacco Co. (UST) reveal that the researchers were interested in how much nicotine was absorbed into the body, how much was metabolized, and how fast nicotine and its metabolites were eliminated from the body. Documents admitted into evidence in a court case reveal that the company investigated the disposition profile of nicotine and its metabolite in both plasma and urine in naive and habituated users of tobacco snuff.[317] The study found no difference between these two populations. UST also performed a study to compare the pharmacokinetics of nicotine and its metabolites following administration of snuff and cigarettes.[318] According to a report of the study, the purpose of this research was to "delineate the similarities and differences in nicotine pharmacokinetics after acute and chronic use of smoked and smokeless tobacco products."[319]

The tobacco industry has also investigated the difference between minimum acceptable and optimum nicotine levels. Project Wheat was designed to test the assumption that the optimum level of nicotine might vary for different types of smokers. The study report concludes that the optimum nicotine delivery for U.K. male smokers is approximately 1.5 mg of nicotine. An earlier Imperial Tobacco study referenced in the Project Wheat report had similarly concluded that the optimum nicotine delivery for U.K. smokers was around 1.4 mg per cigarette and that stepwise reduction in nicotine delivery caused progressive rejection of

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[317] U.S. Tobacco Co. *Pharmacokinetics of Nicotine and its Major Metabolites in Naive and Habituated Snuff Takers*. Plaintiff's exhibit 3.27 from *Marsee v. U.S. Tobacco* (W.D. Ok. 1986) (Civil Action No. 84-2777R).

[318] U.S. Tobacco Co. *Results of Comparison of Routes of Nicotine Administration.* Plaintiffs exhibit 3.28 from *Marsee v. U.S. Tobacco*, note 317, *supra.*

[319] *Id.*

the 1.4-mg cigarette by consumers.[320]

These documents make clear that the industry is aware that tobacco products must deliver an adequate dose of nicotine, that there is a minimum dose below which the desired pharmacological effects of nicotine are not elicited, and that consumers will not accept a product that does not deliver an adequate dose of nicotine.[321]

[320] *See* Project Wheat - Part 2, note 204, *supra,* at p. BW-W2-01721-2.

[321] Although currently marketed low-delivery products may "yield" less than the amount of nicotine shown in these industry documents to be the minimum accepted dose, machine measured yields may underestimate the amount of nicotine smokers actually obtain from cigarettes. *See* FINDINGS § I.C. at p. 112.

3. Industry Research on How Consumers "Compensate" to Achieve an Adequate Dose of Nicotine

When smokers are given cigarettes with a lower nicotine yield (as measured by a smoking machine), than their regular brands, they often "compensate" by smoking the cigarette more intensely, e.g., by taking larger or more puffs, or by smoking more cigarettes.[322] Tobacco company documents reveal that the industry recognizes both that smokers compensate and that the purpose of compensating behavior is to allow smokers to obtain a dose of nicotine that satisfies their physiological need for nicotine.[323] The industry's

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[322] *See, e.g.:*

Guyatt AR, Kirkham AJ, Baldry AG, Dixon M, Cumming G. *How Does Puffing Behavior Alter During Smoking of a Single Cigarette?* Pharmacol. Biochem. Behav. 1989;33(1):189-195.

Benowitz NL, Hall SM, Herning RI, Jacob P III, Jones RT, Osman AL. *Smokers of Low-Yield Cigarettes Do Not Consume Less Nicotine.* N. Engl. J. Med. 1983;309(3):139-142.

Memorandum from P.N. Lee to H.R. Bentley. *Tar Reduction and Nicotine Compensation.* July 19, 1979. Attached to the memorandum is a document that reviewed the existing scientific literature on smoking compensation prepared by Lee for the UK's Tobacco Advisory Council, July 19, 1979. The author concluded, at page 4, that:

> *Taken together, the evidence above seems to indicate that a smoker, when switching to a brand with lower nicotine yield, will tend to 'compensate' mainly by altering inhalation patterns but partly perhaps by a small increase in consumption.*

[323] "Compensation" is acknowledged in the following documents, among others:

BATCO Group R&D Conference. *The Effect of Puff Volume on "Extractable Nicotine" and on the Retention of Nicotine in the Mouth.* Laboratory Report No. L.314-R. Southampton, England. August 21, 1969.

Creighton D, McGillivray LM. BATCO R&DE. *Relative Contributions of Nicotine and Carbon Monoxide to Human Physiological Response.* Report No. RD839-R. Southampton, England. November 15, 1971. Page 22.

Armitage AK. Some recent observations relating to the absorption of nicotine from tobacco smoke. In: Dunn WL, ed. *Smoking Behavior: Motives and Incentives.* Washington, DC: VH Winston & Sons; 1973:83:

> *The human smoker can and does adjust the dose of nicotine he takes into his mouth very subtly, by adjusting either the size of his puff or the rate at which he puffs (this was shown very clearly by the elegant experiments of Ashton and Watson [1970], to which*

study of compensation by smokers provides compelling evidence that the industry knows that its market is based on nicotine dependence and that tobacco products are nicotine delivery systems.

Tobacco company researchers have repeatedly recognized the phenomenon of compensation and acknowledge that it occurs because smokers are seeking a specific dose of

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Domino [this volume] referred); . . . and the smoke taken into the mouth can be inhaled very deeply, moderately deeply, slightly, or not at all.

BATCO Group R&D Conference on Smoking Behaviour. October 11-12, 1976. Southampton. Table III. Page BW-W2-02251 (questions whether increase in CO can result when a smoker compensates for reduced nicotine delivery to the mouth.)

Thornton RE. BATCO Group R&D *Some "Benefits" of Smoking*. Report No. RD 1461. January 26, 1977.

Courtney JR, Comer AK. BATCO Group R&D *The Study of Human Smoking Behaviour Using Butt Analysis.* Report No. RD 1608. August 7, 1978.

Lee, note 322, *supra.*

Read G, 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.* March 31, 1981. Pages 9-10.

Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Slides at p. BW-W2-02748-02750, 02754-02759.

Id. Koehn E. Potential of nicotine addiction. Page 64, BW-W2-02651.

Id. Pangritz D. Discussion (Minutes). Page 65, BW-W2-02647-02651.

R.J. Reynolds, note 300, *supra,* at pp. 479, 482-3, 490-2.

Tobacco Advisory Council. *Reduction in Sales Weighted Average Cigarette Brand Tar Yield: Problems Associated with the Suggestion to Achieve Further Stages According to a Fixed Timetable* (prepared by TAC for members of the Independent Scientific Committee on Smoking and Health) at p. 3:

There are circumstances in which smokers, when switching to a brand with a reduced tar yield, will tend to 'compensate' whether consciously or subconsciously, if they find some aspect of a new cigarette less acceptable than that of their normal brand, in such a way as to restore to some extent the loss of satisfaction associated with the reduced tar yield itself, or associated with some inevitable consequence of the reduced tar yield, for example reduced nicotine yield. . . .

nicotine from each cigarette. For example, Senior Philip Morris scientist William L. Dunn wrote to an outside researcher in 1975 that smokers compensate for reduced nicotine in cigarettes through a variety of techniques designed to increase the amount of nicotine that enters the bloodstream:

> *The ultimate index [of nicotine consumption] is how much passes over into the bloodstream . . . We're now looking at the fate of the smoke entering the mouth; how much goes down, how much comes back out, and related behavioral events that we anticipate finding to be dose-regulating mechanisms of remarkable precision and sensitivity.*
>
> *Thus to accommodate to the 15 percent reduction in available Marlboro nicotine, the smoker who was getting 50 percent of the available nicotine over into his blood from the Marlboro delivering 1.1 mg of nicotine into a smoking machine now must get 59 percent of what the current Marlboro offers him. He can take bigger puffs, or inhale more from the supply drawn into the mouth . . . or for more efficient extraction of the goodies, he can draw it in deeper or hold it longer.*[323a] [Emphasis added.]

[323a] Letter to Stanley Schachter, Columbia University from William L. Dunn. September 8, 1975. *In* Cong Rec. H7662 (daily ed. July 25, 1995).

See also:

Memorandum to T.S. Osdene from W.L. Dunn. Behavioral Research Accomplishments-1977. December 19, 1977. *In* Cong Rec. H7666, *supra*:

> *[N]icotine compensation is a real phenomenon . . .*

In this report, the researchers describe a study confirming their hypothesis that "some people smoke for nicotine, and that these people try to obtain a relatively constant amount of nicotine from their cigarettes." The internal study showed that smokers they called "nicotine regulators" obtained more nicotine from their cigarettes following a period of deprivation than when allowed to smoke freely.

Dunn WL. 1600/Smoker Psychology/January 1-31, 1976 [Monthly Report]. February 10, 1976. *In* Cong Rec. H7663, *supra*. This report describes a new study being undertaken by Philip Morris "to identify nicotine regulators and non-regulators." The study design involved measuring "the daily nicotine intakes" of a group of smokers when allowed to smoke their own cigarettes, then measuring their nicotine intakes when given cigarettes with higher or lower delivery than their own brand:

> *We want to find out if we can "force" our potential regulators to modify their puff volumes, inhalation volumes, and/or smoke retention times in order to obtain their usual nicotine dose.* [Emphasis added.]

Memorandum from W.L. Dunn to T.S. Osdene. Quarterly Report - January 1-March 31, 1975. March 25, 1975. *In* Cong Rec. H7662, *supra*. Reports on a Philip Morris study showing compensation behavior in smokers:

> *Preliminary data suggest that more cigarettes are smoked and more puffs taken when the observations follow a two-hour deprivation period than following two hours when smoking is*

In 1984, the minutes of the BATCO Smoking Conference included the following summary of the researchers' discussion of compensation:

> *Compensation*
>
> *There are two general forms of compensation:*
>
> *a) Number of cigarettes smoked eg. [sic] low tar smokers increasing consumption.*
> *b) Puffing/inhalation regime eg. [sic] increasing or decreasing/puff volume, duration, puff frequency, amount inhaled.*[324]

The researchers further stated that:

> *it is accepted that nicotine is both the driving force and the signal (as impact) for compensation in human smoking behaviour.*[325]

In fact, the tobacco industry is not merely aware of compensation behavior but has conducted extensive research on compensation. Company researchers administer cigarettes that deliver a range of nicotine doses to smokers and then measure the amount of nicotine

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permitted.

Dunn WL. 1600/Smoker Psychology/October 1-31, 1977 [Monthly Report]. November 11, 1977. *In* Cong Rec. H7665, *supra*. Philip Morris researchers describe a study on whether smokers who smoke many cigarettes out of "need" will demonstrate compensation behavior if given low nicotine cigarettes.

Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives - 1980. January 7, 1980. *In* Cong Rec. H7665, *supra*. This document describes Philip Morris' development of specialized monitoring devices designed to determine whether smokers, when given cigarettes with different nicotine deliveries "regulate or 'titrate' the amount of nicotine taken up via inspiration of smoke."

[324] Brooks GO. Minutes from BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Page 55.

[325] *Id.* at p. 56.

Later at the same conference, there was a discussion of a study showing that when given a cigarette with a significantly different yield than his own, a smoker will alter his puffing behavior but will not alter his inhalation pattern. To explain this phenomenon, "[d]elegates were reminded that a smoker extracts virtually all of the nicotine from the smoke even with a shallow inhalation. Therefore what has he to gain by deliberately inhaling more deeply?" *Id.* at p. 69.

actually absorbed by the smoker, per puff or per cigarette.[326] These studies show that smokers tend to obtain close to the same amount of nicotine from each cigarette, despite differences in yield as measured by the smoking machine. In a 1974 BATCO conference, researchers described the results of one such study:

> *The Kippa study in Germany 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).* [Emphasis added.][327]

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[326] *See:*
BATCO Group R&D Conference on Smoking Behaviour. Southampton, England. October 11-12, 1976. Page BW-W2-02253-85.

Adams PI. Research Dept., Imperial Tobacco Ltd. Changes in personal smoking habits brought about by changes in cigarette smoke yield. In: *Proceedings of the Sixth International Tobacco Scientific Congress.* November 1976. Pages 102-108.

BATCO, note 310, *supra,* at p. 2.

> *Although conflicting results were presented, the prevailing view is that smokers do tend to compensate in some way when going from a high tar (nicotine) to a low tar (nicotine) cigarette, or vice versa. Studies have been carried out with high and low nicotine cigarettes, "anti-smoking" cigarette holders, and cigarettes with shortened tobacco sections.*

Pritchard WS, Robinson JH. The sensory role of nicotine in cigarette "taste", smoking satisfaction, and desire to smoke. As abstracted in: *International Symposium on Nicotine: The Effects of Nicotine on Biological Systems II.* Satellite Symposium of the 12th International Congress of Pharmacology. Montreal, Canada. July 21-24, 1994. Page 113.

See also:
Ashton H, Stepney R, Thompson JW. Self-titration by cigarette smokers. *British Medical Journal.* 1979;2:357-360.

[327] Notes on the BATCO Group R&D Conference at Duck Key, FL. January 12-18, 1974. (Attended by Hughes, Sanford, Esterle of B&W). Page 2.

See also Notes from the German presentation. BATCO Group R&D Conference 1979. Part I, February 5-9, 1979. Page BW-W2-03536:

> *One of the interesting results from the KIPA studies is that cigarettes which vary from 1.1 - 0.4 mg nicotine by machine smoking are smoked by humans in the narrow range of 0.8 - 0.7 mg nicotine.*

At a 1984 conference, a BATCO researcher also reviewed several other studies indicating that when smokers are given cigarettes with higher or lower nicotine levels than their regular brands, they tend to adjust both the number of cigarettes they smoke and the way they smoke them to attain a steady dose of nicotine.[328] In support of this conclusion, the BATCO researcher presented a chart showing that between 1965 and 1975, as the machine-measured nicotine yield of cigarettes went down, the annual consumption of cigarettes per smoker went up.[329]

The researcher concluded that "increased consumption is related to reduced nicotine"[330] but that the relationship is not one-to-one. Instead, he found that a 10% reduction in nicotine resulted in a 1% rise in the number of cigarettes smoked, and a 50% reduction in nicotine resulted in a 10% rise in the number of cigarettes smoked.[331] As a result of this finding, he concluded that "most compensation must occur at the individual cigarette level;"[332] i.e., by altering the way the smokers smoked individual cigarettes. In fact, the data he presented showed that when smokers were given cigarettes with a range of nicotine yields, their nicotine intake from each cigarette hovered around the amount they took in from their regular brand rather than varying to the degree that would have been predicted from the

[328] Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Ferris. Pages BW-W2-02748 - 02750, BW-W2-02754 - 02759.

[329] *Id.* at p. BW-W2-02754.

[330] *Id.* at p. BW-W2-02755.

[331] *Id.*

[332] *Id.*

machine yields.[333]

Other tobacco company studies show similar results.[334] A report on research conducted by Philip Morris Europe in the early 1970's concluded that smokers tended to obtain the same amount of nicotine from a cigarette, regardless of the nicotine content of the cigarette or its machine-tested yield:

> *The most frequent nicotine yield was 0.4 to 0.5 mg of nicotine per cigarette. This yield is not dependent upon the nicotine content of the tobacco and is not related to the nicotine yield under Coresta (machine) smoking conditions. The difference between nicotine yields obtained under standard laboratory procedures and yields obtained under "real" smoking conditions is explained by the existence of a compensation mechanism in the smoker. This compensation mechanism seems to be in operation for a proportion of the consumer population to adjust the nicotine yield to their needs or liking.*[334a]

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[333] *Id.* at p. BW-W2-02757. Ashton, Stepney, and Thompson (1979b). *Expected and observed nicotine intake in a brand-switching experiment.* (Chart.)

[334] *See:*

BATCO Group R&D Proceedings of the R & D Conference. Montreal, Canada. October 25, 1967. Page 4.

> *The development of low TPM [total particulate matter], low nicotine cigarette should be expanded. This raises the question of the level of nicotine required and the consumer study by Bristol can be helpful in determining this . . . there was evidence that in Germany per capita cigarette consumption increased for the lower nicotine brands.*

Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference, Session I. July 9-12, 1984. Presentation slide BW-W2-03231. Under the heading *Brand Switching Down Delivery*, the chart provides a list of three "means to achieve a higher dose[:] . . . increase in puffing parameters, increase in numbers of cigs. smoked, more puffs taken."

Read GA. Internal v. external studies. Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session II. July 9-12, 1984. Page 19.

> *The German butt analysis studies have indicated how smokers respond to reductions in machine smoked nicotine deliveries under natural smoking conditions. This observation of product oversmoking supports the laboratory findings of an increase in smoking behaviour parameters in subjects switched to lower delivery products.*

R.J. Reynolds, note 300, *supra,* at pp. 479, 482-3, 490-2.

[334a] Gustafson and Haisch. PME Research: 1972-1974. *In* Cong Rec. H7662 (daily ed. July 25, 1995).

[Emphasis added.]

Thus, the tobacco companies' own studies demonstrate that smokers use the cigarette as a nicotine delivery system and vary their smoking behavior to obtain a specific dose of nicotine.

4. Industry Research and Knowledge of Tobacco Users' Inability to Quit

Tobacco companies are aware of the large number of smokers who have tried to quit using tobacco, and of the very small number who actually succeed. The evidence known to tobacco companies about smokers' unsuccessful attempts to quit shows that tobacco companies know that a large percentage of their market consists of people who demonstrate one of the characteristic features of addiction. See p. 81 et seq.

The great difficulty smokers experience when they try to quit was conceded by Joseph F. Cullman, III, the former chief executive officer of Philip Morris. Mr. Cullman was called as a witness in the Cipollone lawsuit and gave the following answers in response to questions from one of the plaintiff's attorneys:

Q. But it is difficult [to quit]?

A. That's what it says here and I'm not disagreeing with it.

Q. They said it was very difficult. Do you agree with that?

A. I would say it's difficult.

Q. And it's difficult for the vast majority of smokers, you would agree with that, too, would you not?

A. That's a question of semantics. What's the vast majority? A lot of smokers have a hard time quiting [sic].

Q. Let's see, most smokers have a tough time giving up cigarettes?

A. Well, if they didn't, there would be many fewer smokers than there are today.[335] [Emphasis added.]

Furthermore, internal Brown and Williamson documents reveal that the tobacco

[335] Examination of Joseph Cullman, III, former chief executive officer, Philip Morris, Inc. *Cipollone v. Liggett Group, Inc., et al.*, Civil Action No. 83-2864 (SA)(D.N.J.). February 29, 1988. Afternoon Session. Transcript of proceedings, at pp. 3311-3314.

industry is extremely interested in rates of attempted and successful quitting, and keeps close track of these rates. At the 1984 BATCO Smoking Behaviour-Marketing Conference, attended by representatives from various BATCO companies, including Brown and Williamson, each of the participating companies was asked to fill out a questionnaire that asked how many smokers in their respective countries attempted to quit in each of the previous 5 years and how many actually quit (for as long as 6 months). Brown and Williamson's response to the questionnaire, which covered quitting rates in the United States, reported that, for the years 1981 through 1983, 32 million to 34 million Americans attempted to quit each year, while only 9 million to 10 million of those were able to quit for as long as 6 months.[336] Thus, Brown and Williamson's own data reveal that while almost half the total number of U.S. smokers attempted to quit each year, only about a third of those who tried to stop smoking were able to quit for as long as 6 months. These tobacco industry data suggest that at least one-third of U.S. consumers of cigarettes are purchasing cigarettes because they are unable to stop smoking.

In fact, data reported at the same conference showed that the percentage of smokers who continue to smoke even though they do not want to is much higher than suggested by 6-month data. Data from the Canadian tobacco company representatives indicated that rates of permanent quitting were well below quitting rates reported at 6 months. A Canadian participant reported to the assembled BATCO researchers that only 10% to 12% of those Canadian smokers attempting to quit succeeded for up to 1 year; less than 4% were able to

[336] Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session I. July 9-12, 1984. Page BW-W2-03212. No figures were provided by B&W on attempts to quit for the years 1979 and 1980.

quit permanently.[337]

The presenter responsible for summing up the results of the conference questionnaire agreed that, while a large percentage of smokers do not want to smoke, most of those smokers feel compelled to continue to smoke:

> *Although intentions and attempts to quit are relatively high (30-40% of smokers [in a given year]), the actual success rate of quitting is relatively low and stable.*[338]

It was thus well known to the participating companies that a very large percentage of their customers were smoking not out of choice but because they could not quit.

Other companies also understand that many of their consumers would like to quit but are unable to do so.[339] A Philip Morris researcher who studied a "cold turkey" campaign in

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[337] Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference. July 9-12, 1984. Session IV. Page BW-W2-03381. *See also* Session III at p. 83 (BW-W2-03379-03382). The researcher also presented data showing that while 22% of smokers claimed that they intended to "cut down," in fact "both the claimed and calculated rate of daily usage (21.6 and 25.6 [cigarettes] respectively) have increased since the introduction of lights." (BW-W2-02790, 03379, 033820). Other data reported at the same conference provided additional confirmation of the large percentage of smokers who would prefer not to smoke. A study on "Smoker Consonance-Dissonance Breakdown" was presented which showed that approximately 75% of smokers surveyed had attempted to quit, and approximately 60% were currently serious about quitting. Session III at p. BW-W2-03386.

See also, Larsen PS, Silvette H. *Tobacco Experimental and Clinical Studies: A Comprehensive Account of the World Literature, Supplement I.* (1968), Chapter 15; *Supplement II* (1971), Chapter 17; *Supplement III* (1975), Chapter 21, which contain discussions of surveys concerning smokers' desire to quit and difficulty in successfully quitting. This review was funded by the Council for Tobacco Research.

[338] Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session IV. July 9-12, 1984. Page 12.

[339] *See:*
R.J. Reynolds Tobacco Company, response to Citizen Petitions 94-0069/CP1 and 94P-0077/CP1. November 2, 1994. Pages 66-69.

RJR-MI Brand Group and Ogilvy & Mather (Canada) Ltd. *Vantage Brand Positioning Statement.* 1979. Page 80041:

B. User Image

Primarily female, white collar, extremely concerned about their health, and would like to

the small Iowa town of Greenfield in 1969 reported that those who succeed in quitting smoking over the long term are a much smaller group than those who would like to quit and who attempt to quit.[340] The researcher cited the findings of Hunt and Matarazzo[341] in proposing that most attempts to quit smoking are not long-lasting: "[I]n summarizing many reports of long-term quitting using various techniques, [the authors] show that the percentage of nonrecidivists [successful quitters] decreases as a function of time . . . in a negatively accelerated fashion."[342] The Philip Morris researcher found that in Greenfield only 28% of those smokers who agreed to quit as part of the cold turkey campaign were still not smoking after 7 months. The researcher then observed that the small number of Greenfield residents who managed to stay off cigarettes for more than 7 months was, based on other published reports of success rates for quitting smoking, about average.[343]

The researcher also described findings that revealed in part why it is so hard for smokers to quit. He reported that smokers who quit for more than 7 months continued to

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quit smoking.

Kwechansky Marketing Research for Imperial Tobacco Ltd. *Project 16*. October 18, 1977. Page vi.

Kwechansky Marketing Research for Imperial Tobacco Ltd. *Project Plus/Minus*. May 7, 1982. Page i.

[340] Ryan FJ. Philip Morris Research Center. Cold turkey in Greenfield, Iowa: a follow-up study. In: Dunn WL, ed. *Smoking Behavior: Motives and Incentives*. Washington, DC: VH Winston & Sons; 1973:231-241.

[341] *Id.* at p. 233.

[342] *Id.* at p. 233.

[343] Ryan FJ. Bird-I. A study of the quit-smoking campaign in Greenfield, Iowa, in conjunction with the movie, *Cold Turkey*. Appendix 1, p. 1000348712. The author also appended to the unpublished version of this report excerpts from internal company memos, pointing out that although the cold turkey campaign in Greenfield was as intense an anti-smoking effort as could be imagined, "carton sales at the Super Value store have shown a strong increase since the dog days of August."

suffer a variety of adverse effects related to quitting, including weight gain, restlessness, depression, ill-temper, constipation, nervous mannerisms, and loss of energy.[344] These are some of the classic symptoms of nicotine withdrawal, described earlier.[345]

Market research documents also show that tobacco companies have conducted research in quitting behavior and have documented the reasons why people quit and why they fail to quit, despite a desire to do so.[346] A market research firm reporting on a survey of smokers' views about the health implications of smoking observed that:

> *a minority expresses a resentment about the addictive aspects of smoking. Being "out of control," unable to quit causes them to feel somehow unworthy . . . . Nicotine is usually singled out as the culprit here. However, even these smokers would be reluctant to give up the satisfaction elements in smoking. So they are in a quandry [sic]."* [347]

Another market research firm reported its findings about the inability of young smokers to quit when they want to:

> *However intriguing smoking was at 11, 12 or 13, by the age of 16 or 17 many regretted their use of cigarettes for health reasons and because they feel*

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[344] *See* Ryan, note 340, *supra,* at p. 234.

[345] *See* FINDINGS § I.B., *supra.*

[346] *See e.g.* The Creative Research Group. *Project Viking, Vol. III: Product Issues.* Prepared for Imperial Tobacco Ltd., Feb/Mar 1986.

Kwechansky Marketing Research for Imperial Tobacco Ltd. *Project Plus/Minus.* May 7, 1982. Pages 41-51.

[347] The Creative Research Group. *Project Day-Exploratory Phase in Edmonton.* Prepared for Imperial Tobacco Ltd. August 1988. Page 11.

See also Market System, Inc. *Project Eli Focus Groups Final Report.* Prepared for Imperial Tobacco Ltd. July, 1982. Page 5. Smokers refer to smoking as "satisfying a craving."

unable to stop smoking when they want to.[348]

The fact that many smokers smoke even though they do not enjoy smoking is conceded in a candid marketing research document prepared for Imperial Tobacco Ltd., which reported that it is particularly difficult to sell cigarettes by "trading on the positives" because the industry is "vexed by the unique problem that users of the category do not necessarily like the product."[349] Another document reports that many smokers of ultra-low tar and nicotine cigarettes want to quit and "refer to their behavior in terms of 'satisfying a craving' while smokers of stronger cigarettes talk about taste and satisfaction."[350]

In summary, the tobacco companies' data show that users find it extremely difficult to quit smoking and that many tobacco users would quit if they could. Their data also show that, of those smokers who try to quit, only a small percentage succeed permanently. Consequently, tobacco manufacturers are aware that the large percentage of their customers who try to quit but fail continue to buy and use tobacco products, in large part to satisfy their dependence on nicotine-containing tobacco. Use of tobacco to satisfy nicotine dependence is

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[348] *See* Kwechansky Marketing Research. *Project 16*, note 339, *supra,* at p. vi.

See also Kwechansky Marketing Research. *Project Plus/Minus*. May 7, 1982. Study Highlights. In a follow-up study, the same market research firm reported the following results:

> *The desire to quit seems to come earlier now than before, even prior to the end of high school....However, the desire to quit, and actually carrying it out, are two quite different things, as the would be quitter soons [sic] learns...*

According to a report in *Newsday*, a 1957 "motivation survey" prepared for Liggett on smoker attitudes about smoking amid growing health concerns contained the following statement:

> *What smokers are really saying is: 'I wish I had never started to smoke . . . but now that it's got me, I know that I can't stop.'*

Riley J. Smoke-Trial Documents Make Titillating Reading. *Newsday*. July 19, 1988.

[349] *See* The Creative Research Group Ltd., note 346, *supra,* at p. 64451.

[350] *See* Market System Inc., note 347, *supra,* at p. 5.

a use that affects the structure or function of the body.

D. INDUSTRY PRODUCT DEVELOPMENT RESEARCH TO ENSURE AN ADEQUATE DOSE OF NICOTINE

1. Industry Emphasis on Nicotine in Product Development Research

Tobacco industry documents show that adequate nicotine delivery is a dominant consideration in product development research. As discussed above, many tobacco industry documents demonstrate the industry's understanding that the amount of nicotine delivered from tobacco must not fall below a certain threshold.[351] These and other documents also reflect the industry's recognition that below that threshold, tobacco fails to deliver a pharmacologically active dose of nicotine, and that consumers will reject the resulting product. The documents described in this and the next section reveal the industry's extensive product development research to maintain or increase nicotine delivery from tobacco products.

Industry patents disclose that the industry has long recognized the importance of developing methods to maintain or increase the amount of nicotine in tobacco, and that the purpose of these methods is to ensure that consumers experience nicotine's pharmacological effects. For example, a patent held by Philip Morris states:

> *Maintaining the nicotine content at a sufficiently high level to provide the desired physiological activity, taste, and odor . . . can thus be seen to be a significant problem in the tobacco art. The addition of nicotine to tobacco in such a way that it remains inert and stable in the product and yet is released in a controlled amount into the smoke aerosol when the tobacco is pyrolyzed, is a*

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[351] *See* documents cited in FINDINGS § II.C.1. and 2.

See also F.H. [Initials of BATCO R&D employee] Memorandum. *Developments in the Product in the Next Ten years.* 1973-1974. Page 3. ("The maintenance of adequate levels of nicotine in cigarettes could become a difficult problem as more synthetics are used.")

result which is greatly desirable. [Emphasis added.][352]

In fact, over the past several decades, enhancing and optimizing nicotine delivery has been a major focus of tobacco industry product design research. The American Tobacco Company (ATC) devoted substantial research to finding methods of increasing the amount of nicotine delivered by its cigarettes. For example, in 1963, ATC conducted research on increasing the nicotine yield in Lucky Strike cigarettes by increasing the proportion of Burley tobacco, a high-nicotine tobacco, in the tobacco blend used to make the cigarettes.[353] The company found that it could increase the nicotine yield of the cigarettes up to 10% in this manner and that smokers perceived the resulting cigarettes as having more "strength."[354] In 1969, ATC test-marketed Lucky Strike cigarettes that had been enriched with added nicotine.[355] ATC developed other methods for increasing the amount of nicotine delivered by its cigarettes over the subsequent decades, including:

- the use of carbon tips in the filter "impregnated with nicotine or nicotine salts" to

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[352] U.S. Patent No. 3,280,823. Bavley A, Air D, Robb E II. *Additive-Releasing Filter for Releasing Additives into Tobacco Smoke.* Philip Morris, Inc. October 25, 1966. Page C1:43-48.

[353] "Tobacco Blends for Filter Cigarettes: Effect of Increasing the Concentration of Burley Tobacco in a Blend" at Page 1. June 21, 1963. The various ATC documents discussed in this section were provided by the company to the Subcommittee on Health and the Environment of the House Energy and Commerce Committee, and attached as exhibits to the Dec. 20, 1994, Subcommittee Staff Report, entitled, "Evidence of Nicotine Manipulation by the American Tobacco Company."

[354] *Id.* at pp. 4, 5. The company again experimented with increasing the nicotine content of Lucky Strikes through changes in the tobacco blend in 1968. Memo to Mr. H.V.H. Stoever, Jr., Manager, Durham Branch, from O.N. Coty, Manager-Quality Control, Research and Development (June 4, 1968). Pages 1-2; Tables X003384-3387. *See also* memo to R.F. MacDonald from O.N. Coty, July 5, 1968.

[355] Letter from Chadbourne & Park, representing ATC, to the Honorable Henry A. Waxman, Chairman, Subcommittee on Health and the Environment of the House Committee on Energy and Commerce. Oct. 14, 1994. Page 3 of attachment to ATC Response.

increase the nicotine content of cigarette smoke;[356]

- direct addition of commercial nicotine to reconstituted tobacco;[357]
- addition of nicotine to the "finishing flavor" used in Pall Mall 85's;[358]
- growing tobacco plants in different locations to determine, among other things, whether varieties with different ratios of nicotine to tar could be produced;[359]
- addition of nicotine to the "dip casing" (one of several solutions used in the manufacture of cigarettes) to compensate for loss of nicotine from other manipulations

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[356] Memo to E.S. Harlow from ATC Analytical Chemistry Section, Group I, Aug. 8, 1963, Progress Report, March 1962-July 1963," with attached smoke analysis 2-12-68, 2-1-68, 1-29-68, 1-15-68, 1-4-68, 12-28-67, 12-22-67 (impregnating a carbon tip with nicotine permitted transfer of about 22% of the added nicotine to the smoke).

[357] ATC experimented with adding nicotine to reconstituted tobacco on several occasions. *See*:

"The Effect of the Addition of 1% Nicotine on the Quality of RC Tobacco" (Oct. 8, 1963) (nicotine citrate was added to reconstituted tobacco to triple its nicotine content, from about 1/2% to about 1 1/2%). Pages 1,2,6.

"Evaluation of Nicotine-Fortified RC-A Tobacco" (May 2, 1968) (nicotine malate was added to reconstituted tobacco to increase its nicotine content from .94% to 1.27%; the company concluded that "to markedly improve RC [reconstituted tobacco] . . . in addition to increasing its nicotine content it should also include the other constituents present in natural leaf tobacco, particularly those tobaccos of high nicotine content."). Pages 1-2.

Memo to J.B. McCarthy, Executive Vice President, from R.M. Irby, Jr., Manager-New Products Div., Research and Development, "Nicotine Content of Reconstituted Tobacco." June 5, 1974. (Nicotine added to tobacco extract which is applied to reconstituted tobacco, doubling the nicotine content of the reconstituted tobacco from 0.9% to about 1.8%.) Page 1.

[358] Memo to E.S. Harlow from O.N. Coty *Special PALL MALL 85's with added nicotine*. July 12, 1968. (Nicotine content of final blend increased by 0.47%; smoke panel preferred regular blend.)

[359] Memo to Dr. E.C. Cogbill, Manager-Analytical Research, Research and Development from J.M. Moseley Manager-Basic Materials Research, Research and Development. *Genetic Variation in "Tar" Delivery*. January 8, 1969.

of the tobacco blend;[360]

- addition of nicotine to both Pall Mall and Lucky Strike cigarettes, increasing their nicotine content 35% per cigarette (41% per puff for Pall Mall, slightly less per puff for Lucky Strike);[361] and
- addition of nicotine to tobacco stems (which are used in the manufacture of cigarettes) to increase their nicotine content from 0.5% to 1.87%.[362]

ATC also considered replacing the tobacco used in its reconstituted tobacco with "high nicotine tobacco such as Malawi sun-cured scrap (5% nicotine)" to increase the nicotine content from 0.9% to about 1.6%,[363] increasing "nicotine transfer to the smoke" by dilution or use of filter additives,[364] and increasing, in various ways, the proportion of nicotine relative to tar by adding nicotine to the tobacco, the filter, and the cigarette paper.[365]

Philip Morris documents show that it, too, conducted research on altering and optimizing nicotine delivery from its cigarettes. According to a 1972 memo from William

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[360] Memo to Mr. J.B. McCarthy, Vice President, Manufacture and Leaf from J.T. Ashworth, Manager - Process Development, Research and Development. "Experimental *LUCKY STRIKE Cigarettes (RC-E)*." May 29, 1969. (The author recommends that the experimental cigarettes with added nicotine replace the regular Lucky Strike brand; these may be the cigarettes that were test marketed in 1969). This memo refers to nicotine as "Compound W". An earlier ATC memo instructs employees to refer to nicotine as "Compound W" in all future experimental work, reports, and memorandums. ATC memo to W.W. Sadler, J.G. Brooks, and R.D. Chumney, from John T. Ashworth, "Compound W" (May 14, 1969).

[361] Memo to Mr. V.B. Lougee, III, from R.M. Irby, Jr. *Compound W.* April 29, 1974. Pages 1-2.

[362] *Id.* at p. 2.

[363] Irby memo, note 357, *supra,* at p. 2.

[364] *Id.* at p. 3.

[365] Memo to Dr. P.H. Leake from P.M. Pedersen, transmitting a copy of *A Study of the Nicotine to Tar Ratio.* April 18, 1977. Pages 3-4.

Dunn, a senior official at Philip Morris, research was underway to identify optimal nicotine levels for menthol cigarettes:

> *This study has a three stage design. The first stage is designed to identify those nicotine delivery levels which we might reasonably wish to consider for menthol cigarettes. Having identified these nicotine delivery levels, in stage 2 we will determine combinations of nicotine and menthol which make for optimal acceptability. And then in stage 3, cigarettes with these combinations will be tested against current brands of known quality and sales potential.*[365a]

Philip Morris was thus engaged in research in which nicotine delivery was systematically manipulated, independent of other tobacco variables.

Industry patents from various tobacco companies show that substantial research throughout the industry has been directed at developing methods for selectively increasing nicotine levels and the amount of nicotine delivered by tobacco products.[366] BATCO documents show significant research efforts directed at increasing nicotine delivery. A 1978 BATCO R&D Conference included a discussion of the economic importance of increasing the proportion of nicotine that is actually delivered from the tobacco to the smoker during the consumption of the product:

[365a] P.A. Eichorn and W.L. Dunn. Quarterly Report-Projects 1600 and 2302. October 5, 1972. *In* Cong Rec. H7649 (daily ed. July 25, 1995).

[366] *See, e.g.*:
U.S. Patent No. 5,031,646 at C5:65-68 ("nicotine can be incorporated into the expansion solvents used to provide a volume expanded processed tobacco material having a high nicotine content").

U.S. Patent No. 4,676,259 at C2:30-33, 53-56 ("The present invention provides a nicotine-enhanced smoking device with a high nicotine release efficiency").

U.S. Patent No. 4,898,188 at C1:37-47 (utilizing supercritical extraction to transfer nicotine from high-nicotine tobacco to lower-nicotine tobaccos, thereby increasing the nicotine content of the latter).

U.S. Patent No. 5,065,775 (describing technology for modifying the nicotine content of tobacco filler, enabling a manufacturer to double the nicotine content of tobacco).

> *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.*[367]

In other words, BATCO wanted to increase the amount of nicotine delivered to the consumer without changing the amount of nicotine already present in the tobacco. (This is what one or more tobacco companies have in fact achieved by the use of the "ammonia technology" described in § II.E., infra.) A 1968 BATCO study approached the objective of enhancing nicotine delivery from a different angle. This study was intended to help develop methods of increasing the smoker's absorption of nicotine, while decreasing other undesirable physiological effects of inhaling tobacco smoke. The study examined the factors that influence the amount of nicotine that is absorbed from tobacco through the oral mucosa (mouth), with an eye toward designing products that would increase nicotine absorption in the mouth, thus avoiding or reducing the need to inhale smoke into the lungs. The study authors maintained that:

> *If it can be shown that appreciable amounts of nicotine can be absorbed via the mouth, and which factors contribute to enhanced absorption, it may be possible to design cigarettes so that it would only be necessary to inhale the smoke to a very limited extent.*[368]

This focus on absorption makes clear that the industry's primary interest is in delivering nicotine to the blood for its systemic effects, rather than in the immediate sensory effects in the mouth (e.g., flavor). Methods of optimizing nicotine delivery were also discussed at two

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[367] BATCO Group Research & Development Conference, Sydney. March 1978. Page 4. Notes on Group Research R&D.

[368] Evelyn SR. BATCO Group Research & Development. *Absorption of Nicotine via the Mouth: Studies Using Model Systems*. Report No. RD 560-R. May 9, 1968. Page 4.

separate BATCO R&D conferences in 1984.[369]

The industry has also developed product design options to manipulate the amount of nicotine delivered to ensure smoker satisfaction, even at the level of the individual puff. For example, an industry patent states:

> *It is a further object of this invention to provide a cigarette which delivers a larger amount of nicotine in the first few puffs of the cigarette than in the last few puffs.*[370]

The focus on nicotine delivery in product development and the fact that nicotine manipulation is intended to ensure that consumers experience nicotine's pharmacological effects is also shown by the tobacco industry's research to improve tobacco "satisfaction." "Satisfaction" is one of the industry's principal product development research objectives. As already described in FINDINGS § II.C.1., supra, the term "satisfaction" is generally used by the tobacco industry to refer to the ability of a tobacco product to satisfy the consumer's desire for the pharmacological

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[369] *See* BATCO Group R&D Research Conference. September 1984. Proposed Revisions for 1985-1987. Pages 1-2:

> *The experimental cigarettes used in 1(b)[denicotinized, then supplemented with varying levels of nicotine] will also be used to improve the efficient use of smoke nicotine through pH modification. These studies will identify the relationship between nicotine dose and nicotine-related subjective improvement. This will further help to identify the relationship between product acceptability and smoker satisfaction.* [Emphasis added.]

Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Ferris at p. 81:

> *How we use this perspective in terms of marketing action requires careful consideration since most of this evidence is ostensibly of industry strategic defence value. However product development to optimise efficiency of nicotine delivery, and a better understanding of the "visual-tactile" smoker (albeit limited segment) are obvious starting points.* [Emphasis added.]

[370] U.S. Patent No. 4,595,024. Greene TB, Townsend DE, Perfetti TA. *Segmented Cigarette*. R.J. Reynolds Tobacco Company. June 17, 1986. C2:23-26.

See also U.S. Patent No. 3,280,823 Bavley A, Air B, Robb II EW. *Additive-Releasing Filter for Releasing Additives into Tobacco Smoke*. Philip Morris Inc. October 25, 1966. C2:37-40 ("This invention permits the release into tobacco smoke, in controlled amounts . . . and when desired of nicotine into tobacco smoke").

effects of nicotine, and is understood by the industry as an essential component of consumer acceptance of tobacco products. The conferees at a 1983 BATCO Research Conference in Rio de Janeiro sought to expand research efforts on nicotine as the principal source of smoker satisfaction and to "develop products that give improved smoker satisfaction."[371] The conferees agreed that to achieve this goal, BATCO must know as much as possible about nicotine, including:

- *factors that affect the transfer of nicotine from leaf to smoke aerosol*
- *factors that influence the rate of transfer of nicotine from particulate matter to the vapour phase*
- *the contribution of nicotine to smoke sensory characteristics (including harshness and irritation)*
- *the site and mechanisms of absorption of nicotine within the human system*
- *the way nicotine stimulates both the central nervous system and the peripheral organs (eg heart and lung)*
- *the metabolism of nicotine within the body, including rates and equilibrium levels.* [Emphasis added.][372]

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[371] BATCO Group R&D Research Conference. Rio de Janeiro, Brazil. August 22-26, 1983. Page BW-W2-01837.

[372] *Id.* at p. 13. Philip Morris documents similarly show that that company's research on manipulating nicotine delivery was aimed at ensuring that smokers experience nicotine's pharmacological effects. *See e.g.:*

Philip Morris employee (almost certainly W.L. Dunn). *Smoker Psychology Program Review.* October 19. 1977. This paper sets forth questions being asked by researchers at Philip Morris, at pages 5-6:

a) What is the lower delivery level limit beyond which the smoking act is not reinforced?
b) Within what limits can we vary nicotine concentration relative to other smoke constituents?
1) What is the optimum nicotine/tar ratio?
c) Given a fixed quantity of nicotine in the tobacco, what factors in cigarette design determine its availability for delivery to the smoker?. . . .
e) Does the smoker seek spike effects, bloodstream constancy?. . . .
g) How important is the form of the delivered nicotine? (salt vs. free base? pH? particle size?)

Ryan, FJ, Jones, BW, Martin, PG, Dunn, WL. Behavioral Research Annual Report. July 18, 1975. Page

This list of product development research objectives makes clear BATCO's interest in the delivery of nicotine for absorption into the bloodstream and in its systemic effects once absorbed.

The tobacco industry's product development research on manipulating the amount and manner in which nicotine is delivered to the consumer demonstrates the industry's intent to sell tobacco products that provide a pharmacologically active dose of nicotine.

17:

As deliveries drop we reasoned that eventually they could reach a point where all the cigarettes in a pack would be unsatisfying.

The same document reports on Philip Morris studies of: 1) acceptability of various nicotine/tar ratios in a 10 mg tar cigarette, and 2) methods of producing a low delivery cigarettes "with impact and flavor." Pages 23-25.

Dunn, WL. Project 1600/Consumer Psychology/Annual Report. November 18, 1966. Page 9.

Is the transition to preference for a lower delivery cigarette more explicable in terms of (a) Reduction in sought dosage level, or (b) Adaptation of puffing pattern?

Memo to T.S. Osdene from W.L. Dunn. Plans and Objectives - 1982. November 5, 1981. Discusses Philip Morris research on changes in inhalation behavior and puff parameters as a result of changes in nicotine delivery, and on which parameters influence nicotine retention. Pages 7-8.

2. Industry Research on Maintaining Adequate Nicotine Delivery When Lowering Tar

Product design to ensure adequate nicotine absorption by the smoker appears to have been driven, to a large extent, by the growing awareness of smoking-related diseases and the resulting efforts of the tobacco companies to provide cigarettes that delivered lower quantities of known toxic smoke constituents, in particular tar. However, reducing tar levels tends to also reduce the nicotine content.[373] Thus, the industry has known that in designing lower-yield products, nicotine delivery could not be reduced below a certain threshold.[374] In order to reduce tar while maintaining a level of nicotine delivery that would satisfy consumers' desire for the pharmacological effects of nicotine, the industry has focused considerable attention and research on how to maintain or enhance the amount of nicotine delivered by lower-tar products.

A patent held by Imperial Tobacco Ltd. states that the purpose of the technology described in the patent is to permit a cigarette manufacturer to maintain or increase nicotine levels while lowering levels of "undesirable" smoke constituents:

> *[This] invention concerns . . . the problem of maintaining or increasing the nicotine content of the smoke whilst avoiding an undesirable level of particulate*

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[373] *See:*
Spears AW, Jones ST. Chemical and physical criteria for tobacco leaf of modern day cigarettes. *Recent Advances in Tobacco Science.* 1981;7:19-39.

Regulation of Nicotine under the Federal Food, Drug and Cosmetic Act: Hearings Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 103rd Cong., 2d Sess. (March 25, 1994) (statement of AW Spears, at pp. 1-3).

[374] *See* Project Wheat - Part 2 , note 204, *supra,* at p. 48:
> *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 nicotine deliveries could be brought within the range required by groups of consumer[s].*

matter in the smoke . . .[375]

A 1976 BATCO "Smoking Behavior" conference report states the industry's dilemma more succinctly:

> *[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 . . . .*[376]

Philip Morris conducted research to find the optimum nicotine delivery level and the optimum nicotine-to-tar ratio for low tar cigarettes. In 1970, a company document stated that Philip Morris planned to conduct a test in which it would reduce tar and add nicotine to Marlboro:

> *We are initiating a study of the effect of systematic variation of the nicotine/tar ratio upon smoking rate and acceptability measures. Using Marlboro as a base cigarette we will reduce the tar delivery incrementally . . . and increase the nicotine delivery by adding a nicotine salt [a commercial form of nicotine].*[376a]

A 1972 Philip Morris document identifies the natural nicotine-to-tar ratio in tobacco as 0.07, which is "characteristic of a broad range of natural leaf."[376b] Within the next three years, Philip Morris had studied and found the "optimal" nicotine-to-tar ratio for consumer ratings of acceptability and "strength." A 1975 Philip Morris document containing the results of a study

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[375] U.S. Patent No. 3,861,400. Perkins PR, Bale CR. *Nicotine Fortification of Smoking Products.* Imperial Tobacco Group Limited. January 21, 1975. C1:1-10.

[376] BATCO Group R&D Conference. Southampton, England. October 11-12, 1976. Page 4.

[376a] P.A. Eichorn and W.L. Dunn. Quarterly Report of Projects 1600 and 2302. December 31, 1970. *In* 141 Cong. Rec. H8008 (daily ed. July 31, 1995)(statement of Rep. Waxman). These studies of optimal nicotine/tar ratios were intended to be used "to provide insight leading to new cigaret designs." Philip Morris, USA. Research and Development Five Year Plan, 1974-1978. May 1973. *In* 141 Cong. Rec. H8008, *supra.*

[376b] Memorandum to P.A. Eichorn from W.L. Dunn et al. Plans for 1972. September 8, 1971. *In* 141 Cong. Rec. H8008 (daily ed. July 31, 1995)(statement of Rep. Waxman).

conducted by the company stated that the optimal nicotine-to-tar ratio was about 0.1, higher than the "natural" ratio:

> *This study provides evidence that the optimum nicotine-to-tar (N/T) ratio for a 10mg tar cigarette is somewhat higher than occurring in smoke from the natural state of tobacco.*[376c]

In other words, the study showed that for a given level of tar (10 mg), it was optimal to supply a higher level of nicotine than would occur naturally in tobacco. According to the authors, the study shows that smokers prefer a higher nicotine delivery in low tar cigarettes than the delivery level that would occur if nicotine were allowed to fall proportionately with tar:

> *[T]he experimental cigarette with the moderate level of nicotine addition was rated higher in acceptability than the proportional reduction cigarette and equal to the Marlboro control.*[376d]

A later quote from the same document, reported in the New York Times, indicates that this study was conducted to provide data on how to alter the natural nicotine-to-tar ratio of a low tar cigarette in such a way as to make the cigarette comparable to Marlboro (Philip Morris' most popular high tar cigarette) in consumer acceptability and "strength":

> *We are using the guidelines suggested by this study to attempt to make a 10mg tar cigarette that will equal a Marlboro in both subjective acceptability and strength.*[376e]

[376c] Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication. Approved by W.L. Dunn and distributed to H. Wakeham. October, 1975. *In* 141 Cong. Rec. H8009 (daily ed. July 31, 1995)(statement of Rep. Waxman).
See also:
Hilts PJ. "Documents Disclose Philip Morris Studied Nicotine's Effect on Body." *New York Times.* June 8, 1995.

[376d] Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication. Approved by W.L. Dunn and distributed to H. Wakeham. October, 1975. *In* 141 Cong. Rec. H8009 (daily ed. July 31, 1995)(statement of Rep. Waxman).

[376e] Hilts PJ. "Documents Disclose Philip Morris Studied Nicotine's Effect on Body." *New York Times.* June 8, 1995.

The term "strength," as used in industry documents, is associated with nicotine delivery. A Philip Morris document from 1978 describes further studies being conducted by that company to systematically vary the nicotine-to-tar ratio to find the "optimal" ratio for the company's ultra low (5-7 mg) tar products.[376f]

As early as 1965, a Brown and Williamson official reported to other Brown and Williamson executives that BATCO research was focused on "the smoking and health problem" and that:

> *Their approach seems to be to find ways of obtaining maximum nicotine for minimum tar. Approaches being used include:*
> *(a) P.E.I. treatment of filters*
> *(b) Nicotine fortification of cigarette paper*
> *(c) Addition of nicotine containing powders to tobacco*
> *(d) Alteration of blends.*[377]

Minutes from BATCO Group Research & Development Conferences in 1967 and 1969 reflect the importance of nicotine to the industry when considering product modifications to respond to concerns about smoking and health issues. Among other things, it was recommended that:

> *The development of low TPM [tar], normal nicotine cigarettes should continue. In this connection, the use of filter additives, such as PEI could be helpful in rendering the nicotine more available to the smoker.*
>
> *The development of a low TPM, low nicotine cigarette should be expanded. This raises the question of the level of nicotine required and the consumer study by*

[376f] Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1979. December 6, 1978. *In* 141 Cong Rec. H7670 (daily ed. July 25, 1995).

> *[W]e will evaluate low delivery experimental cigarettes in the 5-7 mg FTC tar range but with nicotine levels which are discernibly higher than, equal to, and lower than the typical level expected of cigarettes in this range (which would be .53 mg).*

[377] Griffith RB. Report to the Executive Committee. With attached handwritten note. July 1, 1965. Page 2.

> *Bristol can be helpful in determining this. [It was] pointed out that there was evidence that . . . per capita cigarette consumption increased for the lower nicotine brands. It cannot, however, be assumed that the minimum nicotine offered to the smoker is the optimal level, and some consideration should be given to establishing this.* [Emphasis added.][378]

Similarly, a 1975 BATCO Group Research & Development Conference report states that:

> *Once again the need for normal nicotine low tar cigarettes which appeal to the consumer was identified.*[379] [Emphasis added.]

Another BATCO document recommended in 1976 that when tar levels are lowered, nicotine delivery should be maintained:

> *A second approach which could be made both with existing brands and with new brands 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.* [Emphasis added.][380]

At the 1976 BATCO "Smoking Behavior" conference it was also observed that "there would

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[378] *See:*
BATCO Group R&D Conference. Montreal, Canada. October 25, 1967. Pages 4-5.

BATCO R&D Conference. Kronberg, Germany. June 2-6, 1969.

[379] BATCO Group R&D Conference. Merano, N. Italy. April 2-8, 1975. Page 4.

See also BATCO Group Research & Development, Conference on Smoking Behavior, Southampton, UK, October 11-12, 1976. Page 8:

> *Provided we can get smokers to dissociate tar from nicotine in their minds in terms of a possible health hazard, then there is a clear opportunity for a range of products which at present do not exist in order to suit those who combine above average inner need [nicotine requirement - see p. 184, supra] with above average concern for health. This is very much in line with some of Russell's pronouncements, and the fact that he is advocating the 'low tar normal nicotine' cigarette fairly forcibly is something we could turn to our advantage when considering how to market such cigarettes.*

[380] Morini HA. *Cigarettes with health reassurance.* BATCO Opinion. 1976. Page 1.

appear to be a forthcoming demand for high nicotine tobaccos"[381] in order to develop cigarettes that provide a higher nicotine to tar ratio.

A 1978 BATCO Group R&D Conference, which focused on product design issues, discussed several options for maintaining pharmacological satisfaction from low-tar cigarettes, including use of pharmacologically active nicotine substitutes:

> *Marketing opportunities will exist for cigarettes which are designed to replace the '1 mg cigarette.' Innovation on taste, tighter control of deliveries which may include a wider range of specified compounds, and improved control of the physical properties of the cigarette will obviously require attention. The pressure to retain smoking satisfaction may require more attention to be paid to the puff-by-puff delivery profile of the cigarette and perhaps the use of alternative active materials to augment or replace nicotine*. [Emphasis added.][382]

A 1979 BATCO R&D Policy Conference recommended continued research on aerosol growth, yet another means of reducing tar without simultaneously reducing nicotine:

> *Research on aerosol growth between inhalation and exhalation offers a way of reducing the retention of tar without at the same time reducing nicotine retention; this offers great potential to the Industry and should be continued.*[383]

A report by Imperial Tobacco Ltd. also focused on the importance of developing low-yield cigarettes that address smokers' concerns about health, but that nevertheless provide the desired "physiological satisfaction":

> *A cigarette that delivers physiological satisfaction, yet is low in T & N, must*

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[381] BATCO Conference on Smoking and Behavior, Southampton, England. October 11, 1976. Page BW-W2-02311.

[382] Green SJ. Notes on Group Research & Development Conference. Sydney, Australia. March 1978. Page 3.

[383] BATCO Notes on the R&D Policy Conference. Chewton Glen (February 10, 1979), Torquay (February 12-14, 1979). Page 4.

surely be a major objective and represents an R & D challenge.[384]

American Tobacco Company memoranda written in 1980 reveal a similar focus on increasing nicotine in relation to tar deliveries. The company conducted research on the addition of potassium carbonate to Tareyton and Pall Mall cigarettes to "increas[e] the amount of nicotine that is transferred from the tobacco to the mainstream smoke while leaving the 'tar' level unchanged."[385] One of these memoranda states that the company plans additional research on "addition of sodium carbonate, [and] treatment of stems with alkali base" with the apparent goal of "liberat[ing] nicotine as a free base . . . and thereby increas[ing] the amount of nicotine in the smoke."[386]

A large number of industry patents also demonstrate that the industry has focused substantial resources on developing methods of maintaining adequate nicotine delivery to ensure smoker satisfaction while lowering levels of other smoke constituents.[387]

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[384] Imperial Tobacco Ltd. Summary of Matinee marketing plans 1971. Page 11.

[385] *See:*
Bodenhamer NL. *Leaf Services Monthly Report for June; Increasing Nicotine Transfer in Smoke.* Memo to Dr. Eugene Glock. June 30, 1980.

Bodenhamer NL. *Leaf Services Monthly Report for August.* Memo to Dr. Eugene Glock. August 29, 1980.

[386] Memo to Dr. Eugene Glock dated July 31, 1980. Page 2. [The first page of this memo is missing from the exhibits to the Staff Report prepared by the majority Staff of the Subcommittee on Health and the Environment, 103 Cong. 2d. Sess., entitled "Evidence of Nicotine Manipulation by the American Tobacco Company" (Dec. 20, 1994).]

[387] *See, e.g.:*
U.S. Patent No. 3,584,630. Inskeep GE. *Tobacco Product Having Low Nicotine Content Associated with a Release Agent Having Nicotine Weakly Absorbed Thereon.* Philip Morris Inc. June 15, 1971. C2:5-15

U.S. Patent No. 3,861,400. Perkins PR, Bale CR. *Nicotine Fortification of Smoking Products.* Imperial Tobacco Group Limited. January 21, 1975. C1:1-10.

Industry studies on smoker compensation[388] have also led companies to be concerned that decreases in tar and nicotine yields will lead to dissatisfaction with smoking unless cigarettes are designed to allow smokers to compensate for the reduction in nicotine.[389] Consequently, tobacco manufacturers have actually attempted to assist smokers to compensate for lower nicotine yields, i.e., to obtain more nicotine from a cigarette than its machine-tested yield. They have done so by attempting to design cigarettes with "elasticity." "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 he needs, e.g., through more or longer puffs or by covering ventilation holes.[390]

BATCO researchers described corporate policy on compensation and elasticity at a 1984 conference:

U.S. Patent No. 4,215,706. Larson TM, Moring TB, Ireland MS. *Nicotine Transfer Process*. Loew's Theatres, Inc. C1:40-48, C3:61-66.

U.S. Patent No. 4,236,532. Schweizer AD, et al. *Smoking Rod Wrapper*. Gallaher Limited. December 2, 1980. C1:35-40.

U.S. Patent No. 4,830,028. Lawson JW, Bullings BR, Perfetti A. *Salts Provided From Nicotine and Organic Acid as Cigarette Additives*. R.J. Reynolds Tobacco Company. May 16, 1989. C1:40-47.

[388] *See* FINDINGS § II.C.3., *supra*.

[389] *See* Adams, note 326, *supra*, at p. 108:

> *We believe in overall conclusion, that our data shows Firstly, that individual smokers adapt their smoking habit to the type of cigarette being smoked in order to try to obtain what they need from their cigarette*
>
> . . . .
>
> *Thirdly, that if because of the design of the cigarette they cannot adapt sufficiently, dissatisfaction will result.*

[390] BATCO R&D Conference. 1983. Brazil. Page BW-W2-03952: A paper on the effects of filters on cigarette smoke stated that elasticity was one of the factors that allowed a greater impression of "strength" (which is related to nicotine delivery) "within a given tar segment."

Compensation by modifying smoking regime [increasing or decreasing/puff volume, duration, puff frequency, amount inhaled] is a topic which is being explored at GR & DC 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. [Emphasis added.][391]

Tobacco companies have attempted to improve elasticity through a variety of techniques. BATCO researchers noted at a 1983 conference that "elasticity can be designed into a cigarette using tobacco blend and pressure drop components. . . ."[392] Researchers at a 1972 BATCO Conference cited the need for "means of increasing the puff number of low density, low delivery cigarettes . . . in addition to those at present available."[393] At a 1975 conference, BATCO researchers were told about a German cigarette that had a number of design features that were intended to allow human smokers to obtain higher yields than the smoking machine. These design features included a higher than normal moisture content, reduced humectant, shorter cigarette rods, increased paper burn rate, additives, porous tipping, perforated tipping, acid filters, and the addition of sugars.[394]

At a 1983 BATCO R&D Conference, one of the workshops was entitled "Making the Smoke Work Harder." Notes of suggestions from that workshop include the question "What

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[391] Proceedings of the BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III. July 9-12, 1984. Page 55.

[392] BATCO Smoking Behavior Conference Overview, 1983. Page BW-W2-03292.

[393] BATCO. Notes from Group R&D Conference, Chelwood; 1972. Page BW-W2-01764.

[394] BATCO Group R&D Conference, 1975, note 379, *supra,* at p. 4.

factors control human ability to change T[ar]/N[icotine] ratios?," i.e., how can a smoker, through his own behavior, alter the amount of tar and nicotine he obtains from a cigarette of a particular machine-derived yield? Many of the remaining suggestions from the workshop offer possible methods to alter the tar/nicotine ratio of a cigarette, including manipulating the pH of the smoke, and altering the ratio of free to bound nicotine. By 1984, BATCO marketing and product development personnel were recommending the use of "compensatable" filters, intended "[t]o make it easier for smokers to take what they require from a cigarette."[395]

These documents show the extent of the tobacco industry's focus on nicotine in the face of increasing pressure to alter other characteristics of their products for health reasons. The documents reveal the industry's concern with the trend toward lower-tar products, and the industry's intense preoccupation with the need to provide adequate nicotine deliveries despite lowered tar deliveries. The documents establish that the industry's rationale for seeking to provide adequate nicotine deliveries in lower-delivery products is to ensure that these low-delivery products provide smoker satisfaction. These and other documents have shown the tobacco industry's awareness that smoker satisfaction is a function of the pharmacological effects of nicotine on the brain, and the industry's keen desire to be able to offer cigarettes that will allow smokers to obtain the threshold level of nicotine necessary to experience these effects.

[395] Structured Creativity Conference, Southampton, June 25-28, 1984. Page BW-W2-01993; attended by Ted Parrack of Brown and Williamson.

THIS SECTION OF THE DOCUMENT CONTAINS INFORMATION THAT MAY BE CONSIDERED TO BE OF A TRADE SECRET OR COMMERCIAL CONFIDENTIAL NATURE. EACH PAGE CONTAINING SUCH INFORMATION BEARS A NOTE ON THE TOP OF THE PAGE AND THE INFORMATION HAS BEEN PURGED FROM THE TEXT.

E. INDUSTRY MANIPULATION AND CONTROL OF NICOTINE DELIVERY IN MARKETED TOBACCO PRODUCTS

1. Industry Manipulation and Control of Nicotine in Cigarettes

FDA's investigation has revealed the painstaking attention that tobacco companies pay to nicotine during every phase of cigarette manufacture. This section details the methods used by the industry to manipulate nicotine delivery at each stage of production and some of the effects of these manipulations on the nicotine content (the amount of nicotine in the tobacco rod) and delivery (the amount of nicotine delivered in the smoke for absorption into the bloodstream of the smoker) of modern cigarettes.

At each step -- from tobacco growing, purchasing of tobacco leaves, and blending different types of tobacco, to cigarette design and manufacture -- ensuring adequate nicotine delivery is a central objective of cigarette manufacturers. According to a tobacco industry official:

> *Generally speaking, the nicotine yield of a cigarette is determined by the nicotine content of the tobacco; the static burn rate or amount of tobacco consumed during puffing; the pressure drop of the tobacco column; porosity of the wrapper and or ventilation at the filter; the pressure drop of the filter, the filter material, the surface area of the filter material; and the affinity of the filter material for nicotine particularly as a function of smoke pH. Through the combination of these variables, plant genetics, and commercial processes to remove nicotine from tobacco, it is possible to manipulate the yield of nicotine from about .1 mg to*

4 mg per cigarette.[395a] [Emphasis added.]

The first manufacturing step in nicotine control is the development and selection of raw materials. The tobacco industry has, through breeding and cultivation practices, developed high-nicotine tobacco plants that provide higher-potency raw material, giving manufacturers greater flexibility in blending and in providing uniform and sufficient nicotine deliveries.

Even without the selective breeding and cultivation of plants for nicotine content, careful tobacco leaf purchasing plans permit the manufacturers to control nicotine content in their products. For example, nicotine content varies among types of tobacco and from one crop year to the next. Awareness of these basic differences and monitoring of the nicotine levels in purchased tobacco allows the companies to produce cigarettes with nicotine deliveries consistent to a tenth of one percent, despite variations as high as 25% in the nicotine content of the raw material originating in the same area, from year to year.

The primary control of nicotine delivery (the amount received by the smoker), however, is in the design and careful, sophisticated manufacture of the cigarette, to ensure that the smoker obtains the precise amount of nicotine intended by the manufacturer. FDA's investigation has revealed that despite reductions in the amount of tar delivered by cigarettes over the past several decades, nicotine delivery in low-yield[396] cigarettes has not fallen proportionately with the reductions in tar. Instead, nicotine delivery has apparently risen over the last decade, a result

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[395a] Spears, AW. Lorillard Tobacco Co. *Factors Affecting Smoke Delivery of Nicotine and Carbon Monoxide*. Presented at the 1975 Symposium- Nicotine and Carbon Dioxide. November 17-18, 1975. In Symposium Proceedings-1, at p.12. FDA notes that when the author testified before Congress, he stated that nicotine manipulation does not occur and that nicotine yields simply follow tar yields. *See* note 479, *infra*. In this article he does not mention tar yield as factor in determining nicotine yield.

[396] "Low-yield" is used to denote cigarettes advertised as low-tar and low-nicotine.

that confirms that nicotine delivery is being independently and carefully manipulated by tobacco manufacturers. This newly gathered information, together with the other evidence of the industry's breeding, purchasing, blending, and manufacturing practices, reveals the extent to which manufacturers control the amount of nicotine that is delivered to the consumer from cigarettes and provides further support for the Agency's conclusion that tobacco manufacturers intend their products to affect the structure or function of the human body.

a. Tobacco Leaf Growing

The industry's control and manipulation of nicotine in the production of cigarettes begins long before the cured tobacco leaf reaches the manufacturing plant. The characteristics of leaf tobacco, including nicotine content, are established by the genetic makeup of the plant, developed during growing, and fixed by post-harvest handling. Like other raw agricultural commodities, the physical and chemical properties of tobacco, including nicotine, can vary widely, depending on genetic differences, growing season conditions, and soil type. This subsection describes the methods used by the tobacco industry to control and manipulate nicotine through careful genetic breeding and agronomic practices. As one industry expert stated, "nicotine is the key chemical constituent of the leaf and smoke and the reason for which tobacco is grown."[397]

Modern types of cultivated tobacco (*Nicotiana tabacum L*) have been selected for a relatively high level of nicotine.[398] Five major types of tobacco make up nearly all tobacco

[397] Adapting agronomy to the needs of the low-tar era. *World Tobacco*. October 1977. Page 137.

[398] *Id.*

products marketed in the United States: Burley, flue-cured, Maryland, the Dark tobaccos, and Oriental. These tobaccos vary both in nicotine levels and in pH. The pH of a tobacco can have a significant influence on the amount of, and rate at which, nicotine is absorbed into the bloodstream of the tobacco user and delivered to the brain.

Of the five major types of tobacco, Burley tobacco generally contains the highest nicotine levels compared to other tobacco varieties, and it has an alkaline pH. Flue-cured tobacco represents the major tobacco ingredient in American cigarettes. In comparison with other tobacco varieties, flue-cured tobacco has a medium nicotine content and is somewhat acidic.[399] Maryland tobacco has a low nicotine content in comparison with other varieties and has an alkaline pH. The Dark tobaccos produce an alkaline smoke, and are the traditional tobaccos for cigar wrappers and fillers as well as for chewing tobacco and for many pipe tobacco mixtures. Oriental tobaccos, cultivated in southeastern Europe and Turkey, are used for their characteristic aroma; they have a low nicotine content, and low pH.[400]

American tobaccos of all types have undergone cumulative increases in total nicotine levels since the 1950's.[401] As the following chart demonstrates, nicotine levels in the most widely grown American tobaccos increased almost 10% for Burley and more than 50% for flue-cured between 1955 and 1980:

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[399] Browne CL. *The Design of Cigarettes*. Hoechst Celanese Corporation; 1990. Page 43.

[400] *Id.* at pp. 22, 44.

[401] DeJong DW. The role of American tobacco leaf chemistry in low-yield cigarettes: an agricultural viewpoint. *Tabak Journal International.* May 1985. Pages 376-83. DeJong notes that higher-nicotine American tobaccos are needed in limited quantities to "spike" low yield cigarette blends. He further notes that off-shore tobaccos are invariably lower in nicotine, but serve to provide "filler" style leaf materials deemed necessary for the manufacturing of low-tar cigarettes, which comprise the majority of the U.S. market.

Tobacco Type	Percent Nicotine	
	1955	1980
U.S. BURLEY	2.91	3.18
U.S. FLUE-CURED	1.93	3.07

Two tobacco industry activities over the last several decades appear to be responsible for this increase: 1) the industry's active and controlling participation in the Minimum Standards Program, which ensures that nicotine levels of U.S.-grown and marketed tobacco are maintained within specified ranges;[402] and 2) the industry's breeding and cultivation of tobacco for high nicotine levels.

The Minimum Standards Program, which began in 1963 for flue-cured tobacco and in 1977 for Burley tobacco,[403] is a component of the tobacco price-support program administered by the U.S. Department of Agriculture (USDA). With regard to domestically grown tobaccos, the industry maintains control over which varieties are suitable for growing in the United States

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[402] *Id.* at p. 382.

[403] *See:*
Letter to M. Murray, FDA, from E. Wersman, North Carolina State University, March 23, 1994, transmitting:
1) The Burley Tobacco Quality Committee-Varieties "Testing Procedure to Assure Acceptable Quality In Burly Tobacco Varieties" revised February 24, 1993.
2) The Flue-Cured Tobacco Quality Committee-Varieties "Testing Procedure to Assure Acceptable Quality In Flue-Cured Tobacco Varieties" amended January 1991.

Letter to M. Zeller, FDA, from E.M. Pfeifer, King & Spalding on behalf of the Brown and Williamson Tobacco Corp., pp.1-8, with enclosures:
Attachment 1 "Flue-Cured Tobacco Variety Committee";
Attachment 2 "Burley Variety Evaluation Committee Membership";
Attachment 3 Slides, pp. 90025-90091.

and thereby eligible for price support.

One key objective of the tobacco industry's involvement in the Minimum Standards Program appears to be to ensure that nicotine levels in marketed tobacco do not fall below specified levels. The program was initiated in response to the emergence, in the 1950's , of several so-called "discount" varieties of tobacco (e.g., "Coker 139," "Coker 187-Golden Wilt," "Coker 282," "Coker 140," "Coker 316," and "Reams 64") that failed to meet current industry specifications established, among other things, to control the amount of nicotine delivery when used in manufacturing filtered cigarettes. To insure the elimination of "discount" or low-nicotine varieties from the market, the industry obtained the necessary cooperation from USDA to eliminate these varieties from the price-support program. In fact, to be eligible under this program, growers must certify, even to this day, that "discount" varieties are not being grown.[404]

In 1979, one major U.S. manufacturer requested that the tobacco variety committee under the Minimum Standards Program lower the acceptable nicotine range, established in 1967, for the specific tobacco varieties used as the standard. Support for lowering the acceptable nicotine range was not forthcoming from the rest of the industry and the change was never adopted.[405] In fact, in spite of the trend toward marketing cigarettes advertised as low delivery, the criteria under the Minimum Standards Program for nicotine content of new varieties have not changed since 1967.

While the Minimum Standards Program ensured that nicotine levels in marketed tobaccos

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[404] USDA Agricultural Stabilization and Conservation Service (ASCS) Manual. "Identification of certain flue-cured tobacco varieties under the price support program." April, 1964. Pages 3-5, 8, 10-11. Obtained on June 15, 1994, from USDA-ARS-SAA, Crops Research Laboratory.

[405] Collins WK. Cultural practices increase nicotine content of U.S. flue-cured leaf. *Tabak Journal International.* [4] 1981:328, 330.

did not fall, breeding and cultivation initiatives undertaken by the industry caused nicotine levels to increase. When health concerns prompted the tobacco industry to begin to market low-tar cigarettes in the 1960's and 70's, the industry turned to tobacco breeders to develop tobacco varieties that produced less tar. Breeders found that without intervention in the breeding of these varieties, nicotine levels were reduced along with tars.[406] Thus, the industry has long been able to grow low-tar and low-nicotine varieties of tobacco for use in manufacturing cigarettes.

By 1978, however, the industry had abandoned its interest in the development of low-tar/low-nicotine varieties of tobacco for manufacturing low-yield cigarettes, and instead turned to the development of higher nicotine varieties. According to one expert in the field, it was necessary to focus on developing tobacco that was higher in nicotine, not lower:

> *. . . manufacturers have means of reducing tars but most of the methods reduce nicotine and other constituents at the same time. Therefore it may be desirable to develop levels constant or to develop lines higher in nicotine so that when the tar and nicotine are reduced there will still be enough nicotine left to satisfy the smoker.*[407] [Emphasis added.]

Industry experts agreed, stating in 1981 that the nicotine content of tobacco "will increase if the very low 'tar' brands continue to expand in market share,"[408] They further stated that:

> *[c]urrent research is directed toward increasing the nicotine levels while maintaining or marginally reducing the 'tar' deliveries.*[409]

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[406] Tailoring tobacco plants to meet future demands. *World Tobacco*. October 1978. Page 148. Abbreviation of talk by J.F. Chaplin at meeting of CORESTA scientists in Sofia, Bulgaria.

[407] *Id.*

[408] Spears AW, Jones ST. Chemical and physical criteria for tobacco leaf of modern day cigarettes. *Recent Advances in Tobacco Science.* 1981;7:19-39, 37.

[409] *Id* at p. 31. *See* DeJong, note 401, *supra,* at p. 378. In anticipation of a move toward low-yield cigarettes, USDA was once petitioned by the industry to promulgate regulations to allow for the growing of ultra-low nicotine tobacco. The regulations were actually published in the *Federal Register* in June 1947. The nicotine concentration was to be no higher than 0.8%, which is significantly lower than the

The industry has elsewhere acknowledged that the role of American tobacco is to provide high levels of nicotine in the finished product to offset the diluting effect of bland foreign tobaccos and reconstituted tobacco sheet.[410]

FDA's investigation has revealed that at least one cigarette manufacturer, Brown and Williamson, has developed and marketed a tobacco so high in nicotine that it exceeded the limits imposed for U.S.-grown tobacco under the Minimum Standards Program. These limits cannot be exceeded without significant risk of losing government-administered price support. However, foreign-grown tobaccos are not subject to these specifications and are not subject to testing for nicotine content upon entry into the United States. This high-nicotine tobacco was therefore grown in South America.

FDA found that Brown and Williamson was involved for more than a decade in developing, through a combination of conventional and advanced genetic breeding techniques, a high-nicotine, flue-cured tobacco plant, named "Y-1," for use in a number of low-tar brands of cigarettes in the United States.

Brown and Williamson characterized its achievement in a patent filing in the following way:

> *By the present invention or discovery, applicants have succeeded in developing a tobacco plant that is agronomically and morphologically suitable for commercial tobacco production, i.e. it closely resembles SC 58, and provides a pleasant taste and aroma when included in smoking tobacco products, yet it is possessed of the N. rustica high-nicotine attribute. So far as we know, this has not been*

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concentration of nicotine in domestic tobaccos. These low-nicotine varieties were to be kept entirely separate and marketed under contract. These regulations remain in the Code of Federal Regulations (7 CFR 30), but they have never been taken advantage of, indicating industry's lack of interest in the development of ultra-low nicotine tobaccos.

[410] *See* DeJong, note 401, *supra.*

accomplished before . . . [Emphasis in original.] [411]

The development of Y-1 dates back to at least the mid-1970's. In 1977, James F. Chaplin, who was affiliated with both USDA and North Carolina State University, indicated that tobacco could be bred to increase nicotine levels, by crossbreeding commercial varieties of tobacco with *Nicotiana rustica*. *N. rustica* is a wild tobacco variety that is very high in nicotine, but is not used in manufacturing cigarettes because of its harshness.[412]

By combining conventional and advanced breeding techniques, Brown and Williamson succeeded in developing commercially viable Y-1 from seeds initially produced by Chaplin's crossbreeding work. The nicotine content of the leaf of this variety is about 6% by weight, which is higher than that of any other varieties of tobacco commercially grown in the United States. (Domestically grown varieties of flue-cured tobacco, for example, naturally contain 2.5% to 3.5% nicotine.[413])

Company officials admitted to FDA that Y-1 was intended as a "blending tool" to enable the company to design products that were lower in tar but not lower in nicotine.[414] The company disclosed to FDA that Y-1 had been used commercially in the manufacturing of Viceroy King Size, Viceroy Lights King Size, Richland King Size, and Richland Lights King Size and it

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[411] U.S. patent application No. 761,312 submitted on September 17, 1991.

[412] Chaplin JF. *Breeding for varying levels of nicotine in tobacco.* Proceedings from a symposium on Recent Advances in the Chemical Composition of Tobacco and Tobacco Smoke. 1977. Page 334.

[413] Letter to D.A. Kessler, FDA, from J. W. Johnston, R.J. Reynolds Tobacco Co. February 28, 1994. Pages 1-2.

[414] Transcript of FDA meeting with Brown and Williamson. June 17, 1994. Pages 18, 29, 85-86, 124.

constituted about 10% of the tobacco blend of these products.[415] These brands were manufactured and distributed throughout the United States in 1993.[416] FDA's investigation revealed that, as of mid-1994, Brown and Williamson still had between 3.5 million and 4 million pounds of this high-nicotine tobacco on hand.[417]

In addition to breeding high-nicotine tobacco varieties, the tobacco industry engages in a number of agronomic practices that increase nicotine levels in tobacco. Heavy application of nitrogen fertilizers, early topping, and tight "sucker" (i.e., bud growth at the junction of stalk and leaves) control have all acted in concert to push nicotine levels upward.[418] In addition, tobacco varieties have been selected for tolerance to brown spot, a leaf disease that makes early harvest necessary. Leaves of disease-resistant varieties tend to remain in the field longer, resulting in maximum nicotine accumulation.[419] Since the introduction in 1965 of the acreage-poundage control system, farmers have reduced the number of harvestable leaves per plant and have tended to increase plant spacing. Both of these practices tend to increase nicotine content in the leaf.[420] Finally, tobacco growers are transplanting tobacco crops earlier, which, coupled with the widespread use of pesticides in the soil, often results in slow early season growth, and also tends

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[415] *Id.* at pp. 153, 165.

[416] *Regulation of Nicotine under the Federal Food, Drug, and Cosmetic Act: 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. (June 21, 1994)(statement of David A. Kessler, M.D., Commissioner of Food and Drugs, "The Control and Manipulation of Nicotine in Cigarettes," at pp. 9-12). The Commissioner's statement is included as Appendix 8 to this document.

[417] *See* Transcript, note 414, *supra,* at p. 124.

[418] *See* DeJong, note 401, *supra,* at p. 382.

[419] *See* Collins, note 405, *supra,* at p. 330.

[420] *Id.*

to increase nicotine content in the leaves.[421]

These nicotine-raising agronomic practices have been adopted by U.S. growers in recent years, even though over 50% of the U.S. cigarette market is now characterized as low delivery. Thus, the tobacco industry has developed a number of sophisticated methods for manipulating nicotine levels through breeding and cultivation of tobacco plants and has used these methods to maintain and increase concentrations of nicotine in tobacco leaves. These methods enable the industry to use high-nicotine leaf in low-tar cigarettes, so that, paradoxically, certain low-tar cigarettes now contain more of the higher nicotine tobacco in their blend than cigarettes with higher tar deliveries.[422] See p. 261 infra. The use of these methods demonstrates that the industry manipulates nicotine independently of other tobacco components to ensure that cigarettes contain sufficient nicotine to satisfy smokers.

b. Leaf Purchasing

Nicotine is perhaps the most important criterion employed by cigarette companies in the purchase of tobacco leaf. As one tobacco company official stated over 20 years ago in an industry publication:

> *It is believed that one important reason why the consumer smokes cigarettes is for the nicotine which they contain . . . Manufacturers, therefore, must have all options open in selecting leaf to buy.*
>
> *They are most concerned with the nicotine levels in leaf, so that after manufacture of their blends, the nicotine percentages in the cigarettes will vary minimally both*

[421] *See* Collins, note 405, *supra.*

[422] *See* Spears, note 408, *supra,* at p. 22.

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from one to another within a packet, and from packet to packet.[423] [Emphasis added.]

The key factor related to nicotine in leaf purchasing is stalk position. The concentration of nicotine is lowest at the bottom of the plant and highest in the top leaves of flue-cured tobacco.[424] Thus, the position of the leaf on the stalk determines how much nicotine the leaf will contain. In fact, "stalk position" is an industry euphemism for nicotine content. The stalk position of a leaf can be determined by its appearance, shape, color, and thickness, even after harvest.[425] Therefore, an experienced buyer, whose instructions are dictated by the manufacturer's chemists,[426] need only be concerned with these physical characteristics in identifying leaves of varying nicotine content.

The significance of stalk position in leaf purchasing was confirmed when FDA visited cigarette manufacturers. [redacted] [427]

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[423] What changing technology means for leaf producers and packers. *World Tobacco*. September 1971. Page 137. Based upon lecture by J.S. Campbell, American Organisation of the Imperial Tobacco Group Ltd. at a Conference on Social and Economic Issues Confronting the Tobacco Industry in the Seventies, Lexington, KY.

[424] *See* 1977 *World Tobacco* article, note 397, *supra. See also* Browne, note 399, *supra,* at p. 15.

[425] *See* 1977 *World Tobacco* article, note 397, *supra.*

[426] Evolving techniques of making cigarettes milder. *World Tobacco.* April 1979. Page 95.

[427] FDA officials Mitch Zeller, Kevin Budich, Barbara Frazier, and Bob Spiller visited the sites of R.J. Reynolds Tobacco Company on April 11-12, 1994, and Brown and Williamson Tobacco Company on May 3, 1994. The following references refer to their summary notes of the visits.

Zeller notes from RJR visit at p. 2.
Budich notes from RJR visit at p. 3.

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Furthermore, this RJR representative revealed that "impact" is a criterion in leaf purchasing and that "impact" is "basically a function of nicotine in tobacco."[428] RJR also indicated that "impact" is measured in the company's laboratories if there is enough time to do so prior to purchase.[429]

Representatives from Brown and Williamson also described the significant role that nicotine plays in the purchase of tobacco leaf. The company stated that stalk position is the "first thing" they look for during leaf purchasing.[430] At Brown and Williamson, the lower stalk positions are considered to have the least amount of "smoke quality," which was defined as including "impact level."[431] The company defines "impact" as "the hit or punch in the back of the throat when you first inhale."[432]

Nicotine levels are so crucial to leaf purchasing at Brown and Williamson that the

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[428] Zeller notes from RJR visit at p. 2.
Budich notes from RJR visit at p. 3.
Frazier notes from RJR visit at p. 2.
RJR overhead was provided at visit.

[429] Zeller notes from RJR visit at p. 2. [redacted]

[430] Zeller notes from B&W visit at p. 2.
Frazier notes from B&W visit at p. 2.
Spiller notes from B&W visit at p. 2.

[431] Zeller notes from B&W visit at p. 2.

[432] Zeller notes from B&W visit at p. 2.
Budich notes from B&W visit at p. 4.
Frazier notes from B&W visit at p. 2.
Spiller notes from B&W visit at p. 2.

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company actually adjusts the stalk positions of its leaf purchases based upon the results of nicotine analyses that are performed during the course of the buying season.[433] In addition, Brown and Williamson employs special measures when purchasing foreign tobacco to ensure adequate nicotine levels. The company stated that foreign Burley and flue-cured tobaccos are smoked prior to their purchase so that they get some sense of the "impact" of the tobacco,[434]

[redacted][435]

c. Leaf Blending

After purchase, tobacco leaves are blended to attain target levels of nicotine and tar in the smoke. FDA's investigation noted particular attention on the part of manufacturers to the nicotine content of the leaf in the blending operation. As noted above, blending practices by manufacturers are designed to: (1) control the naturally occurring variations in nicotine and other components caused by genetics, growing season conditions, and soil type within a given type and grade; and (2) particularly for low-tar cigarettes, to increase nicotine concentrations and thereby maintain an acceptable nicotine level in the cigarettes.

As described above, each type of tobacco has unique characteristics of nicotine and tar delivery. Moreover, within each type, levels of nicotine increase with ascending stalk position

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[433] Frazier notes from B&W visit at p. 2.

[434] Spiller notes from B&W visit at p. 2.
Frazier notes from B&W visit at p. 2.

[435] [redacted]

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(grade). Armed with this knowledge, tobacco manufacturers blend various types of tobaccos and various stalk positions to achieve specific nicotine levels in particular brands.

Manufacturers also pay attention to other features of tobaccos that can affect nicotine delivery during blending. For example, cigarette filling power (bulk), pressure drop or resistance to draw, and static burn rate are all decreased with ascending stalk position. Decreases in burn rate increase the puff count, and thereby result in the delivery of more nicotine to the smoker because less tobacco is burned between puffs.[436]

The pH of cigarette smoke directly affects the delivery of nicotine because it alters the amount of nicotine that is absorbed in the mouth or lungs.[437] PH is controlled by the manufacturer in the selection of the type of tobacco used and blended. For example, smoke-condensate pH is higher from certain tobacco varieties as well as from leaves at upper stalk positions.

Blending techniques have been used to finely control nicotine concentrations in marketed cigarettes. [redacted][438] This is a high

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[436] *See* Browne, note 399, *supra,* at p. 12.

[437] *See* Surgeon General's Report. *Nicotine Addiction.* 1988. Pages 29-31.

[438] [redacted]

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degree of control even in a product manufactured from synthetic, homogeneous materials. It is a remarkable degree of control for a product such as cigarettes, which are made from highly variable biological materials whose nicotine content is ordinarily dependent upon such uncontrollable factors as weather and plant attack by insects and plant diseases.

Significant 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. FDA has observed the industry's use of proportionately greater amounts of higher nicotine-containing Burley tobacco in the tobacco blends of the lowest-tar varieties of cigarettes. In fact, Thomas Sandefur, the chief executive officer of Brown and Williamson, admitted to Congress that nicotine levels can be adjusted "up or down" depending on the blend of tobaccos used in a particular cigarette.[439] Industry scientists have also acknowledged that tobacco manufacturers blend high-nicotine tobaccos to compensate for the reductions in nicotine caused by innovations in cigarette design and manufacturing to reduce tar deliveries.[440]

[439] *Regulation of Nicotine under the Federal Food, Drug, and Cosmetic Act: 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. (June 23, 1994) (testimony of Thomas E. Sandefur, Jr., CEO, Brown and Williamson Corp., transcript at p.133).

[440] *See:*
DeJong, note 401, *supra.*

Spears, note 408, *supra,* at pages 22-24.

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[redacted][441] These examples demonstrate that tobacco manufacturers deliberately increase the proportion of high-nicotine tobaccos in low-tar cigarettes to prevent reductions in nicotine delivery that would otherwise result in these products.

Moreover, as described above, Brown and Williamson developed "Y-1," its ultra-high nicotine tobacco, for the purpose of having a "blending tool" that could be used to maintain nicotine delivery while reducing tar.

d. Cigarette Design and Manufacture

Cigarettes are not simply cut tobacco rolled into a paper tube. Modern cigarettes, as sold in the United States, are painstakingly designed and manufactured to control the amount of nicotine delivered to the smoker. The following aspects of cigarette design and manufacturing all affect the nicotine delivery of a finished cigarette:

(i) the chemical manipulation of tobacco smoke;

(ii) the use of flavors and casings;

(iii) filtration;

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[441] Zeller M, Budich K. Notes from March 22-23, 1994 meeting with Philip Morris and April 10-12, 1994, meeting with RJR. Mitch Zeller's notes, at pp. 2-3, and Kevin Budich's notes at p. 9.

(iv) the use of reconstituted tobacco; and

(v) use of wider tipping paper.

(i) Chemical Manipulation

Tobacco manufacturers add certain chemicals to the tobacco to enhance the efficient extraction by the smoker of nicotine from the tobacco in the rod. For example, certain additives can alter the pH of cigarette smoke, which is known to affect the rate of absorption of nicotine into the bloodstream of the smoker.[442]

FDA's investigation has disclosed efforts by the industry to chemically enhance nicotine delivery. A major American tobacco company's 1991 handbook on leaf blending and product development shows that ammonia from such sources as diammonium phosphate (DAP),[443] ammonium hydroxide, and urea can be used in cigarette manufacturing to increase the amount of nicotine delivered to the smoker.

The handbook states that ammonia in cigarette smoke:

> *can liberate free nicotine from the blend, which is associated with increases in impact and 'satisfaction' reported by smokers.*[444]

The handbook goes on to describe ammonia as an "impact booster":

> *Ammonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine. As a result of such change, 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*

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[442] Surgeon General's Report. *Nicotine Addiction.* 1988. Pages 29-31.

[443] *See* Statement of David A. Kessler, note 416, *supra,* at pp. 9-12.

[444] *Id.* at p. 10.

cigarette smoke and this is how ammonia can act as an impact booster.[445]

Ammonia increases the pH of the smoke and thereby enhances the absorption of nicotine by the body.[446] FDA's investigation has revealed at least one common site for the application of ammonia and ammonia-like compounds: reconstituted tobacco. The agency has found levels of these compounds to be as high as 10 % in reconstituted tobacco.

The company handbook describes the benefits of the treated reconstituted tobacco as a source of ammonia to absorb nicotine from higher alkaloid-containing components in the blend. This company handbook also describes the application of ammonia directly to the leaf tobacco.

With regard to the question of the efficiency of this technology in increasing nicotine delivery, the handbook states that smoke analysis shows that an experimental cigarette made of reconstituted tobacco treated with ammonia has almost double the nicotine transfer efficiency of tobacco.[447] This handbook also states that many U.S. tobacco manufacturers utilize ammonia technology. One company has admitted to FDA that it uses DAP in manufacturing cigarettes, and that such use increases nicotine delivery.[448]

(ii) Flavors and Casings

Various substances are added to tobacco components to affect the flavor and palatability of smoke, alter smoke composition and yield, modify burn rate, and alter pH to optimize nicotine

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[445] *Id.*

[446] Surgeon General's Report. *Nicotine Addiction.* 1988. Pages 29-31.

[447] *See* Statement of David A. Kessler, note 416, *supra,* at pp. 10-12.

[448] *See* King and Spalding letter, note 403, *supra,* at p. 6.

delivery. According to one industry expert,[449] the major contribution of the tobacco flavor specialist is to:

> *help provide a rich, clean, full-bodied tobacco flavour, to keep to a minimum hotness and irritation in the mouth, and to ensure high satisfaction from an adequate level of nicotine per puff. . . requirements that guarantee the consumer a pleasurable smoke . . .*

So-called "casings" are solutions of usually water-soluble ingredients that provide a means of incorporating flavorings and other additives into the tobacco blend. Casings are often used in tobacco processing to reduce the harshness of nicotine in high-nicotine tobaccos, thus permitting greater use of these tobaccos in cigarette manufacture. This use of casings is described by an industry "flavorist" in the following quote:

> *It is assumed that nicotine is one of the primary satisfaction factors for which tobacco products are used. However, in air-cured tobaccos (cigar, burley, Maryland), the pH of the smoke is generally alkaline and the flavor effect of nicotine is a "harshness" which can be choking and unpleasant. In the case of tobaccos containing sugars (flue-cured, oriental), the tobacco is weakly acidic, the effect of the nicotine is greatly modified, and the harshness is dramatically reduced. This same effect is often achieved by addition of sugars to air-cured tobaccos to "mellow" the smoke and/or by the blending of air-cured tobaccos with flue-cured and oriental. [Citation omitted.] Thus, smoke pH and leaf sugar content are factors which play an important role in the nicotine strength perceived in the smoking process.*[450]

As is clear from this quote, casings are used to permit the incorporation of high-nicotine tobaccos in cigarette blends, <u>despite</u> their unpleasant taste. Casings composed of such additives as sugar, licorice, or cocoa help to overcome the bitterness of nicotine in smoke. The lengths to which tobacco manufacturers go to use high-nicotine tobaccos, despite the harsh taste of

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[449] Hertz AN. The flavourist's role in the cigarette design team. *World Tobacco.* March 1985. Page 97.

[450] Leffingwell JC. Nitrogen components of leaf and their relationship to smoking quality and aroma. *Recent Advances in Tobacco Science.* Volume 2. Page 9.

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nicotine, reveals that the nicotine in these tobaccos is not being used for its taste but for another purpose.

FDA's investigation revealed the following example of the application of casings to permit a use of a high-nicotine tobacco that would otherwise have been unpalatable to consumers. [redacted][451]

Manufacturers also reduce harshness by routinely adding acids to tobacco to lower the pH of the smoke.[452] Manufacturers also use conventional casing materials, such as sugars and cocoa, to produce acids in the smoke and reduce harshness.[453] Harshness from nicotine is also reduced by spraying on top dressings after the tobacco is cut and shredded for cigarette making.[454]

Casings often include a humectant, usually glycerine or a higher glycol, which serves to

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[451] [redacted]

[452] *See* King and Spalding letter, note 403, *supra,* at p. 6.

[453] *Id.*

[454] *Id.*

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keep the tobacco moist and less sensitive to changes in humidity.[455] RJR acknowledged using glycerine as a humectant.[456] Tobacco industry officials acknowledge that controlling moisture content is essential to ensure that nicotine content does not fall.[457] Humectants also act to control particle size in the formation of the smoke aerosol, making the smoke "smoother" or less harsh on the back of the throat. Smoother smoke facilitates inhalation, ensuring that the nicotine will be taken into the lungs and rapidly and completely absorbed.

Nicotine can also be added to cigarettes through application of tobacco extracts in the processing of tobacco. Although calling the contribution of flavored tobacco extracts to the overall nicotine delivery from cigarettes "trivial," tobacco companies admitted to having used such extracts in testimony before Congress,[458] in other public statements,[459] [redacted]

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[455] *See* Browne, note 399, *supra,* at pp. 55-56.

[456] Budich K. Notes from April 10-12, 1994, meeting with RJR. Page 8.

[457] DeBardeleben MZ, Clafin WE, Gannon WF. (Philip Morris Research Center). Role of cigarette physical characteristics on smoke composition. *Recent Advances in Tobacco Science.* Volume 4. Page 98 ("Nicotine decreases on a per puff basis as moisture content increases . . . . The decrease is dramatic as moisture content rises above 12%").

[458] *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,* 103 Cong. 2d Sess. 592, 596 (April 14, 1994) (testimony of Edward A. Horrigan, Jr., Liggett Group, Inc. and Andrew Tisch, Lorillard Tobacco Co.).

[459] Philip Morris press release. *Philip Morris Statement on Nicotine in Cigarettes.* March 25, 1994. Page 2.

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[redacted][460]

(iii) Filtration

The filter plug provides a mouthpiece that captures particulate matter from the smoke and absorbs vapors. The filter can be used as a vehicle to carry filter aids such as charcoal and other solids and liquid additives that permit selective filtration of certain chemicals. The manufacturer's selection of a particular filter is determined largely by the target levels of nicotine and tar.[461]

Significant research has been conducted by the tobacco industry on the use of filter additives to enhance nicotine delivery.[462] FDA's investigation revealed that at least one major cigarette manufacturer has added a chemical to the filters used on its marketed cigarettes that increases the amount of nicotine delivered to smokers, by increasing the amount of nicotine that is eluted from the filter. "Elution" is the process by which nicotine that is initially trapped on a

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[460] *See:*

Hunter J. FDA memo to the record. Conversation with Steve Block of IFF. March 23, 1994.

Layloff T, FDA. Memo to James Hunter, FDA. Tobacco Extract Analyses. February 24, 1995.

[redacted] The actual contribution of tobacco extracts to total nicotine delivered to the smoker by tobacco so treated is unclear. The industry has conducted research to examine the specific activity of added versus naturally occurring nicotine. *See* Jenkins RW, Comes RA. Exogenous vs Endogenous Transfer of Nicotine During Smoking. *Int. J. Appl. Radiat. Isotopes.* 1976;27:323-324.

[461] *See* Browne, note 399, *supra,* at p. 66.

[462] Reynolds ML. Influence of filter additives on smoke composition. Page 54. Undated.

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filter is remobilized into the mainstream smoke by hot vapors and becomes available for inhalation by the smoker. [redacted][463]

Filter ventilation, which is accomplished by making holes in the filter wrap and tipping paper, is also a major means of controlling the nicotine delivery of a cigarette. Ventilation has apparently now largely replaced interest in filter additives as a means of enhancing nicotine delivery.[464] Ventilation holes allow fresh air to be pulled in by the smoker's suction, thereby diluting the smoke. Ventilation does not, however, simply reduce the concentration of each smoke component in proportion to the degree of dilution. Instead (while ventilation does reduce the tar and nicotine deliveries compared to a non-ventilated cigarette), ventilation can be used to increase the proportion of nicotine compared to tar.[465]

Tobacco manufacturers control filter ventilation by (1) changing the number and location

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[463] [redacted]

[464] *See* Reynolds, note 462, *supra,* at p. 61.

[465] Kiefer JE. Ventilated Filters and their Effect on Smoke Composition. In: *Recent Advances in Tobacco Science.* Volume 4. Physical Parameters which Affect the Composition of Cigarette Smoke from 32nd Tobacco Chemists Research Conference. October 30 - November 1, 1978. Montreal, Canada. Pages 78,79.

of holes in the filter tipping paper, which surrounds the filter at the smoker's end of the cigarette rod; and (2) by controlling the porosity of the plug wrap, which underlies the tipping paper and surrounds the filter.[466]

As the amount of ventilation increases, the amount of tar and nicotine are not proportionately reduced. Instead, tar is reduced at a greater rate than nicotine, thereby increasing the proportion of nicotine to tar. For instance in one reported measurement, as the proportion of filter ventilation went from 0% to 50%, mainstream smoke tar dropped 47% (29.38 to 15.71 mg/cigarette), while mainstream smoke nicotine dropped 37% (1.70 to 1.07 mg/cigarette).[467] The effect of using such ventilation is that the manufacturer has selectively reduced tar while delivering a higher percentage of the available nicotine to the smoker.

Filter ventilation can produce low nicotine and tar delivery ratings when measured by the FTC smoking machine, yet still manage to deliver higher nicotine levels to the smoker than indicated by the FTC yield. Research has shown that, unlike the FTC smoking machine, 32% to 69% of low-tar cigarette smokers block the perforations in ventilated filters with their fingers or lips. This behavior is not unexpected because some smokers are unaware of these ventilation holes or their function, and because the holes are generally tiny, laser-generated perforations and difficult for the smoker to see. Blockage of these holes results in greater nicotine yields to the smoker than those measured by the FTC smoking machine.[468] This filter design provides a

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[466] *See* Browne, note 399, *supra,* at p. 10.

[467] *See* Browne, note 399, *supra,* at p. 84.

[468] Kozlowski LT, Frecker RC, Khouw V, Pope MA. The misuse of 'less hazardous' cigarettes and its detection: hole-blocking of ventilated filters. *American Journal of Public Health.* 1980;70(11):1202-1203.

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means of compensating for reductions in nicotine delivery that are produced by unblocked filter ventilation. The ability to block ventilation holes is thus a means of improving a cigarette's "elasticity," i.e., a design feature that allows smokers to "compensate" for nicotine losses that would otherwise be caused by tar-reducing modifications. See p. 229, supra.

Another ingenious compensatory method to boost nicotine delivery has been the development of the so-called channel-ventilated filter system. This system has been employed by Brown and Williamson for its BARCLAY brand launched in 1981, and represents an attempt to avoid some of the reduction in nicotine that can accompany the use of ventilated conventional filters. The channel-ventilated filter functioned differently when tested on the FTC smoking machine than when used by humans. In fact, in an investigation that commenced in 1981, the FTC found that air flow through these channels is indeed compromised during actual smoking and that BARCLAY's channel filter actually delivers considerably more nicotine and tar to the smoker than is obtained using the FTC's testing method.[469] In 1983, the FTC successfully sued to enjoin Brown and Williamson from using nicotine, tar, and carbon monoxide results obtained from the FTC's smoking machine testing method in its BARCLAY advertising.[470] [redacted]

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[469] Federal Trade Commission. "Report to Congress Pursuant to the Federal Cigarette Labeling and Advertising Act," for the year 1981(July 1984) and 1984(1986).

[470] FTC v. Brown & Williamson Tobacco Corp., 580 F. Supp. 981, 983, 987, n. 35, and 988 (D.D.C.1983), aff'd in part (affirmed holding that the 1 mg tar claim had a tendency to deceive) and remanded in part, 778 F. 2d 35 (D.C. Cir. 1985). RJR and Philip Morris had complained to the F.T.C. that Brown and Williamson's Barclay advertisement claim of 1 mg tar was inaccurate and misleading, and that "when the cigarette is smoked between human lips its air ventilation system is inevitably obstructed and the cigarette delivers disproportionately more tar and nicotine than other comparably rated cigarettes." 778 F.2d at 37. Brown and Williamson argued, among other things, that Barclay had a higher ratio of nicotine to tar. 580 F. Supp. at 981, 984.

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[redacted] [471]

(iv) Reconstituted Tobacco

Cigarette manufacturers claim that the development and use of reconstituted tobacco sheet represents a cost-cutting measure to minimize tobacco waste. But the role of reconstituted tobacco in reducing tar and in controlling nicotine delivery is also apparent. The first use of reconstituted tobacco occurred in the 1950's by RJR, primarily as a method for reducing tar, in WINSTON cigarettes.[472] RJR estimates that reconstituted tobacco is used in virtually every cigarette brand on the market.[473] U.S. manufacturers generally use between 20% and 25% of this material.[474]

In the reconstitution process, pieces of tobacco material undergo treatment that results in the extraction of some soluble components, including nicotine. The pieces are then physically formed into a sheet of tobacco material, to which the extracted nicotine is re-added. Even if this

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[471] Budich K. Notes from May 3, 1994, meeting with Brown and Williamson. Page 12.

Federal Trade Commission. "Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes." 1994. Pages 9-10.

[472] Chemical and Biological Studies On New Cigarette Prototypes That Heat Instead of Burn Tobacco, R.J. Reynolds Tobacco Co. Winston-Salem, NC. 1988. Page 29. By increasing the use of reconstituted tobacco sheet in the cigarette rod (thereby reducing the amount of cut tobacco leaf needed) and using increasingly more efficient filtration, the levels of tar have been further reduced by the industry since the 1950's.

[473] *Id.*

[474] *See* Browne, note 399, *supra,* at p. 47.

reconstituted material contains only the original nicotine, its recombination with the tobacco material may be viewed as adding nicotine to the cigarette because the nicotine had been removed. Although denied by tobacco executives,[475] it is publicly reported that this process adjusts nicotine levels in the products, and that one manufacturer "readily admits to setting levels of nicotine . . . for the tobacco sheet."[476]

The agency has observed that the primary methods of producing reconstituted tobacco sheet are closely monitored and controlled to preserve the amount of nicotine in the tobacco components. These processes enable the manufacturer to precisely control and evenly disperse nicotine throughout this material, bringing a high degree of uniformity and consistency to the composition of a raw agricultural commodity. This control is so refined that despite the wide variability in the nicotine content of unprocessed tobaccos, reconstituted tobacco contains a generally uniform concentration of nicotine of around 1%, industry-wide. And, as described below, the reconstitution process can actually be used to elevate the level of available nicotine.

At least one company, LTR Industries, LeMans, France, which is involved exclusively in the production of reconstituted tobacco sheet for the cigarette industry, has publicly acknowledged the extent to which the production of such material can be controlled to precisely affect nicotine and tar deliveries.

According to an article appearing in the February 1983 issue of Tobacco Journal International, LTR claims that its process can produce reconstituted tobacco sheet to satisfy any

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[475] *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 Representaives,* 103 Cong. 2d Sess. 543 (April 14, 1994) (testimony of William I. Campbell, President and CEO, Philip Morris U.S.A.).

[476] Sisele S. Tobacco scrap: cigarette makers are taking heat for adjusting nicotine levels. *The Charlotte Observer.* March 6, 1994. Page 1C.

manufacturer's specifications for nicotine delivery. In this article, LTR states that "based on the idea that reconstituted tobacco could be used as a nicotine regulator, we have developed products with reduced or fortified nicotine." LTR has also been identified as having the ability to manipulate nicotine levels in reconstituted tobacco either by working into the scrap and waste new nicotine-rich tobacco of the "*rustica* type," or by adding purified salts of nicotine into the slurry, to boost the levels of nicotine in the finished reconstituted tobacco sheet.[477]

(v) Use of Wider Tipping Paper

Another means to compensate for nicotine losses from tar-reducing design options is the industry's use of wider tipping paper overwrap. According to a study conducted by Grunberg et al.,[478] between 1967 and 1978, the width of the overwrap was increased on 18 brands of filter cigarettes, even though there was smokable tobacco under the widened overwrap. The Grunberg study found that the wider tipping paper reduced the amount of tobacco smoked during the FTC testing method, because the FTC method prescribes that cigarettes be smoked down to within 3 millimeters of the tipping paper rather than until all of the tobacco is burned. Thus, use of wider tipping paper causes a decrease in the FTC yields of tar and nicotine while permitting smokers to obtain a higher yield of both tar and nicotine from the cigarette. Like the use of ventilation holes, use of wider tipping paper constitutes a form of built-in "elasticity" because it increases the amount of nicotine a smoker can obtain from a cigarette over the advertised FTC yield.

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[477] Evolving techniques of making cigarettes milder. *World Tobacco.* April 1979. Pages 93-101.

[478] Grunberg NE, Morse DE, Maycock VA, Kozlowski LT. Changes in overwrap and butt length of American filter cigarettes. *NY State Journal of Medicine*. July 1985. Pages 310-312.

e. Manipulation of Nicotine in Low-Yield Cigarettes

The manipulation and control of nicotine in cigarette design and manufacture is particularly apparent when low-yield cigarettes are analyzed. Since the genesis of the low-tar cigarette, the industry has recognized that the use of tar-reducing modifications, such as those described above, can reduce nicotine delivery. This has led some manufacturers to compensate for the effects of tar reduction to ensure an adequate delivery of nicotine in the low-yield products.[479] As one article in a 1979 industry publication states, the current practice is "to prefer tobaccos rich in flavour elements, even though that may mean their having more nicotine and tar than is desirable, and seeking to reduce the latter without doing too much harm to the former."[480]

To a remarkable degree, the cigarette industry has accomplished the task of maintaining delivery of nicotine while decreasing tar in low-tar products. In 1988, Jacob et al.[481] found that,

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[479] The tobacco industry has repeatedly stated that reductions in tar yields result in proportionate reductions in nicotine yields. *See, e.g. 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,* 103rd Cong., 2d Sess. 363 (1994) (statement of R. J. Reynolds Tobacco Company); *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,* 103rd Cong., 2d Sess. 378 (1994) (statement of Alexander W. Spears, Vice Chairman and Chief Operating Officer, Lorillard Tobacco Company); ATC letter to the Honorable Henry A. Waxman, note 355, *supra,* at pp. 2-3 of attachment. The evidence in this section demonstrates that nicotine levels in some cigarettes have not fallen proportionately with tar and, in fact, are subjected to independent manipulation and control.

[480] *See* 1979 *World Tobacco* article, note 426, *supra,* at page 95.

The manipulation of nicotine levels relative to tar levels in European cigarettes was noted in *The Lancet* in 1979. The author reported that the tar-to-nicotine ratio had declined from 1973 to 1979 and concluded that "the consistent fall in tar yield relative to nicotine over a period of years suggests an element of conscious manipulation." Tar: nicotine ratio of cigarettes 1973-79. *The Lancet.* No. 8139. August 25, 1979. Pages 422-423. [Emphasis added.]

[481] *See:*
Jacob P, Benowitz NL, Shulgin AT. Recent studies of nicotine metabolism in humans. *Pharmacology, Biochemistry, and Behavior.* 1988. Volume 30. Pages 249-250. In a more recent study, Benowitz states that cigarettes currently contain 8 to 9 mg of nicotine. Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. *N Engl J Med.* 1994;331:123-125.

regardless of the labeled and advertised FTC nicotine yields and manufacturers' claims of low-nicotine delivery for certain brands, all cigarettes contained at least about 10 mg of nicotine in the cigarette rod. Consistent with this finding, a study by Benowitz and Hall et al.[482] in 1983 demonstrated that cigarettes advertised as having a low-nicotine yield do not contain less nicotine than high-yield cigarettes. Moreover, the nicotine yield of cigarettes, as defined by the FTC smoking machine tests, correlates inversely with nicotine concentrations in the tobacco.[483] In other words, cigarettes advertised as low-tar and low-nicotine have higher concentrations of nicotine, by weight, than high-yield cigarettes. This has been accomplished by a combination of the methods described above for boosting nicotine delivery to compensate for nicotine losses from the application of tar-reducing design modifications.

FDA's analysis of marketed cigarettes has disclosed similar results. There is little variation in nicotine content from one U.S. brand to another. FDA also measured the actual amount of nicotine contained in several brands of cigarettes, and the amount of nicotine in three varieties of the Merit brand of cigarettes: one regular, one low-tar, and one ultra low-tar. The results of this testing showed that the variety labeled and advertised as the lowest in nicotine actually had the highest nicotine concentration, suggesting that the nicotine content was

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Benowitz NL. Dosimetric studies of compensatory cigarette smoking. In: Wald N, Froggatt P, eds. *Nicotine, Smoking and The Low Tar Programme*. Oxford, England: Oxford University Press; 1989:chap 10.

[482] Benowitz NL, Hall SM, Herning RI, Jacob III P, Jones RT, Osman A. Smokers of low yield cigarettes do not consume less nicotine. *New England Journal of Medicine*. 1983;309:139-142.

[483] *Id.*

manipulated to compensate for reductions caused by design features intended to reduce tar.[484]

In addition, FDA evaluated the tar and nicotine data for domestically marketed cigarettes published by the FTC for 1994. These data demonstrate that the lowest tar products have a markedly higher ratio of nicotine to tar than higher tar products. None of the 153 products with 14 or more milligrams of tar (high tar) had a nicotine to tar ratio greater than 1 to 12. By contrast, 88 of the 93 products with 6 or fewer milligrams of tar (ultra-low tar) had a nicotine to tar ratio greater than 1 to 12.[485]

The increase in nicotine-to-tar ratios between 1972 and 1994, see note 485, especially in low tar cigarettes, is particularly revealing in the light of industry research dating from the 1970's showing that the "optimum" nicotine-to-tar ratio for acceptability of low tar cigarettes is higher than the "natural" ratio. As described earlier, a 1975 Philip Morris study showed that "the optimum nicotine-to-tar (N/T) ratio for a 10mg [low] tar cigarette is somewhat higher than

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[484] According to FDA's analysis, whereas Merit Regular 100's contained 1.46% nicotine, Merit Low Tar 100's contained 1.67% nicotine, and Merit Ultra Low Tar 100's contained 1.99% nicotine. *See 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 Representarives,* 103 Cong. 2d Sess. 121 (March 25, 1994) (statement of David A. Kessler, M.D., Commissioner of Food and Drugs, "The Control and Manipulation of Nicotine in Cigarettes," Chart P). The Commissioner's statement is included as Appendix 7 to this document.

[485] Federal Trade Commission. 1994 report of the tar and nicotine content of domestic cigarettes. (FDA's analysis included only those products that were evaluated by the Tobacco Industry Testing Laboratory.) By contrast, only 2 of the 142 marketed cigarettes included in the FTC report for 1972 had a nicotine to tar ratio greater than 1 to 12. (Federal Trade Commission. 1972 report of the tar and nicotine content of domestic cigarettes.) On a percentage basis, only 1.4 percent of the 1972 products had a nicotine to tar ratio greater than 1 to 12. In 1994, that figure grew to 26.3 percent overall, and rose to 95 percent for the 93 products in the lowest tar category. This suggests that as the market for lower yield cigarettes has grown over the last 20 years, the cigarette industry has altered the traditional ratio of nicotine to tar.

occurring in smoke from the natural state of tobacco."[485a] [Emphasis added.] The Philip Morris researchers went on to say that this study would be used to "attempt to make a 10 mg [low tar] cigarette that will equal a Marlboro in subjective acceptability and strength." According to these researchers, the naturally occurring nicotine-to-tar ratio was 0.07, while the optimal ratio was about 0.1. See p. 223, supra.[485b]

As noted above, tobacco industry officials have repeatedly stated that nicotine yields are not manipulated and are simply a function of tar yields, i.e., that reductions in tar yields result in proportionate reductions in nicotine yields. For example, the chief operating officer of Lorillard

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[485a] Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication. Approved by W.L. Dunn and distributed to H. Wakeham. October, 1975. *In* 141 Cong. Rec. H8009 (daily ed. July 31, 1995)(statement of Rep. Waxman). *Also in* Hilts PJ. Documents Disclose Philip Morris Studied Nicotine's Effect on Body. *New York Times.* June 8, 1995.

[485b] According to an analysis of FTC nicotine and tar delivery levels conducted by a member of Congress, at least two Philip Morris low-tar products show evidence that the data on "optimal" nicotine-to tar ratios was applied by the company to make changes in the nicotine-to-tar ratios of marketed cigarettes. One marketed cigarette underwent an increase in its nicotine-to-tar ratio, beginning in 1978, that closely corresponds to the change from the "natural" ratio to the "optimum" ratio described by Philip Morris researchers in 1975. From 1968 to 1978, tar and nicotine levels in regular Benson & Hedges filtered cigarettes dropped from 21 mg tar and 1.29 mg nicotine to 0.9 mg tar and 0.06 mg nicotine. Throughout this period, the nicotine-to tar ratio in the cigarettes remained stable, i.e., tar and nicotine delivery levels were falling proportionately. The ratio during this period was 0.7, the ratio described by Philip Morris researchers as "natural" for tobacco. Then, beginning in 1978, nicotine delivery from Benson & Hedges began to increase, while tar remained stable. By 1983, the nicotine delivery had jumped from 0.06 to 0.1, an increase of over 60%. The result was an increase in the nicotine-to tar ratio to 0.11, approximately the same level found by Philip Morris researchers to be "optimal." Congressman Waxman reported that the chance that this change in the nicotine-to-tar ratio could have been due to random fluctuations in tar and nicotine levels is less than 1 in 100,000. The tar-to-nicotine ratio for Benson & Hedges dropped back to 0.07 in 1984 and 1985. Although the reasons for this change are unknown, Congressman Waxman noted that the change could have been due to a decision to phase out the product or to the use of technologies that permit manipulation of the amount of nicotine delivered to the smoker but that do not affect the amount of nicotine measured by a smoke machine. Waxman also analyzed Philip Morris product, Merit Ultra Lights. This product was introduced in 1981 with a nicotine/tar ratio of 0.11, which corresponds to the "optimal" ratio found by Philip Morris researchers, rather than to the "natural" ratio of 0.07. The elevated nicotine-to-tar ratio in Merit Ultra Lights has remained constant in the years since its introduction. 141 Cong. Rec. H8009-10 (daily ed. July 31, 1995)(statement of Rep. Waxman). Philip Morris denied that the changes were deliberate. Hilts PJ. Philip Morris Denies Charge By Lawmaker. *New York Times.* August 2, 1995.

Tobacco Co. testified before Congress in 1994 that:

> *We do not set nicotine levels for particular brands of cigarettes. Nicotine levels follow the tar level . . . . The correlation coefficient of 0.975 is essentially perfect correlation between tar and nicotine and shows that there is no manipulation of nicotine.*[485c]

The significant increase in the nicotine to tar ratio for low delivery products contradicts these statements and provides strong evidence that nicotine deliveries are independently manipulated. In fact, an industry document states that the nicotine-to-tar ratios in ultra low tar cigarettes are higher than would be expected if nicotine fell proportionately with tar. In 1978, Philip Morris surveyed the nicotine-to-tar ratios in its competitors' ultra low tar products (5-7 mg tar) and found that these ultra low tar cigarettes "seem to be higher in nicotine delivery than we would otherwise expect" and found further that "nicotine/tar ratios go up as tar goes down":

> *The table [of nicotine-to-tar ratios for a range of low tar brands] suggests that Philip Morris brands (asterisked) have lower nicotine/tar ratios than do other brands with about the same FTC tar delivery . . . . The table also suggests that nicotine/tar ratios go up as tar goes down, and that our competitors' brands . . . seem to be higher in nicotine delivery than we would otherwise expect from our own experience with low delivery cigarettes . . . .*
>
> *It appears therefore that the mechanics of cigarette engineering and the deliberate decisions of our competitors are such as to suggest high nicotine/tar ratios be used at ultra low tar levels.*[485d] [Emphasis added.]

The Philip Morris researchers suggest that the high nicotine-to-tar ratios in the low tar products of Philip Morris' competitors have been achieved through certain kinds of filters and by "the use of

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[485c] *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,* 103rd Cong., 2d Sess. 378 (1994) (statement of Alexander W. Spears, Vice Chairman and Chief Operating Officer, Lorillard Tobacco Company)

[485d] Memorandum to T.S. Osdene from W.L. Dunn. Plans and Objectives-1979. December 6, 1978. *In* 141 Cong. Rec. H7670 (daily ed. July 25, 1995).

high alkaloid blends,"[485e] i.e., the use of tobaccos containing high nicotine levels.

FDA also analyzed other information supplied by the FTC that was derived from the FTC's database on nicotine levels in cigarettes. FDA's analysis of the FTC data demonstrates two very important results. First, there is an apparent increase in the sales-weighted FTC nicotine delivery ratings, for all cigarettes, since 1982 (the earliest year for which the computer database is available). Second, consistent with the data on the increase in nicotine to tar ratios, when FDA segmented FTC's sales data into high-tar, low-tar, and ultra low-tar cigarettes, nicotine yields had the greatest increase in the ultra low-tar group.[486] These findings are depicted in the following charts:

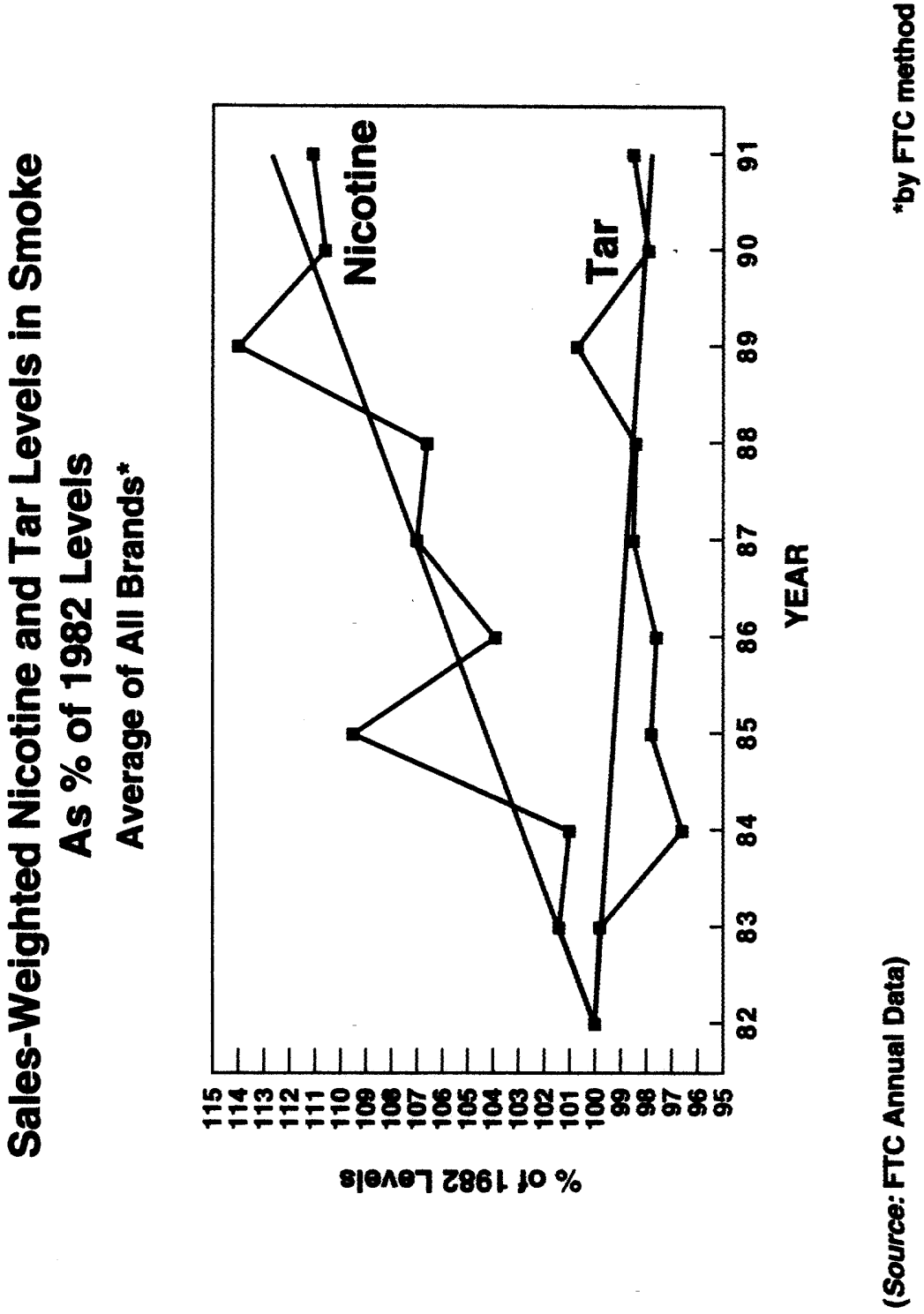
[485e] *Id.*

[486] *See:*

Kessler, note 484, *supra,* at charts Q, R, S, T. "Sales-weighted" nicotine delivery ratings represent the average nicotine yield of all cigarette brands sold in a given year, adjusted (weighted) to reflect the actual sales of the brands.

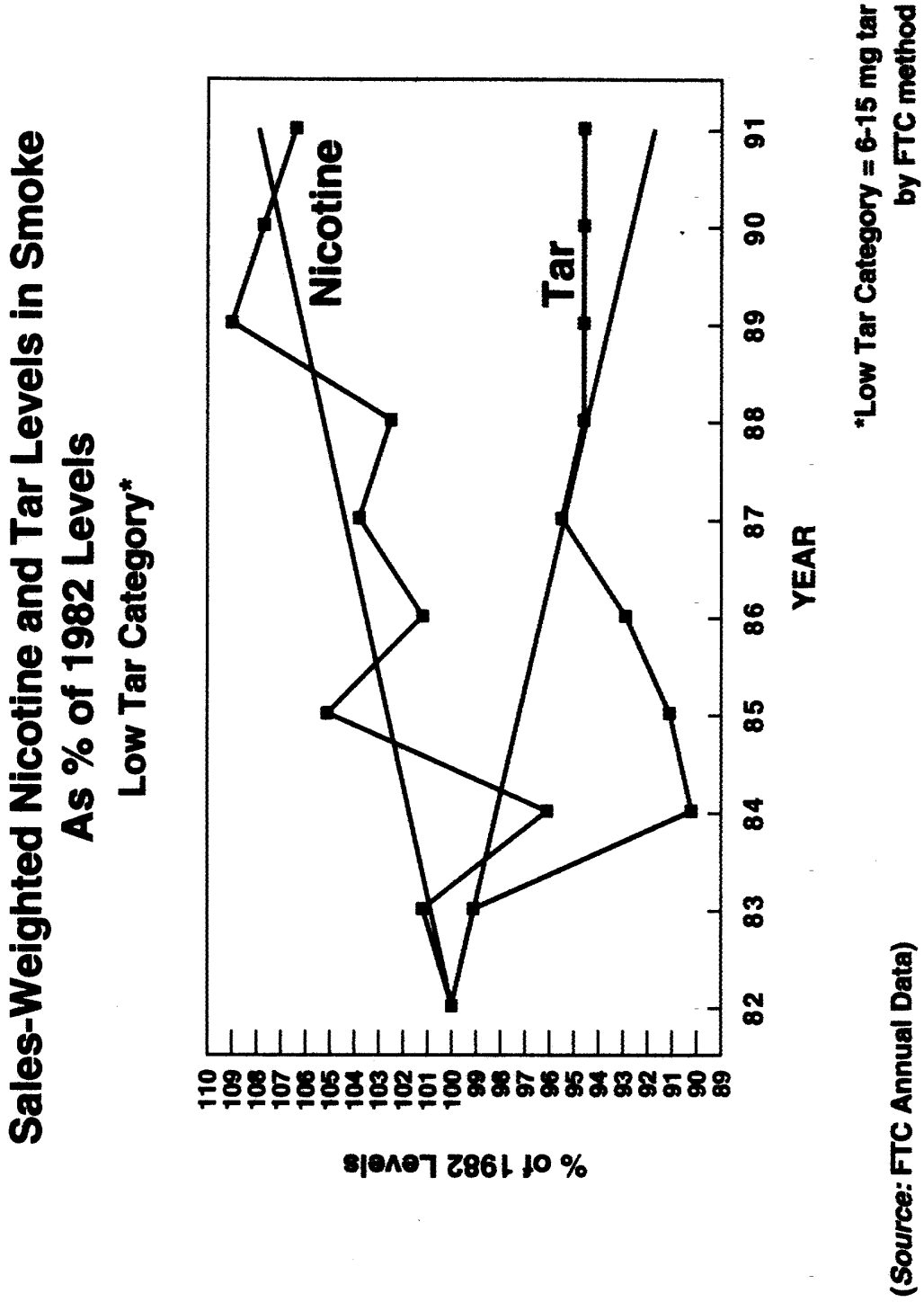
Hoffman D, Hoffman I. On the Reduction in Cigarette Smoke. In: Wald and Froggatt, note 481, *supra,* at pp. 200-201.

267

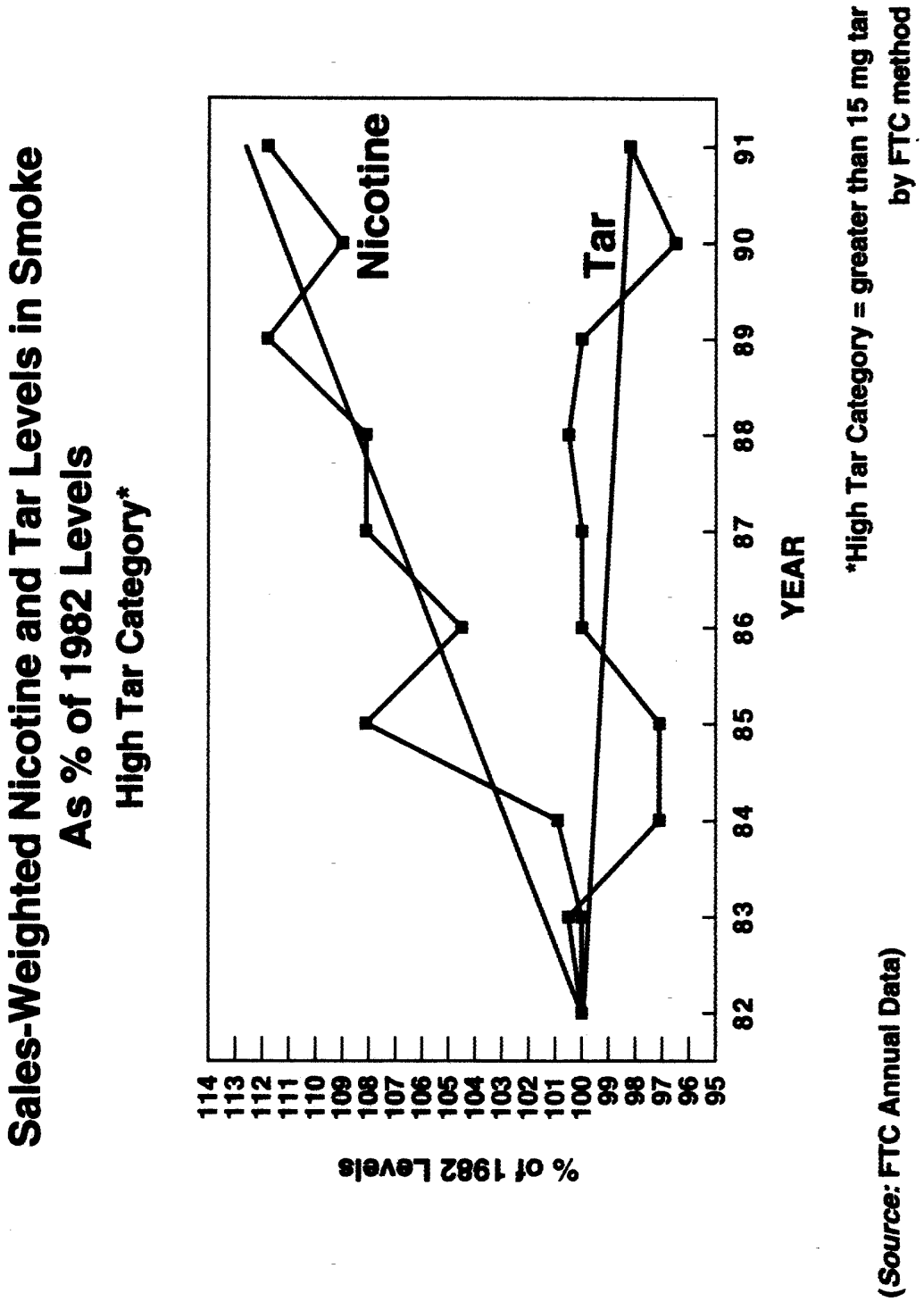


(*Source:* FTC Annual Data)

268



(*Source:* FTC Annual Data)


Sales-Weighted Nicotine and Tar Levels in Smoke
As % of 1982 Levels
High Tar Category*
Nicotine
Tar
% of 1982 Levels
114
113
112
111
110
109
108
107
106
105
104
103
102
101
100
99
98
97
96
95
82
83
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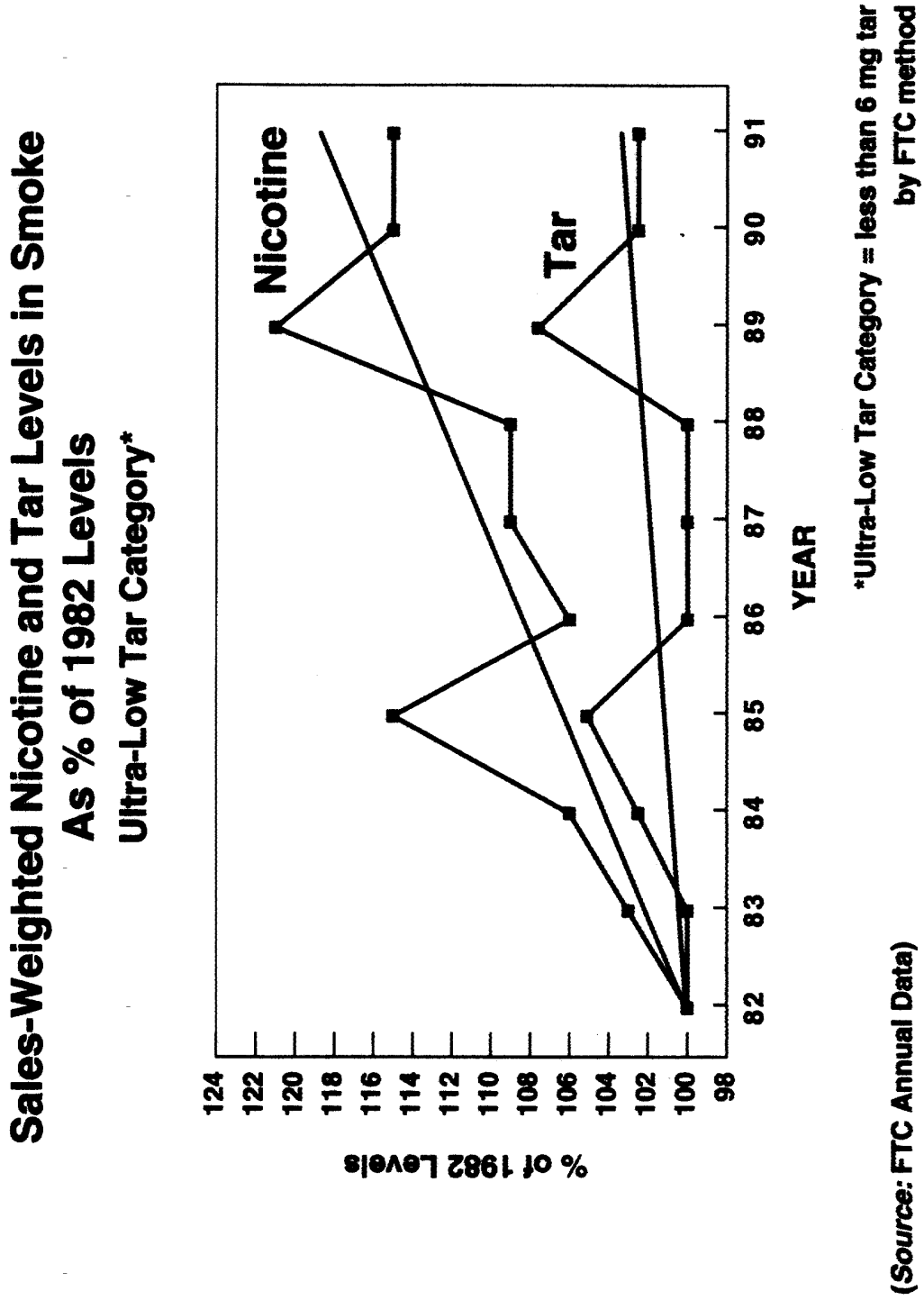
91
YEAR
*High Tar Category = greater than 15 mg tar by FTC method
(Source: FTC Annual Data)

270


Sales-Weighted Nicotine and Tar Levels in Smoke
As % of 1982 Levels
Ultra-Low Tar Category*
Nicotine
Tar
% of 1982 Levels
124
122
120
118
116
114
112
110
108
106
104
102
100
98
82
83
84
85
86
87
88
89
90
91
YEAR
*Ultra-Low Tar Category = less than 6 mg tar by FTC method
(Source: FTC Annual Data)

f. Conclusion

The information in the preceding sections demonstrates that cigarette manufacturers manipulate and control the delivery of nicotine in marketed products. Cigarettes are designed to supply nicotine at consistent levels despite the wide variations in the nicotine levels of the raw materials, the immensely complicated combustion chemistry, and the complex chemical flow properties of a modern cigarette.

Manufacturers use many techniques to control nicotine deliveries. The application of these modifications in cigarette design and their interactive nature pose complex problems in maintaining brand uniformity and consistency regarding nicotine delivery. Yet, the nicotine content and delivery of each brand of cigarettes is remarkably consistent from batch-to-batch and year-to-year. This level of control is analogous to that of the pharmaceutical industry in the production of prescription drugs. In fact, to determine how well nicotine content is controlled in cigarettes, FDA laboratories compared the content uniformity of drugs in tablet or capsule form to the content uniformity of nicotine in cigarettes. The results showed that nicotine content varies from cigarette to cigarette no more than the content of active ingredients in marketed pharmaceuticals.[487]

FDA's investigation has also disclosed that the tobacco industry uses a number of methods to boost nicotine delivery in low-yield cigarettes. The cigarette industry has successfully used these methods to maintain adequate nicotine delivery from low-yield products. Without the independent manipulation of nicotine, many of the techniques used to reduce tar

[487] FDA, CDER, DDA, Report on Analysis of Packages of Cigarettes, April 4, 1994. *See* Kessler, note 416, *supra,* at p. 12.

would also substantially reduce nicotine. Instead, regardless of differences in labeled/advertised FTC nicotine yields and manufacturers' claims of low-nicotine delivery for certain brands, all cigarettes contain approximately the same amount of nicotine in the rod, and deliver about 1 mg of nicotine, enough to produce pharmacological effects. See p. 108, supra. Moreover, studies by FDA and others have demonstrated that the lowest-yield cigarettes have the highest concentrations of nicotine, demonstrating that nicotine delivery has been independently manipulated.

The tobacco industry's control and manipulation of nicotine delivery from cigarettes provides additional evidence of the industry's intent to deliver pharmacologically satisfying levels of nicotine to smokers.

2. Industry Manipulation and Control of Nicotine in Smokeless Tobacco

Smokeless tobacco manufacturers control the delivery of nicotine from smokeless tobacco to produce a line of smokeless products that deliver nicotine in graduated amounts. Products that deliver lower doses of nicotine are marketed to new users of smokeless tobacco. Smokeless tobacco marketing then encourages them to "graduate" to products that deliver higher doses of nicotine. Smokeless tobacco manufacturers' manipulation of nicotine deliveries and marketing of low-nicotine products to new users and high-delivery nicotine products to experienced users demonstrates their intention to market products that facilitate nicotine dependence, a significant effect on the structure and function of the body. Smokeless tobacco manufacturers' products are thus intended to affect the structure and function of the body.

Moist snuff is the most popular form of smokeless tobacco. U.S. Tobacco Co. ("UST"), which accounts for 85% of the moist snuff sales in the U.S.[488] markets a line of moist snuff products that includes Skoal Bandits, Skoal Long Cut, Original Fine Cut Skoal, and Copenhagen. Skoal Bandits deliver a very small amount of absorbable nicotine, Skoal Long Cut and Original Fine Cut Skoal deliver sequentially more absorbable nicotine, while Copenhagen delivers the highest amount of absorbable nicotine. UST representatives in fact acknowledge that the company's products provide users with a range of nicotine deliveries.[489]

Smokeless tobacco manufacturers produce graduated nicotine delivery products primarily

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[488] *See* Appendix 5.

[489] *Marsee v. U.S. Tobacco,* note 317, *supra.* (Remarks of Mr. Finnegan, attorney for U.S. Tobacco.) In: 1.7 TPLR 3.202.

See also deposition of Erik Lindqvist, Senior Vice President for Marketing, U.S. Tobacco, in *Marsee v. U.S. Tobacco*. Transcript of Jury Trial Proceedings, at pp. 1648-1676.

by manipulating the pH of the tobacco.[490] Smokeless manufacturers add compounds and manipulate the design of each smokeless product to create a specific pH. The higher the pH of a product, the more nicotine is transformed from the salt form to "free nicotine." Both forms of nicotine are highly soluble in saliva. However, the free form of nicotine is absorbed more rapidly in the mouth of smokeless tobacco users and into the bloodstream for delivery to the brain. Raising the salivary pH from 7.0 to 8.0 increases the percentage of free nicotine available for absorption from 10% to 50%, a fivefold increase.[491]

Various documents show that UST understands the relationship between the pH of its products and their nicotine delivery. For example, in a deposition, UST's Senior Vice President for Marketing acknowledged that he had written a memo in which he had recommended a specific pH level for a new product and that he understood that there was a relationship between pH and nicotine.[492] When asked whether pH affected nicotine absorption, he agreed:

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[490] *See:*

Henningfield JE, Radzius A, Cone EJ. Estimation of available nicotine content of six smokeless tobacco products. (Submitted to *Tobacco Control* November 17, 1994.)

U.S. Food and Drug Administration. *Report on study of smokeless tobacco products: pH and free base nicotine.* November 4, 1994.

U.S. Food and Drug Administration. National Forensic Chemistry Center. Cincinnati Laboratory. *National survey of smokeless tobacco products.* December 13, 1994, memo from Laura Ciolino, Research Chemist to Fred Fricke, Director.

[491] *See:*

Armitage AK. Some recent observations relating to the absorption of nicotine from tobacco smoke. In: Dunn WL. ed. *Smoking Behavior: Motives and Incentives*. Washington, DC: VH Winston & Sons; 1973. Pages 86 (figure 2) and 87.

Henningfield JE, Radzius AC, Cooper TM, Clayton RR. Drinking coffee and carbonated beverages blocks absorption of nicotine from nicotine polacrilex gum. *JAMA*. 1990;264(12):1560.

[492] Transcript of Jury Trial Proceedings, *Marsee v. U.S. Tobacco*, note 317, *supra,* at pp. 1666-8.

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?

A. That would be my understanding, yes.[493]

The major smokeless tobacco manufacturers in the United States each market products that range from low to high pH, producing a corresponding graduation in the amount of "free nicotine" delivered by these products. The products with the lowest pH deliver the least amount of absorbable nicotine, while those with the highest pH deliver a significantly higher amount of absorbable nicotine.[494]

FDA laboratories comprehensively analyzed several marketed snuff products.[495] The following table demonstrates the characteristics of marketed smokeless tobacco products related to nicotine delivery.[496]

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[493] *Id.* at p. 1668.
See also:
U.S. Tobacco Company documents discuss the pH of various brands, also suggesting a knowledge of the relationship between pH and nicotine absorption:

> *Red Seal Menthol. . . 2. Lower pH than Skoal through flavor if possible. . . Premium project. . . Full tobacco flavor, pH at the level of Copenhagen or higher.*

U.S. Tobacco memo from Erik Lindqvist. (This document was discussed in the trial in *Marsee v. U.S. Tobacco*, note 317, *supra*. These quotes were authenticated by Erik Lindqvist, the author, in his deposition. Transcript of Jury Trial Proceedings, at pp.1666-1671.)

According to the trial transcript of *Marsee*, UST recognizes that pH can affect how much of the nicotine is free. (U.S. Tobacco document No. 4486792, dated Oct. 5, 1981. In: 1.7 TPLR 3.208, July/August 1986.)

[494] The amount of absorbable nicotine is dependent on the pH and not the total amount of nicotine that is in the product. For this reason, the total amount of nicotine in the products throughout the product line can remain relatively constant and still permit graduated nicotine delivery.

[495] FDA laboratories in St. Louis and Cincinnati performed these studies. The results are summarized in two separate reports. *See* note 490, *supra*.

[496] This table reflects the two separate studies which were performed by the two FDA laboratories in St. Louis, MO and Cincinnati, OH. Both laboratories used the same analytical procedures for these analyses.

MANUFACTURER/ PRODUCT NAME	pH		% Free Nicotine*		Total 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	45.5	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
C.C. 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	4.0
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.

This table demonstrates that each of the smokeless tobacco companies whose products were tested by the FDA laboratories markets products that have low, medium, and high pH values, delivering corresponding low, medium, and high levels of free nicotine to the users of the products.[497] It is apparent from the data that providing graduated nicotine deliveries through manipulation of pH is an industry-wide practice. Other researchers have described similar findings.[498]

Other features of these products demonstrate how the smokeless tobacco companies use product design features to control nicotine delivery. For example, UST's Skoal Bandits and Pinkerton's Renegades are packaged in teabag-like pouches, which both limits the amount of snuff that is placed into the mouth and creates a barrier that retards nicotine release from the product. FDA laboratory analysis shows that the effect of the Bandits' pouch is to delay nicotine release by an average factor of three, compared to the same tobacco tested outside of the pouch, during the first 2 minutes of the study.[499] Thus, users of Skoal Bandits get less nicotine into their mouth, and the nicotine is released into their mouths at a slower rate.

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[497] In the chart, the first column lists the products marketed by specific manufacturers. For each manufacturer, the products are listed in descending order of nicotine delivery. The second and third columns list the pH of each product as measured by two separate FDA labs. The fourth and fifth columns list the amount of absorbable (free) nicotine in each product, calculated from the pH measured at each of the two labs. The sixth and seventh columns list the total nicotine content of each of the products as measured by each of the two labs.

[498] *See* Henningfield, note 490, *supra,* at p. 2. This study found that Skoal Bandits have a pH of about 6.9, providing only 7% of its nicotine in the free form. Skoal Long Cuts have a pH of about 7.4-7.5, providing 19%-23% free nicotine. Original Fine Cut Skoal has a pH of about 7.6, providing 28% free nicotine. Copenhagen was found to be a potent form of snuff, with a pH of about 8.6, producing 79% free nicotine, a very high level for absorption. Page 2 and figure 1.

[499] Department of Health and Human Services, FDA, National Forensic Chemistry Center. *Relative Buffering Capacity of Saliva and Moist Snuff* and *Moist Snuff Nicotine Content Code Date Survey.* Memorandum from Laura A. Ciolino to Elizabeth Berbakos and Thomas Layloff. September 28, 1994.

Smokeless tobacco products are also engineered in such a way that users get a bolus dose of nicotine within the first 5 minutes of inserting the product into the mouth.[500] After the first 5 minutes, nicotine is still released from the product but at a much slower rate. An FDA study showed widely divergent results when comparing Copenhagen and Skoal Bandits under typical use conditions.[501] The amount of nicotine released from a usual "pinch" of Copenhagen (about 1.5 gm) was 12 times higher than from a pouch of Bandits (about 0.5 grams) in the first 2 minutes of the experiment. The bolus dose results in nicotine concentrations in the bloodstream that produce a peak pharmacological concentration in users. These pharmacological concentrations are then maintained by the slow continued release of nicotine from the products following the bolus dose.

Both nicotine release and pH of smokeless products are also affected by the tobacco fermentation process used to make smokeless tobacco products. Tobacco fermentation causes an increase in pH with fermentation time.[502] The age of packaged smokeless products is thus a factor in each product's pH because fermentation can continue within the package due to the high

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[500] *See:*

U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Analysis. *Nicotine Studies of Chewing and Smokeless Tobacco Products.* Memorandum from Henry D. Drew, Chief, Drug Monitoring Branch, to Elizabeth Berbakos. September 22, 1994. Table 4.

U.S. Food and Drug Administration. National Forensic Chemistry Center. Cincinnati Laboratory. *Moist Snuff Nicotine Release Studies.* September 28, 1994, memo from Laura Ciolino, Research Chemist to Fred Fricke, Director. Page 1.

[501] *Id.* September 28, 1994, memorandum.

[502] Tso TC. *Kirk-Othmer Encyclopedia of Chemical Technology.* John Wiley and Sons; 1970;20:510. This occurs because organic acids are lost through oxidation and decarboxylation.

moisture content of the tobacco.[503] Because fermentation increases pH, and increasing pH increases free nicotine, continued fermentation increases the amount of nicotine that is delivered to smokeless tobacco users. Fermentation also breaks down the plant tissue. This results in nicotine release from the plant intracellular tissue, causing much of the nicotine to come to the surface of the tobacco leaf.[504]

Manufacturers also add humectants to their products to increase or maintain the moisture content. The resulting high moisture content of smokeless products affects nicotine delivery by ensuring that tobacco leaves are well wetted, thus allowing nicotine easily to go into solution (i.e., saliva).

The evidence demonstrates that smokeless tobacco manufacturers design their products to deliver controlled amounts of nicotine to the user by manipulating pH, placing starter products in pouches, and using additives that control the moisture content of the products. Smokeless manufacturers use these sophisticated design features to manipulate the pharmacological response of the user to the product. In doing so, manufacturers intend to market products that affect the structure or function of the body.

The marketing practices of the smokeless tobacco industry further demonstrate the intent of manufacturers to factilitate nicotine dependence among smokeless tobacco users. Until the 1970's, smokeless tobacco companies were marketing only products with high nicotine delivery.

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[503] Andersen RA, Fleming PD, Hamilton-Kemp TR, Hildebrand DF. pH changes in smokeless tobaccos undergoing nitrosation during prolonged storage: effects of moisture, temperature, and duration. *J. Agric. Food. Chem.* 1993;41:968-972.

[504] This may explain the fast nicotine release from the tobacco products studied by FDA under *in vitro* conditions.

Their market was steadily diminishing because these products were not well tolerated by new users. Evidence from the files of smokeless tobacco companies shows that, in the late 1960's or early 1970's, these companies began to try to entice new users of smokeless tobacco, including people as young as 15 years old.[505] To do so, they developed low-nicotine products in teabag-like pouches to encourage people to begin using smokeless tobacco. A UST document describes the company's rationale for developing a new oral snuff product under the code name "The Lotus Project":

AIM: *To make it easier for a new user to use tobacco in the mouth.*

TARGET GROUP: *New users, mainly cigarette smokers age group 15-35*

PRODUCT: *A. Strength*

1. Nicotine Satisfaction

Mild like Happy Days [a low-nicotine product]
Instant but not shocking

2. Feeling in the mouth

As little harshness as possible on the gum and in the throat

* * *

PACK: *A. Size of Pinch*

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[505] *See* documents on "Lotus Project":
Undated document entitled "The Lotus Project." From *Marsee v. U.S. Tobacco*, note 317, *supra*, Trial Exhibit 159.

U.S. Tobacco Co. Intra-company Correspondence from W.W. Watson, President - United Scandia International to Mr. L.A. Bantle, President. June 2, 1972. From *Marsee v. U.S. Tobacco*, Trial exhibit 158.

Minutes from a Meeting in Greenwich at Mr. L.A. Bantle's Office. July 18, 1972. From *Marsee v. U.S. Tobacco*, Trial exhibit 159.

> *Small enough for a new user to manage . . . This point has to be closely worked out, takes into consideration the desired effect mentioned under "Strength."*[506]

This document clearly discloses UST's intention to develop a low-nicotine product suitable for "new users," i.e., those not yet tolerant to the harsh effects of nicotine on the gum and throat, and not yet requiring high levels of nicotine for "satisfaction."

Another UST document that discusses the "Lotus Project" and product development discloses the company's intent to produce products with varying amounts of nicotine.[507] The document states:

> *"[t]here 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. . ."*[508]

By acknowledging that the objective is to produce products with varying strengths of nicotine and differentiating strength from taste, the document demonstrates the company's intent to manufacture products with distinct pharmacological effects based on the nicotine delivery.

A document that posed potential questions and answers related to UST's introduction of Skoal Bandits in a new market also demonstrates the manufacturer's intention to provide nicotine

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[506] *Id.* Trial Exhibit 159 (minutes from July 18, 1972, meeting).

[507] *See* Watson, note 505, *supra,* at p. 2.

[508] *Id.*

for absorption and thereby to produce "satisfaction" in the user of the product.[509] The document provides the following questions and anwers about Skoal:

> *3. - How does it work ?*
>
> > *It gives the satisfaction from tobacco want* [sic]. *It is real tobacco and contains nicotine. . .*
>
> *4. - How much nicotine does it contain ? Is it absorbed ?*
>
> > *The nicotine contents are more or less equivalent to that of a good quality cigarette of average strength. The nicotine is absorbed, given [sic] satisfaction to the smoker.*

A senior UST official stated in another memorandum that "satisfaction" refers to the "kick" that users obtain from tobacco products.[510]

Shortly after the "Lotus Project" documents were written, UST began to aggressively market the low-nicotine "starter" products to new users of smokeless tobacco. An early advertisement for "Happy Days," one of the first low-nicotine products, targeted the product "for you guys just starting out."[511] The marketing of starter products relied heavily on "sampling," a technique in which company representatives distribute free samples on college campuses and sports events, and encourage nonusers to use smokeless tobacco.[512] Advertisements then

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[509] *Potential Questions and Answers.* Bate stamp nos. 2054948-2054951, submitted in *Marsee v. U.S. Tobacco*, note 317, *supra.*

[510] *Marsee v. U.S. Tobacco*, note 317, *supra.* Deposition of Erik Lindqvist, Senior Vice President, Marketing. Transcript of Jury Trial Proceedings, at p.1662.

[511] Connelly GN. In the search for a perfect starter product: manipulation of nicotine in oral snuff brands. August 1994. (Unpublished.)

[512] U.S. Tobacco Company. College Representative Manual. Revised July 31, 1985:
Success in reaching the college students today will determine the continued popularity and growth for our products in our adult market segments tomorrow.

Achieving these goals will require strong consumer sampling efforts. Success in this area can

encouraged established users to graduate to higher-nicotine products. For example, an advertisement for Copenhagen, the highest nicotine product, said "Sooner or Later, It's Copenhagen."[513]

In the 1980's, "long cut" smokeless tobacco products were introduced. An internal UST memorandum, dated June 8, 1984, reported that customers and distributors of the Skoal "Long Cut" considered it a "'perfect' starter product," in part due to its relatively low "strength" (i.e., low delivery of nicotine).[514] This memorandum also acknowledges the role of low-nicotine products in facilitating graduation to high-nicotine brands like Copenhagen. In a long list of positive anecdotes about the introduction of Long Cut, the memorandum states that college representatives reported that "Long Cut makes it easier to become accustomed to using Cope[enhagen]" as well as "having sampled a person with Long Cut, and then seeing that person weeks later as a regular Cope consumer."[515] The same memorandum reports that Copenhagen sales "continue to rise on a weekly basis since the intro of Long Cut."[516]

A chart prepared by UST's marketing department further demonstrates the company's knowledge that consumer use of its products follows the graduated nicotine deliveries of those products and shows the company's desire to capitalize on a "graduation process" to enhance sales

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only be achieved with an aggressive, efficient program. . .

[513] Connelly, note 511, *supra*, at p. 5.

[514] U.S. Tobacco Company. Intra-company Correspondence from K.C. Carlsen to O.M. Bryant. *Skoal Long Cut.* June 8, 1984. Page 1.

[515] *Id.* at pp. 2-3.

[516] *Id.* at p. 2.

of its highest nicotine products.[517] The chart is labeled "graduation process" and shows a hierarchy of products, with arrows pointing from Skoal Bandits to Happy Days and Skoal Long Cuts, and culminating with Copenhagen. This "graduation" corresponds exactly to the progression of nicotine deliveries from the listed products.

The company's reliance on the graduation process is further evidenced in a UST document entitled "Expanding User Base", which depicts a "bullseye" chart that lists the company's moist snuff products.[518] The chart follows:

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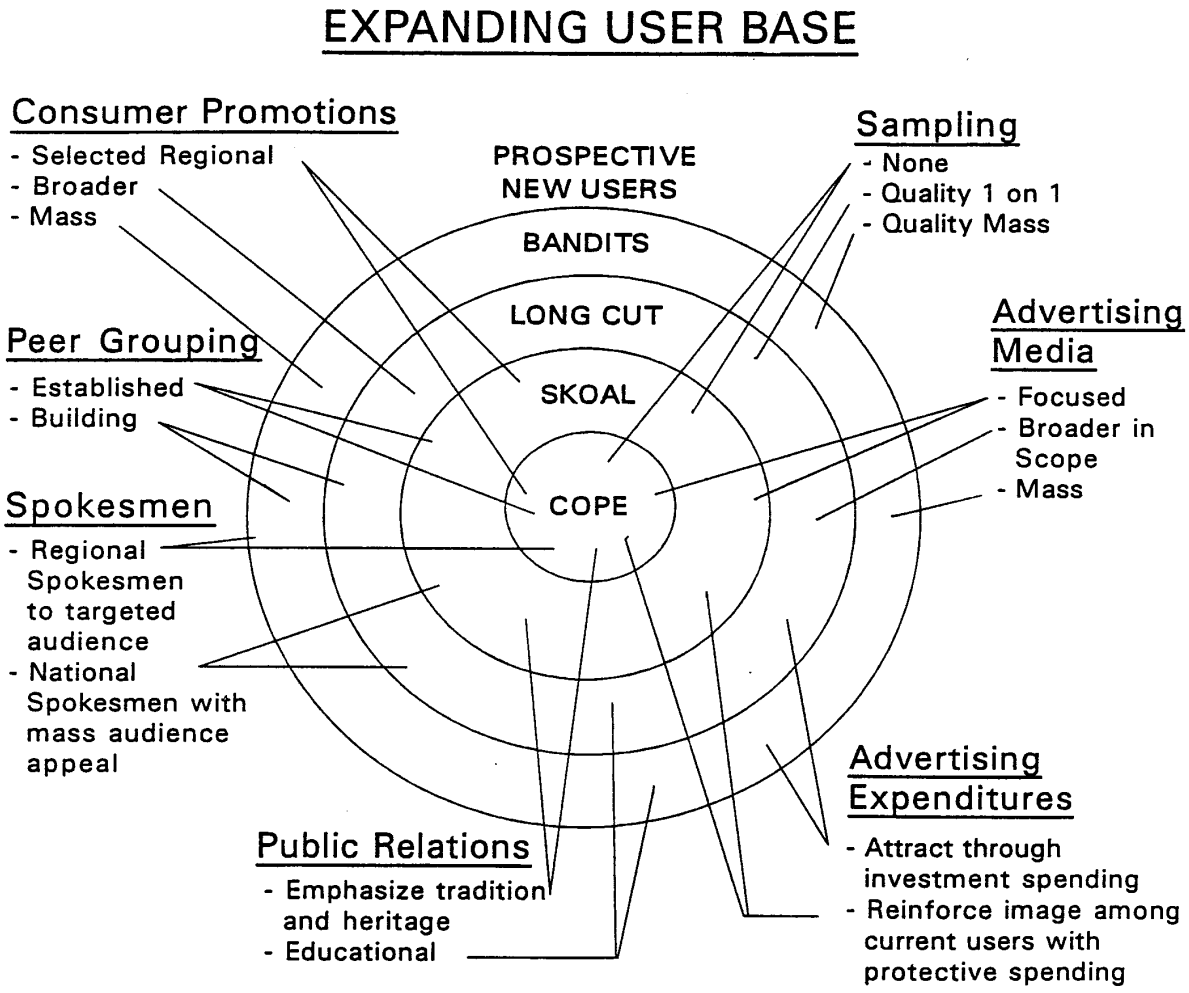
[517] *Marsee v. U.S. Tobacco*, note 317, *supra*, Plaintiff's Exhibit 100, "Graduation Process." (Undated.)

See also U.S. Tobacco Company. One-on-one interview with Mr. Manuel Leitao, Executive Vice President, U.S. Tobacco and President Tobacco Division. *Up to Snuff.* Autumn 1984:2:

> *Some people will remain with the Bandits, and some people will get into a sort of graduation process. The bottom line, and we must never forget the bottom line, is that Bandits is a vehicle that is going to expand the use of smokeless tobacco.*

Another company document sets out a similar strategy for entering new markets. The strategy involved starting users on the lower nicotine Skoal Bandits with an eye toward "establishing a normal graduation process." U.S. Tobacco Company. International Division-Very Optimistic About U.S. Tobacco's Worldwide Expansion. *Up to Snuff.* March 15, 1988. Page 2.

[518] U.S. Tobacco Company. *Expanding User Base.* (Undated.) This document was disclosed during discovery in *Marsee v. U.S. Tobacco,* note 317, *supra.* The document was authenticated by Dr. Jack Henningfield in a letter to Rep. Henry Waxman (D-Ca), in which Dr. Henningfield states his awareness of the origins of the chart as "provided by the United States Tobacco Company to the plaintiffs in the *Marsee v. United States Tobacco Company* law suit in which I served as an expert witness in 1986. This chart was provided to me by the plaintiffs attorney, Mr. Braly, to review." Letter from Jack E. Henningfield, Ph.D., Chief, Clinical Pharmacology Branch, National Institute on Drug Abuse to The Honorable Henry A. Waxman, Chairman, Subcommittee on Health and the Environment, House of Representatives (Dec. 13, 1994).



Adapted from a chart provided by U.S. Tobacco during discovery in Marsee v. U.S. Tobacco

Outside the outermost ring of the chart is the label "Prospective New Users"; the subsequent concentric rings are labeled "Bandits," "Long Cut, and "Skoal," respectively, and a ring labeled "Cope" (representing Copenhagen) is the bullseye in the middle. The rings of the chart thus progress from the lowest delivery nicotine products on the outside to the highest nicotine delivery products in the center of the bullseye. The chart's further annotations - - "Consumer Promotions," "Peer Grouping," "Spokesmen," "Public Relations," "Advertising Expenditures," "Advertising Media," and "Sampling" - - clearly demonstrate the company's intent to advertise, promote, and provide free samples of the lower delivery nicotine products, which are on the lowest level of the "graduation process," to new users. The highest nicotine products, however, are to be advertised only to current users in a highly focused manner.

Several other company documents discuss the graduation process. A UST document discussed in a trial transcript mentions Skoal Bandits and the company's intent to use the product to fuel the graduation process:

> *Skoal Bandits, which is at the bottom of the previous graduation chart, 'will continue to fuel the new user base to assure graduation to our priority moist brands'.*[519]

Another UST document, discussed in the same trial transcript, again acknowledges the company's deliberate use of the graduation process:

> *. . . sample Skoal Bandits often and intensively in and around the retail account to create new customers and feed the graduation process.*[520]

These marketing strategies for smokeless tobacco have been extremely successful in

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[519] UST document No. 2077832, in *Marsee v. U.S. Tobacco,* note 317, *supra.* In:1.7 TPLR 3.209. Another U.S. Tobacco document (no. 1023186-89), discussed in *Marsee* mentions introducing a product that will fill the gap between Bandits and Skoal in the graduation process. In:1.7 TPLR 3.209.

[520] UST document No. 2101576, discussed in *Marsee v. U.S. Tobacco*, note 317, *supra* (1.7 TPLR 3.210).

recruiting new users. Use of smokeless tobacco products has risen substantially since the 1970's: overall, consumption of moist snuff almost tripled from 1972 through 1991; use by adolescent males aged 18 to 19 increased almost 1,500% between 1970 and 1991.[521] The success of the graduation strategy in getting users to the point where they want to consume the high-nicotine products is demonstrated by the market share of various products. While the majority of advertising dollars are spent on the low and medium nicotine products like Skoal Long Cuts, the great bulk of the increased sales is in Copenhagen, the high-nicotine product.[522] The consistently small market share for the low-nicotine products shows that they serve only as a steppingstone to the high-nicotine products. Consistent with the graduation strategy, a recent study found that older smokeless tobacco users are more likely to purchase the brands that deliver high levels of nicotine than are younger smokeless tobacco users.[523]

The evidence of manipulation of nicotine delivery in smokeless tobacco and the deliberate marketing of higher and higher nicotine-containing products shows clearly that smokeless tobacco manufacturers intend consumers to become tolerant to, and dependent on, the

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[521] *See:*

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).

Marcus AC, Crane LA, Shopland DR, Lynn WR. Use of smokeless tobacco in the United States: Recent estimates from the current population survey. In: *Smokeless Tobacco Use in the United States: NCI Monographs.* 1989;8:17-23.

Sullivan LW. Keynote Address. In: *Smokeless Tobacco or Health: An International Perspective: Smoking and Tobacco Control Monograph 2.* National Cancer Institute. NIH Pub. No. 92-3461. 1992.

[522] *See* Connolly, note 511, *supra,* at p. 5.

[523] Hatsukami D, Nelson R, Jensen J. Smokeless tobacco: current status and future directions. *Brit. J. of Addiction.* 1991; 86:559-563.

nicotine in smokeless tobacco. Both tolerance and dependence are effects on the structure and function of the body produced by nicotine. Accordingly, smokeless tobacco products, as designed and marketed by the tobacco industry, are intended to affect the structure or function of the body.

F. INDUSTRY ALTERNATIVE TOBACCO PRODUCTS

1. Industry Development of Nicotine Substitutes That Mimic Nicotine's Drug Effects

Tobacco manufacturers' intention to offer tobacco products that will be used to affect the structure or function of the body is further demonstrated by the research programs tobacco companies have undertaken to develop "nicotine analogues." Nicotine analogues are chemical substances that are closely related to nicotine. Both Philip Morris and Brown and Williamson have had substantial research programs to identify nicotine analogues that would produce nicotine-like effects on the central nervous system[524] and that either could be substituted for nicotine if nicotine-containing tobacco became regulated or unattractive to consumers, or that could be added to currently marketed products to enhance the effects of nicotine.

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[524] *See the following documents:*

Kilburn KD, Underwood JG. BATCO Group Research and Development Center. *Preparation and Properties of Nicotine Analogues*. Report No. RD 953-R. November 9, 1972.

Kilburn KD, Underwood JG. BATCO Group Research and Development Center. *Preparation and Properties of Nicotine Analogues, Part II.* Report No. RD 1048-R. October 11, 1973

Kilburn KD. BATCO Group Research and Development Center. *Preparation and Properties of Nicotine Analogues, Part III.* June 20, 1979.

BATCO R&D. *Notes on the R&D Conference*. October 29, 1979 - November 1, 1979. Page 01794-01808.

Declaration of former Philip Morris scientist Victor John DeNoble, Ph.D., executed on February 2, 1995. (hereafter cited as DeNoble Declaration) (A copy of the declaration is on file at FDA.)

The Council for Tobacco Research - U.S.A. and the American Tobacco Co. also funded research on nicotine analogues. *See, e.g.:*

Report of the Council for Tobacco Research - U.S.A., Inc. 1978.

Meacham RH, Bowman ER, McKennis H. Additional routes in the metabolism of nicotine to 3 pyridylacetate. The metabolism of dihydrometanicotine. *J-Biol-Chem.* 1972;247(3):902-08.

These programs were also designed to identify substances that shared nicotine's "desired" effects on the central nervous system, without producing nicotine's undesirable effects on the cardiovascular system.[525] In the words of former Philip Morris scientist Dr. Victor J. DeNoble:

> *Our goal was to identify the effects of nicotine in the central nervous system, and to establish structural activity relationships among organically synthesized analogues of nicotine. The purpose of this nicotine analogue program was to develop an analogue that would retain the physiological effects of nicotine in the brain as well as the behavioral effects, but not have adverse effects on the cardiovascular system.*[526]

The tobacco industry's programs to develop nicotine analogues were, according to company documents, prompted by the industry's recognition that the market for tobacco depends on the pharmacological effects of nicotine on the central nervous system. For example, in 1968, BATCO researchers reported the following conclusion at a research conference:

> *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. The possibility that nicotine and other substances together may exert effects larger than either separately (synergism) should be studied and if necessary the attention of Marketing Departments should be drawn to these possibilities.* [Emphasis

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[525] BATCO R&D. BATCO Research Conference. Hilton Head, SC. September 24-30, 1968. Page 3.

See also:
U.S. Patent No. 5,138,062. Osdene TS, Secor HV, Seeman JI. *Nicotine Analogues*. Philip Morris Inc. August 11, 1992. C1:57-60.

U.S. Patent No. 5,015,741. Osdene TS, Secor HV, Seeman JI. *Nicotine Analogues*. Philip Morris Inc. May 14, 1991. C1:56-60.

See DeNoble Declaration, note 524, *supra,* at pp. 3-4.

[526] *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.* 103rd Cong. 2d Sess. 5 (April 28, 1994) (testimony of former Philip Morris scientist Victor J. DeNoble).

added.][527]

This document shows that BATCO was interested in using chemicals with nicotine-like effects to replace nicotine or enhance the drug effects of nicotine in cigarettes.[528] Another BATCO document underscores the fact that the search for nicotine analogues was designed to implement the industry's belief that nicotine's drug effects are essential to sustain the market for tobacco. S.J. Green, director of research at BATCO, in a paper on future research policy, stated:

> *While other factors cannot be ignored and their influence is not completely understood, it seems a good assumption that nicotine plays a predominant role for many smokers. So that a good part of the tobacco industry is concerned with the administration of nicotine to consumers. If this assumption is correct two long-range research projects become immediately apparent. These are to find pharmacological alternatives to nicotine and to explore alternatives to tobacco as a source of nicotine.*[529]

Other documents show that nicotine analogues were also believed by BATCO to be necessary to protect against three potential threats to the company's nicotine-based market: 1) government action to prohibit the use of nicotine because of nicotine's cardiovascular toxicity; 2) the development by other pharmaceutical companies of alternative, more socially and medically acceptable means of administering nicotine; or 3) the discovery and use by pharmaceutical companies or anti-tobacco activists of nicotine "antagonists," that is, substances that block the

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[527] *See* BATCO Research Conference, note 525, *supra,* at p. 3.

[528] *See also* U.S. Patent No. 4,340,072. Bolt AJ, Chard B. *Smokable Device.* Imperial Group Ltd. (1982). This patent describes an alternative cigarette-like device providing an aerosol that may contain nicotine or another psychoactive substance:

> *The aerosol material may, as an alternative to a flavourant solution, comprise a solution of a flavourant and/or nicotine in triacetin or benzyl benzoate. Any psycho-active or physiologically active compound such as ephedrine or a nicotine/ephedrine mixture may be used.*

[529] Green SJ. *BAT Group Research.* September 4, 1968. Page 2.

effects of nicotine on the central nervous system.

A BATCO research report dated November 9, 1972, and entitled "Preparation and Properties of Nicotine Analogues," provided the following rationale for BATCO's long-term research program to develop nicotine analogues:

> *Summary*
> *Should nicotine become less attractive to smokers, the future of the tobacco industry would become less secure.*
>
> *Factors that could influence the attractiveness of nicotine are discussed, and it is concluded that substances closely related to nicotine in structure (nicotine analogues) could be important.*
>
> . . . .
>
> *Introduction*
> *It has been suggested that a considerable proportion of smokers depend on the pharmacological action of nicotine for their motivation to continue smoking (1, 2, 3[530]).*
>
> *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.*
>
> *A commercial threat would arise if either an alternative product became acceptable or the effect of nicotine was changed.*
>
> *An alternative product could come from the pharmaceutical industry. With a socially acceptable route for administration, and with medical endorsement, the product could be successful.*
>
> *The effect of nicotine could be inhibited by an antagonist, and cigarettes would tend to become insipid. Such an antagonist could arise by accident or design from the pharmaceutical industry. It might be used tactically to advance that industry's alternative product, or its general use could be advocated by the anti-smoking lobby, with or without government support.*
>
> *The obvious starting point of a search, either for alternatives or antagonists to nicotine, is the nicotine molecule and close analogues of it. The present report*

[530] The page of the report that contains the citations for these footnotes is missing from the document provided by Brown and Williamson to Congress.

discussed nicotine and some of its analogues. . .[531]

These internal documents reflect the tobacco industry's awareness that nicotine's drug effects are critical to the continued success of tobacco in the marketplace. Indeed, they show that the industry views nicotine's drug effects as so important that if nicotine's drug effects were interfered with in any way, tobacco companies would seek to substitute another drug for nicotine to ensure the continued market for tobacco.

Internal documents from Philip Morris' nicotine analogue program show that this company also sought nicotine analogues with pharmacological effects on the central nervous system, including effects associated with addiction.

For example, an internal 1980 company memorandum describes the rationale for Philip Morris' research into nicotine analogues. After asserting that nicotine "is a powerful pharmacological agent" which is "cited often as 'the reason for smoking,'" the memorandum describes the importance of discovering compounds related to nicotine:

> *[O]ur ability to ascertain the structural features of the nicotine molecule which are responsible for its various pharmacological properties can lead to the design of compounds with enhanced desirable properties (central nervous system effects) and minimized suspect properties (peripheral nervous system effects). There are many opportunities for acquiring proprietary compounds which can serve as a firm foundation for new and innovative products in the future.*[532]

Between 1980 and 1984, Dr. DeNoble conducted research for Philip Morris on nicotine analogues,[533] first identifying the pharmacological effects of nicotine on the brains and behavior

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[531] *See* Kilburn (1972), note 524, *supra,* at pp. 1-2.

[532] Philip Morris Interoffice Correspondence from J.L. Charles to Dr. R. B. Seligman. Nicotine Receptor Program-University of Rochester. March 18, 1980.

[533] The nicotine analogue program at Philip Morris began before Dr. DeNoble's arrival. *See*, e.g. Secor HV, Edwards WB. Philip Morris Research Center. Nicotine analogues: synthesis of pyridylazetidines. *J.*

of animals[534] and then comparing these effects to the physiological and pharmacological effects of nicotine analogues synthesized by chemists at Philip Morris.[535] Dr. DeNoble's studies, which were conducted as part of the "Behavioral Pharmacology" Program at Philip Morris, were intended to characterize the pharmacologic effects of nicotine and then to identify those analogues that affected the central nervous system in the same way that nicotine affects the central nervous system. An internal Philip Morris document states:

> *Major objectives of the Behavioral Pharmacology Program are (1) To develop a better understanding of the reinforcing actions of nicotine and nicotine*

Org. Chem. 1979;44(18):3136.

See DeNoble Declaration, note 524, *supra,* at p. 4.

[534] Dunn WL. Philip Morris Inter-Office Correspondence to T.S. Osdene. *Possible Restructuring of the Behavioral Research Lab.* June 18, 1980. Page 100019244.

[535] *See:*
DeNoble Declaration, note 524, *supra,* at pp. 2-9.

U.S. Patent No. 4,452,984. Edwards III WB. *Optically Active Nicotine Analogues and Process For Their Preparation.* Philip Morris Inc. June 5, 1984.

U.S. Patent No. 4,442,292. Edwards III WB. *Optically Active Nicotine Analogues and Process For Their Preparation.* Philip Morris Inc. April 10, 1984.

U.S. Patent No. 4,332,945. Edwards III WB. *Optically Active Nicotine Analogues and Process For Their Preparation.* Philip Morris Inc. June 1, 1982.

U.S. Patent No. 4,321,387. Chavdarian CG, Sanders EB. *Process for the Preparation of Optically Active Nicotine Analogues.* Philip Morris Inc. March 23, 1982.

U.S. Patent No. 4,220,781. Sanders EB, Secor HV, Seeman JI. *Process for Preparing 2-ALKYL Nicotinoids.* Philip Morris Inc. September 2, 1980.

U.S. Patent No. 4,155,909. Sanders EB, Secor HV, Seeman JI. *2-ALKYL Nicotinoids and Processes For Their Production.* Philip Morris Inc. May 22, 1979.

Work on nicotine analogues continued after Dr. DeNoble's departure from the company. *See* U.S. Patent No. 5,138,062, note 525, *supra.*; U.S. Patent No. 5,015,741, note 525, *supra.*; U.S. Patent No. 4,590,278. Edwards III WB. *Nicotine Analogues.* Philip Morris Inc. May 20, 1986.

analogues, (2) To gain insight into the neurobehavioral actions of nicotine, and (3) To develop and use animal behavior techniques to screen nicotine analogues for their nicotine eliciting properties.[536]

Dr. DeNoble's research and that of other scientists working at Philip Morris on the pharmacologic effects of nicotine showed that nicotine is self-administered by rats (i.e., is a "positive reinforcer"), produces tolerance, causes a unique "prostration syndrome" when injected into the rat brain that correlates to nicotine's ability to produce behavioral changes, and that nicotine loses its effects when the rat is pretreated with mecamylamine, a substance that blocks nicotine's effects in the brain.[537] These studies also demonstrated that nicotine has pharmacological activity in the brain, and that it has characteristics of other addictive substances that make it likely to be abused.[538] To evaluate potential nicotine analogues, Philip Morris tested numerous substances to determine whether they duplicated nicotine's effects on the brain and whether they had the same characteristics associated with abuse liability.[539] Dr. DeNoble and

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[536] DeNoble VJ, Carron L. Philip Morris Inter-Office Correspondence to Dr. T. Osdene. *Progress Report: The Behavioral Pharmacology Program*. October 14, 1980.

See Dunn, note 534, *supra,* which proposes the creation of the "Behavioral Pharmacology Project."

[537] *See:*
DeNoble Declaration, note 524, *supra,* at pp. 5-9.

DeNoble VJ. Philip Morris Inter-Office Correspondence to W.L. Dunn. *Nicotine Program-Behavioral Research Laboratory.* April 24, 1980. Page 2.

DeNoble VJ, Mele PC, Ryan FJ. Philip Morris Research Center. *Nicotine as a Positive Reinforcer for Rats: Effects of Infusion Dose and Fixed Ratio Size*. Unpublished Manuscript.

Dunn, note 534, *supra,* at p. 100019244.

[538] *See* DeNoble Declaration, note 524, *supra,* at pp. 7-9. *See also* FINDINGS § II.A.2., *supra.*

[539] *See:*
DeNoble, note 536, *supra.*

other scientists working at and for Philip Morris used nicotine analogues in discrimination tests in rats, in prostration studies, and in self-administration studies.[540] As noted in FINDINGS § I.B.3., supra, discrimination and self-administration studies provide key evidence of the likelihood that a substance will be addictive in humans.

Philip Morris documents state explicitly that the purpose of the research on nicotine analogues was to find nicotine substitutes that were behaviorally active and had the same reinforcing properties as nicotine; i.e., produced effects on the central nervous system associated with addiction. A progress report from the behavioral pharmacology group identified as its major objectives:

> *Nicotine Analogues*
>
> *Research Objectives*
>
> 1. *Determine if behaviorally active nicotine analogues can be directly substituted for nicotine in rats for which nicotine is functioning as an intravenously delivered positive reinforcer.*
> 2. *Establish nicotine analogues as an intravenously delivered positive reinforcer.*
> 3. *Compare the potencies of nicotine analogues to nicotine in producing positive reinforcing effects.*[541]

The objectives of the studies conducted by the behavioral pharmacology group were developed in conjunction with senior management at Philip Morris, and the study results were shared with

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DeNoble Declaration, note 524, *supra,* at pp. 4-5.

[540] DeNoble VJ, Carron L. Philip Morris Inter-Office Correspondence to W.L Dunn. *Research Progress Concerning Discrimination and Prostration Studies*. August 18, 1980. Pages 1003030001-1003030007.

Carron LM, Levy CJ, Allen A. Philip Morris Inter-Office Correspondence to V.J. DeNoble. *Discrimination Studies*. May 7, 1980. Pages 1003030008, 1003030009.

[541] DeNoble VJ, Carron L. Philip Morris Inter-Office Correspondence to W. Dunn. *Progress in Behavior Pharmacology Laboratory*. March 27, 1981. Pages 1-32.

upper management as well.[542]

Thus, it is evident from tobacco manufacturers' interest in developing nicotine analogues with central nervous system effects comparable to nicotine that these manufacturers (1) believe that the pharmacological effects of nicotine on the central nervous system, and in particular the pharmacological effects that reinforce continued tobacco use, are necessary to ensure a long-term market for tobacco; and (2) intend to market products that affect the central nervous systems of their customers.

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[542] *See:*
DeNoble Declaration, note 524, *supra,* at pp. 4, 11-12.

Charles JL. Philip Morris Inter-Office Correspondence to T.S. Osdene. March 1, 1983. Page 2: "Because of the sensitive nature of Vic's assignment, documentation of much of his work has been restricted to the Director and Vice President level."

2. Industry Research on Acetaldehyde As a Reinforcer

The behavioral pharmacology program at Philip Morris also conducted pharmacological and behavioral research on another constituent of cigarette smoke, acetaldehyde. This research was intended to find a combined dose of acetaldehyde and nicotine in cigarettes that would produce "maximal reinforcing effects."[543] The reinforcing capability of a drug is a measure of the dependence-producing properties of a drug.[544] In undertaking research on how to maximize the reinforcing effects of cigarettes, Philip Morris demonstrated its understanding of the dependence-producing nature of cigarettes and its intention to manufacture and sell cigarettes that affect the structure or function of the smoker's body.

Acetaldehyde, like nicotine, is present in, and delivered to the smoker from, cigarette smoke.[545] At the time Philip Morris conducted research on the reinforcing properties of acetaldehyde in cigarettes, acetaldehyde had been studied as a potential contributing factor to the

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[543] DeNoble VJ. Philip Morris U.S.A. Inter-office correspondence to J.L. Charles. *Project Number 1610 (Behavioral Pharmacology) Objectives and Plans - 1982-1983.* July 20, 1982. Page 2.

[544] *See:*
Balster RL. Drug abuse potential evaluation in animals. *Brit. J. of Addiction.* 1991;86:1549-1558.

Henningfield JE, Cohen C, Heishman SJ. Drug self-administration methods in abuse liability evaluation. *Brit. J. of Addiction.* 1991;86:1571-1577.

Griffiths RR, Lamb RJ, Ator NA, Roache JD, Brady JV. Relative abuse liability of triazolam: experimental assessment in animals and humans. *Neuroscience and Biobehavioral Reviews.* 1985;9:133-151.

[545] Acetaldehyde is present in tobacco at 1.6 - 7.4 mg/gm of processed tobacco. It is contained in mainstream smoke at 18-1400 mg per cigarette. U.S. Department of Health and Human Services. *Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of U.S. Surgeon General.* U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. DHHS Publication No. (CDC) 89-8411, 1989.

rewarding effects of alcohol.[546] This information led Philip Morris to explore its reinforcing properties in cigarettes.[547]

Researchers in Philip Morris' behavioral pharmacology program first conducted studies that showed that acetaldehyde acts on the brain and is a positive reinforcer when present in amounts comparable to those delivered by cigarette smoke.[548] By this time, the company had already demonstrated that nicotine was also a positive reinforcer. The researchers noted that it was well-known that the presence of two reinforcers together can modify the behavioral effect of either one, and decided to study whether rats would self-administer nicotine and acetaldehyde in combination. Recognizing that the reinforcing effects of nicotine and acetaldehyde are pharmacological, the researchers stated that their efforts were intended to determine whether the combination produced a "modification of the pharmacologic effect of one compound by the other."[549] The researchers found that rats self-administered the combination of acetaldehyde and

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[546] *See:*
Schuckit MA, Rayses V. Ethanol ingestion: Differences in blood acetaldehyde concentrations in relatives of alcoholics and controls. *Science.* 1979;203:54-55.

Brown ZW, Amit Z, Smith B. Intraventricular self-administration of acetaldehyde and voluntary consumption of ethanol in rats. *Behavioral and Neural Biology.* 1980;28:150-155.

[547] *See* DeNoble Declaration, note 524, *supra,* at p.10.

[548] *See:*
DeNoble VJ. Philip Morris U.S.A. Inter-office correspondence to W.L. Dunn. *Progress Report* from the Behavioral Pharmacology Laboratory for the period beginning September 1, 1980, to March 30, 1981. August 24, 1981. Pages 12-16.

DeNoble Declaration, note 524, *supra,* at pp. 10-11.

[549] DeNoble VJ, Mele PC. Philip Morris U.S.A. Inter-office correspondence to W.L. Dunn. *Progress Report* from the Behavioral Pharmacology Laboratory for the period beginning March 1, 1981, to March 1, 1982. April 21, 1982. Pages 18-19.

nicotine to a greater extent than either compound alone.[550] This finding suggested that the combination was a more potent positive reinforcer than nicotine or acetaldehyde alone.[551]

The culmination of this research was Philip Morris' attempt to establish the "optimum" ratio of acetaldehyde to nicotine in cigarette smoke:

> *Since both acetaldehyde and nicotine are reinforcing agents and each are contained in smoke it becomes important to determine [sic] ratio of acetaldehyde to nicotine which produce maximal reinforcing effects. . . This will allow us to determine the optimum ratio of acetaldehyde to nicotine that maintains the most behavior.*[552] [Emphasis added.]

As this passage makes clear, Philip Morris viewed the "optimal" ratio of acetaldehyde to nicotine as the ratio that would maximize the positive reinforcing effects of cigarettes; i.e., maximize their potential to produce dependence in smokers.

The behavioral pharmacology group conducted further studies suggesting that the ratio of acetaldehyde to nicotine that produced the greatest positive reinforcement in rats was in the range of 4:1.[553] While FDA does not know whether or how this research was implemented by Philip Morris, Dr. DeNoble was present at a meeting at which Philip Morris officials discussed the possibility of producing a cigarette with this ratio of acetaldehyde to nicotine and test-

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[550] *Id.* at pp. 19-21.

[551] *See* DeNoble Declaration, note 524, *supra,* at p. 11.

[552] DeNoble, note 543, *supra,* at p. 2.

[553] Philip Morris U.S.A. Behavioral Pharmacology Annual Report - June 1, 1983. Philip Morris Research Center. Richmond, VA. Pages 20-23. This work was still going on at the time the Behavioral Pharmacology program was terminated at the Philip Morris Research Center in Richmond, VA.

See also, DeNoble VJ. Philip Morris U.S.A. Inter-office correspondence to J.L. Charles. *Project 1610 (Behavioral Pharmacology) Objectives and Plans, 1984.* September 6, 1983. (Continued research on the ratio of acetaldehyde and nicotine with optimum reinforcing effects scheduled for 1984.)

marketing it in South America.[554]

It is thus clear that Philip Morris was interested in implementing the research to maximize the reinforcing effects of cigarettes by manipulating acetaldehyde and nicotine. The data on the reinforcing properties of particular ratios of acetaldehyde and nicotine were also used by researchers at Philip Morris to predict cigarette sales based on the delivery of nicotine and acetaldehyde. The researchers found that they could predict sales of particular brands with an accuracy above 80 % by comparing nicotine and acetaldehyde ratios.[555] This evidence compellingly demonstrates Philip Morris' reliance on, and intention to increase, the reinforcing effect of cigarettes on the structure or function of the smoker's body.

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[554] *See* DeNoble Declaration, note 524, *supra,* at p. 12.

[555] *Id.* at p. 11.

3. Industry Development of Alternative Cigarettes That Deliver Nicotine

Tobacco companies have developed a number of cigarette alternatives. These alternatives to conventional cigarettes have generally been created in response to perceived societal pressure to market safer cigarettes. In developing cigarette alternatives, tobacco companies have sought to eliminate many of the traditional components and characteristics of cigarettes and cigarette smoke, such as tar and carbon monoxide. Tobacco companies have consistently recognized, however, that cigarette alternatives must deliver adequate amounts of nicotine to satisfy consumers. As a result, most of the alternative cigarette products developed by tobacco companies are simply nicotine delivery systems.

Tobacco company development of alternatives to cigarettes demonstrates the industry's knowledge that nicotine is the critical or "active" ingredient in cigarettes, and that smokers smoke primarily to obtain nicotine. The nature of the alternatives they believe could be substituted for currently marketed tobacco products strongly supports the inference that companies intend currently marketed tobacco products to serve as nicotine delivery systems.

In the late 1980's, RJR developed Premier, a "smokeless" cigarette that contained very little tobacco.[556] Although designed to be "smoked" and inhaled, Premier actually worked by

[556] Premier resembled a conventional cigarette in outward appearance only. It contained a carbon tip which served as the heat source. RJR informed FDA that at least 70% of the nicotine delivered by "Premier" was provided from spray-dried tobacco. This 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. 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. Letter with enclosures from Peter B. Hutt, outside counsel for RJR, to Kevin M. Budich, FDA, January 26, 1988.

heating rather than burning tobacco.[557] RJR claimed that by altering the composition of conventional cigarettes and by eliminating the pyrolysis products produced by burning, Premier reduced by about 90% the chemical compounds delivered to smokers by conventional cigarettes.[558] Virtually the only compound (other than the paper and the filter) that was present in Premier in quantities similar to conventional cigarettes was nicotine.[559]

RJR's willingness to eliminate from Premier almost every conventional cigarette component but nicotine was not a coincidence. According to a memorandum of meeting dated October 23, 1987, the attorney representing RJR told FDA officials that for a cigarette substitute like Premier to be successful in the marketplace, it must contain nicotine.[560] Observing that herbal cigarettes had failed as substitutes due to the absence of nicotine, the attorney said that RJR would never eliminate nicotine from Premier because "without nicotine, you don't have a cigarette."[561]

RJR documents also show that the purpose of including nicotine in Premier was to deliver nicotine to the smoker's blood and brain. Studies conducted by RJR to determine

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[557] *See* R.J. Reynolds, note 300, *supra*. Premier was withdrawn from the market shortly after its introduction.

[558] *Id.* at p. 8.

Department of Health and Human Services. *RJR's "Smokeless" Cigarette*. October 23, 1987, memorandum of meeting between Peter B. Hutt, representing RJR Nabisco Inc., and FDA representatives (Daniel L. Michels, Sammie R. Young, Rudolf Apodaca, and Kevin M. Budich).

[559] *See* R.J. Reynolds, note 300, *supra,* at pp. 1-10. In the mainstream smoke produced by Premier, the only components that were similar in quantity to conventional cigarettes were nicotine and carbon dioxide.

[560] *See* Memorandum of Meeting, note 558, *supra.*

[561] *Id.*

whether Premier would be an acceptable cigarette substitute show unequivocally that RJR was interested in Premier's ability to deliver specific blood levels of nicotine to the smoker. Delivery of nicotine to the smoker's blood is relevant only if the company was interested in producing physiological effects in the smoker's body. The company itself reported, in a book published at the time of Premier's introduction, that it wanted to assess whether differences in composition and function between Premier and conventional cigarettes might alter nicotine delivery to the smoker's blood and body.[562] To assure itself that the absorption of nicotine into the smoker's body from Premier and conventional cigarettes was similar, RJR conducted plasma studies on rats and humans comparing the levels of nicotine in smokers' blood produced by smoking conventional cigarettes with the levels of nicotine produced by smoking Premier.[563]

RJR found the absorption and elimination of nicotine from Premier to be comparable to conventional cigarettes.[564] Because, however, Premier contained somewhat less nicotine than the reference cigarette tested, the blood levels of nicotine found in smokers of Premier were somewhat lower than those from the reference cigarette. The blood-level studies conducted by

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[562] *See* R.J. Reynolds, note 300, *supra,* at p. 460.

[563] During its investigation FDA asked R.J. Reynolds about the company's use of human body fluid testing to measure nicotine levels in smokers. Counsel to R.J. Reynolds informed FDA that it "should come as no surprise to the Agency that RJRT [R.J. Reynolds Tobacco Company] did some body fluids testing and used the services of Bellomy Research, Inc. to solicit participants." Letter to E. Blumberg, FDA, from R. Cooper, Williams & Connolly, on behalf of R. J. Reynolds. November 18, 1994. Page 2. It appears that R.J. Reynolds has conducted such testing not only in conjunction with the development of Premier, but in other circumstances "in which a developmental product incorporated new technology, and the testing was conducted in order to understand . . . for example, whether nicotine is absorbed or metabolized differently by smokers smoking the new technology product when compared to other cigarettes . . ." *Id.*

[564] *See* R.J. Reynolds, note 300, *supra,* at pp. 496-497. *See also* p. xii:

> *. . . in the short-term measurements of nicotine pharmacokinetics, the [Peer Review] Committee agreed with the conclusion that there was no significant difference in this response in individuals smoking either the reference or the new cigarette.*

RJR demonstrated that smokers compensated for the lower levels of nicotine in Premier. The researchers stated that subjects smoked Premier more intensely, speculating that they inhaled a greater volume of the smoke from Premier.[565] Thus, while Premier contained about 52% of the nicotine of the reference cigarette, after 39 days of smoking Premier the volunteers were absorbing 69% of the nicotine they had absorbed from the reference cigarette.[566] RJR has patented other cigarette alternatives whose basic function is also to deliver nicotine.[567]

More recently, RJR detailed plans to unveil a low-smoke cigarette, Eclipse, in 1995. It has a charcoal heat source for the tip. Behind the charcoal tip, there are processed tobacco parts containing more than 50% glycerine, which vaporizes at temperatures below those that burn tobacco. Behind the processed tobacco, there is blended tobacco. The charcoal heats the processed tobacco and glycerine, which creates smoke-like vapor. The glycerine vapor then passes through the blended tobacco, picking up flavor and nicotine before passing through a standard cellulose filter, and into the smoker's mouth. According to RJR, Eclipse vapor contains about 85% water, glycerol, and nicotine (versus 25% in standard cigarette smoke) and about 15% tars and related particles (versus 75% in standard smoke).[568]

Other tobacco companies have also developed cigarette alternatives similar to Premier in design and intent. In the 1960's, Charles Ellis of BATCO developed "Ariel." Like Premier,

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[565] *Id.* at p. 482.

[566] *Id.* at pp. 479, 482-483, 490-492.

[567] U.S. Patent No. 5,285,798. Banerjee et al. *Tobacco smoking article with electrochemical heat source.* R.J. Reynolds Tobacco Company. February 15, 1994. (Alternative cigarette that is designed to generate enough heat, without burning, to volatilize and deliver to the smoker only the nicotine and flavor materials in the tobacco).

[568] Hilts P. Little smoke, little tar, but still lots of nicotine. *New York Times.* November 27, 1994;A1.

Ariel eliminated most of the compounds delivered by conventional cigarettes, but ensured delivery of a sufficient amount of nicotine to satisfy smokers' need for nicotine. Ariel was an alternative smoking device that contained a capsule of nicotine-enriched tobacco. The nicotine-enriched tobacco was heated by burning tobacco surrounding the capsule.[569] The nicotine was supposed to be released into an aerosol and inhaled by the smoker. The patents for this device make clear that its purpose was to provide an alternative to conventional cigarettes that would provide the same "satisfaction" as a traditional cigarette. The principal (indeed, almost the only) ingredient it was designed to deliver to achieve this goal was nicotine:

> *This invention relates to an improved smoking device whereby an improved smoke stream of a controlled character is delivered to the smoker.*
>
> . . . .
>
> *A further object is the provision of an improved smoking device of the above character which simulates a conventional or traditional smoking device, such as a cigarette, in appearance and in social habit attributes, and which affords the same benefits, pleasure and satisfaction without the attendant disadvantages.*
>
> . . . .
>
> *Our invention contemplates the provision of an improved smoking device having the appearance of a traditional smoking device and embodying a composition which releases nicotine vapor and potentially aerosol forming materials, including water vapor, when subjected to an elevated temperature . . .*[570]

A subsequent patent for a modification of this device stated that:

> *the invention thus 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*

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[569] *See:*

U.S. Patent No. 3,258,015. Ellis CD, Dean C, Schachner H, Williamson D. *Smoking Device*. Battelle Memorial Institute. June 28, 1966.

U.S. Patent No. 3,356,094. Ellis CD, Dean C, Hughes IW. *Smoking Devices*. Battelle Memorial Institute. December 5, 1967.

[570] *See* U.S. Patent No. 3,258,015, note 569, *supra*.

smoking a conventional cigarette . . .[571] [Emphasis added.]

At a 1968 conference of BATCO researchers, the conferees succinctly described Ariel as a "device[] for the controlled administration of nicotine."[572]

Other documents reveal that tobacco companies have consistently recognized that alternative tobacco products must contain sufficient amounts of nicotine to satisfy users.[573] For example, the minutes of a BATCO Group R&D Conference held in 1969 disclose that the conferees agreed that non-tobacco cigarettes could not succeed in the marketplace without the addition of nicotine:

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[571] *See* U.S. Patent No. 3,356,094, note 569, *supra.*

[572] BATCO Research Conference. Hilton Head Island, SC. September 24-30, 1968. Page 3.

[573] *See the following documents:*
BATCO Group Research Conference. St. Adele, Quebec. November 9-13, 1970.

S.J. Green. *Appendix I. Smoking and Health: Some Recent Findings.* Memo to D.S.F. Hobson. March 2, 1967. Page 2:

A non-tobacco smoking material has been made from cellulose and nicotine . . .

Proceedings of the BATCO Smoking Behaviour - Marketing Conference. July 9-12, 1984.

Ayres CI. *Notes from the 1984 GR&DC Nicotine Conference.* Conference Outline. July 9-12, 1984.

U. S. Patent No. 5,050,621. Creighton DE, Grieg CC. *Smoking Articles.* BATCO. September 24, 1991.

Abstract: There is provided a smoking article comprising a heating unit aerosol generation section in flow communication at a first end thereof with the heating unit, nicotine source in flow communication at a first end thereof with said heating unit, a mixing space with which said aerosol generation section and nicotine source means are in flow communication at or via respective second ends thereof, and a velocity accelerating orifice in flow communication with the mixing space. [Emphasis added.]

In a document submitted to the Food and Drug Administration in 1985 pursuant to an FDA examination of their product, Advance Tobacco Products, Inc., offered the following description of their smokeless cigarette:

[It] has the appearance and feel and provides a sensation similar to a conventional cigarette, but [ ] delivers nicotine satisfaction to the user by inhalation of nicotine vapor in a manner not requiring the combustion of tobacco.

> *There was a general discussion on non-tobacco materials and, largely due to the difficulties foreseen with the addition of nicotine, the Conference did not envisage at present the likely success of a totally non-tobacco cigarette.*[574]

The conferees went on to express their view that, if non-tobacco ingredients were used as part of the tobacco blend in cigarettes, cigarette manufacturers would have to compensate for the absence of nicotine in the non-tobacco materials by using high-nicotine tobaccos:

> *However, it now seems quite likely that non-tobacco materials will be successfully incorporated into cigarettes as blend constituents, particularly in health orientated products. A large usage of non-tobacco materials would be likely to increase the demand for high-nicotine tobaccos.*[575]

A 1970 BATCO R&D Conference included a particularly telling illustration of the tobacco industry's recognition of the central importance of nicotine in cigarette alternatives. The minutes of that conference contain the following finding, agreed to by the conference attendees:

> *It was agreed that, if and when total cigarette consumption declined, great opportunities for supplying the demands of other socially acceptable habits could follow. Discussion followed on those opportunities which might arise. Amongst those discussed were a) chewing products, and b) wet snuff* [both of which are smokeless tobacco products]. *It was felt that this whole area, much of which is already in the tobacco industry, should be examined more thoroughly. Particular attention should be given to buccal administration of nicotine and other physiologically active ingredients. At the same time, it was re-affirmed that we would not contemplate the incorporation of nicotine in edible products.*[576] [Emphasis added.]

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[574] BATCO Research Conference. Kronberg, Germany. June 6, 1969. Page 8. Brown and Williamson representatives attended.

[575] *Id.*

See also, BATCO, note 573, *supra,* at p. 4. A similar expression of the need to increase the nicotine content of the tobacco blend where tobacco substitutes without nicotine are used as part of the blend is contained in the minutes of a 1970 BATCO research conference:

> *The addition of nicotine to SM [a tobacco substitute] was considered, and it was recommended that nicotine per se, should not be used inside any tobacco factory. However, high nicotine content tobacco extract might be added.*

[576] *Id.* BATCO Group Research Conference at p. 3.

In 1984, BATCO marketers and "product application thinkers" convened to discuss innovative product ideas and were still convinced that if the tobacco industry lost a significant number of smokers, the industry should move to administration of nicotine through moist snuff. According to the conferees, the objective of shifting to moist snuff would be:

> *To capitalise on the potential downtrend of the smoking habit as the only means to achieve nicotine satisfaction by participating in a parallel product market free of social/health concerns and with attractive profitability.*[577] [Emphasis added.]

As these passages make clear, tobacco manufacturers understand that what both cigarettes and smokeless tobacco products have in common is the ability to administer nicotine to consumers, and that the purpose of the nicotine is to produce physiological effects on the consumer. If nicotine-containing cigarettes were to become socially unacceptable, it was the tobacco industry's intention to find another method of supplying nicotine to consumers.

Smokeless tobacco manufacturers, like cigarette manufacturers, understand that tobacco substitutes must include nicotine. Unlike BATCO, however, the major smokeless tobacco manufacturer, UST, has considered adding nicotine to food to create a nicotine delivery system that would function as an alternative to smokeless tobacco. At a meeting of UST executives, researchers, and marketers held in 1968 to discuss future directions for the company, the director of research proposed that the company develop a "swallowable chew: a confection with nicotine (artificial snuff)."[578] Later in the same document, he made clear that the purpose of adding nicotine to artificial snuff would be to "satisfy" snuff users;[579] i.e., to satisfy their need for

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[577] BATCO. *Structured Creativity Conference*. Southampton, England. June 25-28, 1984. List C.

[578] Minutes of Snuff and Chewing Tobacco Research - Manufacturing - Marketing Meeting. New York Hilton. January 22-23, 1968. Page 5.

[579] *Id.* at p. 10.

nicotine.

Thus, company documents related to the development of alternatives to cigarettes and smokeless tobacco establish tobacco manufacturers' knowledge that nicotine is the critical or "active" ingredient in cigarettes and smokeless tobacco, and that consumers use these products primarily for nicotine. Moreover, the fact that currently marketed and alternative products are studied for their ability to deliver nicotine to the bloodstream shows that the companies know that consumers use currently marketed tobacco products for the effects of nicotine on the structure and function of their bodies, rather than for taste or flavor. The fact that the tobacco industry considers nicotine delivery systems to be functional equivalents to tobacco demonstrates that tobacco companies intend their currently marketed tobacco products to deliver nicotine to consumers to affect the structure or function of their bodies.

G. INDUSTRY KNOWLEDGE THAT NICOTINE'S SENSORY EFFECTS ARE SECONDARY TO ITS PHARMACOLOGICAL EFFECTS

Despite the tobacco industry's public assertions that nicotine is in cigarettes only to provide flavor, taste, or mouth feel (immediate sensory effects) to the smoker,[580] the evidence shows that tobacco companies view nicotine's primary role as providing the smoker with the pharmacological effects that smokers seek from tobacco.

As described earlier, the tobacco industry knows that the primary significance of nicotine in tobacco is to provide pharmacological effects, both acute (mood regulation, weight control) and long-term (reinforcing effects that create a continuing physiological need for nicotine). While nicotine in tobacco has both systemic pharmacological effects and acute sensory effects in the mouth, nose, and throat,[581] the evidence in the preceding sections and other industry documents demonstrates that the acute sensory effects of nicotine are secondary in importance to

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[580] *See:*
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, 103 Cong. 2d Sess. 763 (April 14, 1994). (testimony of TF Riehl, Vice President for Research & Development, Brown and Williamson Tobacco Corp.):

We blend for taste, not nicotine.

Id. 103 Cong. 2d Sess. 590 (statement of Thomas E. Sandefur, Jr., CEO Brown and Williamson Tobacco Corp.) :

Without nicotine, cigarettes simply would not taste like cigarettes.

Statement of Brennan Dawson, Vice President, Tobacco Institute. *Face the Nation.* March 27, 1994. Page 7:

Nicotine is essential. It has a taste. It has what's called a mouth feel.

[581] *See, e.g.*, Proceedings of the BATCO Smoking Behaviour-Marketing Conference, Session III. Montreal, Canada. July 9-12, 1984. Pages BW-W2-02709, BW-W2-02698. Breaks down smoke sensations into (1) mouth sensations, including mouth feel, texture and taste; (2) sensations on inhalation, including throat feel, irritation, and impact; and (3) wholebody pharmacological and psychological effects.

the pharmacological effects of nicotine that underlie consumer satisfaction. For example, a 1972 Philip Morris document from a Council for Tobacco Research conference addressing the issue of why people smoke makes clear that:

> *The primary incentive to cigarette smoking is the immediate salutory effect of inhaled smoke upon body function . . . . The physiological effect serves as the primary incentive; all other incentives are secondary.*[582] [Emphasis added.]

A nicotine monograph prepared for the Tobacco Advisory Council in the United Kingdom also makes clear that smoking satisfaction is dependent on the inhalation of nicotine.

> *Whilst smoking fulfils [sic] a psychological need in certain individuals it is only the inhaling cigarette smoker who is likely to gain psychopharmacological satisfaction from nicotine and become dependent on it.*[583]

Many industry documents reveal that the industry draws a clear distinction between nicotine's pharmacological effects and any effects it has on flavor. A 1984 letter from a BATCO Group R&D researcher to a Brown and Williamson executive drew the distinction between nicotine's pharmacological effects and the sensory properties of cigarette smoke, underscoring the distinction by pointing out that people inhale cigarette smoke (an act that occurs after any sensory effects of cigarette smoke are felt in the nose, mouth, and throat) in order to obtain nicotine's pharmacological effects on the brain:

> *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. . . . . The organoleptic [sensory] properties of smoke are more complex since they involve*

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[582] Dunn WL. Philip Morris Research Center. *Motives and Incentives in Cigarette Smoking*. Philip Morris Research Center. Richmond, VA. 1972. Pages 3-4.

[583] Cohen AJ, Roe FJC. *Monograph on the Pharmacology and Toxicology of Nicotine and its Role in Tobacco Smoking.* Tobacco Advisory Council. U.K. July 1979. Page 38.

the stimulation of a variety of areas in the mouth, nose and throat.[584]

At the 1983 BATCO Research Conference in Rio de Janeiro, the industry discussed its understanding that nicotine "satisfaction" comes from inhalation and absorption of nicotine into the bloodstream rather than from its flavor. There was discussion of possible cigarette modifications to reduce inhalation of toxic smoke components and thus reduce smoker health risk. Smoker risk could be reduced (1) by modifying the cigarette to reduce retention of smoke in the lung, or (2) by increasing smoke irritation to reduce depth of inhalation and thus resulting absorption. The conferees were reminded, however, that such modifications, to the extent that they result in decreased nicotine absorption and resulting pharmacological effects, may threaten smoker "satisfaction." They were told that it was therefore essential to pay attention to the amount of nicotine that was inhaled, to determine whether absorption was adequate with less deep inhalation:

> *The basic assumption is that nicotine, which is almost certainly the key smoke component for satisfaction, is fully released to the body system before exhalation takes place. It is essential, therefore to attempt to quantify the change in chemical composition between inhaled and exhaled smoke under different conditions of smoking, ie., shallow, medium and deep inhalation. The absorption of nicotine via the nasal cavity should also be investigated.*[585]

Other BATCO documents also show that the industry treats nicotine's pharmacological

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[584] Ayres CI. BATCO letter to E.E. Kohnhorst, Brown and Williamson, transmitting partial summary of issues presented at Montebello Research Conference in 1982. Page BW-W2-03949. (Summary prepared in 1984.)

See also a BATCO report in which it was hypothesized that "increased smoker response is associated with nicotine reaching the brain more quickly." Backhurst JD. BATCO R&D. *Further Work on "Extractable Nicotine."* Report No. RD 437-R. Southampton, England. September 30, 1966. Page 1.

[585] BATCO Research Conference. Brazil. July 1983. Page 7.

effects as distinct from the flavor characteristics of tobacco.[586] As described in FINDINGS § II.C.1., supra, "Project Wheat" was an industry study intended to aid BATCO in developing cigarettes with increased consumer acceptance.[587] The Project Wheat researchers 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 cigarettes:

> *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.*[588] [Emphasis added.]

Even RJR research scientists publicly acknowledge that the nicotine in cigarettes provides pharmacological and psychological effects to smokers in addition to any mere sensory effects.[589] An internal RJR document from 1972 is more explicit in showing 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 around tar delivery or flavor.*[589a] [Emphasis added.]

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[586] BATCO Group R&D Sydney, Australia. March 1978. Page 6. According to "Notes on Group Research & Development Conference" written by S.J. Green on April 6, 1978, the conferees were asked to assist in developing "an effective means of obtaining a nicotine-rich, and preferably flavour-rich extract from waste tobacco."

[587] *See* Project Wheat - Part 1, note 204, *supra,* at p. 1.

[588] *Id.* at pp. 3-4.

[589] Robinson JH, Pritchard WS. The role of nicotine in tobacco use. *Psychopharmacology.* 1992;108:405.

[589a] Hilts PJ. U.S. Convenes Grand Jury to Look at Tobacco Industry. *New York Times.* July 26, 1995. An internal Philip Morris document similarly reveals the industry's understanding that people smoke for the pharmacological effects of nicotine, not for flavor. Reporting on a survey of the reasons

Industry patents also distinguish the role of nicotine from flavorants.[590] An RJR book on flavoring tobacco lists approximately a thousand flavorants, but fails to list nicotine as a flavoring agent.[591] In fact, nicotine's flavor is unpleasant,[592] and the tobacco industry has gone to significant lengths to mask the flavor of increased levels of nicotine in cigarettes.[593]

Moreover, there is evidence that some of the sensory effects associated with nicotine, e.g., irritation and "impact," are sought by smokers at least in part because these effects are always followed by the pharmacological effects they seek. Thus, smokers learn to associate the sensory impact of nicotine (burning in the throat) with the resulting psychoactive effects of nicotine, and thus look for these sensory signals in tobacco products. This is known as secondary reinforcement.[594] Industry documents show that the industry is aware of this

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people say they smoke, a Philip Morris researcher says that the reasons given fall into three categories: 1) "as a narcotic, tranquilizer, or sedative," 2) at the beginning or end of a basic activity, and 3)automatic smoking behavior. The researcher concludes:

> *It should be noted that there was scarcely any unprompted reference to smoking for "taste," or "flavor," until it was suggested-and then everyone agreed that it was the major element in smoking satisfaction.*

Memorandum from Al Udow, Philip Morris, New York, NY, to Mr. J.J. Morgan. Why People Start to Smoke. June 2, 1976. *In* 141 Cong. Rec. H7665 (daily ed. July 25, 1995).

[590] U.S. Patent No. 3,584,630. Inskeep GE. *Tobacco Product Having Low Nicotine Content Associated with a Release Agent having Nicotine Weakly Absorbed Thereon.* Philip Morris Inc. June 15, 1971. C1:57-58.

[591] Leffingwell JC, Yound HJ. *Tobacco Flavoring for Smoking Products.* Winston-Salem, NC: R.J. Reynolds Tobacco Company; 1972.

[592] Budavari S, O'Neil MJ, Smith A, Heckelman PE, eds. The Merck Index. 11th ed. Rahway, NJ: Merck & Co., Inc. 1989:1030. *The Merck Index* describes nicotine as having "an acrid, burning taste."

[593] *See, e.g.,* U.S. Patent No. 4,830,028. Lawson JW, Bullings BR, Perfetti TA. *Salts Provided from Nicotine and Organic Acid as Cigarette Additives.* R.J. Reynolds Tobacco Company. May 16, 1989. C1. *See also* p. 250 *et seq.*

[594] *See* p. 102. Rose JE, Levin ED. Inter-relationships between conditioned and primary reinforcement in the maintenance of cigarette smoking. *British J. of Addiction.* 1991;86:605-609.

relationship.[595]

The industry's development of nicotine analogues also demonstrates that the industry is more interested in nicotine's pharmacological effects on the central nervous system than in its sensory effects. The focus of industry research has been to develop compounds that will duplicate the pharmacological effects of nicotine on the central nervous system. Nowhere in the referenced tobacco industry documents concerning nicotine analogues is there mention of concern to duplicate any flavor, taste, or other acute sensory effects that may be associated with nicotine. This fact was acknowledged by Dr. DeNoble in his congressional testimony, as evidenced by the following exchange with Congressman Waxman:

> *Waxman: Now, you ran a laboratory that was charged with identifying the essential characteristics of nicotine so that a synthetic form of nicotine could be developed, yet you didn't test for the taste of nicotine. Did you ever hear any serious discussion to the effect that Philip Morris leaves nicotine in cigarettes for taste?*
>
> *DeNoble: No, sir. None at all.*[596]

In summary, tobacco industry documents make clear that the industry understands that the pharmacological effects of nicotine explain why there is a market for cigarettes, and why

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[595] BATCO Conference Outline, 1984, note 287, *supra,* at p. BW-W2-01977:

> *An immediate sensory affect [sic] associated with nicotine is the "impact" on inhaling. Is this sensation a genuine part of the reward a smoker is seeking, or is it a "cue", i.e., a smoker has learnt by experience, that if he perceives a particular level of impact, he will subsequently receive an acceptable degree of satisfaction.*

Other BATCO documents refer to a 1969 BATCO study (B-A.T. R. & D.E. Report No. RD.640-R) whose objective was to determine the relationship between "impact" and physiological response. *See, e.g,* BATCO. Relative Contributions of Nicotine and Carbon Monoxide to Human Physiological Response. Nov. 15, 1971. Page 2. RD.640-R was not among the documents provided to Congress by Brown and Williamson.

[596] *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,* 103 Cong. 2d Sess. 16 (April 28, 1994) (testimony of Victor DeNoble).

nicotine's sensory effects are distinct and quite secondary. Tobacco industry documents concerning nicotine analogues further support the conclusion that the pharmacological effects of nicotine are of much greater importance to the industry than nicotine's sensory effects.

H. INDUSTRY FAILURE TO REMOVE NICOTINE FROM TOBACCO DESPITE AVAILABLE TECHNOLOGY

The tobacco industry has developed, over several decades, technologies to selectively remove nicotine from tobacco. This capability is evidenced by the various patents for methodologies to extract nicotine from tobacco,[597] attempts to market denicotinized cigarettes,[598]

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[597] *See, e.g.:*

U.S. Patent No. 3,139,435. Staley J, Clarke AB. *Process for Selective Extraction of Alkaloid.* Philip Morris Inc. June 30, 1964.

U.S. Patent No. 4,557,280. Gravely LE, Geiss VL, Knobs F, Gregory CF. *Process for Reduction of Nitrate and Nicotine Content of Tobacco by Microbial Treatment.* Brown and Williamson Tobacco Corporation. December 10, 1985.

U.S. Patent No. 3,046,997. Hind JD. *Selective Alkaloid Extraction.* Philip Morris Inc. July 31, 1962.

U.S. Patent No. 4,068,671. Casey WJ. *Nicotine Removal Process.* AMF Inc. January 17, 1978.

U.S. Patent No. 4,821,749. Toft HC, Smith KW, Carpenter CR. *Extruded Tobacco Materials.* R.J. Reynolds Tobacco Company. April 18, 1989.

U.S. Patent No. 5,018,540. Grubbs HJ, Prasad R, Howell TM. *Process for Removal of Basic Materials.* Philip Morris Inc. May 28, 1991.

U.S. Patent No. 5,119,835. Heeman V, Schmekel G, Ebling U, Hauser B, Koene CH, Rabitz H. *Method for Extracting Tobacco Alkaloids.* B.A.T. Cigarettenfabriken GmbH. June 9, 1992.

U.S. Patent No. 4,898,188. Niven Jr BF, Mays CD. *Tobacco Processing.* R.J. Reynolds Tobacco Company. February 6, 1990.

U.S. Patent No. 4,967,771. Fagg BS, Frederickson JD. *Process for Extracting Tobacco.* R.J. Reynolds Tobacco Company. November 6, 1990.

U.S. Patent No. 4,150,677. Osbourne Jr JS, Hartung HA, Bebbs Jr JF. *Treatment of Tobacco.* Philip Morris Inc. April 24, 1979.

U.S. Patent No. 5,065,775. Fagg BS. *Tobacco Processing.* R.J. Reynolds Tobacco Company. November 19, 1991.

European Patent No. 280,817. Grubbs HJ, Prasad H, Howell TM. *Process for Removal of Basic Materials.* Philip Morris Inc. Filed on December 24, 1987.

[598] Citizen Petition submitted by the American Heart Association, the American Lung Association and the American Cancer Society, acting as the Coalition on Smoking OR Health, to the U.S. Food and Drug

and industry practices.[599] Despite these denicotinization methods, the tobacco industry uniformly leaves nicotine, an addictive substance, in cigarettes and smokeless tobacco products at levels that are high enough to maintain a pharmacological response in consumers. See FINDINGS § I.C. The fact that tobacco manufacturers could remove an addictive substance from their products, yet choose to leave nicotine in their products at specified levels, demonstrates the tobacco industry's intent to market products that affect the structure and function of the body.

FDA recognizes that the mere existence of a patent is not confirmation that the patent holder is using the invention claimed in the patent. Evaluation of the type and scope of patent assignments to an individual company does, however, provide evidence of the capabilities and interests of the individual company. Taken as a whole, evaluation of these particular patents demonstrates the tobacco industry's capabilities and technologies available for removing nicotine from tobacco.

Patents assigned to several of the major cigarette manufacturers demonstrate that the industry has been investigating, and has at its disposal, various ways to remove nicotine from tobacco. Many of these patents are for technologies that selectively remove nicotine while maintaining the integrity and utility of the rest of the tobacco.[600]

Administration, requesting Classification of "NEXT" and other DeNicotinized Cigarettes as Drugs under the Food, Drug, and Cosmetic Act. FDA Docket No. 91P-0144, submitted April 8, 1991.

[599] Browne C. *The Design of Cigarettes*. Hoechst Celanese. 1990. Page 43. (The process of manufacturing reconstituted tobacco removes nicotine from the tobacco and most cigarettes contain about 20% reconstituted tobacco.)

[600] *See:*
U.S. Patent No. 3,139,435, note 597, *supra.*

More than 30 years ago Philip Morris was assigned a patent that "relates to an efficient process for selective extraction of nicotine and other alkaloids from tobacco while not materially affecting the content or properties of waxes, aromatics, flavoring, and other constituents of the tobacco."[601] Philip Morris subsequently patented an invention that the company claimed improved prior processes in the ability to extract nicotine from tobacco.[602] The claimed improved invention provided a "simpler and less expensive means for removing nicotine."[603]

R.J. Reynolds also has patented several solvent extraction processes which first produce a tobacco extract and then denicotinize the extract.[604] One particular patent is for a process that removes and then redistributes certain components of a tobacco material.[605] The patent describes the ability to provide a denicotinized tobacco material in which 95% of the nicotine is removed.

A different type of patented extraction process that significantly reduces the nicotine content of tobacco uses ammonia as an exudant. RJR was assigned a patent for this type of denicotinization process.[606]

U.S. Patent No. 3,046,997, note 597, *supra.*
U.S. Patent No. 5,018,540, note 597, *supra.*
U.S. Patent No. 4,967,771, note 597, *supra.*
U.S. Patent No. 4,068,671, note 597, *supra.*

[601] *See* U.S. Patent No. 3,046,997, note 597, *supra.*

[602] *See* U.S. Patent No. 3,139,435, note 597, *supra.*

[603] *Id.* at C:51-52.

[604] *See* U.S. Patent No. 4,967,771, note 597, *supra,* at C2:31-33. (Provides for the removal of greater than 95% weight percent of the nicotine.)

See also U.S. Patent No. 5,065,775, note 597, *supra.*

[605] *Id.* U.S. Patent No. 5,065,775, C1:39-43.

[606] *See* U.S. Patent No. 4,821,749, note 597, *supra.*

Several cigarette manufacturers, including Philip Morris, BATCO, and RJR, have been awarded patents over the last 5 years for supercritical extraction[607] procedures that can selectively remove nicotine from tobacco.[608] In a Philip Morris patent for a supercritical extraction process, the patent states that one of the objects of the invention is transferring "nicotine from one tobacco substrate (leaf material or reconstituted leaf) to a second tobacco substrate (leaf material, reconstituted leaf material, or tobacco stems) or to a non-tobacco substrate."[609] An RJR patent describes the company's patented process for extracting tobacco components from tobacco material for transfer to a "smokable material" that is "suitable for use and/or processing for the manufacture of . . . cigarettes."[610] The component to be extracted, as claimed in the patent, is nicotine.[611]

Brown and Williamson and its parent company, BATCO, have patented several processes

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[607] Supercritical extraction processes use solvents that are in their supercritical state. This means that the solvent is above its critical point with respect to temperature and pressure. (U.S. Food and Drug Administration. Center for Food Safety and Nutrition. Office of Plant & Dairy Foods and Beverages. Division of Natural Products. What is Supercritical Fluid? Standard Guide for Supercritical Fluid Chromatography Terms and Relationships.) Most of the patents use carbon dioxide (CO_2) as the solvent. As described in one of the patents, critical CO_2 occurs when the CO_2 temperature is above its critical temperature of 31.3° C in its gaseous phase under high pressure, e.g., 70 to 1500 atmospheres pressure. U.S. Patent No. 4,153,063. Roselius W, Vitzthum O, Hubert P. *Process for the Extraction of Nicotine from Tobacco.* Studiengesellschaft Kohle mbH. May 8, 1979. C-1.

[608] *See:*
U.S. Patent No. 5,018,540, note 597, *supra.*
U.S. Patent No. 5,119,835, note 597, *supra.*
U.S. Patent No. 4,153,063, note 607, *supra.*
U.S. Patent No. 4,898,188, note 597, *supra.*
European Patent No. 280,817, note 597, *supra.*

[609] *See* U.S. Patent No. 5,018,540, note 597, *supra,* at C2:39-43.

[610] *See* U.S. Patent No. 4,898,188, note 597, *supra,* at C5:12-14.

[611] *Id.* at C9:10-11.

for denicotinizing tobacco by exposing the tobacco to microbes.[612] The processes in these patents are based on the recognition that when tobacco is inoculated with certain types of microorganisms for a specified period of time the nicotine is degraded. The longer the tobacco is exposed to the microorganism, the more nicotine is degraded.

Further evidence of the ability of the tobacco industry to remove nicotine is seen in the marketing of a cigarette that was advertised as "de-nicotined." In 1989, Philip Morris test-marketed a cigarette, NEXT, that contained less than 0.1 milligrams of nicotine. The company's own advertisements for NEXT announced that a process called the "FreePLUS" system "naturally extract[s] nicotine from fine tobaccos, . . . with rich tobacco flavor and less than 0.1 mg nicotine."[613] This product was withdrawn from the market shortly after it was introduced for test-marketing.

Despite this arsenal of nicotine-removing technologies, all brands of currently marketed cigarettes contain levels of nicotine that are sufficient to maintain a pharmacological response in smokers. Although cigarette manufacturers have the ability to market denicotinized tobacco products, to date there has not been any serious attempt, except for NEXT cigarettes, to market these types of products. All cigarettes on the market today have, and deliver, levels of nicotine

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[612] *See:*
U.S. Patent No. 4,557,280, note 597, *supra.*

U.S. Patent No. 4,037,609. Newton RP, Geiss VL, Knobs F, Jewell JN, Gravely LE. *Process for Reduction of Nicotine Content of Tobacco by Microbial Treatment.* Brown and Williamson Tobacco Corporation. July 26, 1977.

U.S. Patent No. 4,038,993. Geiss VL, Knobs F, Gregory CF, Newton RP, Gravely LE. *Process for Reduction of Nicotine Content of Tobacco by Microbial Treatment.* Brown and Williamson Tobacco Corporation. August 2, 1977.

[613] Package label for NEXT brand cigarettes.

that maintain an addiction to the product. These levels are deliberately maintained by the manufacturers. Because tobacco manufacturers can control the amount of nicotine, and even remove nicotine altogether if they choose, it is evident that manufacturers intend to market cigarettes and smokeless tobacco products that affect the structure and function of the body.

PART THREE: REGULATORY OBJECTIVES

Smoking and other tobacco use is the single leading cause of preventable death in the United States. Each year, over one million children and adolescents begin using tobacco products. Most eventually become addicted. Any program devised by the Agency should be comprehensive, effective, and designed to prevent young people from experimenting with and becoming addicted to nicotine.

Currently 3 million young people are regular smokers and another 1 million use smokeless tobacco.[614] Every day another 3,000 children and teenagers become regular smokers.[615] Although adult rates continue to decline, the prevalence of smoking by young people has not declined for the last decade.[616] In fact, between 1992 and 1993, the prevalence of smoking among high school seniors increased from 17.2% to 19%.[617] Additionally, smoking among college freshmen increased from 9% in 1985 to 12.5% in 1994.[618] However, by the time

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[614] U.S. Department of Health and Human Services. Preventing Tobacco Use Among Young People: A Report of the Surgeon General. 1994. Page 58.

[615] Institute of Medicine. Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths. National Academy Press. 1994. Page 5.

[616] *See:*
CDC. Cigarette Smoking Among Adults - United States, 1993. *MMWR.* 43:925-930. Dec. 23, 1994.

U.S. Department of Health and Human Services. Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General. 1989. Page 269.

Institute of Medicine. Growing Up Tobacco Free: Preventing Tobacco Addiction in Children and Youths, *supra* at pp. 7-8.

[617] The University of Michigan. Monitoring the Future Study. January 27, 1994. Table 1 - "Trends in Prevalence of Various Drugs for Three Populations: Eight, Tenth, and Twelfth Grades."

[618] Washington Post, January 9, 1995. Page A2, col. 3.

young people are smoking regularly, they already regret having started.[619] A 1992 Gallup Survey confirmed this, showing that 70% of regular adolescent smokers regretted having begun to smoke and wished they could quit. If an adolescent's cigarette or smokeless tobacco use continues into adulthood, he or she may ultimately become one of the over 400,000 Americans who die from tobacco-caused diseases each year.[620]

Most adult smokers became regular smokers as youngsters. Among those adults who ever smoked regularly, nearly 90% began to smoke, and more than 70% became regular smokers, by age 18.[621] It is clear, therefore, that if smoking does not begin in childhood or adolescence, it is unlikely that it will ever begin. Thus, addiction to nicotine-containing tobacco products is, first and foremost, a pediatric disease.

FDA regulatory action should be based on a youth-centered strategy that is intended to reduce the risk that future generations of Americans will become dependent on nicotine without prohibiting access to these products by adults. The Agency recognizes the need for cigarettes and smokeless tobacco products to remain available to adults, because millions of American adults use and are addicted to these products. The potential disruption to society resulting from the elimination of tobacco products would be great, and therefore FDA does not intend to remove them from the market.

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[619] George A. Gallup International Institute. Teenage Attitudes and Behavior Concerning Tobacco - Report of the Findings. Princeton, New Jersey. 1992.

[620] U.S. Department of Health and Human Services. Reducing The Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General. 1989. Page 5.

[621] U.S. Department of Health and Human Services, Preventing Tobacco Use Among Young People, A Report of the Surgeon General, *supra,* at pp. 63-65.

A comprehensive and effective regulatory approach should be designed to reduce the many avenues of easy access to tobacco products available to children and teenagers, and to make it harder for young people to buy these products. The Agency should also act to reduce the powerful and alluring imagery used in tobacco advertising and promotion that tends to encourage impressionable young people to initiate tobacco use, and should attempt to enhance the positive image of a smoke-free generation. Further, such actions should seek to educate people about the specific and relevant health risks associated with tobacco use and to disseminate information about quitting.[622]

[622] The issues discussed in the "Regulatory Objectives" section were also addressed by David A. Kessler, M.D., Commissioner of Food and Drugs, in a speech at the Columbia University School of Law on March 8, 1994. A copy of the speech appears in Appendix 9.

Dated: August 8, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–20052 Filed 8–10–95; 8:45 am]

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Friday
August 11, 1995

Part VI

The President

Memorandum of August 8, 1995—Expediting Community Right-to-Know Initiatives

Federal Register
Vol. 60, No. 155
Friday, August 11, 1995

Presidential Documents

Title 3—

The President

Memorandum of August 8, 1995

Expediting Community Right-to-Know Initiatives

Memorandum for the Administrator of the Environmental Protection Agency and the Heads of Executive Departments and Agencies

The Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. 11001–11050) (''EPCRA'') and the Pollution Prevention Act of 1990 (42 U.S.C. 13101–13109) provide an innovative approach to protecting public health and the environment by ensuring that communities are informed about the toxic chemicals being released into the air, land, and water by manufacturing facilities. I am committed to the effective implementation of this law, because Community Right-to-Know protections provide a basic informational tool to encourage informed community-based environmental decision making and provide a strong incentive for businesses to find their own ways of preventing pollution.

The laws provide the Environmental Protection Agency with substantial authority to add to the Toxics Release Inventory under EPCRA: (1) new chemicals; (2) new classes of industrial facilities; and (3) additional types of information concerning toxic chemical use at facilities. Community Right-to-Know should be enhanced wherever possible as appropriate. EPA currently is engaged in an on-going process to address potential facility expansion and the collection of use information. I am committed to a full and open process on the policy issues posed by EPA's exercise of these authorities.

So that consideration of these issues can be fully accomplished during this Administration, I am directing the Administrator of the Environmental Protection Agency, in consultation with the Office of Management and Budget and appropriate Federal agencies with applicable technical and functional expertise, as necessary, to take the following actions:

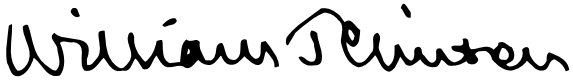
(a) Continuation on an expedited basis of the public notice and comment rulemaking proceedings to consider whether, as appropriate and consistent with section 313(b) of EPCRA, 42 U.S.C. 11023(b), to add to the list of Standard Industrial Classification (''SIC'') Code designations of 20 through 39 (as in effect on July 1, 1985). For SIC Code designations, see ''Standard Industrial Classification Manual'' published by the Office of Management and Budget. EPA shall complete the rulemaking process on an accelerated schedule.

(b) Development and implementation of an expedited, open, and transparent process for consideration of reporting under EPCRA on information on the use of toxic chemicals at facilities, including information on mass balance, materials accounting, or other chemical use date, pursuant to section 313(b)(1)(A) of EPCRA, 42 U.S.C. 11023(b)(1)(A). EPA shall report on the progress of this effort by October 1, 1995, with a goal of obtaining sufficient information to be able to make informed judgments concerning implementation of any appropriate program.

These actions should continue unless specifically prohibited by law. The head of each executive department or agency shall assist the Environmental Protection Agency in implementing this directive as quickly as possible.

This directive is for the internal management of the executive branch and does not create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any person.

The Director of the Office of Management and Budget is authorized and directed to publish this Memorandum in the **Federal Register**.



THE WHITE HOUSE,
Washington, August 8, 1995.

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Vol. 60, No. 155

Friday, August 11, 1995

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FEDERAL REGISTER PAGES AND DATES, AUGUST

39101–39240 1
39241–39624 2
39625–39834 3
39835–40052 4
40053–40258 7
40259–40452 8
40453–40736 9
40737–40992 10
40993–41792 11

CFR PARTS AFFECTED DURING AUGUST

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Executive Orders:
12967 39623
12968 40245
12969 40989

Presidential Determinations:
No. 95–32 of July 28, 1995 40255
No. 95–33 of July 31, 1995 40257

Proclamations:
6814 40451
6815 40736

Administrative Orders:
Memorandums:
August 8, 1995 41791

4 CFR

21 40737

5 CFR

316 39101
532 40744
1201 40744

Proposed Rules:
2421 39878
2422 39878

7 CFR

51 39241
301 .....39101, 39835, 40053, 40993
319 39101
400 .....40054, 40055
401 40055
402 40055
404 40055
800 39242
905 40056
922 39104
923 39104
924 39104
929 40745
931 40058
948 .....39105, 40259
959 40747
981 40059
982 40061
984 40063
989 39837
993 39107
1126 40260

Proposed Rules:
58 40115
273 40311
319 .....39888, 39889
987 40116
1280 40313

8 CFR

103 40064
212 40064
217 40064
235 40064
264 40064
286 40064

9 CFR

160 39840
161 39840

Proposed Rules:
94 39890
308 41029
310 41029
318 41029
320 41029
325 41029
326 41029
327 41029
381 41029

10 CFR

Proposed Rules:
20 40117
30 40117
40 40117
50 40117
51 40117
70 40117
72 40117
490 40539
600 40323

12 CFR

3 .....39226, 39490
6 39226
208 .....39226, 39490
225 39226
325 .....39226, 39490
565 39226
567 39226

Proposed Rules:
3 39495
208 39495
325 39495
327 40776
701 39273
741 39274

14 CFR

25 39625
39 .....39243, 39245, 39627, 39628, 39631, 39633, 39635, 39637, 39842, 40748, 40750, 40753, 40755, 40993
71 .....39247, 39638, 39639, 40069
73 40994
97 .....40070, 40071
189 39614

Proposed Rules:
1 41160
39 .....40118, 40782, 40783, 41030

61 41160
71 ....39280, 39893, 39894, 40020, 40227
141 41160
143 41160

15 CFR

902 39248
905 39249
Proposed Rules:
801 40336
806 39128
944 40540
990 39804

16 CFR

3 39640
234 40262
237 40263
242 40265
248 40267
252 40453
800 40704
803 40704
1500 40785

17 CFR

200 39643
240 40994
Proposed Rules:
270 ....39574, 39592
274 39574

18 CFR

35 39251
284 39252
Proposed Rules:
284 39895

19 CFR

132 39108
191 40995

20 CFR

335 40073
Proposed Rules:
416 40542

21 CFR

175 39645
176 39645
177 ....39647, 40073
178 39648
510 ....39846, 40454, 40455
520 ....39846, 40454
522 39846
529 40455
524 39846
558 ....39846, 39847
Proposed Rules:
801 41314
803 41314
804 41314
897 41314

22 CFR

213 40456

24 CFR

25 39236
26 39236
202 39236

26 CFR

1 ....39649, 40075, 40997
31 39109
40 40079
48 40079
301 ....39652, 40086
602 ....40079, 40997
Proposed Rules:
1 ....39896, 39902, 40792, 40794, 40796
301 39903

28 CFR

2 ....40092, 40094, 40270

29 CFR

20 41016
1910 40457
1926 39254
2606 39848
2609 39848
Proposed Rules:
1910 39281
2510 39208
2615 41033

30 CFR

946 40271
Proposed Rules:
206 ....40120, 40127
250 41034
256 41034

31 CFR

515 39255
Proposed Rules:
1 40797
103 39665

32 CFR

92 40277
Proposed Rules:
220 39285

33 CFR

100 40096
117 40097
126 39788
127 39788
137 39849
165 ....40458, 41017, 41018
Proposed Rules:
1 39130
117 ....39287, 40138
165 40543
183 40545

34 CFR

76 41286
366 39216
667 41286
Proposed Rules:
345 40688

36 CFR

7 39257
242 ....40569, 40461
1253 40416
Proposed Rules:
13 40798
1415 39905

37 CFR

1 41018
2 41018
7 41018
Proposed Rules:
1 41035

38 CFR

2 40756

39 CFR

111 39111

40 CFR

9 40474
51 ....40098, 40465
52 ....39115, 39258, 39851, 39855, 39857, 40101, 40285, 40286, 40291, 40292, 40465, 40758
61 39263
70 ....39862, 40101
75 40295
80 40006
81 ....39115, 39258, 39857, 40297
82 40420
86 ....39264, 40474
93 40098
122 40230
124 40230
136 39586
180 ....40498, 40500, 40503
185 40503
258 40104
712 39654
Proposed Rules:
Ch. I 39668
51 39297
52 ....39298, 39907, 39910, 39911, 40139, 40338, 40799
61 39299
70 ....39911, 40140
80 40009
81 ....39298, 39911, 40338
180 ....39299, 39302, 40545
185 39302
194 39131
258 40799
300 41051
302 40042
355 40042
372 39132
433 40145
438 40145
464 40145

41 CFR

Ch. 114 39864

42 CFR

409 39122
484 39122
Proposed Rules:
412 39304
413 39304
424 39304
485 39304
489 39304

43 CFR

Public Land Orders:
7149 39655
7150 39655

44 CFR

64 39123
65 ....39865, 39867
67 39868
Proposed Rules:
10 39694
67 39912

45 CFR

11 40505
1355 40505

46 CFR

30 ....39267, 40227, 41157
67 40238
150 ....39267, 40227, 41157
160 39268
Proposed Rules:
5 39306
10 39306
12 ....39306, 40145
15 39306
16 40145

47 CFR

1 ....39268, 39656, 40712
2 39657
15 40760
26 40712
73 ....39127, 39659, 40105, 40301, 40761, 41027
87 40227
90 39660
Proposed Rules:
1 39134
61 39136
64 39136
69 39136
73 ....39141, 39142, 39143, 39308, 40146, 40812, 40813, 40814

48 CFR

Ch. II 40105
206 40106
207 40106
215 40106
219 ....40106, 41157
227 41157
235 40107
252 40106
501 40107
519 39660
552 39660
601 39661
602 39661
605 39661
606 39661
609 39661
610 39661
613 39661
616 39661
619 39661
625 39661
636 39661
637 39661
653 39661
939 39871
1801 40508
1803 40508
1804 40508
1805 40508
1808 40508
1809 40508
1810 40508
1812 40508
1814 40508
1815 40508
1819 40508
1822 40508

1825 40508
1827 40508
1829 40508
1831 40508
1833 40508
1835 40508
1837 40508
1839 40508
1846 40508
1849 40508
1850 40508
1852 40508
1853 40508
1870 40508
2801 40108
2802 40108
2804 40108
2805 40108
2807 40108
2808 40108
2809 40108
2810 40108
2812 40108
2813 40108
2814 40108
2815 40108
2816 40108
2817 40108
2828 40108
2829 40108
2830 40108
2832 40108
2833 40108
2835 40108
2845 40108
2852 40108
2870 40108

Proposed Rules:

209 40146
216 40146
217 40146
246 40146
252 40146

49 CFR

171 ....39608, 40030
172 ....39608, 39991, 40030
173 40030
178 40030
390 40761
571 41028
575 39269
653 39618
654 39618
800 40111
830 40111
831 40111
1023 39874

Proposed Rules:

5 39919
571 39308
1051 40548
1220 40548
1312 39143

50 CFR

2 40301
100 ....40459, 40461
204 39248
210 39271
216 39271
250 39271
270 39271
301 ....39663, 40227
604 39271
625 40113
661 ....39991, 40302
662 40303
663 39875
671 40763
672 ....40304, 40763
675 ....39877, 40304, 40763
676 ....40304, 40763
677 40763

Proposed Rules:

17 ....39309, 39314, 39326, 39337, 40149, 40339, 40549
23 39347
402 39921
Ch. VI 40340, 40815
638 40150
642 39698
646 40815
649 40341
650 40341
651 40341
663 39144
697 39700